



THE ONCOLOGY CARE MODEL 2.0

A Proposal to the Physician-Focused Payment Model
Technical Advisory Committee (PTAC)

Submitted by: Community Oncology Alliance (COA)
1225 New York Ave. NW, Suite 600
Washington, DC 20005

Key contact: Bo Gamble
Director of Strategic Practice Initiatives
Phone: (919) 394-1397
Email: bgamble@COAcancer.org

Tuesday, May 28, 2019



COMMUNITY ONCOLOGY ALLIANCE
Innovating and Advocating for Community Cancer Care

1225 New York Avenue, NW, Suite 600
Washington, DC 20005
(202) 729-8147 | communityoncology.org

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May 10, 2019

Physician-Focused Payment Model Technical Advisory Committee (PTAC)
C/O HHS Asst. Secretary for Planning and Evaluation Office of Health Policy
200 Independence Avenue S.W.
Washington, D.C. 20201
PTAC@hhs.gov

Re: The Oncology Care Model 2.0

Dear Committee Members:

On behalf of the Board of Directors of the Community Oncology Alliance (COA), we are pleased to submit this proposal to the Physician-Focused Payment Model Technical Advisory Committee (PTAC).

COA is a national, non-profit organization that is dedicated to advocating for the complex care and access needs of patients with cancer and the community oncology practices that serve them, especially vulnerable seniors with cancer. COA is the only organization in the United States dedicated solely to independent community oncology practices, which serve the majority of Americans receiving cancer treatment. COA's mission is to ensure that patients with cancer receive the highest quality, affordable, and accessible cancer care in their own communities, close to where they live and work. For more than 16 years, COA has built a national grassroots network of community oncology practices to advocate for public policies to support their patients with cancer.

COA and community oncology as a whole are committed to meaningful, patient-centered oncology payment reform. We have been on the forefront of national efforts to advance this, including leading a collaborative network of over 80% of the participants in the Oncology Care Model ("OCM"), which provides a forum to share best practices and ideas. COA routinely communicates with the CMS Innovation Center's OCM team on suggestions designed to address problems and concerns with the OCM. While we are committed to making the OCM a success, we have dedicated significant time and resources to developing this proposal which we are calling the "OCM 2.0" – an evolved version of the OCM 1.0 that, among other improvements, streamlines the model and incorporates value-based drug performance directly into the model. We see this as not just a Medicare model, as with the OCM 1.0, but a universal model of oncology payment.

We look forward to continuing to engage with you on this innovative model. As you consider this proposal, please feel free to contact Bo Gamble, COA's director of strategic practice initiatives at bgamble@COAcancer.org.

Sincerely,

Michael Diaz, MD
President, Community Oncology Alliance

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Technical Advisory Committee (PTAC)**

Presented by the Community Oncology Alliance

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Abstract

The “Oncology Care Model (OCM) 2.0” is a payment reform model developed by the Community Oncology Alliance (COA), a champion for universal reform, and a recognized advocate for community oncology and access to quality, local, affordable cancer care for all patients. Cancer patients are the motivation and focus in all of COA's efforts.

This application identifies the components in current reform models that are working well, areas where improvements are needed, and areas that have yet to be addressed. COA emphasizes the areas that need improvement and will lead to standardization and expansion of reform initiatives. The following stakeholders were consulted in the development of this document; active participants in the Center for Medicare & Medicaid Innovation (CMMI) OCM, other oncology reform models, and/or international value-based healthcare delivery models.

Purpose: The purpose of the OCM 2.0 is to apply the lessons learned and feedback from participants from CMMI OCM model and other initiatives. COA has identified 20 active payment reform models in the United States. All have a vested interest in improving quality in cancer care and lowering costs. All of these models are different. There are some similarities related to outcomes measures, but each model is unique. This application describes the path to continued improvement of these attempts while also standardizing the base requirements of care and value-based systems. Standardization of the following concepts in the OCM 2.0 model will increase understanding and manageability to the benefit of the cancer patient and their family.

Foundation: This application addresses many obstacles that are limiting the progress of implementing value-based programs. The majority of these hurdles are due to program design, to timeliness delays and misaligned incentives. This model addresses drugs, or treatments, and the costs of these drugs and treatments in the total cost of care. COA's involvement in other reform models have clarified the principles that will assist with standardization and universal acceptance:

Collaboration
Transparency

Communications
Incentives

Timeliness
Measurements

How: This model includes two main themes: 1) standardized clinical improvements and 2) baseline payment methodology criteria. The commonality are measures that provide evidence of outstanding quality and value. These measures are then used to regulate or substantiate financial incentives within the payment methodology.

COA has partnered with the American Society of Clinical Oncology (ASCO) to update the Oncology Medical Home program while including automation, or efficiency, to extract the measures that will be used for benchmarking performance in payment models. These measures will be used as the base for a collaborative payment model.

The OCM 2.0 initiative is unique and directly addresses the value and price of drugs. COA researched the complexities and complications surrounding value-based arrangements with pharmaceutical manufacturers and the industry. Some of the findings were alarming, some were unexplainable, and others begged for simple solutions. COA's goal is to promote value-based arrangements that also include care teams by addressing regulatory roadblocks.

Model Description

This physician-focused payment model (PFPM) is submitted by the Community Oncology Alliance (COA). It is titled "OCM 2.0" to build on, enhance, and further the transformation and improvements in quality and value achieved in the Center for Medicare & Medicaid Innovation's Oncology Care Model (CMMI's OCM). However, the OCM 2.0 is fundamentally different than the OCM in that it explicitly includes cancer drugs, not just cancer care services, in the model.

Background - COA has been a leader representing independent, community-based cancer care for the highest quality cancer care and since 2002. This leadership role has been demonstrated in many aspects of cancer care, including the following:

- COA's Administrators' Network (CAN)—This private, peer-to-peer network of 278 community cancer centers, includes the largest community cancer centers in the US.
- COA's Patient Advocacy Network (CPAN)—This is community based, non-cancer-type-specific network of patients in active treatment, survivors, family members, and caregivers. The 23 CPAN national chapters in 14 states represent approximately 142,200 new patients with cancer annually and 1,890,600 visits to their local oncologists.
- COA's Community Oncology Pharmacy Association (COPA)—This network of 601 members helps community cancer clinics enhance outcomes of patients with cancer who are treated with oncolytic agents.
- COA's Oncology Care Model Support Network—This private network for OCM participants includes 378 cancer care leaders, accounting for over 80% of the original 195 participants. This network spotlights leaders and advances in OCM efforts.
- COA's Fellows Initiative—COA's latest initiative provides education and orientation to oncology fellows regarding the benefits and need for oncologists in the community setting. To date, COA has spoken to over 16 different groups of oncology fellows.
- COA's Annual Community Oncology Conference—COA's annual two-day conference that is focused completely on the needs of community oncology practices, professionals, and patients. It features 1,400+ attendees who learn and network from world class faculty and presenters.

COA's overall work to lead innovation and advocacy for independent cancer care reaches tens of thousands of cancer care stakeholders of all types, including patients, patient advocacy groups, physicians, administrators, pharmaceutical/biotechnology companies (pharma/bio companies), payers, employers, policymakers, and other organizations that support cancer care.

Overview - COA's experience, diversity and involvement in all aspects of cancer care has informed the development of this application. OCM 2.0 has four key features, which are summarized below.

1. **Transparency and uniformity**—Traditional billing and adjudication of health care claims has been understood and manageable. It is important for all partners in any new payment methodology to have an understanding and agreement on all formulas and processes. This includes patients and their families who should receive some information regarding their enhanced care.

New payment plans have become more complicated and less transparent as they have evolved. Some of the initiatives by state or regional payers have been more transparent than others. There are at least 20 active innovative payment models nationwide. According to a focus group of eight administrators that participate in the OCM and at least one other model, the payment models that are the most transparent—Aetna, Cigna and Priority Health—are considered to be "best." The OCM has one of the most complex payment methodologies. Since this model is intended to further the OCM, emphasis is on greater simplicity, clarity, transparency, understanding, and timely reporting and communications.

- 2. An accreditation program to recognize and monitor exceptional cancer care**—The Oncology Medical Home (OMH) is solely for cancer care so the standards for clinical care are for cancer care only. The standards in this model were authored by a variety of thought leaders in cancer care and were introduced over four years ago. These standards have been revised and updated with the assistance and cooperation of the American Society of Clinical Oncology (ASCO). A small number of meaningful measures are now associated with some of these measures. These measures represent are the same measures that are used in most of the active oncology payment reform models.

The OMH will include an on-site accreditation by well-trained and qualified personnel. This program will work cooperatively; minimize expense to cancer care teams, such as unnecessary overhead in the pursuit of accreditation; and will be involved in continuous quality improvement throughout the three-year accreditation period.

- 3. Incentives to ensure value in cancer drug selection and use in an era of rapid clinical advances and increasing drug costs**—Many past and present initiatives to improve cancer care payment systems failed to ensure value in the drug treatment decision-making process. The CMMI's OCM attempts to include drugs in the model but the focus is based on prior historical trends by the care teams and drug costs. The OCM 2.0 emphasizes promoting and supporting value-based clinical decision-making relating to drugs that achieves important and recognized endpoints in cancer care outcomes (e.g., progression-free and overall survival, attainment of disease control, cure)

Additionally, in the OCM 2.0, high-value drug treatment choices would be prioritized. These incentives will be supported current coverage guidelines, relevant diagnostics and national coverage guidelines. An example of high-value (versus low-value) choice:

- The use of trastuzumab emtansine in the adjuvant setting for patients with HER2-positive high-risk breast cancer,¹ contrasted with the low-value choice of neratinib employment in a similar patient population.²

The OCM 2.0 addresses the statutory and regulatory barriers preventing the implementation of innovative value-based pilots in Medicare. These barriers and requests to address discussed in *Section 3, Payment Methodology*. The emphasis of drug payment reform within the OCM 2.0 would focus on direct arrangements between pharma/bio companies and provider care sites, with a strong focus on patient experience and outcomes.

4. **Standards and flexibility for new performance-based payment (PBP) methodologies**—This model focuses on establishing a base framework for PBPs but also allows flexibility and growth. During the recent Making Accountable Sustainable Oncology Networks (MASON) public meeting, members of the PTAC committee commented on the lack of acceptance of OCM concepts among commercial payers. OCM 2.0 reflects an effort that is designed to correct that. Although this application is specific to the authority conferred on HHS regarding the Medicare program, COA's goal with the OCM 2.0 is a flexible and adaptable universal payment reform model for all aspects of cancer care, regardless of payer. This application describes the base features and opportunities for flexibility for the growth of payment reform while also addressing CMMI requirements.

Patient's Perspective – As described above and within the OCM 2.0 application, OMH recognition would be a tangible indication that patients receive high quality cancer care, that is validated by ongoing review, and their care would balance this high-quality care with high value. And, patients will receive benefits from this dual attention to quality and value.

Provider's Perspective – Providers of all types: primary care, referring, direct care teams, specialist and ancillary entities would also be cognizant of improvements in the delivery of care cancer. For them it will be most evident by enhanced coordination, more efficient communications, community-wide focus on value and quality through the cancer care journey.

This comprehensive OCM 2.0 model aspires to lower the total cost of cancer care while simultaneously increasing quality (*see "Cost increases are concentrated in Part D [and Part B chew)] " in the Appendix*).

Criteria

1. Scope of PFPM

The U.S. health care industry is unique in at least two regards: the consumer of the end-product is often not the sole decision-maker in acquiring the product, and a third party often pays for the costs related to the choices made. These two items have a major impact on the health care delivery system. The proposed OCM 2.0 intends to reshape these dynamics.

While unequivocal positive strides have been made in patient education, involvement, and engagement in their own health care needs, the physician still often remains the main decision maker. Health care delivery systems grow by recruiting more physician providers in the hope of providing care to an increasing population of patients. Industries, similarly, often grow by attracting more direct consumers. In health care, and notably especially in cancer care, growth occurs by recruiting more decision makers. Physicians are tasked and challenged to review, absorb, and understand a tremendous volume of information in order to prescribe the correct treatments in an increasingly personalized fashion. Patients and their caregivers are often ill-equipped to understand the complexity of cancer care delivery, and they struggle to understand the specifics of managing their illnesses. Nonetheless, patients continue to want to be more involved in this decision-making process with the expectation of engagement in validating and accepting the choices of site of care and treatment options. The primary goal of OCM 2.0 is to foster patient

involvement in the entire decision-making process. The patient-focused standards within the OMH program serve to facilitate this effort (see “Table 1. OCM Compared with OCM 2.0” and “OMH Standards” in the Appendix).

Another critical aspect of health care delivery relates to the payment system being utilized. Health insurance is typically acquired to meet the expenses of unanticipated illness, including life-threatening diseases like cancer. Oftentimes, the amount of insurance acquired remains woefully inadequate to cover the essential expenses of the needed care. This, in turn, often leads to “financial toxicity,” an evolving true epidemic in the cancer-afflicted patient population in the U.S. Historically, health care has been perceived by the populace as a basic right in our culture. No other sector of our society has a third party as the primary bearer of such a large and potentially catastrophic financial responsibility. Insurance coverage is often inadequate and financial toxicity is an increasingly common and devastating consequence. The scope of this model is to lower the total cost of care while simultaneously reducing the patients’ out-of-pocket costs. OCM 2.0 is specifically focused on processes designed to improve these dynamics in the following ways:

- Community-based providers are increasingly encountering obstacles working against their survival (e.g., the 340B payment structure favors hospitals, the interference of pharmacy benefit managers [PBMs], dispensing networks are closed to physician-based networks, and payment differences between hospitals and private practices for the same services (see “Cost Differences Associated with Oncology Care Delivered in a Community Setting Versus a Hospital Setting: A Matched-Claims Analysis of Patients with Breast, Colorectal, and Lung Cancers” and “2018 Community Oncology Practice Impact Report” in the Appendix).
- Addressing the statutory and regulatory obstacles preventing value-based arrangements between pharma/bio companies and provider teams (*regulatory challenges are outlined in Section 3, Payment Methodology*). Initiatives in these areas would allow for piloting of practical, long-term, value-based arrangements.
- The development and validation of value-based systems and adjudication processes to steer cancer care costs downward while simultaneously increasing quality.
- The adoption of benchmarking strategies to allow benefit designers to identify and steer patients to high-value sites of care.
- Organized processes to assist community-based teams to become more entrepreneurial in their operational plans. Examples include guided assistance in marketing their value and quality to large group employers; fostering creativity to ensure patients have 24-hour access to care without the typical high cost of after working hours access; and tools to assist community teams to be leaders in designing reform models with their local/regional payers.

In summary, the scope of OCM 2.0 is to foster the following:

- Increased education and ownership of care choices by and for the patient. For other payers, this education extends to health insurance benefit managers and employers. This would be accomplished when cancer care teams are recognized as centers of excellence in a fashion that is understood and appreciated by the stakeholders.

- Development and implementation of creative value-based payment innovations benefiting the patient over the interests of other stakeholders. These arrangements would occur with different payers, regional employers, as well as pharma/bio companies.
- Education and direct support to community-based cancer care teams to execute, implement, and monitor noticeable differences in the quality and value of the care they provide, and to promote and market these differences to other stakeholders: patients, payers, and employers.

Focusing on these areas would change the dynamics of how differences in cancer care are perceived and serve as a springboard to foster further downstream innovations.

2. Quality and Cost

Antineoplastic drugs constitute the therapeutic drug class with the highest spending on a global basis within the pharmaceutical arena.³ In the U.S., approximately 15.5 million people have a history of cancer, with a sustained current estimate of 1,668,780 new cases per year and 609,640 deaths occurring annually.⁴ Additionally, in the last decade, the average monthly cost of antineoplastic drugs in the U.S. has more than doubled, from an estimated \$4,500 to \$10,000;⁵⁻⁷ newly approved cancer therapies cost \$6,000 to \$13,000 per month.¹ Simultaneously, the improvements in cancer care in the U.S. have resulted in significant improvements in cancer outcomes and survival.⁸ The price of these improvements, however, remains high, creating “financial toxicity” of an unsustainable nature. A recent retrospective study of patients older than 50 years of age with a newly diagnosed cancer found that 42.4% of individuals had depleted their life assets two years following diagnosis.⁹ In the absence of meaningful cost containment measures, cancer will continue to relentlessly strain the patient community, as well as the payer and employer sectors of health care delivery.

OCM 2.0 intends to address avenues to begin to rein in the described trends, despite the obvious barriers of change. Even in the current OCM, widely viewed as having some preliminary success in the cancer care delivery marketplace for Medicare patients, drug costs have continued to climb, with the most recent Reporting Period Two data indicating that drug costs constituted 59.2% of the overall cost of care.¹⁰

Specific programmatic changes in Medicare oncology care delivery would be required to shift the paradigm from volume to value. Many COA-affiliated practices (approximately 80% of the OCM participants) are leading the way toward the creation of value in the marketplace. However, even these practices and their initiatives have failed to bend the drug expenditures to date.

OCM 2.0 is meant to represent the next step in this evolution toward value. It promotes and maintains the best aspects of the OCM program but additionally focuses on aspects of care not precisely managed in the OCM. It seeks to continue the alignment of financial incentives to provide better outcomes for patients with cancer, targeting wise choices in oral and intravenous cancer drugs, as well as fostering emphasis on quality-based decisions regarding advanced imaging and molecular diagnostics.

OCM 2.0 also addresses particularly problematic aspects of the OCM program. The OCM has proven to be overly complex, associated with poor communication of data in a timely fashion, and

gives participants little confidence to choose engagement in shared savings and two-sided risk. No attention has been paid to advanced imaging and molecular diagnostics standardization and reimbursement, areas in which value-based contracting in cancer management are rapidly evolving. These areas are included in the OCM 2.0 in order to achieve significant impact in the total cost of delivered care, though no measures are individually implemented or specifically audited at the initiation of the program.

OCM 2.0 specifically focuses attention on the utilization and management of the pharmacologic component of care delivery. It would seek statutory and regulatory relief to foster specific value-based initiatives in Medicare relating to drug utilization. Additionally, OCM 2.0 would foster utilization of biosimilars more in line with comparable use in Europe, in particular, where price discounts in the 15% to 40% range have been achieved compared to reference innovators.¹¹ This is an active component of the current FDA policy, and its adoption would likely achieve comparable savings in the proposed program, if utilized appropriately and efficiently.¹²

The OMH component of the OCM 2.0 requires adherence to a set of clinical delivery standards, and the successful implementation of these standards would be measured (*see “Validation Through Measures” in Section 3, Payment Methodology*). High marks in these outcome measures would then translate to higher quality of care. OCM 2.0 would further this analysis by benchmarking the cost of care differences among peers. These measures have become standard for cancer care so the administrative burden of capturing these measures are lighter. The systems and processes used in the ASCO Quality Oncology Practice Initiative (QOPI) and their Qualified Clinical Data Registry (QCDR) program would be used in this effort.¹³

Finally, the target patient participant initially would be oriented toward the Medicare population, although the model would be viable and usable in commercially insured populations. It is anticipated that provider groups would most likely consist of community-based oncology centers, predominantly COA-affiliated, though no specific exclusion to hospital-based providers would be mandated. Electronic health record (EHR) support would be enlisted, as provider group participants are identified and engaged, to facilitate the seamless implementation of the program prior to its actual launch. The payment system favored would be shared savings. One of the goals of OCM 2.0 is to lower the total costs of cancer care by a factor of 10% to 15% with a special focus on notable reduction in drug costs as a specific target area.

3. Payment Methodology

A payment system focused on recognizing and rewarding high quality and value is the prerequisite to meaningful, long-term, positive improvement in cancer care delivery. This, in conjunction with lowering patient out-of-pocket costs, are the goals of OCM 2.0. Oncologists would be responsible for ensuring that high-quality care is delivered under this model utilizing this payment methodology. That would require all stakeholders to be engaged in the design, implementation, and reconciliation of payments and services integral to understanding and managing these process and design improvements. Existing payment structures have been developed on a fee-for-service foundation that rewards services utilization, regardless of the degree of effectiveness or efficiency. New systems and processes are needed to underpin not only cancer-related services but, more broadly, value- and outcomes-based care for the entire cancer care delivery system. Key to the

success of the described interventions are communication, collaboration, clarity, and a spirit of cooperation between all participants and stakeholders tasked with adopting and operationalizing this model.

Implementation of this model would require a much higher degree of collaboration than what has been demonstrated in the OCM. Cancer care is complex and in a rapid and constant state of flux due to ever-increasing improvements in biotechnology and pharmaceutical breakthroughs. It is understood and expected that adjustments would, of necessity, keep pace accordingly and dynamically through the life of this model. All revisions or improvements to this initiative would be accomplished through regularly scheduled meetings of a small group of appointed decision-makers. These individuals would be recognized leaders of the participating provider and payer groups.

Financial risks for physicians in OCM 2.0 would be similar to the risks they have carried in traditional models but with greater amplification. In the past, financial risks have involved carrying a high inventory of chemotherapy drugs with minimal guarantee that the practice would effectively manage the inventory. This risk would remain with OCM 2.0. Oncologists would need to continue managing this risk or their practice would no longer be financially viable.

The following highlights the major features of OCM 2.0:

Target Population—This model is applicable for all Medicare patients, whether traditional Medicare or Medicare Advantage, who are actively receiving care in Parts A, B and/or D services, utilizing the ICD-10 diagnoses in a similar manner to the OCM program. It would be anticipated that payers underwriting Medicare Advantage plans may choose to limit the types of cancers that are covered under this model based on their perceived intermediate and long-term goals, decision making tools, and information technology. *Universal Adoption: Commercial payers may opt for a staged approach and may select, for example, patients with breast, lung and colon cancer as a more limited and manageable introduction in this PFPM. This could allow for organic expansion to a broader diagnostic group of patients over time.*

Target Conditions—As mentioned above, patients included in this model would be treated by a medical oncologist and would have a primary or secondary ICD-10 diagnosis code of CXX.

Eligible Providers—Individuals or groups of physicians dedicated to providing medical oncology services to patients that have been diagnosed with cancer, and with a common tax indentation number (TIN), would be the participants in this PFPM. *(See the Benchmarking section below for how these groups would be compared to all oncology practices.)*

Episode Trigger—Patient enrollment in this model would be triggered by the submission of a G-code, or similar code. This code would correspond to the recommended cancer treatment plan that has been shared and discussed with the patient. This code would be submitted within 30 days of providing this treatment plan. The proposed payment amount associated with this code would be approximately \$150. The amount for this G-code would be finalized by the specific payer prior to the launch of the model. *Universal Adoption: For commercial payers this would be their stage 1 option. The enrollment process in this model would replace the function required in typical prior-authorization efforts by non-Medicare payers, and align closely with the management standards in the OMH. This would serve to remove the redundancy and administrative effort required by the*

OCM's preauthorization process. Efficiencies would be added to the insurer and provider processes by eliminating the traditional preauthorization process.

Attribution—Patients that have been identified through the G-code would be attributed to the participating team. The payer (CMMI/CMS or commercial payer) would assist with an initial reconciliation and a final reconciliation. The initial reconciliation would occur 90 days after the close of the episode from the date the code is filed. Final reconciliation, or true-up, would be completed as soon as possible and not later than a year after the end of the planned and approved episode filing date. This final reconciliation time may vary based on the capability and run-out period by payer.

Plurality—Assignment of the patient to the team is primarily determined by the submission of the above code. In the rare instance in which different oncology teams are attributed to the same patient, the attribution would be made determined based on the number of Evaluation and Management billing codes of 99212-99215 (established patients, levels 2 to 5) for the agreed upon time period. *Universal Adoption: It is expected that the use of plurality for attribution would be minimal in the commercial payer space.*

Episodes—Episodes would be six months in length and patients may be eligible for several sequential episodes. The episode periods would be from January through June, and July through December. These episode parameters are consistent with previous reform models for cancer care. Patients may have several sequential episodes. Reporting would commence 90 days after the end of each episode and would reflect all patients that were attributed during the prior reporting period.

Care Management—In addition to the trigger (G) code payment, as described previously, a monthly care management fee would be applied. This care management fee payment would be \$160 per-patient-per-month (PPPM), provided that OMH accreditation had been achieved and maintained. On-going compliance for accreditation would be evidenced by semi-annual quality improvement reporting to the accreditor. The PPPM would be finalized by the individual payer before this PPFM is implemented. The initial trigger amount and the care management amounts would be included in the total cost of care when being compared to peer groups for benchmarking and shared savings purposes.

Drugs and Therapies—The medical management of patients with cancer, whether it be the employment of necessary antineoplastic agents and/or attendant supportive care drugs, remains the predominant expense in the care delivery process. The cost of cancer care delivery currently exceeds \$124 billion annually in the U.S., and the indirect costs of premature morbidity and mortality exceed \$147 billion.¹⁴ Scientific progress in the areas of immunotherapy, as well as cell and gene therapies, are adding to unprecedented progress in the cancer care arena and, not surprisingly, serving to fuel a sustained upward cost trajectory. Though OCM 2.0 would not provide an independent mechanism to buffer this dilemma, it proposes to manage those costs in a value-based fashion.

In the U.S., as reported by the Berkeley Research Group, pharma/bio companies realized 39% of the total drug cost, while 42% of the total is credited to non-manufacturing entities, including amounts realized by other supply chain participants (22%) and, finally, 20% credited to stakeholders through rebates, discounts, and fees.¹⁵ Thus, with a projected 60% of drug costs

earmarked for entities other than the patient, addressing the drug downstream process in distribution would likely prove the greatest opportunity for meaningful cost containment. Unfortunately, this programmatic reform model certainly would not suffice as a remedy to these complex problems.

Other obstacles interfering with creative, value-centric drug-related expense reforms are structural in nature. Commercial payers exploit leeway in the negotiation of specific drug usage and price in collaboration with the pharma/bio companies. These have historically led to rebates, prior authorization obstacles, and step therapy programs that often serve to effectively limit appropriate and value-based provider and patient choices in the oncology marketplace.

A recent comprehensive analysis of cost trends in the OCM indicates that traditional costs by category have remained somewhat flat at 25% over five years. **However, the total spent in oral oncolytic drugs increased 280% in the same year.** Oral pharmaceuticals are not subject to the same cost controls that are present in traditional IV therapies. OCM 2.0 is part of COA's national effort to increase transparency in all drug pricing while also lowering the price of drugs (*see "Cost increases are concentrated in Part D [and Part B chemo]" in the Appendix*)

Regulatory Barriers—OCM 2.0 would pursue waivers for drug companies for the following statutes and regulations:

- 42 USC § 1320a-7b. Criminal penalties for acts involving Federal health care programs
- 42 CFR § 1001.952. Program Integrity – Medicare and State Health Care Programs. Subpart C. Permissive Exclusions– Exceptions
- 68 FR 23731. OIG Compliance Program Guidance to Pharmaceutical Manufacturers
- 42 USC § 1396r-8. Payment for covered outpatient drugs
- 42 CFR § 447.505. Code of Federal Regulations. Determination of best price.
- 42 USC § 1395w-3a. Use of average sales price payment methodology
- 42 CFR § 414.804. Basis of Payment

These statutes and regulations must be addressed and revised to open the door for positive changes in drug pricing. CMMI has the latitude to address these obstacles directly with health care providers, the stakeholder whose primary responsibility is to care for the patient, to allow for the value arrangements. CMMI waivers were not found for any of the regulations in any CMMI models.¹⁶ Appropriate waivers must be provided in advance of value-based and cost-reducing interventions between drug companies and cancer care teams. Some examples that would be considered include:

- Guaranteed specified tumor reduction or money back to the provider and/or the patient;
- guaranteed reduction in the total cost of care for a specified time frame and as compared to traditional treatment for the same disease; and
- guaranteed lowest cost per progression-free survival year.

Value-Based Arrangements—COA led an initiative to better understand the progress and obstacles to furthering value-based arrangements in cancer care. This effort took place over a three-month time period and involved a series of 15 two-hour meetings with leading pharma/bio

companies. The goal of these meetings was to gain a clearer understanding of their prior and future efforts toward value-based care and the challenges as they saw them. Some of the key findings include:

- Regulatory obstacles are preventing the adoption and proliferation of value-based cancer care for the products and services provided.
- The regulatory obstacles are real and fixed. These roadblocks are preventing progress.
- Cancer care providers are rarely included in the design and implementation of value-based arrangements.
- Patients, the most important stakeholder, are historically excluded from value-based discussions regarding their treatments.
- Much is still to be learned on what makes for a successful program, both in relation to structures and outcomes. A need exists for the creation of models to define a template, or blueprint, for effective value-based arrangements that benefit patients while simultaneously aggressively seeking ways to lower the cost of cancer care.

Among the pharma/bio companies COA has met with and have consented to consider pursuing value-based pilot programs with OCM 2.0 participating cancer sites, provided the above itemized regulatory obstacles are addressed, are as follows:

- AstraZeneca
- Boehringer Ingelheim
- Janssen
- Lilly
- Merck
- Sanofi

Again, this is with the condition that the above statutes and regulations are addressed in a way that would permit these controlled, limited models. These companies would implement different pilots for value-based arrangements with cancer care providers. These pilots would be a critical aspect of OCM 2.0. All other described components of this model would apply to these pilots.

Value-Based Insurance Design (VBID)—The Center for Value-Based Insurance Design has identified five low-value health care services and they have been accepted nationally for primary care (see “*Top 5 Low-Value Services for Purchaser Action*” in the *Appendix*). OCM 2.0 intends to incorporate VBID principles that facilitate providing the correct care for each individual patient. This would be done by removing obstacles to the correct high-value care while sustaining disincentives for suboptimal low-value care (see *Section 4, Value over Volume*). ASCO has identified five areas where VBID concepts can be applied to cancer care in their “Choosing Wisely” program (see ASCO’s “*Choosing Wisely: Five Things Physicians and Patients Should Question*” in the *Appendix*). OCM 2.0 would encourage and support Choosing Wisely.

Oral and Supportive Care Therapies—OCM 2.0 supports increased continuity, higher quality, and lower cost throughout the entire care process. This demands more transparency in all aspects of the care delivery and reimbursement processes. This model continues previous COA efforts to improve quality and cost issues that have occurred in PBM networks.¹⁷ The OCM 2.0 supports

quality and cost benchmarking comparing in-office dispensing of oral therapeutic and supportive care agents at the site of service to PBM processes. COA has observed a 50% increase in the filling of oral prescriptions by the community oncologist from 2014 to 2017.^{18,19} We attribute this to the higher quality and value that is realized by patients and their families. COA supports in-office dispensing as described in the Model Description.

New Treatments—Biotechnology in oncology is constantly evolving. Breakthrough therapies continue to outpace even the best efforts to predict the introduction and growth of new pharmaceutical agents in any payment model to date. This has been evident in the OCM. The OCM attempts to predict the changes in cancer care costs by applying a “trend factor” based on care and the costs of that care from January 2012 through June 2015 (see “*OCM Performance-Based Methodology*” in the Appendix). The goal of this adjustment is to function as a type of cancer care cost “inflation factor.” Unfortunately, this factor has not considered the emergence of immunotherapy that began to occur just before the launch of the OCM (see “*The Value and Cost of Immunotherapy Cancer Treatments*” in the Appendix). This relatively new science has continued to evolve along with other targeted precision medicine. These important scientific developments require real-time benchmarking techniques and reporting. OCM 2.0 would establish the platform for both with near time reporting and reconciliations. The goal is to eliminate as many prediction adjustments as possible. The result would be a model that reflects current science and more timely decision making for the participants.

Clinical Trials—Clinical trials are essential to the advancement of cancer care. Although management and support of patients enrolled in clinical trials may demand a higher degree of resources, this effort is typically supported by clinical trial sponsors, serving to reduce the overall cost of treatment to the payer. Clinical trial patients sponsored by either the pharma/bio industry or the National Cancer Institute must be included in any payment model. These patients would be triggered for inclusion in OCM 2.0 using the identical processes as non-trial patients. By way of contrast, the OCM does not recognize clinical trial patients, which may have an adverse effect on reducing the total cost of care for patients in that model.

Risk Adjustment Methodology—One of the more complicated and variable aspects of all active reform models for cancer care is how similar cases are normalized for benchmarking purposes. This remains an area that has the highest degree of confusion, questions, and frustration. The methodology applied in the OCM is very complex with multiple layers of calculations. Most of the changes to the existing risk methodology have been prompted by third-party analytic consultants. These entities, currently to the exclusion of the cancer care teams, have had the ability to critique OCM issues and suggest process changes and improvements. (Since this application is specific to Medicare, the recommended methodology for risk adjustment would be discussed and finalized when CMMI approves OCM 2.0 as a viable model for the care of Medicare beneficiaries). OCM 2.0 intends to engage a small group of cancer care providers, in conjunction with CMMI staff, to shape a mutually acceptable risk methodology. This team would discuss, revise, and improve the CMMI 12-step process for risk methodology targets, Hierarchical Condition Categories (HCCs), and related issues in a completely transparent manner to foster acceptance. **It is important to note that commercial payers do not utilize such complicated processes.** Less complicated and more transparent methodology promotes higher model acceptance. None of the other 17 active payment models utilize such a complex set of adjustments as defined in the OCM.

Comparing similar types of cancer and their related comorbidities is important, and there may be a degree of complexity as a universal payment model evolves. However, if meaningful reform is to continue, particularly for Medicare patients, there needs to be more collaboration and education before a new model is implemented. Examples of this include:

- The OCM was launched July 1, 2016. The “methodology example” educational model illustrating the 12-step process was not released until after August 17, 2017—more than a year later and after two OCM performance periods.
- The alternative two-sided risk component was introduced in November 2018. To date, an educational methodology example has not been distributed, and there are several questions pending answers from CMMI regarding this new methodology.

The minimum risk grouping for OCM 2.0 is the patients’ cancer. This is indicated by the first three digits of their ICD-10 diagnosis code – CXX. All other calculations for this new model should be developed collaboratively and complete educational material should be delivered prior to the launch of the model.

Outliers—Cancer care is complex, and each patient presents with a unique set of cancer specific and medical comorbidities. This results in a wide variety of potential costs for the exact same disease. The OCM 2.0 accounts for these outliers via a Winsorization process. Outliers would be excluded from the benchmarking process. Cases with total costs that are 10% above or below other cases for the same grouping would be excluded in the category averages.

Other Adjustments—Generally, Medicare varies payments for Evaluation and Management (E&M) services through a geographic adjustment factor. The reimbursement for drugs does not vary by state and drug costs account for the largest amount of direct cancer costs. Therefore, the only geographic consideration under this PFFM is at the state level. This is specifically for benchmarking against the total cost of care. (Variations to this policy would be considered for larger states and provided any such variation is operational for the payer.)

Benchmarking Methodology—The methodology for benchmarking, or shared savings, would be determined by grouping similar cases as described above in *Risk Adjustment Methodology* and *Other Adjustments*. The minimal groupings would be by similar cancers and by age. Other more detail groupings would be mutually agreed upon. The total cost of care for the entire episode period would be compared with that by other cancer care teams within that state. Community cancer care teams that are enrolled in OCM 2.0 would be compared against all other cancer care teams. If the community-based cancer team demonstrated a lower cost of care they would receive 50% of the savings. *Universal Adoption: When applicable and agreed upon, the shared savings would be shared among the cancer care team, the commercial payer and the employer for the patient.*

Validation Through Measures—There are seven outcomes and process measures to validate the care provided in this model. The primary goal of this model is to reduce the total cost of cancer care, including drug costs. Measures would be used to ensure quality care is being provided. These measures are included in the OMH program, which is described in greater detail in other sections of this application. These measures were chosen based on the current and planned effort to extract relevant numerators and denominators electronically and for eventual access from a repository. These measures are:

- A comprehensive care plan is provided to the patient.
- Adherence to recognized pathway and treatment guidelines.
- Screening for clinical depression and follow-up plan. (The goal is to shift this measure towards distress screening and follow-up.)
- A survivorship care plan is given to the patient.
- Pneumococcal vaccination is provided to older adults.
- Proportion of patients with cancer receiving chemotherapy in the last 14 days of life.
- Proportion of patients with cancer that died but without being admitted to hospice.

The average of the seven measures must be at or above the payer’s measures for the grouped practices for that state. This comparison would be made with all practices enrolled in OCM 2.0. How teams compare to the average of other OCM 2.0 participants would determine the percentage of savings they would realize. For example:

- Teams that are above the average would receive their full allotment of shared savings;
- Teams that were at 49% of the comparative average would receive 49% of their allotted shared savings;
- Teams that were at 5% of the compared average would receive only 5% of the shared savings.

An exact percentage would be used versus quartiles in order to minimize participant anxiety of “just missing” the next quartile and to also encourage marginal increases in their scores.

These calculations would apply to every episode period. *Universal Adoption: Participating entities would agree on how these measures would be used in the program. Options include but are not limited to the following:*

- *Threshold reporting—A degree of measure submission would be required to participate in any aspect of shared savings.*
- *Multiplier—Measure scores could be used as a multiplier for the allocation of shared savings. Cut points, or ranges, would need to be prospectively determined.*
- *Combination—A combination of the above.*
- *Other—As otherwise specified and if all entities agree.*

Shared Savings—Reform in cancer care is important to all stakeholders: payers, providers, patients, and employers. This model is intended to incentivize groups of these stakeholders to work together to ensure that patients receive the highest quality cancer care at the lowest cost. Services would continue to be paid as billed under existing approval and adjudication processes. The total cost of care and for the episodes specified would be compared to the same cases, regardless of their participation in OCM 2.0, within a specified state to determine if shared savings are applicable. This model is upside only, provided the team achieves savings. Teams would view the ongoing ability to participate in shared savings as success in this model. *Universal Adoption: This model would allocate savings achieved through this program to these entities; provider group, payer, employer associated with the patient and, when appropriate, the patient.*

Patient Participation—This model would apply to all traditional Medicare patients seen by any cancer care team that participates in this model. Medicare Advantage patients may be included if the Medicare Advantage plan participates in this model. Medicare Advantage plans may select the universal adoption choices within this model since they would be easier to implement. All patients that participate in this program would be receiving exceptional cancer care under the OMH standards.

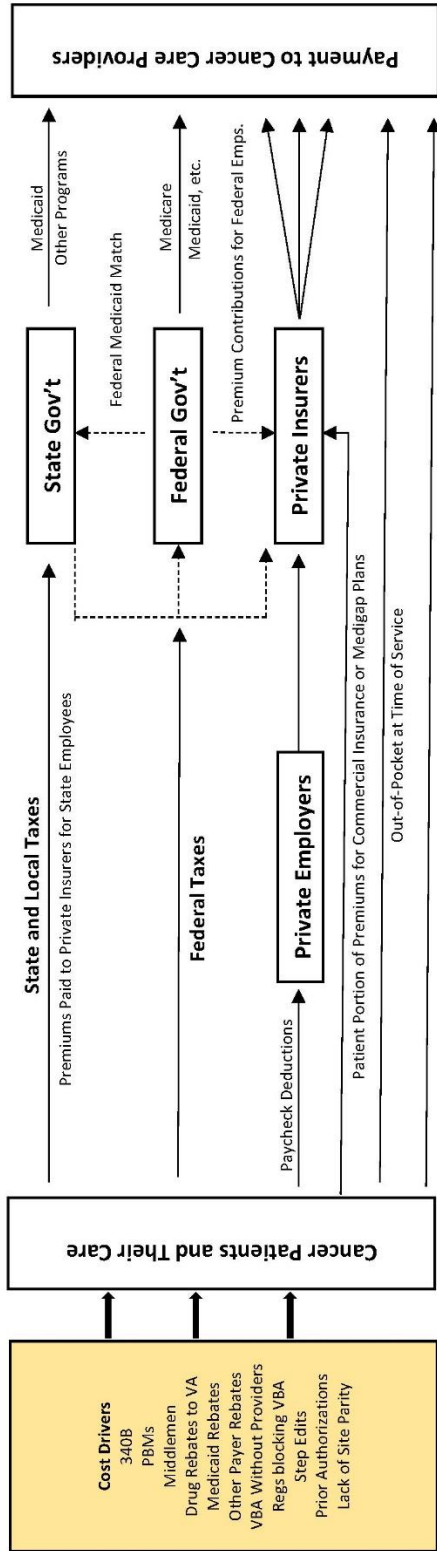
Reconciliation—Timing, report content, maintaining lists of participating patients, and ongoing and frequent communications are fundamental to the success of this model and to minimizing administrative burden to all stakeholders in managing the model. CMMI, or participating payers, would be prepared to produce a list of subscribers with patient name, attribution start date, diagnosis codes, assigned physician, and total amounts billed (and allowed, if available) by site and by cost category and within 90 days of the episode end date. This reconciliation would be for all active patients in the OCM 2.0. Participating practices would have 30 days to dispute patients that were attributed to their practice and should not have been or were not included on this initial reconciliation report and should have been. Submission for changes would include evidence that supports the practice’s argument. All payers, including CMMI, would be given an additional 30 days to respond to these challenges.

For patients that have completed a course of cancer treatment, there would be a final shared savings report. This report would be for patients who have not received chemotherapy in the past 90 days or have expired. This report would be used to reconcile total cost of care for the patient and for the distribution of shared savings. Total costs would be through the date of death or 30 days following the last date of IV chemotherapy or the dispensing of an oral chemotherapy agent. This report would reflect the same format as the above interim report.

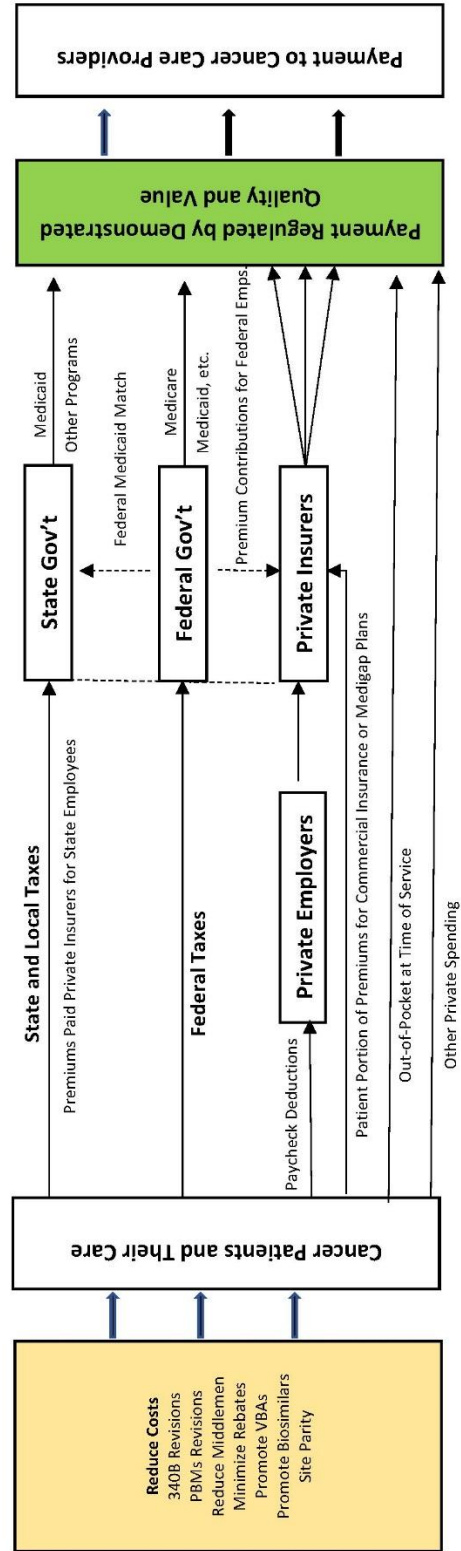
This interim shared savings report would be followed by a final shared savings report. This report would be produced 12 months after the initial shared savings report and would include the same demographic data and allowed amounts by site and by category. Also included would be groupings by patient category (*described above under Risk Adjustment Methodology*) and how this practice performed against peer practices for shared savings. This comparison would be against all cancer care teams, not just those participating in OCM 2.0. The final report would detail how the team compared with other participants regarding the process and outcomes measures listed above. This final calculation would be used to calculate the interim shared savings. Also similar to the above, are the timing and details for challenging this information.

Two-Sided Risk— The above is specifically for a one-sided PFPM. Options for a two-sided risk for any payer, including CMMI, could be considered and defined after OCM 2.0 has been implemented for a minimum of 24 months and after the participating providers and payers collaborate on the details of a two-sided risk option.

Current Cancer Care Payment Diagram for Medicare and Other Payers – Continually Rising Costs



Cancer Care Payment Diagram for COA PFPM – Lower Costs While Increasing Quality



4. Value Over Volume

The fee-for-service based U.S. health care system predominantly rewards volume, i.e., resource utilization, typically without direct consideration of value. Historically, even when the data has been prospectively collected, outcomes have rarely influenced the payments rendered, and the patient experience is often not addressed other than in a minor and cursory fashion. The only checks and balances in the current Medicare system to measure even the appropriateness of rendered services have taken the form of Local or National Coverage Determinations, Recovery Audit Contractor (RAC) audits, and the use of prior authorizations, including step therapies. Though these well-intentioned processes have attempted to focus on value, to date, most have fallen short of achieving such. Even in the successful OCM program, whereby its provider participants are measured and incentivized to deliver high-quality care while avoiding unnecessary services, value has not been realized in the fashion anticipated, in large measure because of the inability to control drug-related costs and resource utilization. OCM 2.0 posits that the greatest opportunity for achieving strides on value in cancer care delivery are achievable with a focus on managing drug choices and their costs. Innovative and commonsense value-based initiatives in this domain have great potential to achieve better value connected to these choices when operationalized in a value-based framework. In short, COA would promote thoughtful, value-based clinical decision-making conjoined with a strong focus on value-based arrangements in the pharma/bio aspects of care delivery.

Specific examples of fostering value would include, but are not limited to, the following:

- OCM 2.0's algorithm process includes the adoption of the ASCO Choosing Wisely standards (*see ASCO's "Choosing Wisely: Five Things Physicians and Patients Should Question" in the Appendix*).
- Identification of the sites with the lowest total cost of care would be identified in the same manner that is done currently – by the payer that launched and is monitoring the model participants. The analysis would include attention to differentials in the costs of advanced imaging procedures and advanced laboratory diagnostics, with special emphasis on molecular diagnostic assessments. As geographic pools become accessible, benchmarking the distinctions would be prioritized to reward cost effective choices across the full landscape of diagnostic and therapeutic interventions in the continuum of care delivery.
- Despite the achievements of the OCM program since its launch in 2016, little progress has been reported to date on the expediency to bend the curve of dollars spent on the utilization of, most notably, novel therapeutics, especially within the arena of immunotherapies and bio-genetic products. At present, the proportion of drug-related costs as a percentage of the total cost of care has been sustained in a still escalating manner. COA has deeply engaged the pharma/bio companies since May 2018, with the intention of making inroads in the arena of drug cost escalation. OCM 2.0 would foster the creation of a wide-ranging portfolio of solutions targeting the creation of value in the drug arena, without detrimental effects on the provider and patient communities so dependent on effective and available drugs in the care delivery process. This would, correspondingly, address obstacles to access to drugs (*see Section 3, Payment Methodology*).

Providers participating in OCM 2.0 would pledge to achieve timely OMH recognition and to adhere to the attendant mandates of care delivery inherent to such. These standards, soon to be

finalized, would address adherence to high standards of care in therapeutic and diagnostic decisions, resource utilization in the implementation of care pathways, and the essential use of clinical decision-making standards with a patient-facing focus on outcomes, survivorship, and continuous process improvement. These care improvements would be rewarded in a predictable and cost-effective fashion. This value would be demonstrated in paired payment models that support the OMH. Planned group-wide information systems networking would enhance peer-to-peer interactions and performance improvement processes, while still striving to not be excessively prescriptive. Communication and interaction among participating practice groups would be facilitated.

Finally, OCM 2.0 recognizes the imperative for cost containment in the delivery of care to Americans afflicted, now and in the future, by cancer. To achieve meaningful success in this endeavor, it is COA's belief that the key stakeholders must not only support the tenets of value-based care but also become meaningfully engaged in the process. COA has sought to build consensus within the oncology provider community, pharma/bio companies, payers, employers, and the patient and survivorship advocacy communities in the process of practical change in how cancer care is delivered. Excellent patient-centric cancer care is the goal. The diverse parties engaged and sharing in such a commitment would have the best opportunity to make the changes needed to achieve these goals, and thereby shift the paradigm from volume to value.

5. Flexibility

The descriptions of OCM 2.0 components in this proposal emphasize the need for flexibility and transparency. Reform concepts are more prevalent than ever, and stakeholders are coalescing around common concepts and goals. Despite the progress and standardization that has evolved over the past five to six years, the need for flexibility remains very important. OCM 2.0 responds to this need in two ways: the ability to adjust the model components based on payer capabilities and, secondly, the structural creation of options for health care providers to administer the requirements. These distinctions are identified in the subsequent narrative.

Leaders of any reform initiative by necessity require a thorough understanding of the goals and capabilities for transformation for the communities they represent. Required processes, measures, reporting requirements, communications, and other critical process issues necessitate a degree of flexibility coupled with the need to understand and accommodate the capabilities of the involved stakeholders. This includes, but would not be limited to:

- The focus and blend of quality and value in the network.
- The technical ability to acquire, submit, and report measures data in a timely manner to validate compliance and foster improvement.
- The long-term success of prior reform initiatives required a collaborative decision process for reform elements. This process is emphasized in OCM 2.0 and primarily outlined in *Section 3, Payment Methodology*. The primary engaged payers must have a firm understanding and plan for the initiative. However, including the care teams in this process development would serve to promote ownership and increase the likelihood of successful model implementation.

Flexibility, collaboration, and communication are all critically important within this model. Cancer care teams, by nature, come in different shapes, sizes, and capabilities, and each has unique characteristics. Since engagement is critically important to all stakeholders and providers of health care, any reform initiative should include flexibility for each team on how best to meet the basic reporting characteristics demanded within the defined and specified core requirements. Examples of how flexibility is emphasized in this model include the following:

- **Access to care**—This does not necessarily imply the physical access to care. Cancer care teams should have a working knowledge, and then utilize, all CPT codes that have been approved for the delivery and documentation of virtual care. They should also be prepared to discuss and propose payment options for virtual, or telephonic care, when the appropriate and necessary codes are approved.
- **Patient communications**—Some forms of patient communication are more effective when they involve one-on-one contact with the patient and caregiver. Depending on the topic, flexibility and sensitivity to the patient’s needs always should be of paramount importance in every communication. In the same manner, this model is designed to promote efficiency in the care processes, which would be emphasized within the requirements and implementation of this model.
- **Other**—Flexibility is fundamental to OCM 2.0, and the details have been itemized in *Section 3, Payment Methodology*. As has been learned from the OCM, capabilities and infrastructures needed for robust reform models vary within the caregiver and payer communities. Specific details should be defined when entities understand the concepts to the point that they are able to manage these details. This might range from attribution to member-per-month payments to risk adjustments and would include shared savings.

Flexibility is also proven critical as OCM 2.0 is to be adopted by universal payers. Other payers historically follow Medicare’s lead in many care delivery aspects, ranging from coverage determinations to reimbursement systems. This recently has been proven true for other Medicare initiatives, including most notably the ongoing OCM program. The goal of this model, with the anticipation of built-in flexibility, is to grow participation. Of the 17 active oncology reform models, only one is recruiting for additional participants. One of the original national reform initiatives with a commercial insurance company was implemented in only seven states and has been discontinued. A new revised model has taken its place with the goal of implementing the new model in 24 states.

Commercial payers participating in the OCM are not confined to these same criteria in a rigorous fashion. Their only obligations are to utilize agreed upon measures and offer a two-sided risk option. Though the degree of flexibility is workable in the OCM process, OCM 2.0 presents some new ideas and concepts for any payers, providers, and employers who are contemplating the pursuit of a reform model. A certain degree of consistency for cancer care teams participating in multiple reform models is desirable, and these core components would serve to promote consistency (*see “Table 1, OCM Compared with OCM 2.0” in the Appendix*).

Options for other payers are itemized in *Section 3, Payment Methodology*. These are not only intended for the payer but for the participating EHR or IT vendors as well. These other

opportunities are designed to foster additional options oriented toward achieving high quality and high value in cancer care.

6. Ability to be Evaluated

The ability to be evaluated is fundamental to the success of OCM 2.0. Its intention is to address a key underlying issue in health care: by what measures is a model good and how could it be improved in a measurable fashion if implemented? This model includes outcomes measures that reflect quality and relative value.

COA is very much aligned with the intermediate and long-term goals of HHS, CMS and CMMI to reform how quality health care is to be recognized and rewarded. OCM 2.0 recognizes that all stakeholders should engage in this effort, but they need to employ transparent, timely, objective, and meaningful metrics to evaluate progress and success. This would be primarily accomplished through the following:

- A reputable third-party entity or entities to develop and deploy the road map to evaluate and foster the necessary components of excellence in cancer care. This entity would be responsible for validating that the cancer care delivery processes and related reporting requirements were done so according to the standards specified in the OMH program.
- Outcome measures that are readily available validate that the care processes defined in the OMH standards resulted in better care with high value. OCM 2.0 would ease the administrative burden of capturing and reporting quality and value measures—a process that all stakeholders would find comprehensible and practical as a driver for all cancer care teams toward continuous quality improvement.
- A payment model with defined options to invite the least sophisticated payers, in addition to known leaders in oncology payment reform. OCM 2.0's flexible payment methodology (*see Section 3, Payment Methodology*) would support providers, care teams, payers and employers who adopt these changes. It would be anticipated that ample opportunity to modify or improve the model as it matures would be part of the process of change as the entire cancer community continues to align on concepts. Transparency, timely reporting, responsible communications, and collaboration are at the core of this model and all variations of the methodology, and they would be protected. Too often a model fails due to the lack of attention to detail in this regard.
- Removing regulatory and cultural obstacles that are preventing value-based arrangements between drug companies and the cancer care community. Addressing these obstacles would allow numerous pilot programs to be implemented in this area. Such efforts would identify value-focused payment reform strategies that could be standardized (*see Section 3, Payment Methodology*). This critical issue would almost certainly present the biggest challenge in the model. A diverse variety of initiatives to creatively address issues in this domain are in development. Consistency in implementation and assessment of outcomes would result in the identification of best practices with different constructs to be explored. This would represent the largest first step in bridging the best of scientific development to affordable and practical application to patient care across the broad construct of the Medicare program and expected alternative payers in the U.S.

These features would assist all in evaluating the care and the new payment methodology in this model. Ensuring an understanding of when and how to determine success would promote growth and universal appeal.

Patients often judge the quality of their care based on the courtesy and compassion of their care team. This may apply to the attention to an urgent care need and, in cancer care, all too often, through a journey related to a chronic disease state experience. COA recently engaged a group of cancer survivors who were also actively employed. The question was asked: how did you decide on an oncologist? The responders frequently attested that their decisions were often affected by communications with their co-workers, and often choices were based on who was perceived as the “nicest.” Often, no mention was made regarding who had demonstrated the best understanding of the latest science, whether clinical trials were available in the clinic setting, or whether the highest rate of survivorship and other outcomes of care for their disease had been assessed compared to national or regional norms. Overall, cost was rarely mentioned.

As mentioned previously, health care is unique in that the purchaser of services is not the consumer (the patient). This adds another layer of complexity and separation to the ability to evaluate the overall quality of cancer care being rendered. Historically, payers evaluate the single cost of an item or the cumulative cost of all items for a pre-determined period. The assessed value of the delivered service over time may be different depending on the perspective of the various stakeholders involved in the delivery process. These valuations may also be blurred by misaligned benefits that lack rewards for care that prevents higher utilization or punishments for care resulting in perceived excess expense. These perspectives have increasingly been affected by the creation and standardization of VBID benefits. These benefits serve to remove obstacles for effective preventive care while simultaneously adding disincentives for less effective care. At present, the payer community is not perceived as being concerned about the long-term medical economics of a good or service. Additionally, these perspectives and evaluations do not always align with their subscribers, care delivery teams, or employer organizations.

An emerging trend is evolving within small, medium, and large employer groups. These organizations continue to grapple with rising health care costs resulting in increased premiums which are passed on to concerned and often dissatisfied employees. Until recent years, these groups have typically accepted a menu of benefit options offered from their chosen payer. Their choices typically represented a balance of what they can afford counterbalanced by the generosity of the benefit. The option to engage in dialogue to design benefits from the ground up was not available. Employers are increasingly focusing emphasis on these issues, but they—as do most key stakeholders—lack the tools or understanding of the clinical and financial metrics of the various and diverse aspects of cancer care delivery.

Finally, the provider communities need to be engaged in the process in an integral fashion. Again, all too often their ability to evaluate, implement, and promote significant process innovations to the comprehensive treatment of patients with cancer is limited. This is unfortunate in that the providers are uniquely qualified and, if empowered, pivotal in managing and promulgating improvements in affecting the best cancer care at an affordable level, while ensuring patient engagement and outcome initiatives at the patient and societal level. Payers are often viewed as foes instead of friends in the day-to-day delivery processes. Creating decision-making algorithms that result in the best care should be the mandate of the provider communities in alignment with

the cost and outcome needs of the payers and, more importantly, the patients. Initiatives to accomplish these ends exist in organized pockets and variously designed efforts around the country.

In conclusion, an immediate imperative exists for a unified approach to recognize, evaluate, and reward excellence in cancer care—with emphasis on quality, value, and focused cost containment strategies. OCM 2.0 is not a solution for all existing inadequacies. However, COA with its network of leading cancer centers, community of payers, and employer health groups intends to set the foundation for improvement so that each stakeholder would become more informed and begin to make more objective and impactful decisions regarding cancer care delivery.

7. Integration and Care Coordination

At the core of efficiently delivering cancer care in a value-based environment rests the issue of identifying the diverse clinical and resource needs of patients over a broad spectrum of diseases while encompassing each patient’s individual care issues. Solving these challenges demands a focus on the identification of medical comorbidities and creating individual care plans that address the specific needs of each patient. This challenge is further compounded by variable economic resources, the availability of dedicated caregivers, and the capacity to facilitate coordinated care, inclusive of laboratory tests, imaging studies, support services, and other diagnostic and therapeutic interventions.

The OMH program is central to the clinical care component in OCM 2.0. The OMH concept empowers the medical oncology team to be the hub of this delivery paradigm. Cancer care in recent years has rapidly embraced the “team concept” as the only way to ensure quality while simultaneously controlling cost—the essence of value creation. This team is simultaneously providing care while communicating with the referring network of primary care physicians, surgeons, and other specialists. This, in its essence, elevates the oncology team as the primary care provider for the patient.

OMH standards are categorized as follows (*for a full description of OMH’s 14 care standards, see “OMH Standards” in the Appendix*):

- Patient Engagement
- Expanded Access
- Evidenced-Based Medicine
- Comprehensive Team-Based Care
- Quality Improvement
- Chemotherapy Safety

The OMH standards do not prescribe how to provide integrated and coordinated care. Instead, the requirements define what is to be anticipated.

Practice applicants fulfilling these rigorous requirements would be accredited by the Accreditation Commission for Health Care (ACHC). **This process differs from others in that it emphasizes and requires outcome measures to validate improvement.** It also requires on-site review, by

programmatically-designated oncology professional reviewers, and the submission of frequent quality assurance reports to the accrediting body.

Integration and coordination would mandate routine systematic communication among the cancer care team and with the patient at not less than monthly intervals, allowing adjustment of supportive care services throughout each active therapy course with the goal of assuring the highest quality and value, while simultaneously assessing patient and caregiver satisfaction throughout the care delivery process.

COA has recently fostered an initiative that has taken integration and care coordination into the workplace. This *Florida Oncology Connections* project serves to introduce a cancer care reform model in Florida that engages employers as key stakeholders in care coordination efforts. Workplace support systems and co-worker interactions have been identified as important and influential to patients facing the overwhelming stresses of a cancer diagnosis. Although the OCM 2.0 application is specific to the Medicare population, many of whom are retired or unemployed, this novel employer program also would be incorporated into the OCM 2.0.

Evaluations of new models are conducted through various processes. Patient input is instrumental to monitoring effectiveness of the model. Another source of evaluation has been model designers. The January 2019 Abt report, “The Evaluation of the Oncology Care Model – Period One,” is an excellent example of the comprehensive review of the model from the implementation team (*see “Evaluation of the Oncology Care Model” in the Appendix*). OCM 2.0 would expand this feedback process to gather detailed feedback from the participants on management components and technicalities. This would assist in shaping on-going education materials and strengthening support areas.

Cancer care delivery will continue to become increasingly sophisticated in the coming years. Maintaining effective and efficient integration channels for care coordination will be a constant challenge. Creating programs to sustain progress while controlling costs in the presence of therapeutic advances will prove to be the hallmark of this high-quality program. The incentives and other requirements in this model create financial and non-financial rewards for the individuals involved in cancer care delivery, most especially the oncologists involved in directing care. This serves to encourage clinical and financial buy-in and accountability for the complete portfolio of received cancer services.

Integrated and coordinated care in the OCM 2.0 would be enhanced beyond the OCM. Correctly integrated in the manner described, each patient would receive the right care, at the right time, and in the right place. Achieving this milestone while simultaneously lowering the total cost of care for the patient would suffice, in the end, to guarantee achievable benefits to patients, providers, employers, and other guardians of the health care dollars.

8. Patient Choice

COA was founded in 2003 with the purpose of promoting and improving cancer care for all patients in all communities throughout the U.S. Although cancer treatment has improved dramatically in this time span, disparities in patient choice are looming with increasingly larger

obstacles in accessing service in high-quality and affordable settings. The health care consolidation trend has directionally affected how care is being delivered and by whom. This has resulted in a corresponding limitation of care choices in many markets, most especially in rural and underserved population areas. Inequalities in payments for care delivered under the Medicare Physician Fee Schedule versus the Medicare Hospital Outpatient Prospective Payment System, unchecked expansion of the 340B Drug Discount Program, and other regulatory and reimbursement issues have further exacerbated care discrepancies with the resultant unintended increase in the overall cost of care. This increase is due in large part to the shift of oncology providers and their patients to hospital-based centers and away from the lower cost independent physician community setting. COA believes, and has the evidence to support its contention, that high-quality care at the lowest cost is most efficiently and effectively delivered close to the homes of patients suffering from cancer.

OCM 2.0 was designed to promote more informed patient choices regarding their access to cancer care. The model would be open to all community-based oncology care teams, large and small, who are able to meet the standards of care required of participating teams. Initially, the focus would be on the recruitment of community oncology teams delivering care under a common TIN identity. It would serve to provide the underpinnings for care delivery by supporting infrastructural changes in clinics, large and small, in disparate markets across the country. Access to the necessary technology and information systems to support and assess care delivery and outcomes would continue to present the single biggest challenge to providing care to Medicare beneficiaries, regardless of race, ethnicity, gender, or geography. OCM 2.0 would assist with quantifying and highlighting outstanding achievements in quality and value in cancer care. It would serve to fully engage patients and caregivers in the pathway to excellence. Recognition of the provider teams would be based on proven excellence in clinical care, communications, validation of doing the right things at the right time and place, and positive outcomes when compared with their peers.

Oncologists pledge to deliver the best care for patients regardless of race, color, or ability to pay. OCM 2.0 would protect this commitment. Additionally, attention would be focused on serving and maintaining high-quality care in underserved areas. The model's measures place emphasis on total cost of care and value-based arrangements would allow more informed choices for patients and their care teams. The providers would not be as restricted as they historically have been due to misaligned payment systems and regulatory obstacles.

Finally, the components of care delivery and payment systems would be supported in the anticipated continuous movement from fee-for-service to value-based care models. These concepts are foreign to patients and their families, as well as to other constituencies in the U.S. cancer care enterprise. OCM 2.0 would promote education and awareness. With a shrinking oncology workforce projected in the near term, an increased emphasis on team-based and coordinated care would become paramount in response to the other demands of quality care delivery. Special attention would be directed to these teams to ensure that patient choice remains a high-priority target in the decision-making process. This model is intended to raise the bar for quality and value for all aspects of cancer care, while also providing the recognition and education processes to educate and empower patients to be active participants in their course of management. It would improve patient choice and have an enduring positive effect on the total health continuum, extending from diagnosis through the therapeutic process and, increasingly, to the successful transition to survivorship.

9. Patient Safety

In the spirit of always keeping the patient first, the OCM 2.0 would guarantee state-of-the-art care delivered in an environment that fosters safety as a top priority. The backbone of care delivery would be the OMH process, which rigorously mandates care that is consistent with the highest national standards. This continuum would include diagnostic and therapeutic excellence in a measurable fashion delivered in a culture that ensures that the patient's clinical needs and satisfaction are both documented and clearly communicated. This includes the continued emphasis on the safety and comfort of the patient. True value is not achievable unless these aspirations are met.

The majority of cancer care continues to be delivered in the communities in which patients reside. OCM 2.0 intends for cancer care to be available close to home and local support systems while at the same time sustaining the major advancements in survival and innovation that have been achieved in the past 25 years. Participation in clinical trials with the National Cancer Institute and pharma/bio companies, would be a special feature of this program. Clinical trials demand a higher level of personal patient care by the care team and this translates to an increased emphasis on patient safety. Careful monitoring of all facets of the care delivery process, especially of the safety of care rendered against national standards, would be expected of the program and all its provider participants.

10. Health Information Technology

Health information technology (HIT) would play a critical role in the OCM 2.0. The OMH, Medicare COME HOME demonstration (already completed), OCM, and ASCO's QOPI, as well as other novel oncology models, defined and promoted new data points to EMR and practice management (PM) systems spanning the past several years. These efforts have been directed toward identifying and systematically reporting the numerators and denominators for a wide variety of quality and value measures. OCM 2.0 benefited from these prior efforts and would encourage continuation of these developments that serve to promote increased efficiency and standardization. This model proposes enhanced use of HIT for more effective data and enhanced information sharing, with the attendant overall improved interoperability to facilitate the goals of the payment model.

- **Data Sharing**—Prior reform efforts have made stepwise strides in this area. However, these efforts were frustrated by the varying capacities of EMR and PM companies, and an inability to utilize the data effectively due to the inconsistencies in measure requirements and a lack of standardization in reporting. OCM 2.0 utilizes an emerging smaller standard set of measures. The clinical component of this model is based on updated OMH standards, with the collaboration of ASCO, which would serve to bring its IT infrastructure with EMR and PM partners in conjunction with existing data submission channels from over 300 cancer sites to this model. This information would be submitted to ASCO and incorporated into their approved Quality Clinical Data Repository (QCDR).
- **Improved interoperability**—Cancer care teams would be encouraged to initiate and lead the implementation of health information exchanges (HIE) for their communities. This would enhance their ability to gather and report key measures not necessarily generated by the cancer care team. Included would be measures that have proven to be relevant to and indicative of higher quality care, e.g., ER utilization, hospice and end-of-life services utilization, hospital admission rates, and other measures appropriate and necessary in the determination of quality care. Data generated by HIEs is considered more accurate than data captured and reported manually, lending credibility to an individual practice's reported performance measures. Supportive care entities that utilize an HIE would be given preference on patient referrals.
- **Other efficiencies**—CPT codes have been updated and revised over the past two years to encourage telehealth. These new codes, plus additional telehealth enhancements, would be encouraged throughout the life of this model. HHS and CMS have expressed a goal of increased efficiency for all evaluation and management services, as well as greater use of telehealth, while also reducing onerous documentation requirements. OCM 2.0 supports this position and would encourage creative efforts that promote this efficiency.

References & Citations

1. Von Minckwitz, G. Huang CS, Mano MS, et al. Trastuzumab emtansine for residual Invasive HER-2 positive breast cancer. *N Engl J Med.* 2019;380(7):617-628. Epub 2018 Dec 5.
2. Martin, M. Holmes FA, Ejlertsen B, et al. Neratinib after trastuzumab-based adjuvant therapy in HER2-positive breast cancer (ExteNET): 5-year analysis of a randomised, double-blind, placebo-controlled, Phase 3 Trial. *Lancet Oncol.* 2017;18(12):1688-1700. Epub 2017 Nov 13.
3. IMS Institute: Global Oncology Trend Report: A Review of 2015 and Outlook to 2020, Available at: <https://morningconsult.com/wp-content/uploads/2016/06/IMS-Institute-Global-Oncology-Report-05.31.16.pdf>. Accessed February 2, 2019.
4. American Cancer Society. Cancer Facts & Figures. Atlanta, GA: American Cancer Society; 2018. Available at: <https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2018/cancer-facts-and-figures-2018.pdf>. Accessed February 2, 2019.
5. Kantarjian HM, Fojo T, Mathisen M, et al. Cancer drugs in the United States: Justum Pretium — the just price. *J Clin Oncol.* 2013;31(28):3600-3604.
6. Smith TJ, Hillner BE. Bending the cost curve in cancer care. *N Engl J Med.* 2011;364(21):2060-2065.
7. Fojo T, Grady C. How much is life worth: Cetuximab, non-small cell lung cancer, and the \$440 billion question. *J Natl Cancer Inst.* 2009;101(15):1044-1048.
8. American Cancer Society. Cancer Facts & Figures 2008 Special Section: Insurance and Cost-Related Barriers to Cancer Care. Atlanta, GA: American Cancer Society, 2008. Available at: <https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2008/cancer-facts-and-figures-2008.pdf>. Accessed February 7, 2019.
9. Gilligan AM, Alberts DS, Roe DJ, Skrepnek GH. Death or Debt? National estimates of financial toxicity in persons with newly-diagnosed cancer. *Am J Med.* 2018;131(10):1187-1199.
10. Center for Medicare & Medicaid Innovation. Evaluation of the Oncology Care Model. Performance Period One. Available at: <https://innovation.cms.gov/Files/reports/ocm-secondannualeval-pp1.pdf>. Accessed January 27, 2019.
11. Zuñiga L, Calvo B. Regulatory aspects of biosimilars in Europe. *Trends Biotechnol.* 2009; 27(7):385-387.
12. Nabhan C, Valley A, Feinberg B. Barriers to oncology biosimilars uptake in the United States. *Oncologist.* 2018;23(11):1261-1265.
13. American Society of Clinical Oncology. Quality Programs. <https://practice.asco.org/quality-improvement/quality-programs>
14. Yabroff KR, Lund J, Kepka E, Mariotto A. Economic burden of cancer in the US: estimates, projections, and future research. *Cancer Epidemiol Biomarkers Prev.* 2011;20(10):2006-2014.
15. Berkeley Research Group. The Pharmaceutical Supply Chain: Gross Drug Expenditures Realized by Stakeholders. January 2017. Available at:

https://www.thinkbrg.com/media/publication/863_Vandervelde_PhRMA-January-2017_WEB-FINAL.pdf. Accessed January 27, 2019.

16. Centers for Medicare & Medicaid Services. Notice of waivers of certain fraud and abuse laws in connection with the Oncology Care Model, April 28, 2016. Available at: <https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/OCM-Waiver.pdf>. Accessed January 27, 2019.
17. Community Oncology Alliance. The Real-Life Patient Impact of Pharmacy Benefit Managers, April 2017. Available at: <https://www.communityoncology.org/wp-content/uploads/sites/20/2018/08/PBM-HorrorStories-Volume1-final.pdf>. Accessed January 27, 2019.
18. Ogle.J. Personal communication and analysis. 2019, March 13.
19. COAnalyzer. Internal analysis of oncology practice data. <https://coanalyzer.net/>

Appendix

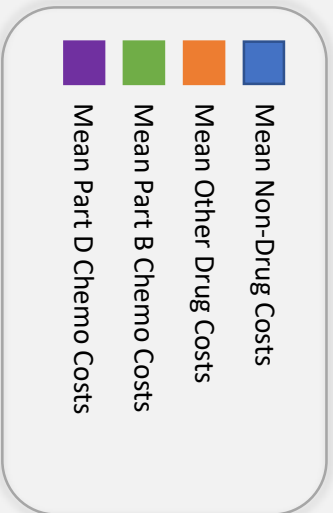
Cost increases are concentrated in Part D (and Part B chemo)



* Costs are defined per specification of the CMS OCM methodology



Episode Cost



Sources: * Abt Associates, Evaluation of the Oncology Care Model: Performance Period One, Dec. 2018

* Abt Associates, First Annual Report from the Evaluation of the Oncology Care Model: Baseline Period, Feb. 2018;

*Tupole Health Analysis

Table 1. OCM Compared With OCM 2.0

	OCM	OCM 2.0	Major Difference
Care requirements	IOM 13 Point Care Plan and Other	6 OMH Standards	
	IOM 1. Patient information	Usual and customary cancer care	
	IOM 2. Diagnosis, including specific tissue information, relevant biomarkers and stage	Usual and customary cancer care	
	IOM 3. Prognosis	Usual and customary cancer care	
	IOM 4. Treatment goals	Usual and customary cancer care	
	IOM 5. Initial plan for treatment and proposed duration, including specific chemotherapy drug names, doses and schedule as well as surgery and radiation therapy (if applicable).	OMH Standard 1.3: All patients are provided with education on their cancer diagnosis and an individualized treatment plan	
	IOM 6. Expected response to treatment	Usual and customary cancer care	
	IOM 7. Treatment benefits and harms, including common and rare toxicities and how to manage these toxicities, as well as short-term and late effects of treatment	Usual and customary cancer care	
	IOM 8. Information on quality of life and patient’s likely experience with treatment	OMH Standard 5.2: The OMH practice administers a patient satisfaction survey to cancer patients at least twice each calendar year or on an ongoing basis. The results of the survey are analyzed and used to guide quality improvement activities	*
	IOM 9. Who will take responsibility for specific aspects of a patient’s care	Usual and customary cancer care	
	IOM 10. Advance care plans, including advanced directives and other legal documents	Usual and customary cancer care	
	IOM 11. Estimated total and out-of-pocket costs of cancer treatment	OMH Standard 1.2: Patient financial counseling services	

		are available within the OMH practice	
	IOM 12. A plan for addressing a patient's psychosocial health needs, including psychological, vocational, disability, legal or financial concerns and their management	OMH Standard 4.3: All patients are provided on-site psychosocial distress screening and referral for the provision of psychosocial care, as needed	
	IOM 13. Survivorship plan, including a summary of treatment and information on recommended follow-up activities and surveillance as well as risk reduction and health promotion activities	OMH Standard 4.4: The OMH practice develops and implements a process to disseminate a treatment summary and survivorship care plan to patients within 90 days of the completion of treatment.	
	24/7 access to appropriate clinician who has real-time access to patients' records	OMH Standard 2.1: The OMH practice institutes expanded access and a triage system to ensure that patients can easily access the practice and their providers	
	Core functions of patient navigation	OMH Standard 4.1: A medical oncologist directs the patient's care team within the OMH practice and manages or co-manages the inpatient team-based care OMH Standard 4.2: The OMH practice establishes relationships for effective communication with outside providers for the appropriate management of patient care	* *
	N/A	OMH Standard 1.1: All patients are provided education on the OMH practice and concept	
	The use of therapies consistent with the nationally recognized clinical guidelines	OMH Standard 3.1: Evidence-based treatment guidelines and/or pathways are used for treatment planning	
	The use of data for continuous quality improvement	OMH Standard 5.1: The OMH practice records, reviews, and monitors	*

		<p>completeness of clinical data for initiating quality improvement activities</p> <p>OMH Standard 5.3: Each calendar year, the OMH practice develops, analyzes, and documents at least one quality improvement study associated with improving clinical outcomes and implements at least one quality improvement based on study results</p>	
	Practice is required to use CEHRT	Practice is required to use CEHRT	
	N/A	OMH Standard 6: Practice meets QCP Chemotherapy Safety Standards	
Accreditation of improved care	N/A	The above would be validated by a site visit of experienced leaders in cancer care. This entity would be responsible for assuring all general practice quality improvement activity is completed in a timely manner through the 3-year accreditation period	*
Measures	<p>In addition to the below, 33 additional data points related to staging and other clinical data, should be submitted to CMMI</p> <p>This data must be gathered and reported as a specific upload or through manual entry</p> <p>Some of the below is captured through billing data. Other must be manually gathered and submitted</p>	<p>No additional data will be required for OCM 2.0</p> <p>The numerators and denominators for the below would be captured and reported electronically</p>	<p>*</p> <p>*</p>
	Risk-adjusted proportion of patients with all-cause ED visits that did not result in a hospital admission within the 6-month episode	Not measured in OCM 2.0	

	Proportion of patients who died who were admitted to hospice for 3 days or more	Proportion not admitted to hospice	
	Patient-reported experience of care	Not a specific measure in OCM 2.0. Experience is reported through the OMH patient survey	*
	Oncology: medical and radiation – pain intensity quantified	A plan for managing the pain is more important, if or when it occurs, than a single assessment of quantifying the pain. The specific measure to not quantify pain is not included.	
	Oncology: medical and radiation – plan of care for pain	Usual and customary cancer care	
	Preventive care and screening: screening for depression and follow-up plan	Preventive care and screening: screening for clinical depression and follow-up plan	
	Care plan	Care plan	
	N/A	Pathway adherence and compliance rate	
	N/A	Cancer patients – survivorship care plan	
	N/A	Pneumococcal vaccination status for older adults	
	N/A	Hepatitis studies before Rituxan administration	
	N/A	Bisphosphonate treatment q 3 months (not monthly) for breast cancer	
	N/A	Proportion receiving chemotherapy in the last 14 days of life	
Drugs	Novel therapy adjustment in attempt to predict rising drug costs based on historical trends for that cancer team and as compared to national trends.	CMMI is requested to remove regulatory obstacles so that numerous value-based arrangement pilots can be established between manufacturers and cancer care teams. To date, 7 drug companies have volunteered to present their different proposals once these	*

		<p>regulations have been addressed</p> <p>This PFPM would also focus on the value of biosimilars and targeted cancer therapy and their impact on the total cost of cancer care</p>	
Diagnostic testing	Considered only in the total cost of care	The following will be reviewed in the analysis of value and the total cost of care: advanced imaging and laboratory with special emphasis on molecular diagnostic tests	*
Clinical trials	Patients participating in clinical trials sponsored by the NCI are included in the benchmarking calculations. Patients participating in industry clinical trials are excluded	<p>OMH Standard 3.2: Patients are provided clinical research study information by the OMH practice as appropriate for the patient’s clinical condition</p> <p>Patients that participate in NCI or industry-sponsored clinical trials will be included in shared savings benchmarking calculations</p>	*
Payment methodology	Complicated with several “adjustments” and 17 different calculations to determine PBP per team. Excel example includes 7 worksheets as background calculations to some of the 17 calculations	<p>Simplified with many of the “adjustments” eliminated. Calculations for the differences by case and geography have been simplified. Other aspects to be modified in payer/care team(s) individual discussions</p> <p>The goal for all payment methodology initiatives developed under this PFPM is for participant project leaders to be able to understand, recreate, educate others, and explain how their team performs in the PBP calculations. The goal would be for every team to be able to</p>	<p>*</p> <p>*</p>

		state, with confidence why they performed the way they did in on PBP reconciliations	
Initial payment	\$160 for the first episode	Suggested amount is \$160 which would register the patient for the model. This would also replace the pre-certification process for commercial payers that adopted the model	*
Episodes	6 months in length for 5 years. January through June and July through December.	Follows the same primarily since CMMI and other payers have adapted a 6- month episode	
PMPM	\$160 per patient per month for subsequent until the patient expires, is admitted to hospice or 90 days post treatment	Suggested amount is \$160 but to be adjusted and finalized in discussions between care team(s) and payers	
Geographic considerations	Standardizes prices by removing GPCI and the HWI and then multiplying actual to standardized prices. These calculations are applied to all participating team and all teams are compared against all other teams	Participating cancer care teams would participate against all other cancer care teams within that state whether they are participating or not. Comparisons would be at the state level	*
Risk methodology	12 covariates are used to determine target base amounts	Base risk methodology would be the patient's main ICD-10 cancer code. Other layers would be mutually designed in order to assure effective educational material before model launch.	*
Total cost of care	All charges are included in settlement. Charge capture stops at time of death or admission to hospice	Total costs will be through the date of death or 30 days following the last date of IV chemotherapy or the dispensing of an oral chemotherapy agent	*
Benchmarking	Against other OCM teams and national	Against other COA PFPM participants and non-participants in their state.	*
Winsorization	Cost outliers for cases in excess of 5% and 95% are excluded from the PBP calculations	Cost outliers for cases in excess of 10% and 90% are excluded from PBP calculations	

Attribution reports	These reports are not available for at least 1 year following the initial treatment. The average variance between CMMI and the OCM participants is approximately 40% for attributed patients. Teams have 30 days to contest attribution differences	Patients would register with and an assigned HCPCS code to minimize variance. Preliminary attribution reports would be produced 90 days after the trigger	
Settlement reports	Similar to the attribution reports. A full year elapses before settlement reports are available for participants	Preliminary settlement reports would be produced 90 days following the close of each episode. Teams would have 30 days to contest discrepancies. Final settlement reports would be produced 1 year following the preliminary report	*
Shared savings	Participants retain 100% of savings after the numerous PBP adjustments have been applied	Participants would retain a percentage of shared savings depending on their benchmarked quality scores and after PMPM and trigger amounts have been added Participants and commercial insurance companies would share savings 50/50 and given the above criteria. In the event the commercial insurance company is participating in the PFPM with an employer, the savings would be shared 1/3:1/3:1/3	* *
Patient feedback	81 questions. Feedback is available to the participating team after a 1-year delay in a paper report	40 questions, electronic, 5 languages and detail and summary benchmarking are available real-time.	*
Support	Requires a single or multiple; informatic, IT or other consulting resources, to interpret reports and to guide the appropriate next steps to manage the OCM or to achieve a PBP	Goal is to remove most of the need to recruit and retain additional support for model interpretation and management	*

CEHRT, certified electronic health record technology; **COA**, Community Oncology Association; **CMMI**, Center for Medicare & Medicaid Innovation; **ED**, emergency department; **GPCI**, Geographic Price Cost Index; **HCPCS**, Healthcare Common Procedure Coding System; **HWI**, Hospital Wage Index; **ICD-10**, 10th revision of the

International Statistical Classification of Diseases and Related Health Problems; **IT**, information technology; **IOM**, Institute of Medicine; **NCI**, National Cancer Institute; **OCM**, Oncology Care Model; **OMH**, Oncology Medical Home; **PBP**, performance-based payment; **PFPM**, physician-focused payment model; **PMPM**, per member per month; **QCP**, QOPI Certification Program; **QOPI**, Quality Oncology Practice Initiative

Standard 1.1: All patients are provided education on the Oncology Medical Home practice and concept.

STANDARD DEFINITION AND REQUIREMENTS

The practice ensures that a process is in place to educate all cancer patients regarding the specific Oncology Medical Home (OMH) cancer care concept and to understand their responsibilities within the OMH model.

Educational information to be provided includes, but is not limited to:

- Definition, goals, and importance of an OMH.
- The importance of the medical oncologist and the care team as the coordinators for patients before, during and after active cancer care treatment. (From initial diagnosis, second opinions, survivorship and end of life planning)
- Information on how and when to contact the medical oncologist, including evenings and weekends, with issues that need to be addressed.
- Definition of the responsibilities of the patient and the practice.
- Direct contact information for patients' principal care team.

DOCUMENTATION REQUIREMENT: Policies and procedures for providing all patients with education on the OMH practice and a copy of educational materials provided; documentation in patient record that OMH education was provided. (? Accreditation visit or provided in advance)

Standard 1.2: Patient financial counseling services are available within the Oncology Medical Home practice.

STANDARD DEFINITION AND REQUIREMENTS

Financial counseling assists patients with understanding and addressing financial concerns during cancer treatment and care. Counseling includes patient and caregiver education on financial responsibility and the availability of resources, if needed. The practice has a policy in place to regularly review the policies and procedures for financial services and monitor the available resources and funds for patients.

STANDARD SPECIFICATIONS

- Financial counseling services are available to all patients.
- Patients receive information about financial assistance programs as needed.
- When available, medication assistance programs are shared with patients.
- Practice provides information about financial assistance from other sources.

- Patients receive support regarding their estimated total and out-of-pocket costs of cancer treatment.

DOCUMENTATION REQUIREMENT: Policies and procedures for financial counseling services; list of assistance programs available to patients; number of patients receiving financial counselling support; documentation of annual review of financial counseling program with OOC. (*? Accreditation visit or provided in advance*)

Standard 1.3: All patients are provided with education on their cancer diagnosis and an individualized treatment plan.

STANDARD DEFINITION AND REQUIREMENTS

Ongoing communication with patients and caregiver(s) is essential to keep patients engaged and informed about their cancer care. Practices must provide all patients with education and information regarding their disease and treatment plan. Indication that education and a treatment plan was provided is documented in the patients' EHR. The OOC ensures that the practice develops and annually reviews the policies and procedures on new patient education.

STANDARD SPECIFICATIONS

The patient and caregiver(s) are educated and provided with a treatment plan prior to receiving cancer treatment. The education and treatment plan include discussion between patient and caregiver and the opportunity for questions about the following areas (not all inclusive):

- Diagnosis
- Prognosis
- Treatment goals (curative, life-prolonging, symptom control, palliative care)
- Initial plan for treatment and proposed duration, including specific chemotherapy drug names, doses, and schedule as well as surgery and radiation therapy (if applicable)
- Treatment recommendations
- Side effects
- Implications on quality of life
- Treatment benefits and harms, including common and rare toxicities and how to manage these toxicities, as well as short-term and late effects of treatment
- Who will take responsibility for specific aspects of a patient's care (e.g., the Cancer care team, the primary care/geriatrics care team, or other care teams)
- Cancer-related resources and information

Patients are also educated about the use of the Patient Portal and how to access educational materials available on the Portal. OMH education is reinforced as part of the treatment plan discussion.

DOCUMENTATION REQUIREMENT: Policies and procedures for patient and caregiver education regarding cancer diagnosis, treatment plan and expected side effects. (*Accreditation visit*)

MEASURES:

- Practice outcome measure – QPP 47 Care plan.

Standard 2.1: The Oncology Medical Home practice institutes expanded access and a triage system to ensure that patients can easily access the practice and their providers.

STANDARD DEFINITION AND REQUIREMENTS

The heart of the Oncology Medical Home (OMH) practice is patient accessibility when a medical problem arises that can be successfully and safely addressed in the physician's office. OMH practices must ensure that new and established patients have access to their own physician(s) and care team when they require oncology-related care. The OMH practice establishes specific processes to expedite appointments for new patients, as medically required or requested. Urgent (same day) appointments must be made available at the practice.

OMH practices offer extended coverage or expanded access during morning, evening, and/or weekend hours so patients requiring care can be seen either at the practice or another location thus avoiding unnecessary emergency department (ED) visits.

A triage system is in place to support active symptom management of patients and is the command center of the OMH practice. Traditional triage systems where clinical staff may provide advice over the phone with the intention of keeping the patient home are replaced in the OMH model with a triage system that intends to bring patients into the office for active and effective early symptom management.

Policies and procedures are established to standardize the triage system management of walk-in patients. The patients are to be educated and repeatedly encouraged to contact the practice early to address symptoms that can be managed before the patient requires hospitalization or ED use.

Triage system infrastructure and policies to be formulated and reviewed by the OOC must include, but are not limited to:

- Extended hours, expanded access and weekend availability to manage patient issues and reduce ED visits and hospitalizations
- At least one oncologist with access to the EHR on call overnight and on weekends to manage emergencies
- Availability to schedule same-day appointments for patients requiring urgent care
- Accommodation of walk-in patients
- Policy and procedures for direct admissions (bypassing the ED when medically appropriate)
- Specific policies and procedures that expedite appointments for urgent and new patients. These policies and procedures should include a provision for urgent scheduling of appointments based on medical need or patient anxiety

STANDARD EXCEPTIONS

Expanded Access: Some OMH practices may not find it financially feasible to offer extended office hours for a number of reasons, including small practice size, several oncology medical homes in local area leading to redundancy of infrastructure or rural populations that are unlikely to drive to a centralized clinic during evening hours. For this reason, the definition of extended hours is purposefully broad and could include weekend injection clinic, full extended practice hours or physician and staff on call and able to see patients presenting with medical problems in a lower-cost site of care compared with an ED.

DOCUMENTATION REQUIREMENT: Policies and procedures including all elements listed above; policies and procedures regarding availability of same day appointments; documentation of ER visits for patients on active chemotherapy; policies and procedures related to admissions direct from practice; policies and procedures for patient call-backs including maximum call back time for urgent and non-urgent patients according to medical condition. (*? Accreditation visit and/or provided in advance*)

Standard 3.1: Evidence-based treatment guidelines and/or pathways are used for treatment planning.

STANDARD DEFINITION AND REQUIREMENTS

All patients are to be treated in accordance with principles of evidence-based medicine, consistent with clinical guidelines of the American Society of Clinical Oncology (ASCO), the National Comprehensive Cancer Network (NCCN), or other nationally recognized clinical guidelines and/ or clinical treatment pathways based on cancer stage, appropriate biomarkers, and patient performance status, as appropriate for individual clinical circumstances. Using and measuring care against evidence-based guidelines has been shown to improve care quality and outcomes while reducing overall cost of care due to reduction in variation.

OMH practices utilize scientifically validated, evidence-based guidelines and/or pathways for:

- Treatment planning
- Safe medication administration
- Appropriate utilization of resources, laboratory, and imaging studies

STANDARD EXCEPTIONS

- Documentation in the Electronic Health Record (EHR) that patient was offered guideline-adherent care but declined.
- The patient's clinical circumstances (performance status, comorbidities) make guideline-adherent care inappropriate for the patient. Reason(s) for deviations from standard pathways and/or guidelines should be documented in the patient's EHR.
- The patient's clinical circumstances are not included in the guideline/pathways recommendations.

- Patient participation in a clinical trial exempts from guideline/pathway requirement.

DOCUMENTATION REQUIREMENT: Policies and procedures on the utilization of treatment guidelines and/or pathways for patient care. Include pathway compliance rate if applicable.

Standard 3.2: Patients are provided clinical research study information by the Oncology Medical Home practice as appropriate for the patient’s clinical condition.

STANDARD DEFINITION AND REQUIREMENTS

Clinical research advances science and ensures that patient care approaches the highest possible level of quality. Providing information about the availability of cancer-related clinical research studies, in the OMH practice or otherwise accessible to patients, offers patients the opportunity to enroll in treatment or observational research studies and trials. Policies and procedures outline the process of providing clinical research information and available studies that are open for enrollment.

DOCUMENTATION REQUIREMENT: Policies and procedures regarding availability of oncology clinical research studies, either on-site or by referral.

Standard 4.1: A medical oncologist directs the patient’s care team within the Oncology Medical Home practice and manages or co-manages the inpatient team-based care.

STANDARD DEFINITION AND REQUIREMENTS

Under the OMH model, the medical oncologist is responsible for the coordination of oncology care. Care coordination is an essential component of the Oncology Medical Home (OMH) model. A newly diagnosed cancer patient is often overwhelmed with tests, treatments, appointments, communications, and instructions between the various teams of providers who are entrusted with their care.

Oncology care is coordinated with other providers as clinically appropriate as well as outside agencies, such as, home care agencies, rehabilitation, and/or hospice. Communication processes through a patient’s medical oncologist are established to keep other providers, including the primary care physician, informed of a mutual patient’s treatment plan and current status. The process is monitored, and findings are reported to the OMH Oversight Committee (OOC).

DOCUMENTATION REQUIREMENT: Policies and procedures on medical oncologist-directed care including: 1) communication standards to ensure timely communication to referring physicians, primary care physicians, palliative care/symptom management teams, and hospice; 2) process for timely ordering of tests and tracking results, including communication to patients; and 3) documentation of annual review of policies and procedures with OOC. (? Accreditation visit or provided in advance)

Standard 4.2: The Oncology Medical Home practice establishes relationships for effective communication with outside providers for the appropriate management of patient care.

STANDARD DEFINITION AND REQUIREMENTS

As a component of patient-centered care, the practice must coordinate effective communication and referrals to outside providers and ancillary services, as needed. This coordination includes, but is not limited to:

- Updating referring physicians and primary care providers
- Clear communication with consulting physicians and services
- Arrangement of needed ancillary services, such as home health, hospice, and outside testing services
- Expediting patient referrals to outside providers while monitoring the completion of and findings from the referrals

Additionally, policies and procedures are in place to ensure that the patients follow through with testing, referrals, and future appointments with physicians outside of the practice as well as monitoring incomplete referrals. Mechanisms are in place to “close the loop,” retrieve the information from outside providers (tests, consults, documents, and so on) and communicate them to the appropriate provider in a timely manner.

As medically appropriate, the practice provides the following services on-site or by referral:

- Rehabilitation
- Nutritional support/counseling
- Surgical and radiation oncology
- Diagnostic imaging
- Laboratory studies
- Psychosocial evaluation and support
- Genetic counseling
- Palliative care/symptom management
- Home care

DOCUMENTATION REQUIREMENTS: Policies and procedures for scheduling appointments for on-site services or referral process for outside services. (? Accreditation visit or provided in advance)

Standard 4.3: All patients are provided on-site psychosocial distress screening and referral for the provision of psychosocial care, as needed.

STANDARD DEFINITION AND REQUIREMENTS

To address the psychosocial issues experienced by patients with cancer, the 2007 report of the Institute of Medicine (IOM), *Cancer Care for the Whole Patient: Meeting Psychosocial Health Needs*, emphasizes the importance of screening patients for distress and psychosocial health needs as a critical first step to providing high-quality cancer care. In addition, this report emphasizes that all patients with cancer need to be referred for the appropriate provision of care and that high-quality psychosocial cancer care includes systematic follow-up and reevaluation.

Practices must develop a process to incorporate the screening of distress into the standard care of oncology patients including a plan and review of psychological, vocational, disability, legal, or financial concerns, their management and their ability to impact treatment plans and outcomes.

The process must provide the appropriate resources and/or referral to address the patients' psychosocial needs. Distress should be recognized, monitored, and documented and treated at all stages of cancer.

PROCESS REQUIREMENTS

- (a) **Timing of Screening:** All cancer patients must be screened for distress a minimum of one time during a pivotal medical visit as determined by the practice. The OOC defines one or more medical visits that are part of a pivotal time for the distress screening process. Examples of a "pivotal medical visit" may include postsurgical visits, first visit with a medical oncologist to discuss chemotherapy, routine visit with a radiation oncologist, or a post-chemotherapy follow-up visit. Preference should be given at pivotal medical visits when there are known times of greatest risk for distress, such as at the time of diagnosis, transitions during treatment (such as from chemotherapy to radiation therapy), and completion of treatment.
- (b) **Method:** The mode of administration (i.e. patient questionnaire or clinician-administered questionnaire) is to be determined by the OOC and may be tailored to the workflow of the practice. Medical staff, including medical assistants, nurses, and physicians must be trained to properly administer the screening tool.
- (c) **Tools:** The OOC selects and approves the screening tool to be administered to screen for current distress. Preference should be given to standardized, validated instruments or tools with established clinical cutoffs. The POC determines the cutoff score used to identify distressed patients.

Questionnaires or forms that are distributed or returned by mail and/or phone interviews without discussion at a medical visit do not meet the standard because this method does not allow for immediate attention for severe distress or suicidal ideation, if patient reported, and

does not allow for active dialogue with the patient. Practices may have patients complete the distress screening tool through a patient portal or electronic screening method within 24 hours of the pivotal medical visit as long as the screening results are reviewed and discussed with the patient face-to-face at the visit.

- (d) **Assessment and Referral:** The distress screening results must be discussed with the patient at the medical visit. If there is clinical evidence of moderate or severe distress based on the results of the distress screening, a member of patient’s oncology team (physician, nurse, social worker, and/or psychologist) must identify and examine the psychological, behavioral, financial and/or social problems instigating the distress. This evaluation will confirm the presence of physical, psychological, social, spiritual, and financial support needs. The process developed by the OOC includes the psychosocial services or resources available to patients on-site or by referral.
- (e) **Documentation:** The screening process, timing of screening, identified tool, and distress level triggering a referral to services are documented in the OOC minutes.

The distress screening(s) results, referral for provision of care, and any follow-up measures are documented in the patient medical record to facilitate integrated, high-quality care.

DOCUMENTATION REQUIREMENTS: Policies and procedures for process for psychosocial distress screening and resultant interventions. Documentation of annual review of policies by OOC.

MEASURES:

- Practice outcomes measure – QPP 134 Preventive Care and Screening: Screening for Clinical Depression and Follow-Up Plan

Standard 4.4: The Oncology Medical Home practice develops and implements a process to disseminate a treatment summary and survivorship care plan to patients within 90 days of the completion of treatment.

STANDARD DEFINITION AND REQUIREMENTS

The 2005 Institute of Medicine report, *From Cancer Patient to Cancer Survivor*, outlines the importance of providing cancer survivors a comprehensive care summary and follow-up plan once they complete their primary cancer care that reflects the treatment they received and addresses post-treatment needs and follow-up care to improve health and quality of life.

The Survivorship Care Plan (SCP) is a record that summarizes and communicates what transpired during active cancer treatment, recommendations for follow-up care and surveillance testing/examination, referrals for support services the patient may need going forward, and other information pertinent to the survivor’s short- and long-term survivorship

care. It includes a summary of treatment and information on recommended follow-up activities and surveillance, as well as risk reduction and health promotion activities.

Oncology Medical Home practices must develop and implement a process to monitor the dissemination of a SCP as a part of the standard care for all cancer patients who are treated with curative intent for initial cancer occurrence and who have completed active therapy (other than long-term hormonal therapy). If two different practices or facilities are providing treatment, both practices should work together to collaborate in providing a completed SCP. The practice providing follow-up and monitoring of the patient (i.e. medical oncology) should provide the SCP. In all cases, facilities and practices should work together to provide the information necessary for completion of a SCP that contains all required information

The American Society of Clinical Oncology (ASCO) has defined the minimal data elements to be included in a treatment summary and survivorship care plan (Mayer DK, et al. American Society of Clinical Oncology Clinical Expert Statement on Cancer Survivorship Care Planning. *Journal of Oncology Practice*, 2014). This core set of data elements and templates are available on the ASCO website and in the References section of this manual. At a minimum, all SCPs should include ASCO-recommended elements to be included in the treatment summary and follow-up care plan to meet compliance for this standard.

DOCUMENTATION REQUIREMENTS: Policies and procedures for developing and providing treatment summary and survivorship care plan for all eligible patients; sample treatment summary and survivorship care plan to be provided. (*? Accreditation visit or provided in advance*)

MEASURES:

Cancer patients – survivorship care plan (CLLC3)

Standard 5.1: The Oncology Medical Home practice records, reviews, and monitors completeness of clinical data for initiating quality improvement activities.

STANDARD DEFINITION AND REQUIREMENTS

Internal policies and procedures within the practice must identify for physicians and other clinicians the specific clinical data elements that must be captured within the Electronic Health Record (EHR). As a commitment to the process, practices must implement, maintain, and monitor EHR documentation to ensure the completeness of clinical data in searchable areas of the practice health data system(s).

Certain data elements are essential for data-driven, continuous quality improvement. Quality improvements are the actions taken and processes implemented to improve the documentation of the required clinical data elements. The methods used to monitor the EHR data and action plans to correct

problematic findings are set by the OMH Oversight Committee (OOC). The findings of the studies are documented in the POC minutes and shared with the staff at the practice.

Core data elements which must be documented in the EHR include:¹

- Staging
- Intent of therapy
- Adverse events
- Disease status
- Patient status
- Line of therapy

DOCUMENTATION REQUIREMENTS: Practice policies and procedures for completion of EHR with core data elements and measurement of same. (*Accreditation visit; chart review*)

Standard 5.2: The Oncology Medical Home practice administers a patient satisfaction survey to cancer patients at least twice each calendar year or on an ongoing basis. The results of the survey are analyzed and used to guide quality improvement activities.

STANDARD DEFINITION AND REQUIREMENTS

Patient satisfaction is an important component for measuring health care quality due to the impact on patient outcomes. Patients place a high value on the interaction and communication with their providers. In addition, the management of their issues, such as psychosocial distress, pain, and depression, improves patient satisfaction. Oncology Medical Home practices must administer patient satisfaction surveys using a validated, oncology-specific patient satisfaction tool that includes benchmarks.

Practices will evaluate and take actions to improve cancer patient satisfaction scores. The results of patient satisfaction surveys are reviewed by the practice and utilized for clinical and quality improvement activities. The practice documents its activities, improvements, and benchmarks in the OOC minutes.

¹ http://ascopubs.org/doi/abs/10.1200/jco.2012.30.34_suppl.312

DOCUMENTATION REQUIREMENTS: Copy of patient satisfaction tool; annual report of patient satisfaction survey and benchmarked results; documentation of review of process and results with OOC and discussion of quality improvement activities implemented to improve patient satisfaction.

Standard 5.3: Each calendar year, the Oncology Medical Home Practice develops, analyzes, and documents at least one quality improvement study associated with improving clinical outcomes and implements at least one quality improvement based on study results.

STANDARD DEFINITION AND REQUIREMENTS

Annual evaluations and quality improvements provide a baseline to measure practice quality and an opportunity to correct or enhance care and outcomes. Quality improvement efforts focus on evaluating areas of cancer care and must include multidisciplinary representation from clinical, administrative, and patient perspectives.

Quality improvements are the actions taken, processes implemented, or services created to improve cancer care.

The results of a cancer-related quality study provide a baseline to measure and improve quality.

The goal of quality improvement in health care is to improve the overall care and outcomes for patients and providers.

Key performance measures for health care quality include:

- Safety and outcomes of care
- Timely and appropriate care
- Care provision is efficient and equitable
- Care is patient centered

Each calendar year, the POC develops, analyzes, and documents at least one quality improvement study associated with improving clinical outcomes and implements at least one quality improvement based on study results.

Study topics must be selected based on a problematic quality-related issue relevant to the practice and local cancer patient population and is aimed at continuous quality improvement. For example:

- Demonstrated use of reporting/benchmarking within the Quality Oncology Patient Initiative
- Meaningful quality improvement study with implementation of clinical improvement based on identified need for improvement in one or more of the OMH performance measures
- Quality studies can evaluate various spectrums of cancer care, including diagnosis, treatment, and supportive care of patients; within that spectrum can be issues related to structure, process, and outcomes

Sentinel events - defined by The Joint Commission as any unanticipated event in a healthcare setting resulting in death or serious physical or psychological injury to a patient or patients not related to the natural course of the patient's illness - must be addressed in addition to other quality improvement activities. Such events should be immediately identified and reported to the OOC (and any other appropriate practice oversight committee) for root cause analysis and development of preventative measures.

DOCUMENTATION REQUIREMENTS: Annual documentation of at least one quality improvement project that has been fully implemented as a result of data collected from a quality study as directed by the OOC. Studies should measure longitudinal performance over time with a minimum 24 month study period recommended. The recommendations and improvements are reported to the OOC and are documented in the OOC minutes. Successful completion of this standard may include: Active QOPI participation with documentation of review of results and any action taken; or Successful completion of MIPS Improvement Activities requirement.

Standard 6: Practice meets QOPI Certification Program (QCP) Standards

Complete QCP Standards are in Appendix 1

Practices desiring to achieve OMH status will meet the QOPI Certification Program (QCP) Standards. Practices are not required to meet the QOPI chart abstraction/participation requirement but must meet all standards and measures in the QCP program. Practices with current QCP Certification status with at least 12 months remaining of the 36-month cycle, are exempt from Standard 6 but must complete Standards 1 – 5 prior to the expiration of QCP Certification status. QCP Certification status must be maintained to maintain OMH status.

DOMAIN 1: Creating a safe environment – staffing and general policy (QCP Standards 1.1 – 1.8)

DOMAIN 2: Treatment planning, patient consent and education (QCP Standards 2.1 – 2.4)

DOMAIN 3: Ordering, preparing, dispensing and administering chemotherapy (QCP Standards 3.1 – 3.11)

DOMAIN 4: Monitoring after chemotherapy is given, including adherence, toxicity and complications (QCP Standards 4.1 – 4.5)

ReCAPs (Research Contributions Abbreviated for Print) provide a structured, one-page summary of each paper highlighting the main findings and significance of the work. The full version of the article is available online at jop.ascopubs.org.

Florida Cancer Specialists and Research Institute, Gainesville; Xcenda, Palm Harbor, FL; and IntrinsicQ, Fresno, AZ

Corresponding author: Lucio Gordan, MD, Florida Cancer Specialists and Research Institute, Division of Quality and Informatics, 6420 W Newberry Rd, Suite 100, Gainesville, FL 32605; e-mail: lgordan@flcancer.com.

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Cost Differences Associated With Oncology Care Delivered in a Community Setting Versus a Hospital Setting: A Matched-Claims Analysis of Patients With Breast, Colorectal, and Lung Cancers

Lucio Gordan, Marlo Blazer, Vishal Saundankar, Denise Kazzaz, Susan Weidner, and Michael Eaddy

QUESTIONS ASKED: Are there financial ramifications associated with the paradigm shift of cancer care delivery away from community-based clinics (CCs) and toward hospital-based oncology clinics (HCs)? Furthermore, are any cost differences also accompanied by care quality differentials as measured by hospitalizations or emergency department (ED) visits?

SUMMARY ANSWER: In 6,675 patients seen in either a CC or HC setting for their cancer care, total costs of care were lower per patient per month (PPPM) across all tumor types in the CC setting versus the HC setting (\$12,548 [standard deviation {SD}, \$10,507] ν \$20,060 [SD, \$16,555]; $P < .001$). The major driver of the cost differential was lower PPPM medical costs in the CC cohort (\$12,103 [SD, \$10,504] ν \$19,471 [SD, \$16,476]; $P < .001$). Rates of hospitalization 72 hours and 10 days after chemotherapy were similar for patients in both cohorts (CC ν HC at 72 hours: 2.3% ν 2.2% [$P = .6626$]; at 10 days: 7.0% ν 7.3% [$P = .6198$]). However, patients treated in the CC cohort had a 29% reduced risk of ED visits compared with the HC cohort (hazard ratio, 0.71; 95% CI, 0.54 to 0.95; $P = .02$).

WHAT WE DID: Cost data for patients with breast, lung, or colorectal cancer were extracted from the IMS LifeLink database. To control for clinical/demographic disparities between community and hospital patients, patients treated in the community setting were matched with those treated in a hospital-based clinic (2 to 1) on the basis of cancer type (breast

ν colon ν lung cancer), specific chemotherapy received, receipt of radiation, metastatic disease, sex, prior surgery, and geographic region. Chemotherapy-specific costs included the cost of chemotherapy plus costs incurred on the same day of administration. Pharmacy costs included all costs associated with dispensation of outpatient prescriptions under the patients' prescription drug plans. Costs were standardized to 2015 US dollars (\$) and analyzed PPPM. Hospitalizations, ED visits, physician visits, and other outpatient visits that occurred during follow-up were captured.

BIAS, CONFOUNDING FACTOR(S), DRAWBACKS: Although this analysis included a subset of patients age 65 years or older, it did not include evaluation of patients with Medicare or Medicaid as their sole payer. As such, results are not generalizable to these populations.

REAL-LIFE IMPLICATIONS: Treatment in the community practice is associated with lower total cost of treatment compared with hospital-based outpatient practices for patients with breast, lung, or colorectal cancer. An additional notable observation was the difference in ED visits after chemotherapy: those treated in the CC setting experienced fewer ED visits than those treated in the HC setting. These data provide real-world insight that calls for examination of reimbursement differentials across sites of care to ensure that access to high-quality cancer care is not diminished by limiting site of care options. **JOP**

Cost Differences Associated With Oncology Care Delivered in a Community Setting Versus a Hospital Setting: A Matched-Claims Analysis of Patients With Breast, Colorectal, and Lung Cancers

Lucio Gordan, Marlo Blazer, Vishal Saundankar, Denise Kazzaz, Susan Weidner, and Michael Eaddy

Florida Cancer Specialists and Research Institute, Gainesville; Xcenda, Palm Harbor, FL; and IntrinsicQ, Fresno, AZ

ASSOCIATED CONTENT



Data Supplements available online

Abstract

Purpose

Access to high-quality cancer care remains a challenge for many patients. One such barrier is the increasing cost of treatment. With recent shifts in cancer care delivery from community-based to hospital-based clinics, we examined whether this shift could result in increased costs for patients with three common tumor types.

Methods

Cost data for 6,675 patients with breast, lung, and colorectal cancer were extracted from the IMS LifeLink database and analyzed as cost per patient per month (PPPM). Patients treated within a community setting were matched (2 to 1) with those treated at a hospital clinic on the basis of cancer type, chemotherapy regimen, receipt of radiation therapy, presence of metastatic disease, sex, prior surgery, and geographic region. Approximately 84% of patients were younger than 65 years of age.

Results

Mean total PPPM cost was significantly lower for patients treated in a community- versus hospital-based clinic (\$12,548 [standard deviation {SD}, \$10,507] v \$20,060 [SD, \$16,555]; $P < .001$). The PPPM chemotherapy cost was also significantly lower in the community setting (\$4,933 [SD, \$4,983] v \$8,443 [SD, \$10,391]; $P < .001$). The lower cost observed in community practice was irrespective of chemotherapy regimen and tumor type.

Conclusion

We observed significantly increased costs of care for our patient population treated at hospital-based clinics versus those treated at community-based clinics, largely driven by the increased cost of chemotherapy and provider visits in hospital-based clinics. If the site of cancer care delivery continues to shift toward hospital-based clinics, the increased health care spending for payers and patients should be better elucidated and addressed.



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INTRODUCTION

Access to affordable, high-quality cancer care is essential for optimal outcomes, yet it remains a great challenge for patients with cancer.^{1,2} Numerous factors may contribute to barriers for accessing high-quality cancer care, including uneven geographic distribution of oncology centers, health insurance, and increasing treatment costs.¹ Notably, annual cancer care costs are estimated to surpass \$170 billion by 2020.³

An emerging reason for geographic barriers and escalating costs is the shift of care delivery from community-based to hospital-based oncology practices. Since 2008, community-based practice clinic closures have increased 121%, and acquisition of community practices by hospitals has increased by 172%.⁴ This hospital acquisition of community-based practices has greatly increased the overall volume of hospital-based chemotherapy claims.^{5,6} This trend is particularly relevant to the cost of cancer care. Several analyses have sited a large cost differential between chemotherapy administered in community- and hospital-based outpatient clinics.⁶⁻⁸

Given this shift in site-of-care provision, we evaluated the cost differences of cancer care provided to patients with breast, lung, or colorectal cancer treated in a community-based or a hospital-based outpatient clinic to better elucidate the potential financial implications of this trend. A matched-cohort approach was used to control for potential confounding factors while costs were compared for clinically and demographically similar patients treated with the same chemotherapy regimens.

METHODS

Data Source

A 10% random sample of medical and pharmacy claims was obtained from the IMS LifeLink database (Data Supplement). The data source is fully compliant with the Health Insurance Portability and Accountability Act.

Sample Selection

Included patients had at least one medical chemotherapy claim with a diagnosis of breast, lung, or colorectal cancer between July 1, 2010, and June 30, 2015. Patients were grouped into a community-clinic cohort (ie, CC cohort) or hospital-based outpatient-clinic cohort (HC cohort) according to the place-of-service codes and billing category for chemotherapy; patients must have received all chemotherapy in either the CC or HC setting and had continuous eligibility for 6 months in the pre-index period through end of follow-up. Patients with

evidence of administration in both HC and CC settings were excluded. The first chemotherapy date was each patient's index date. Patients were observed for up to 1 year after the index date or until the first-line chemotherapy regimen was discontinued (defined as a 60-day period with no record of chemotherapy administration), whichever occurred first. All chemotherapy agents given within the 28-day post-index period were considered part of the first-line chemotherapy regimen. Regimens were categorized as branded plus generic agent(s), branded agent(s) only, and generic agent(s) only; the cost for each category was calculated separately from overall chemotherapy cost. Costs during first-line chemotherapy were defined as the amount paid for all services rendered during the patient's follow-up time. Total medical costs included all costs except those covered under pharmacy costs. Within total medical costs, chemotherapy-specific costs were defined as the cost paid for chemotherapy plus any costs incurred on the same day of chemotherapy administration. The cost of clinic-administered supportive care not given on the same day as chemotherapy administration was included in other outpatient costs. Pharmacy costs included all costs associated with dispensation of outpatient prescriptions under the patients' prescription drug plans; oral chemotherapy was included in the pharmacy costs. All costs were standardized to 2015 US dollars (\$) and analyzed as cost per patient per month (PPPM). Hospitalizations, emergency department (ED) visits, and physician and other outpatient visits (defined as visits related to laboratory/pathology work, radiology, or outpatient procedures [ie, surgical or diagnostic]) that occurred during follow-up were also captured. Chemotherapy-related ED visits and hospitalizations were defined as those that occurred within 72 hours and 10 days after chemotherapy to ensure that patients in both cohorts had equal opportunity to be evaluated by a provider within a defined timeframe before chemotherapy administration.

Statistical Analysis

To control for clinical and demographic disparities between cohorts, we matched patients treated in the community setting with those treated in a hospital-based clinic (2 to 1); patients were matched according to cancer type (breast *v* colon *v* lung cancer; matched patients had only one of these diagnoses throughout the study period), specific chemotherapy received, receipt of radiation therapy during follow-up, presence of metastatic disease (identified via diagnosis codes; Data

Supplement), sex, prior surgery, and geographic region. Charlson comorbidity index (CCI) scores were computed to assess comorbidities between the cohorts; CCI was similar across both cohorts and was not included in the match.⁹ Results were also stratified by age 65 years or older.

Categoric measures were presented as counts and percentages; means and standard deviations (SDs) were presented for continuous outcomes. The Wilcoxon signed rank sum test was conducted using SAS version 9.2 (SAS Institute; Cary, NC).

RESULTS

A total of 44,870 patients diagnosed and treated for breast, lung, or colorectal cancer were identified; of these, 7,467 patients met all inclusion criteria and 6,675 were matched 2 to 1 (community-based care [$n = 4,450$] ν hospital-based care [$n = 2,225$]) according to characteristics previously described (Fig 1). Patient and disease-related characteristics for matched patients are listed in Table 1; patient and chemotherapy characteristics were similar before and after matching, which indicated that patients included in the matched cohort were not notably different from those excluded in observable characteristics. The mean CCI score was 4.7 (SD, 2.3) in the CC cohort and was 4.8 (SD, 2.4) in the HC cohort. Overall, 4,494 patients (67%) had breast cancer (metastatic disease in 50%), 1,428 (21%) had lung cancer (metastatic disease in 67%), and 753 (11%) had colorectal cancer (metastatic disease in 67%). There were no differences in baseline demographics when patients were separated according to cancer type (Data Supplement). For the Medicare-eligible stratification, 780 patients (17.5%) were in the CC cohort (17.5%), and 318 patients (14.3%) were in HC cohort; patient- and disease-related characteristics were also similar within this subset.

Treatment Patterns

Of the 4,494 matched patients who received chemotherapy for breast cancer ($n = 2,996$ in CC cohort; $n = 1,498$ in HC cohort), the most common regimens were cyclophosphamide plus doxorubicin (34%, each cohort), cyclophosphamide plus docetaxel (21%, each cohort), and trastuzumab, a platinum agent, and docetaxel (11%, each cohort). Overall, 17% received radiation therapy during follow-up (16%, CC cohort; 17%, HC cohort). The majority of patients with breast cancer received generic chemotherapy only (73%, each cohort) followed by combinations of branded and generic chemotherapy (17%, each cohort) and branded chemotherapy only (10%, each cohort). The mean duration of chemotherapy in each cohort

was similar (CC cohort, 96.9 days [SD, 62.1 days], ν HC cohort, 94.4 days [SD, 58.5 days]).

Of the 1,428 patients who received chemotherapy for lung cancer ($n = 952$ in CC cohort; $n = 476$ in HC cohort), the most common regimens were a platinum agent plus either etoposide (28%, each cohort), paclitaxel (26%, each cohort), or pemetrexed (25%, each cohort), and 37% in each cohort received radiation therapy during follow-up. Overall, 63% in each cohort received generic chemotherapy only, 33% received combinations of branded and generic chemotherapy, and 3% received branded chemotherapy only. The mean duration of chemotherapy for lung cancer in each cohort was similar (CC cohort, 95.5 days [SD, 48.5 days], ν HC cohort, 89.4 days [SD, 44.5 days]).

Of the 753 patients who received chemotherapy for colorectal cancer ($n = 502$ in CC cohort; $n = 251$ in HC cohort), 61% received FOLFOX (oxaliplatin, fluorouracil, and leucovorin); this was combined with bevacizumab in 10% of patients in each cohort. Also, 19% in each cohort received single-agent fluorouracil, and 17% in each cohort received radiation therapy during follow-up. The majority of patients with colorectal cancer received generic chemotherapy only (67%, CC cohort; 74%, HC cohort) followed by branded chemotherapy only (17%, each cohort) and a combination of branded and generic chemotherapy (16%, CC cohort; 9%, HC cohort). The mean duration of chemotherapy in each cohort was similar (CC cohort, 123.7 days [SD, 69.5 days], ν HC cohort, 115.9 days [SD, 64.4 days]).

Cost of Care

Across all tumor types, the mean total cost (ie, medical plus pharmacy costs) PPPM during the post-index period was \$15,052 (SD, \$13,321). The mean total cost PPPM was significantly lower in patients treated in a community-based practice compared with those treated in a hospital-based outpatient practice (\$12,548 [SD, \$10,507] ν \$20,060 [SD, \$16,555]; $P < .001$). This trend was maintained for each individual tumor type; patients in the CC cohort had significantly lower costs than those in the HC cohort, as follows: breast cancer, \$11,599 (SD, \$8,129) ν \$19,279 (SD, \$14,358); lung cancer, \$17,566 (SD, \$17,436) ν \$26,980 (SD, \$25,386); colorectal cancer, \$12,368 (SD, \$10,312) ν \$19,346 (SD, \$17,542; $P < .001$ for all analyses; Table 2).

Overall, the major driver of the cost differential between the CC and HC cohorts was lower PPPM medical costs (\$12,103 [SD, \$10,504] ν \$19,471 [SD, \$16,476] in the CC cohort

Table 1. Patient and Disease-Related Characteristics in All Matched Patients

Characteristic	No. (%) of Patients (N = 6,675)	
	Community	Hospital Practice
Total patients	4,450 (67)	2,225 (33)
Female	3,606 (81)	1,803 (81)
Age, years, mean (SD)	56 (10)	54.9 (10)
Age group, years		
< 25	12 (0)	3 (0)
25-34	91 (2)	54 (2)
35-44	435 (10)	303 (14)
45-54	1,418 (32)	662 (30)
55-64	1,714 (39)	885 (40)
65-74	624 (14)	261 (12)
75-84	156 (4)	57 (3)
Geographic region		
East	898 (20)	627 (28)
Midwest	1,716 (39)	680 (31)
South	1,584 (36)	748 (34)
West	252 (6)	170 (8)
Presence of metastatic condition	2,468 (55)	1,234 (55)
Surgery during pre-index period	2,378 (53)	1,189 (53)
Radiation treatment during pre-index period	667 (15)	323 (15)
No switch of chemotherapy	4,450 (100)	2,225 (100)
Surgery during post-index period	140 (3)	59 (3)
Radiation treatment during post-index period	986 (22)	495 (22)
Required inpatient service	426 (10)	233 (10)
Required emergency department service	449 (10)	292 (13)
Mean (SD) Charlson comorbidity index	4.7 (2.3)	4.8 (2.4)
Mean (SD) unique drugs prescribed at baseline	4.4 (3.8)	4.3 (3.7)
Mean (SD) eligible days at baseline	180 (0)	180 (0)
Mean (SD) paid medical cost at baseline, \$	4,604.10 (4,406.00)	5,278.40 (4,868.80)
Mean (SD) allowed medical cost at baseline, \$	5,434.00 (4,803.80)	6,038.30 (5,126.80)
Mean (SD) duration of therapy, days	99.6 (61.0)	95.7 (57.0)
Mean (SD) total cycles of treatment	5.2 (4.2)	4.8 (4.4)

Abbreviation: SD, standard deviation.

compared with the HC cohort; $P < .001$), although the mean pharmacy PPPM costs were also slightly lower in the CC cohort than in the HC cohort (\$445 [SD, \$1,239] v \$589 [SD, \$1,934]; $P = .2708$). This trend in medical costs was consistent across tumor types and was driven by differentials in both

chemotherapy costs and physician visit costs between sites of care (Table 2; $P < .001$ for these analyses across tumor types).

Regarding the costs of chemotherapy specifically, the mean PPPM cost was significantly lower in the community setting (\$4,933 [SD, \$4,983] v \$8,443 [SD, \$10,391]; $P < .001$), and

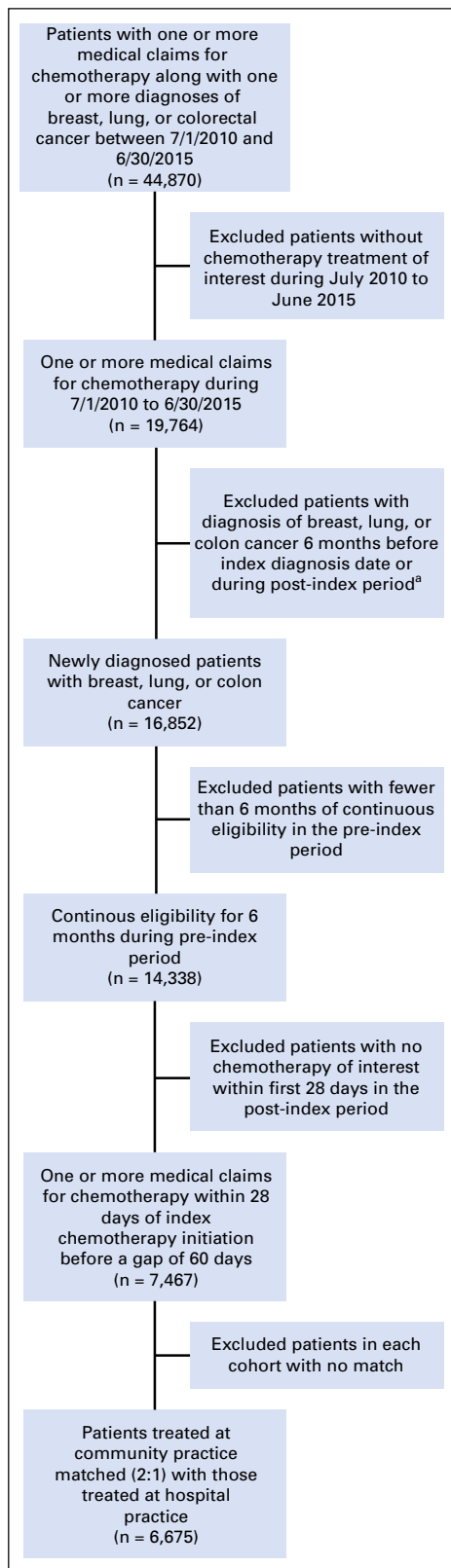


Fig 1. Patient attrition. (a) The index date is the date of the first chemotherapy administration.

patients were matched on type of chemotherapy received. The lower chemotherapy cost in the community practice setting was observed regardless of whether a brand, generic, or combination of brand and generic regimen was used (brand, \$6,674 [SD, \$5,046] ν \$10,900 [SD, \$10,712]; generic, \$2,936 [SD, \$2,585] ν \$5,134 [SD, \$6,306]; brand plus generic, \$11,080 [SD, \$5,889] ν \$19,412 [SD, \$13,869]).

Results for patients who were eligible for Medicare were similar to the overall analysis: the CC cohort had significantly lower costs than the HC cohort; the mean total PPM costs were \$9,414 (SD, \$13,171) in the CC cohort versus \$14,440 (SD, \$19,689) in the HC cohort ($P = .0012$). The cost differential observed in Medicare-eligible patients was, again, driven by lower PPM medical costs (\$9,078 [SD, \$13,757] ν \$14,036 [SD, \$19,721]; $P = .0024$).

Chemotherapy-Related Hospitalizations and ED Visits

Rates of hospitalization 72 hours and 10 days after chemotherapy across all patients were similar for patients treated in the community and hospital settings (CC ν HC cohort: 72 hours after chemotherapy, 2.3% ν 2.2% [$P = .6626$]; 10 days after chemotherapy, 7.0% ν 7.3% [$P = .6198$]). However, rates of ED visits within 72 hours and within 10 days of chemotherapy administration were significantly lower in the CC cohort versus the HC cohort (CC ν HC cohort: within 72 hours, 2.6% ν 3.6% [$P = .0055$]; within 10 days, 7.9% ν 9.8% [$P = .0022$]). This resulted in a risk reduction of 29% for ED visits for patients treated in the CC setting versus the HC setting (hazard ratio, 0.71; 95% CI, 0.54 to 0.95; $P = .02$). Furthermore, of the patients in the CC cohort who had at least one ED visit within 72 hours of chemotherapy administration ($n = 114$), a smaller proportion had multiple ED visits (ie, 2 or more) compared with patients who had at least one ED visit in the HC cohort ($n = 80$, HC; 7.9% ν 16.3%, CC ν HC). In addition to the lower rates of hospitalizations and ED visits in the CC versus HC cohort, patients in the CC cohort had a mean number of 4.4 outpatient physician visits per month (SD, 4.0 visits) compared with 5.0 visits per month (SD, 3.4 visits) for those in the HC cohort ($P < .001$); however, patients in the CC cohort had more other outpatient visits per month than those in the HC cohort (mean [SD], 4.5 [4.1] ν 3.7 [4]; $P < .001$).

DISCUSSION

This study suggests that the cost of cancer care for patients with breast, lung, or colorectal cancer treated in the CC setting is

Table 2. Mean PPM Medical Cost Components in All Matched Patients

Cost by patient group	Cost PPM (\$)				P
	Community Practice		Hospital-Based Practice		
	Mean	SD	Mean	SD	
All matched patients	n = 4,450		n = 2,225		
Mean total costs	12,548	10,507	20,060	16,555	< .001
Total medical costs	12,103	10,504	19,471	16,476	< .001
Chemotherapy	4,933	4,983	8,443	10,391	< .001
Branded agents only	6,674	5,046	10,900	10,712	< .001
Generic agents only	2,936	2,585	5,134	6,306	< .001
Combination regimen*	11,080	5,889	19,412	13,869	< .001
Physician visits	765	1,607	3,316	4,399	< .001
Radiation	1,095	4,153	1,430	4,904	< .001
Inpatient	1,178	6,229	1,498	7,193	.0095
ED visits	121	501	168	620	< .001
Outpatient	3,838	3,681	3,912	5,698	< .001
Other	174	2,405	704	3,353	< .001
Total pharmacy costs	445	1,239	589	1,934	.2708
Patients with breast cancer	n = 2,996		n = 1,498		
Mean total costs	11,599	8,129	19,279	14,358	< .001
Total medical costs	11,139	8,139	18,667	14,403	< .001
Chemotherapy	4,671	4,577	8,206	9,719	< .001
Branded agents only	5,608	4,273	9,279	7,805	< .001
Generic agents only	2,982	2,275	5,084	5,591	< .001
Combination regimen*	11,511	5,647	21,240	13,356	< .001
Physician visits	820	1,813	3,499	4,564	< .001
Radiation	378	1,305	440	1,493	.0561
Inpatient	735	4,230	874	3,804	.0415
ED visits	120	516	162	638	.0045
Outpatient	4,318	3,835	4,735	6,322	.2696
Other	97	718	752	3,461	< .001
Total pharmacy costs	461	1,361	612	1,699	.1084
Patients with lung cancer	n = 952		n = 476		
Mean total costs	17,566	17,436	26,980	25,386	< .001
Total medical costs	17,168	17,380	26,389	25,090	< .001
Chemotherapy	5,095	5,916	8,430	11,143	< .001
Branded agents only	7,969	4,967	7,881	5,974	.8408
Generic agents only	1,856	1,829	3,964	5,248	< .001
Combination regimen*	10,937	6,422	16,938	14,378	< .001
Physician visits	709	1,130	3,015	4,217	< .001
Radiation	3,255	7,845	4,343	8,798	< .001
Inpatient	2,767	10,612	3,413	12,982	.4836
ED visits	140	509	219	670	.0026
Outpatient	3,137	3,155	2,404	3,538	< .001
Other	133	947	506	2,120	< .001
Total pharmacy costs	398	950	591	2,828	.7058
Patients with colorectal cancer	n = 502		n = 251		
Mean total costs	12,368	10,312	19,346	17,542	< .001
Total medical costs	11,915	10,319	18,848	17,479	< .001

(continued on following page)

Table 2. Mean PPPM Medical Cost Components in All Matched Patients (continued)

Cost by patient group	Cost PPPM (\$)				P
	Community Practice		Hospital-Based Practice		
	Mean	SD	Mean	SD	
Chemotherapy	6,189	5,176	9,881	12,518	< .001
Branded agents only	9,862	6,041	17,603	16,676	< .001
Generic agents only	4,573	4,224	7,322	10,171	.0006
Combination regimen*	8,971	4,606	16,428	13,153	.2151
Physician visits	538	894	2,791	3,596	< .001
Radiation	1,274	3,770	1,820	5,597	.0119
Inpatient	802	4,212	1,593	6,637	.0207
ED visits	94	384	107	358	.1927
Outpatient	2,306	2,979	1,864	3,619	< .001
Other	711	6,799	790	4,431	.0019
Total pharmacy costs	454	1,081	498	1,109	.7512

Abbreviations: ED, emergency department; PPPM, per patient per month; SD, standard deviation.

*Combination chemotherapy regimen contained both branded and generic drugs.

significantly lower than for patients treated in the HC setting and that this difference is irrespective of treatment regimen, brand versus generic agents used, or tumor type. Overall, total mean PPPM costs were 59.9% higher in the HC setting than in the CC setting. This cost differential was driven largely by lower chemotherapy costs in community-based practices; this is despite the similarity in the number of cycles and the duration of therapy between the matched-cohort groups. This study supports previous findings, although the prior studies did not necessarily control for potential differences in patient or treatment characteristics. In a claims analysis of 283,502 patients who initiated treatment with infused chemotherapy, total reimbursement during the 6-month treatment episode was 48% lower when administered in physician offices rather than in hospital outpatient clinics (\$43,700 [95% CI, \$42,885 to \$44,517] v \$84,660 [95% CI, \$82,969 to \$86,352]; $P < .001$).⁶ Another claims analysis of patients with cancer who received intravenous chemotherapy indicated that costs were 46.0% higher in a hospital versus community setting (\$143,206 [SD, \$116,105] v \$98,071 [SD, \$69,236]; $P < .001$).⁷ Finally, a commercial claims database analysis demonstrated a 20% to 39% higher mean per member per month cost for patients treated at a hospital-based practice, irrespective of cancer type, geographic location, patient age, and number of chemotherapy sessions.⁸ In each study, the higher costs of cancer care in the hospital-based setting appear primarily driven by the increased cost of chemotherapy, not by disproportionate use of chemotherapy agents or chemotherapy sessions.¹⁰ This is, again, consistent with our finding that the duration of therapy,

overall and by cancer type, was similar within our two matched cohorts and therefore not contributory to the cost differential.

This analysis expands on previous work by matching patients with specific tumor types; treatments; and other possible confounders, such as the presence of metastatic disease, surgery, radiation, and geographic region. Furthermore, upon the request of a peer review, an additional analysis of the data by propensity score matching as well as an evaluation of median cost were performed. The results of the propensity versus direct match and median (interquartile range) versus mean (SD) are available side by side (Data Supplement); these results did not change any conclusions. Stratification to those who were Medicare-eligible patients also showed similar results, although we did not specifically evaluate those with only Medicare as the payer. We anticipate, however, that the cost differential for this patient population would still show lower costs in the CC versus HC setting, because the increased cost of chemotherapy in the HC setting was not the only driver of increased medical costs. However, because Medicare pays the same amount for chemotherapy regardless of site of care, and because chemotherapy cost was a large contributor of the cost differential, the relative rate of increased cost for this population within the HC versus CC cohort may be less pronounced.

This cost differential demonstrated here, which was based on site-of-care delivery, is concerning, because emerging data have revealed a downward shift in access to community-based oncology care sites.⁴ An earlier ASCO census report that focused on private community practices at risk noted that

smaller practices reported the greatest risk of closure.¹¹ The underlying etiology that drives integration of smaller practices with larger health care systems is multifactorial and includes issues such as lower chemotherapy reimbursement, increasing regulatory compliance and facility costs, and payer pressure.^{1,11} Smaller practices may be more willing to integrate into larger systems because of complex changes in payment design, health record requirements, and electronic data exchange.¹² A recent survey of community oncology practices cited reimbursement rates for both drugs (98%) and chemotherapy (90%), as well as the cost of regulatory compliance (87%), as very important or extremely important challenges that threaten their ongoing viability.⁴ As payers attempt to manage costs through narrowing networks, consolidation may be one way for both community- and hospital-based practices to increase their odds of being in network.¹²

Regardless, this shift in site of cancer care provision is concerning as emerging data demonstrate higher costs of care in hospital-based versus community-based practices. In fact, consolidation may be a contributing factor itself in the increasing cost of cancer care as larger health care systems, via their market power, can negotiate higher prices from payers, which could lead to higher prices for patients.¹²

A notable observation in our study was the difference in ED visits after chemotherapy administration, with rates of ED visits within 72 hours of 2.6% in the CC setting versus 3.6% in the HC setting ($P = .0055$); rates within 10 days were 7.9% in the CC setting and 9.8% in the HC setting. Also, a greater proportion of patients in the HC cohort had had multiple ED visits compared with patients in the CC cohort. This is particularly important, because a recent analysis of patients with advanced cancer concluded that 23% of ED visits were avoidable.¹³ In addition, patients in the CC cohort had an increased PPPM number of other (ie, nonphysician) outpatient visits, which perhaps reveals a difference in resource use geared toward patient management in lower-cost outpatient sites that results in a lower need for ED visits. This is also important as we look toward alternative payment models, such as the one endorsed by the Centers for Medicare and Medicaid Services (ie, the Oncology Care Model), which specifically lists ED visits as a required reporting measure for practices to qualify for any performance-based reimbursement.¹⁴

A limitation of this study is that, because the payer-type distribution within the data set is 80% commercial, we did not evaluate the cost differentials in the Medicare and Medicaid populations; therefore, results are not generalizable to these

populations. In addition, despite a robust matching for anticipated confounding factors, other potential confounders, such as socioeconomic data, were not available for any patient. Finally, certain aspects of routine oncology care today (ie, genetic testing/counseling, survivorship care) cannot be evaluated using this type of data.

In conclusion, this study indicates that treatment in the community practice is associated with lower total cost of treatment and cost of chemotherapy when compared with hospital-based outpatient practices for patients with breast, lung, or colorectal cancer. These data provide real-world insight to payers, providers, policy makers, and other health-system stakeholders to examine reimbursement differentials across sites of care, such that patient access to high-quality cancer care is not diminished by limiting site of care options as a result of financial pressures. Because the timeframe of this data predated the widespread use of more expensive therapies, such as immune-checkpoint inhibitors, and because the results lack generalizability to the aging Medicare population as well as the Medicaid population, future research is needed. **JOP**

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Author Contributions

Conception and design: Marlo Blazer, Susan Weidner, Michael Eaddy

Collection and assembly of data: Marlo Blazer, Vishal Saundankar, Denise Kazzaz

Data analysis and interpretation: All authors

Administrative support: Denise Kazzaz

Manuscript writing: All authors

Final approval of manuscript: All authors

Accountable for all aspects of the work: All authors

Corresponding author: Lucio Gordan, MD, Florida Cancer Specialists and Research Institute, Division of Quality and Informatics, 6420 W Newberry Rd, Suite 100, Gainesville, FL 32605; e-mail: lgordan@flcancer.com.

References

1. American Society of Clinical Oncology: The state of cancer care in America, 2017: A report by the American Society of Clinical Oncology. *J Oncol Pract* 13:e353-e394, 2017
2. Parsons SK, Fineberg IC, Lin M, et al: Promoting high-quality cancer care and equity through disciplinary diversity in team composition. *J Oncol Pract* 12: 1141-1147, 2016
3. Nardi EA, Wolfson JA, Rosen ST, et al: Value, access, and cost of cancer care delivery at academic medical centers. *J Natl Compr Canc Netw* 14:837-847, 2016
4. Community Oncology Alliance: Practice impact report. <https://www.communityoncology.org/2016-coa-practice-impact-report/>

5. Vandervelde A, Miller H, Younts J: Impact on Medicare payments of shift in site of care for chemotherapy administration. http://www.communityoncology.org/UserFiles/BRG_340B_SiteofCare_ReportF_6-9-14.pdf
6. Winn AN, Keating NL, Trogon JG, et al: Spending by commercial insurers on chemotherapy based on site of care, 2004-2014. *JAMA Oncol* 4:580-581, 2018
7. Fisher MD, Puneekar R, Yim YM, et al: Differences in health care use and costs among patients with cancer receiving intravenous chemotherapy in physician offices versus in hospital outpatient settings. *J Oncol Pract* 13:e37-e46, 2017
8. Hayes J, Hoverman RJ, Brow ME, et al: Cost differential by site of service for cancer patients receiving chemotherapy. *Am J Manag Care* 21:e189-e196, 2015
9. Charlson ME, Pompei P, Ales KL, et al: A new method of classifying prognostic comorbidity in longitudinal studies: Development and validation. *J Chronic Dis* 40:373-383, 1987
10. Fitch K, Iwasaki K, Pyenson B: Comparing episode of cancer care costs in different settings: An actuarial analysis of patients receiving chemotherapy. https://www.communityoncology.org/UserFiles/Milliman_SiteCostofCancerStudy_2013.pdf
11. American Society of Clinical Oncology: The state of cancer care in America, 2014: A report by the American Society of Clinical Oncology. *J Oncol Pract* 10:119-142, 2014
12. Alpert A, Hsi H, Jacobson M: Evaluating the role of payment policy in driving vertical integration in the oncology market. *Health Aff (Millwood)* 36:680-688, 2017
13. Delgado-Guay MO, Kim YJ, Shin SH, et al: Avoidable and unavoidable visits to the emergency department among patients with advanced cancer receiving outpatient palliative care. *J Pain Symptom Manage* 49:497-504, 2015
14. Kline R, Adelson K, Kirshner JJ, et al: The oncology care model: Perspectives from the Centers for Medicare & Medicaid Services and participating oncology practices in academia and the community. *Am Soc Clin Oncol Educ Book* 37:460-466, 2017

AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST**Cost Differences Associated With Oncology Care Delivered in a Community Setting Versus a Hospital Setting: A Matched-Claims Analysis of Patients with Breast, Colorectal, and Lung Cancers**

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Lucio Gordan**Employment:** Florida Medical Clinic**Leadership:** Florida Cancer Specialists**Honoraria:** Amersis Pharma**Consulting or Advisory Role:** Janssen Oncology**Speakers' Bureau:** Myriad Genetics**Marlo Blazer****Employment:** Xcenda**Vishal Saundankar****Research Funding:** Allergan (Inst), Lilly (Inst), United Therapeutics (Inst), GlaxoSmithKline (Inst)**Denise Kazzaz**

No relationship to disclose

Susan Weidner**Employment:** Amersource Bergen**Leadership:** IntrinsicQ Specialty Solutions**Stock and Other Ownership Interests:** Tesaro, AmersourceBergen**Michael Eaddy****Employment:** Xcenda**Stock and Other Ownership Interests:** AmersourceBergen**Consulting or Advisory Role:** Abbvie (Inst)

2018 Community Oncology Alliance Practice Impact Report



1,653 Community Oncology Clinics and/or Practices Have Closed, Been Acquired by Hospitals, Merged, or Reported Financial Struggles Since 2008

Misguided Public Policies Continue Push and Pull on Community Oncology Practices

The 2018 Community Oncology Alliance (COA) Practice Impact Report tracks the changing landscape of community cancer care in the United States. This is the seventh practice impact report issued by COA and covers a ten-year period from January 2008 through February 2018.

The 2018 COA Practice Impact Report data shows that over the last decade, 1,653 community oncology clinics and/or practices have closed, been acquired by hospitals, undergone corporate mergers, or reported that they are struggling financially. An average of 3.5 community oncology practices have closed per month, a rate that remains unchanged since the last report issued in 2016. Overall, 13.8 practices per month have closed, been acquired by hospitals, or undergone mergers since 2008.

The 2018 Community Oncology Practice Impact Report data shows:

- **423 clinics closed** — Individual clinic treatment sites that have closed.
- **658 practices acquired by hospitals** – Practices (typically comprised of multiple clinic sites) acquired by a hospital or, with less frequency, have entered into a contractual professional services agreement binding them to a hospital.
- **168 practices merged or acquired** – Practices (typically comprised of multiple clinic sites) merged or acquired by a corporate entity.
- **359 practices struggling financially** – Practices (typically comprised of multiple clinic sites) having financial difficulties, struggling to pay bills and/or stay open.
- **45 practices sending patients elsewhere** – Practices (typically comprised of multiple clinic sites) sending their Medicare patients elsewhere for chemotherapy.

Since the last Practice Impact Report in 2016, the data show an 11.3% increase in the number of community cancer clinic closings and an 8% increase in the number of consolidations into the hospital setting. Note that the number of practices struggling financially has declined by 7.9% which is proportional to the number of practices that have been acquired or moved into the hospital setting.

Compiled from public and private data sources, the 2018 Practice Impact Report provides a unique look at community oncology trends at both the national and state levels. At the state level, the largest number of closures is again in Florida (47), followed by Texas (43) and Michigan (36).

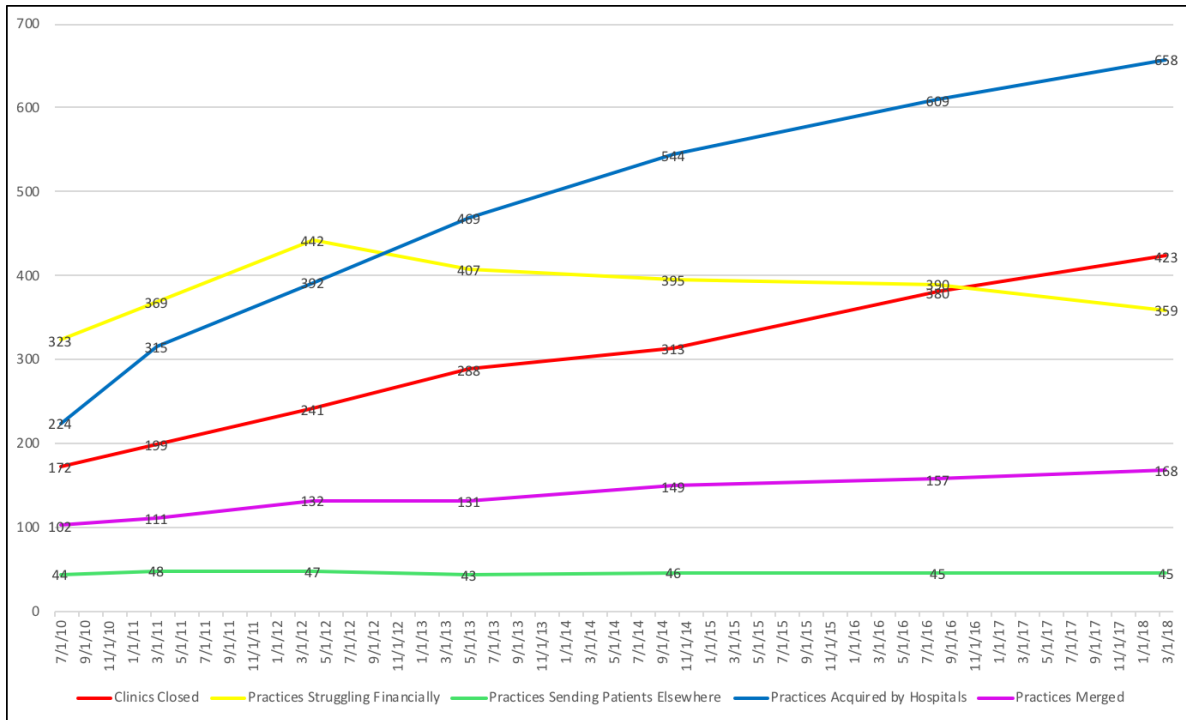
	2010 Report	2011 Report	2012 Report	2013 Report	2014 Report	2016 Report	2018 Report
Clinics Closed	172	199	241	288	313	380	423
Struggling Financially	323	369	442	407	395	390	359
Sending Patients Elsewhere	44	48	47	43	46	45	45
Acquired by Hospital	224	315	392	469	544	609	658
Merged or Acquired	102	111	132	131	149	157	168
Totals	865	1,042	1,254	1,338	1,447	1,581	1,653

Download the full 2018 COA Practice Impact Report at <http://bit.ly/COPIR18>

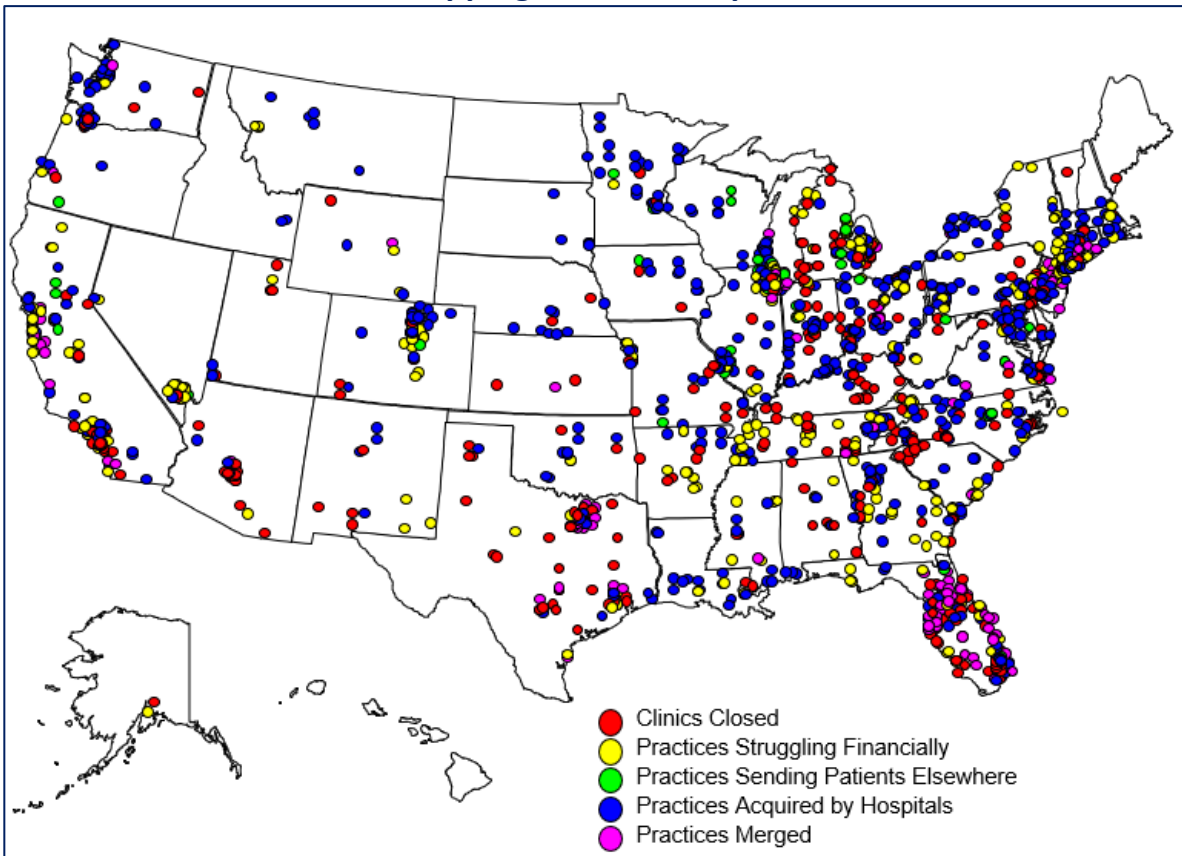
2018 Community Oncology Alliance Practice Impact Report



Trends in the Changing Landscape of Cancer Care (Derived from current and past reports)



Mapping the State Impact



Download the full 2018 COA Practice Impact Report at <http://bit.ly/COPIR18>

2018 Community Oncology Alliance Practice Impact Report



State	Total Sites/Practices Impacted	Clinics Closed	Practices Struggling Financially	Practices Sending Patients Elsewhere	Practices Acquired by Hospitals	Practices Merged
Alabama	18	7	4	0	7	0
Alaska	2	1	1	0	0	0
Arizona	23	5	10	0	5	3
Arkansas	23	16	1	0	6	0
California	124	32	40	4	33	15
Colorado	47	8	15	2	22	0
Connecticut	15	2	2	0	11	0
DC	2	0	2	0	0	0
Delaware	6	5	0	0	1	0
Florida	157	47	19	2	35	54
Georgia	54	14	17	0	23	0
Hawaii	0	0	0	0	0	0
Idaho	2	0	0	0	2	0
Illinois	86	15	28	9	19	15
Indiana	46	16	4	2	23	1
Iowa	12	2	0	1	9	0
Kansas	6	3	0	0	2	1
Kentucky	37	17	2	0	18	0
Louisiana	20	3	4	0	13	0
Maine	1	1	0	0	0	0
Maryland	26	2	7	2	13	2
Massachusetts	21	4	4	0	11	2
Michigan	101	36	42	6	15	2
Minnesota	28	2	1	2	23	0
Mississippi	15	1	5	0	8	1
Missouri	40	10	5	2	22	1
Montana	8	0	3	0	5	0

2018 Community Oncology Alliance Practice Impact Report



State	Total Sites/Practices Impacted	Clinics Closed	Practices Struggling Financially	Practices Sending Patients Elsewhere	Practices Acquired by Hospitals	Practices Merged
Nebraska	10	2	0	0	8	0
Nevada	21	4	15	1	1	0
New Hampshire	1	0	0	0	1	0
New Jersey	42	6	11	0	14	11
New Mexico	11	4	3	0	4	0
New York	99	13	39	0	39	8
North Carolina	51	15	4	4	26	2
North Dakota	1	0	0	0	1	0
Ohio	65	16	8	1	37	3
Oklahoma	12	2	2	0	8	0
Oregon	23	3	2	1	16	1
Pennsylvania	71	10	9	0	49	3
Rhode Island	6	0	3	0	3	0
South Carolina	29	11	4	0	10	4
South Dakota	6	0	0	0	6	0
Tennessee	66	20	25	0	18	3
Texas	90	43	6	1	13	27
Utah	9	5	2	0	2	0
Vermont	1	1	0	0	0	0
Virginia	42	9	5	2	20	6
Washington	28	3	2	0	22	1
West Virginia	11	4	1	1	5	0
Wisconsin	33	2	0	2	28	1
Wyoming	5	1	2	0	1	1
Grand Totals	1,653	423	359	45	658	168

Top 5 Low-Value Services

for Purchaser Action

The US spends more per capita on health than any other nation, but does not achieve outcomes commensurate with that spending. Billions are spent every year on services that harm patients- or at best, offer no clinical value.

A new Task Force on Low-Value Care has identified the "Top Five" low-value clinical services that are unsafe, do not improve health, or both. Drawing on the work of the Choosing Wisely campaign and others, the services were selected based on their association with harm, their cost, their prevalence, and the availability of levers for purchasers to help reduce their delivery.



Diagnostic Testing and Imaging Before Low-Risk Surgery

19.2 million unneeded pre-surgery tests and imaging services

\$9.5 billion in avoidable spending

Vitamin D Screening Tests

6.3 million non-clinically indicated Vitamin D tests

\$800 million in avoidable spending



Prostate-Specific Antigen Testing for Men 75+

>1 million Medicare beneficiaries 75 and older receive a PSA test

\$44 million in avoidable Medicare spending

Imaging for Low-Back Pain within 6 Weeks of Onset

1.6 million unnecessary imaging services for low-back pain

\$500 million in avoidable spending



Branded Drug Use when Chemically Equivalent Generics are Available

\$14.7 billion spent unnecessarily on branded drugs

Select Strategies to Reduce "Top Five" Use

Decision Support



Payment Models



Coverage Policies



Network Design



Provider Profiling



Five Things Physicians and Patients Should Question

The American Society of Clinical Oncology (ASCO) is a medical professional oncology society committed to conquering cancer through research, education, prevention and delivery of high-quality patient care. ASCO recognizes the importance of evidence-based cancer care and making wise choices in the diagnosis and management of patients with cancer. After careful consideration by experienced oncologists, ASCO highlights ten categories of tests, procedures and/or treatments whose common use and clinical value are not supported by available evidence. These test and treatment options should not be administered unless the physician and patient have carefully considered if their use is appropriate in the individual case. As an example, when a patient is enrolled in a clinical trial, these tests, treatments and procedures may be part of the trial protocol and therefore deemed necessary for the patient's participation in the trial.

These items are provided solely for informational purposes and are not intended to replace a medical professional's independent judgment or as a substitute for consultation with a medical professional. Patients with any specific questions about the items on this list or their individual situation should consult their health care provider. New evidence may emerge following the development of these items. ASCO is not responsible for any injury or damage arising out of or related to any use of these items or to any errors or omissions.

1

Don't use cancer-directed therapy for solid tumor patients with the following characteristics: low performance status (3 or 4), no benefit from prior evidence-based interventions, not eligible for a clinical trial, and no strong evidence supporting the clinical value of further anti-cancer treatment.

- Studies show that cancer directed treatments are likely to be ineffective for solid tumor patients who meet the above stated criteria.
- Exceptions include patients with functional limitations due to other conditions resulting in a low performance status or those with disease characteristics (e.g., mutations) that suggest a high likelihood of response to therapy.
- Implementation of this approach should be accompanied with appropriate palliative and supportive care.

2

Don't perform PET, CT, and radionuclide bone scans in the staging of early prostate cancer at low risk for metastasis.

- Imaging with PET, CT, or radionuclide bone scans can be useful in the staging of specific cancer types. However, these tests are often used in the staging evaluation of low-risk cancers, despite a lack of evidence suggesting they improve detection of metastatic disease or survival.
- Evidence does not support the use of these scans for staging of newly diagnosed low grade carcinoma of the prostate (Stage T1c/T2a, prostate-specific antigen (PSA) <10 ng/ml, Gleason score less than or equal to 6) with low risk of distant metastasis.
- Unnecessary imaging can lead to harm through unnecessary invasive procedures, over-treatment, unnecessary radiation exposure, and misdiagnosis.

3

Don't perform PET, CT, and radionuclide bone scans in the staging of early breast cancer at low risk for metastasis.

- Imaging with PET, CT, or radionuclide bone scans can be useful in the staging of specific cancer types. However, these tests are often used in the staging evaluation of low-risk cancers, despite a lack of evidence suggesting they improve detection of metastatic disease or survival.
- In breast cancer, for example, there is a lack of evidence demonstrating a benefit for the use of PET, CT, or radionuclide bone scans in asymptomatic individuals with newly identified ductal carcinoma in situ (DCIS), or clinical stage I or II disease.
- Unnecessary imaging can lead to harm through unnecessary invasive procedures, over-treatment, unnecessary radiation exposure, and misdiagnosis.

4

Don't perform surveillance testing (biomarkers) or imaging (PET, CT, and radionuclide bone scans) for asymptomatic individuals who have been treated for breast cancer with curative intent.

- Surveillance testing with serum tumor markers or imaging has been shown to have clinical value for certain cancers (e.g., colorectal). However for breast cancer that has been treated with curative intent, several studies have shown there is no benefit from routine imaging or serial measurement of serum tumor markers in asymptomatic patients.
- False-positive tests can lead to harm through unnecessary invasive procedures, over-treatment, unnecessary radiation exposure, and misdiagnosis.

5

Don't use white cell stimulating factors for primary prevention of febrile neutropenia for patients with less than 20 percent risk for this complication.

- ASCO guidelines recommend using white cell stimulating factors when the risk of febrile neutropenia, secondary to a recommended chemotherapy regimen, is approximately 20 percent and equally effective treatment programs that do not require white cell stimulating factors are unavailable.
- Exceptions should be made when using regimens that have a lower chance of causing febrile neutropenia if it is determined that the patient is at high risk for this complication (due to age, medical history, or disease characteristics).

Five More Things Physicians and Patients Should Question

6

Don't give patients starting on a chemotherapy regimen that has a low or moderate risk of causing nausea and vomiting antiemetic drugs intended for use with a regimen that has a high risk of causing nausea and vomiting.

- Over the past several years, a large number of effective drugs with fewer side effects have been developed to prevent nausea and vomiting from chemotherapy. When successful, these medications can help patients avoid spending time in the hospital, improve their quality of life and lead to fewer changes in the chemotherapy regimen.
- Oncologists customarily use different antiemetic drugs depending on the likelihood (low, moderate or high) for a particular chemotherapy program to cause nausea and vomiting. For chemotherapy programs that are likely to produce severe and persistent nausea and vomiting, there are new agents that can prevent this side effect. However, these drugs are very expensive and not devoid of side effects. For this reason, these drugs should be used only when the chemotherapy drugs that have a high likelihood of causing severe or persistent nausea and vomiting.
- When using chemotherapy that is less likely to cause nausea and vomiting, there are other effective drugs available at a lower cost.

7

Don't use combination chemotherapy (multiple drugs) instead of chemotherapy with one drug when treating an individual for metastatic breast cancer unless the patient needs a rapid response to relieve tumor-related symptoms.

- Although chemotherapy with multiple drugs, or combination chemotherapy, for metastatic breast cancer may slow tumor growth for a somewhat longer time than occurs when treating with a single agent, use of combination chemotherapy has not been shown to increase overall survival. In fact, the trade-offs of more frequent and severe side effects may have a net effect of worsening a patient's quality of life, necessitating a reduction in the dose of chemotherapy.
- Combination chemotherapy may be useful and worth the risk of more side effects in situations in which the cancer burden must be reduced quickly because it is causing significant symptoms or is life threatening. As a general rule, however, giving effective drugs one at a time lowers the risk of side effects, may improve a patient's quality of life, and does not typically compromise overall survival.

8

Avoid using PET or PET-CT scanning as part of routine follow-up care to monitor for a cancer recurrence in asymptomatic patients who have finished initial treatment to eliminate the cancer unless there is high-level evidence that such imaging will change the outcome.

- PET and PET-CT are used to diagnose, stage and monitor how well treatment is working. Available evidence from clinical studies suggests that using these tests to monitor for recurrence does not improve outcomes and therefore generally is not recommended for this purpose.
- False positive tests can lead to unnecessary and invasive procedures, overtreatment, unnecessary radiation exposure and incorrect diagnoses.
- Until high level evidence demonstrates that routine surveillance with PET or PET-CT scans helps prolong life or promote well-being after treatment for a specific type of cancer, this practice should not be done.

9

Don't perform PSA testing for prostate cancer screening in men with no symptoms of the disease when they are expected to live less than 10 years.

- Since PSA levels in the blood have been linked with prostate cancer, many doctors have used repeated PSA tests in the hope of finding "early" prostate cancer in men with no symptoms of the disease. Unfortunately, PSA is not as useful for screening as many have hoped because many men with prostate cancer do not have high PSA levels, and other conditions that are not cancer (such as benign prostate hyperplasia) can also increase PSA levels.
- Research has shown that men who receive PSA testing are less likely to die specifically from prostate cancer. However when accounting for deaths from all causes, no lives are saved, meaning that men who receive PSA screening have not been shown to live longer than men who do not have PSA screening. Men with medical conditions that limit their life expectancy to less than 10 years are unlikely to benefit from PSA screening as their probability of dying from the underlying medical problem is greater than the chance of dying from asymptomatic prostate cancer.

10

Don't use a targeted therapy intended for use against a specific genetic aberration unless a patient's tumor cells have a specific biomarker that predicts an effective response to the targeted therapy.

- Unlike chemotherapy, targeted therapy can significantly benefit people with cancer because it can target specific gene products, i.e., proteins that cancer cells use to grow and spread, while causing little or no harm to healthy cells. Patients who are most likely to benefit from targeted therapy are those who have a specific biomarker in their tumor cells that indicates the presence or absence of a specific gene alteration that makes the tumor cells susceptible to the targeted agent.
- Compared to chemotherapy, the cost of targeted therapy is generally higher, as these treatments are newer, more expensive to produce and under patent protection. In addition, like all anti-cancer therapies, there are risks to using targeted agents when there is no evidence to support their use because of the potential for serious side effects or reduced efficacy compared with other treatment options.

Abbreviations

CT, computed tomography; DCIS, ductal carcinoma in situ; PET, positron emission tomography; PSA, prostate-specific antigen.

How This List Was Created (1–5)

The American Society of Clinical Oncology (ASCO) has had a standing Cost of Cancer Care Task Force since 2007. The role of the Task Force is to assess the magnitude of rising costs of cancer care and develop strategies to address these challenges. In response to the 2010 *New England Journal of Medicine* article by Howard Brody, MD, “Medicine’s Ethical Responsibility for Health Care Reform – the Top Five List,” a subcommittee of the Cost of Cancer Care Task Force began work to identify common practices in oncology that were both common as well as lacking sufficient evidence for widespread use. Upon joining the Choosing Wisely campaign, the members of the subcommittee conducted a literature search to ensure the proposed list of items were supported by available evidence in oncology; ultimately the proposed Top Five list was approved by the full Task Force. The initial draft list was then presented to the ASCO Clinical Practice Committee, a group composed of community-based oncologists as well as the presidents of the 48 state/regional oncology societies in the United States. Advocacy groups were also asked to weigh in to ensure the recommendations would achieve the dual purpose of increasing physician-patient communication and changing practice patterns. A plurality of more than 200 clinical oncologists reviewed, provided input and supported the list. The final Top Five list in oncology was then presented to, discussed and approved by the Executive Committee of the ASCO Board of Directors and published in the *Journal of Clinical Oncology*. ASCO’s disclosure and conflict of interest policies can be found at www.asco.org.

How This List Was Created (6–10)

To guide ASCO in developing this list, suggestions were elicited from current ASCO committee members (approximately 700 individuals); 115 suggestions were received. After removing duplicates, researching the literature and discussing practice patterns, the Value in Cancer Care Task Force culled the list to 11 items, which comprised an ASCO Top Five voting slate that was sent back to the membership of all standing committees. Approximately 140 oncologists from its leadership cadre voted, providing ASCO with an adequate sample size and perspective on what oncologists find to be of little value. The list was reviewed and finalized by the Value in Cancer Care Task Force and ultimately reviewed and approved by the ASCO Board of Directors and published in the *Journal of Clinical Oncology*. ASCO’s disclosure and conflict of interest policies can be found at www.asco.org.

Sources

- Azzoli CG, Temin S, Aliff T, et al: 2011 focused update of 2009 American Society of Oncology clinical practice guideline update on chemotherapy for stage IV non–small cell lung cancer. *J Clin Oncol* 29:3825–3831, 2011

Ettinger DS, Akerley W, Bepler G, et al: Non-small cell lung cancer. *J Natl Compr Canc Netw* 8:740–801, 2010

Carlson RW, Allred DC, Anderson BO, et al: Breast cancer. *J Natl Compr Canc Netw* 7:122–192, 2009

Engstrom PF, Benson AB 3rd, Chen YJ, et al: Colon cancer clinical practice guidelines. *J Natl Compr Canc Netw* 3:468–491, 2005

Smith TJ, Hillner BE: Bending the cost curve in cancer care. *N Engl J Med* 364:2060–2065, 2011

Peppercorn JM, Smith TJ, Helft PR, et al: American Society of Clinical Oncology statement: Toward individualized care for patients with advanced cancer. *J Clin Oncol* 29:755–760, 2011
- Makarov DV, Desai RA, Yu JB, et al: The population level prevalence and correlates of appropriate and inappropriate imaging to stage incident prostate cancer in the Medicare population. *J Urol* 187:97-102, 2012

National Comprehensive Cancer Network: NCCN clinical practice guidelines in oncology (NCCN guidelines)-Prostate cancer. Version 4.2011

Thompson I, Thrasher JB, Aus G, et al: Guideline for the management of clinically localized prostate cancer: 2007 update. *J Urol* 177:2106–2130, 2007
- Carlson RW, Allred DC, Anderson BO, et al: Invasive breast cancer. *J Natl Compr Canc Netw* 9:136–222, 2011
- Locker GY, Hamilton S, Harris J, et al: ASCO 2006 update of recommendations for the use of tumor markers in gastrointestinal cancer. *J Clin Oncol* 24:5313–5327, 2006

Desch CE, Benson AB 3rd, Somerfield MR, et al: Colorectal cancer surveillance: 2005 update of an American Society of Clinical Oncology practice guideline. *J Clin Oncol* 23:8512-8519, 2005

Carlson RW, Allred DC, Anderson BO, et al: Breast cancer. *J Natl Compr Canc Netw* 7:122–192, 2009

Khatcheressian JL, Wolff AC, Smith TJ, et al: American Society of Clinical Oncology 2006 update of the breast cancer follow-up and management guideline in the adjuvant setting. *J Clin Oncol* 24: 5091–5097, 2006

Harris L, Fritsche H, Mennel R, et al: American Society of Clinical Oncology 2007 update of recommendations for the use of tumor markers in breast cancer. *J Clin Oncol* 25:5287–5312, 2007
- Smith TJ, Khatcheressian J, Lyman GH, et al: ASCO 2006 update of recommendations for the use of white blood cell growth factors: An evidence based clinical practice guideline. *J Clin Oncol* 24:3187–3205, 2006
- Basch E, Prestrud AA, Hesketh PJ, Kris MG, Feyer PC, Somerfield MR, Chesney M, Clark-Snow RA, Flaherty AM, Freundlich B, Morrow G, Rao KV, Schwartz RN, Lyman GH; American Society of Clinical Oncology. Antiemetics: American Society of Clinical Oncology clinical practice guideline update. *J Clin Oncol*. 2011 Nov 1;29:4189–98.

Saito M, Aogi K, Sekine I, Yoshizawa H, Yanagita Y, Sakai H, Inoue K, Kitagawa C, Ogura T, Mitsuhashi S. Palonosetron plus dexamethasone versus granisetron plus dexamethasone for prevention of nausea and vomiting during chemotherapy: a double-blind, double-dummy, randomized, comparative phase III trial. *Lancet Oncol*. 2009 Feb;10(2):115–24.

Aapro M, Fabi A, Nole F, Medici M, Steger G, Bachmann C, Roncoroni S, Roila F. Double-blind, randomised, controlled study of the efficacy and tolerability of palonosetron plus dexamethasone for 1 day with or without dexamethasone on days 2 and 3 in the prevention of nausea and vomiting induced by moderately emetogenic chemotherapy. *Ann Oncol*. 2010 May;21(5):1083–8.

Yu Z, Liu W, Wang L, Liang H, Huang Y, Si X, Zhang H, Liu D, Zhang H. The efficacy and safety of palonosetron compared with granisetron in preventing highly emetogenic chemotherapy-induced vomiting in the Chinese cancer patients: a phase II, multicenter, randomized, double-blind, parallel, comparative clinical trial. *Support Care Cancer*. 2009 Jan;17(1):99–102.

7

Cardoso F, Costa A, Norton L, Cameron D, Cufer T, Fallowfield L, Francis P, Gligorov J, Kyriakides S, Lin N, Pagani O, Senkus E, Thomssen C, Aapro M, Bergh J, Di Leo A, El Saghir N, Ganz PA, Gelmon K, Goldhirsch A, Harbeck N, Houssami N, Hudis C, Kaufman B, Leadbeater M, Mayer M, Rodger A, Rugo H, Sacchini V, Sledge G, van't Veer L, Viale G, Krop I, Winer E. 1st International consensus guidelines for advanced breast cancer (ABC 1). *Breast*. 2012 Jun;21(3):242–52.

Carrick S, Parker S, Thornton CE, Ghersi D, Simes J, Wilken N. Single agent versus combination chemotherapy for metastatic breast cancer. *Cochrane Database Syst Rev*. 2009 Apr 15;(2):CD003372.

National Comprehensive Cancer Network: NCCN clinical practice guidelines in oncology (NCCN Guidelines); breast cancer version: 1.2013.

Slamon DJ, Leyland-Jones B, Shak S, Fuchs H, Paton V, Bajamonde A, Fleming T, Eiermann W, Wolter J, Pegram M, Baselga J, Norton L. Use of chemotherapy plus a monoclonal antibody against HER2 for metastatic breast cancer that overexpresses HER2. *N Engl J Med*. 2001 Mar 15;344(11):783–92.

Howell A, Robertson JF, Quaresma Albano J, Aschermannova A, Mauriac L, Kleeberg UR, Vergote I, Erikstein B, Webster A, Morris C. Fulvestrant, formerly ICI 182,780, is as effective as anastrozole in postmenopausal women with advanced breast cancer progressing after prior endocrine treatment. *J Clin Oncol*. 2002 Aug 15;20(16):3396–403.

Lutz S, Berk L, Chang E, Chow E, Hahn C, Hoskin P, Howell D, Konski A, Kachnic L, Lo S, Sahgal A, Silverman L, von Gunten C, Mendel E, Vassil A, Bruner DW, Hartsell W; American Society for Radiation Oncology (ASTRO). Palliative radiotherapy for bone metastases: an ASTRO evidence-based guideline. *Int J Radiat Oncol Biol Phys*. 2011 Mar 15;79(4):965–76.

8

Phurrough S, Cano C, Dei Cas R, Ballantine L, Carino T; Centers for Medicare and Medicaid Services. Decision memo for positron emission tomography (FDG) for solid tumors (CAG–00181R4). Baltimore (MD): Centers for Medicare and Medicaid Services; 2003 Jul 8. 55 p. Report No.: CAG–00106R.

PET imaging in Ontario [Internet]. Ontario (CA): Cancer Care Ontario; 2012 May 28 [cited 26 Sep 2013]. Available from: www.cancercare.on.ca/ocs/clinicalprogs/imaging/pet.

Labianca R, Nordlinger B, Beretta GD, Brouquet A, Cervantes A; ESMO Guidelines Working Group. Primary colon cancer: ESMO Clinical Practice Guidelines for diagnosis, adjuvant treatment and follow-up. *Ann Oncol*. 2010 May;21 Suppl 5:v70–v7.

9

Raghavan D. PSA – Please Stop Agonizing (over prostate-specific antigen interpretation). *Mayo Clin Proc*. 2013 Jan;88:1–3.

Schroder FH, Hugosson J, Roobol MJ, Tammela TL, Ciatto S, Nelen V, Kwiatkowski M, Lujan M, Lilja H, Zappa M, Denis LJ, Recker F, Páez A, Määttä L, Bangma CH, Aus G, Carlsson S, Villers A, Rebillard X, van der Kwast T, Kujala PM, Blijenberg BG, Stenman UH, Huber A, Taari K, Hakama M, Moss SM, de Koning HJ, Auvinen A; ERSPC Investigators. Prostate-cancer mortality at 11 years of follow-up. *N Engl J Med*. 2012 Mar 15;366(11):981–90.

Hugosson J, Carlsson S, Aus G, Bergdahl S, Khatami A, Lodding P, Pihl C-G, Stranne J, Holmberg E, Lilja H. Mortality results from the Göteborg randomized population-based prostate-cancer screening trial. *Lancet Oncol*. 2010 Aug;11(8):725–32.

Andriole GL, Crawford ED, Grubb RL III, Buys SS, Chia D, Church TR, Fouad MN, Gelmann EP, Kvale PA, Reding DJ, Weissfeld JL, Yokochi LA, O'Brien B, Clapp JD, Rathmell JM, Riley TL, Hayes RB, Kramer BS, Izmirlian G, Miller AB, Pinsky PF, Prorok PC, Gohagan JK, Berg CD; PLCO Project Team. Mortality results from a randomized prostate-cancer screening trial. *N Engl J Med*. 2009 Mar 26;360(12):1310–9.

Moyer VA; U.S. Preventive Services Task Force. Screening for prostate cancer: U.S. Preventive Services Task Force recommendation statement. *Ann Intern Med*. 2012 Jul 17;157(2):1–15.

Qaseem A, Barry MJ, Denberg TD, Owens DK, Shekelle P; Clinical Guidelines Committee of the American College of Physicians. Screening for prostate cancer: A guidance statement from the Clinical Guidelines Committee of the American College of Physicians. *Ann Intern Med*. 2013 May 21;158(10):761–9.

Carter HB, Albertson PC, Barry MJ, Etzioni R, Freedland SJ, Greene KL, Holmberg L, Kantoff P, Konety BR, Murad MH, Penson DF, Zietman AL. Early detection of prostate cancer: AUA Guideline. *J Urol*. 2013 Aug;190(2):419–26.

Basch E, Oliver TK, Vickers A, Thompson I, Kantoff P, Parnes H, Loblaw DA, Roth B, Williams J, Nam RK. Screening for prostate cancer with prostate-specific antigen testing: American Society of Clinical Oncology provisional clinical opinion. *J Clin Oncol*. 2012 Aug 20;30(24):3020–5.

10

Shaw A, Kim D, Nakagawa K, Seto T, Crinó L, Ahn MJ, De Pas T, Besse B, Solomon BJ, Blackhall F, Wu YL, Thomas M, O'Byrne KJ, Moro-Sibilot D, Camidge DR, Mok T, Hirsh V, Rieley GJ, Iyer S, Tassell V, Polli A, Wilner KD, Jänne PA. Crizotinib versus chemotherapy in advanced ALK-positive lung cancer. *N Engl J Med*. 2013 Jun 20;368(25):2385–94.

Sequist L, Yang J, Yamamoto N, O'Byrne K, Hirsh V, Mok T, Geater SL, Orlov S, Tsai CM, Boyer M, Su WC, Bannoun J, Kato T, Gorbunova V, Lee KH, Shah R, Massey D, Zazulina V, Shahidi M, Schuler M. Phase III study of afatinib or cisplatin plus pemetrexed in patients with metastatic lung adenocarcinoma with EGFR mutations. *J Clin Oncol*. 2013 Sep 20;31(27):3327–3334.

Chapman P, Hauschild A, Robert C, Haanen JB, Ascierto P, Larkin J, Dummer R, Garbe C, Testori A, Maio M, Hogg D, Lorigan P, Lebbe C, Jouary T, Schadendorf D, Ribas A, O'Day SJ, Sosman JA, Kirkwood JM, Eggermont AM, Dreno B, Nolop K, Li J, Nelson B, Hou J, Lee RJ, Flaherty KT, McArthur GA; BRIM-3 Study Group. Improved survival with vemurafenib in melanoma with BRAF V600E mutation. *N Engl J Med*. 2011 Jun 30;364(26):2507–16.

Lynch T, Bell D, Sordella R, Gurubhagavatula S, Okimoto RA, Brannigan BW, Harris PL, Haserlat SM, Supko JG, Haluska FG, Louis DN, Christiani DC, Settleman J, Haber DA. Activating mutations in the epidermal growth factor receptor underlying responsiveness of non-small-cell lung cancer to gefitinib. *N Engl J Med*. 2004 May 20;350(21):2129–39.

Keedy V, Temin S, Somerfield M, Beasley MB, Johnson DH, McShane LM, Milton DT, Strawn JR, Wakelee HA, Giaccone G. American Society of Clinical Oncology provisional clinical opinion: epidermal growth factor receptor (EGFR) mutation testing for patients with advanced non-small-cell lung cancer considering first-line EGFR tyrosine kinase inhibitor therapy. *J Clin Oncol*. 2011 May 20;29(15):2121–7.

Allegra C, Jessup J, Somerfield M, Hamilton SR, Hammond EH, Hayes DF, McAllister PK, Morton RF, Schilsky RL. American Society of Clinical Oncology provisional clinical opinion: testing for KRAS gene mutations in patients with metastatic colorectal carcinoma to predict response to anti-epidermal growth factor receptor monoclonal antibody therapy. *J Clin Oncol*. 2009 Apr 20;27(12):2091–6.

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OCM PERFORMANCE-BASED PAYMENT METHODOLOGY

Version 5.1

December 17, 2018

Prepared by:

RTI International
3040 E. Cornwallis Road
Research Triangle Park, NC 27709

Actuarial Research Corporation
6928 Little River Turnpike, Suite E
Annandale, VA 22003

Revision History

Version	Date	Description of Changes
1.0	4/15/16	Initial version.
1.1	6/27/16	<ol style="list-style-type: none"> 1. Revised Section 3.1.1, Prediction Model. 2. Revised Section 7.2, Performance Rates, to clarify minimum denominator size is over two performance periods. 3. Revised Section 7.3.3, Patient Experience of Care Scoring. 4. Added language to Section 7.4, Inapplicable Measures and Measures with Insufficient Denominator Size. 5. Removed Appendix A: OCM Included Cancer Diagnoses and Cancer Types and all references. This information is now located on the CMS OCM website. ICD9 diagnosis code 277.89 was removed from this list. As a result, the remaining appendices have been re-lettered. 6. Added a new appendix, Appendix F: Patient Experience of Care Measure Composites and Scoring. 7. Added a new section (Section 9) for OCM resource information. 8. Added links to the OCM Portal throughout where applicable.
2.0	12/27/16	<ol style="list-style-type: none"> 1. Revised Introduction to reflect earlier availability of choice to elect two- sided risk. 2. Revised Section 7 (Quality Measures and Performance) to reflect modified reporting requirements for the first performance period. 3. Added a new appendix, Appendix D, for the baseline trend factors. As a result, remaining appendices were re-lettered. 4. Added a new appendix, Appendix E, for the baseline Winsorization thresholds. As a result, remaining appendices were re-lettered. 5. Updated measure names in Table 2 to be consistent with the OCM Measures Guide. 6. Updated language in Section 7.3.2 (Practice-Reported Measure Scoring) to modify references to PQRS data. 7. Revised Section 7.3.3 (Patient Experience of Care Scoring) to provide clarification around the scoring approach. 8. Updated links and references to external documents throughout as necessary.

Version	Date	Description of Changes
3.0	4/3/17	<ol style="list-style-type: none"> 1. Updated Section 2 (Calculation of Baseline Episode Expenditures) and Section 5 (Calculation of Actual Episode Expenditures) to reflect changes in the way that episode expenditures will be measured, effective with episodes beginning after July 1, 2017. 2. Updated Section 3.1.1 (Prediction Model) to reflect that one of the risk adjustment factors applies to prostate and bladder cancer in addition to breast cancer, effective with episodes beginning after July 1, 2017. 3. Revised text and formulas in Section 3.1.2 (Experience Adjuster) and Appendix G (Mathematical Description of the Methodology for Establishing Target Amounts) to reflect a consistent definition of the experience adjuster. 4. Revised text in Section 7.3.1 (Claims-Based Measure Scoring) to reflect that performance thresholds have already been calculated and shared with OCM participants. 5. Updated Appendix D (Baseline Trend Adjustments) and Appendix E (Baseline Winsorization Adjustments) to reflect the baseline adjustments associated with the reconciliations for episodes beginning after July 1, 2017. 6. Added a new appendix, Appendix I, for the description of the OCM prediction model. 7. Updated links and references to external documents throughout as necessary.
3.1	6/26/17	<ol style="list-style-type: none"> 1. Revised the quality scoring approach in Section 7 to reflect changes to when measures are counted as P4R and P4P. 2. Updated language in Section 7.3.3 to reflect that performance thresholds have been calculated for the patient-experience measure.

Version	Date	Description of Changes
3.2	12/27/2017	<ol style="list-style-type: none"> 1. Updated language in Sections 3.2.1 (Trend Factor) and 3.2.2 (Adjustment for Novel Therapies) to specify the population used to determine trend and novel therapies adjustments. 2. Updated language in Section 6.2.1 (Geographic Variation Adjustment) to clarify the approach used to determine the geographic adjustment to the PBP. 3. Revised the quality scoring approach in Section 7 to reflect (1) changes to when measures are counted as P4R and P4P, (2) the reporting of OCM-4, OCM-5, and OCM-12 on an aggregate rather than individual basis, (3) the retirement of OCM-7, and (4) information on the data that will be used to score the practice-reported measures for each performance period. 4. Updated language in Section 7.3.3 (Patient Experience of Care Scoring) to reflect information on the surveys that will be used to score OCM-6 for each performance period.
4.0	4/30/2018	<ol style="list-style-type: none"> 1. Clarified the tie-breaker logic used in assigning cancer type in Section 1.1.3 and Appendix B to be consistent with how it is applied. 2. Revised the logic for including MEOS payments in the episode expenditures in Section 5. 3. Revised the quality scoring approach in Section 7 to reflect changes to when measures are counted as P4R and P4P. 4. Revised the approach to episode definition in Appendix A to incorporate the use of chemotherapy and immunotherapy administration diagnosis codes Z51.11 and Z51.12.
5.0	6/11/2018	<ol style="list-style-type: none"> 1. Incorporated throughout the criterion that “qualifying” E&M visits must have been provided by a TIN with at least one oncology provider (see Sections 1.1.2, 1.1.3, 1.2, and Appendix A). 2. Modified the pay-for-reporting scoring related to the OCM FFS Beneficiary measures in Section 7, adding and removing specified measures. 3. Added specifications for claims-based risk adjustment factors to Appendix I. 4. Revised Appendix I to update the definitions of “low risk” and “high risk” breast cancer that are used in the OCM prediction model and to update the terminology for “castration-sensitive” and “castration-resistant” prostate cancer to “low-intensity” and “high-intensity.” 5. Replaced table values in Appendix D (Baseline Trend Adjustments) and Appendix E (Baseline Winsorization Adjustments) with “TBD.”

Version	Date	Description of Changes
5.1	12/17/2018	<ol style="list-style-type: none">1. Incorporated throughout the addition of the alternative two-sided risk arrangement.2. Modified Section 7 to reflect the measure reduction effective with Performance Period 5.3. Added a new appendix, Appendix J, for the description of the ACO Overlap calculation.4. Updated Appendix D and Appendix E to include the corresponding values for the updated baseline.

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Introduction

This paper describes the technical details for the methodology that the Centers for Medicare & Medicaid Services (CMS) will use to determine a practice's or pool's performance-based payment in the Oncology Care Model (OCM).

OCM is a payment model designed to test the effects of better care coordination, improved access to practitioners, and appropriate clinical care on health outcomes and costs of care for Medicare fee-for-service (FFS) beneficiaries with cancer who receive chemotherapy. OCM encourages participating practices to improve care and lower costs through episode-based payments that financially incentivize high-quality coordinated care. CMS expects that these changes made by the practices in response to OCM participation will result in better care, smarter spending, and healthier people.

OCM is a multi-payer model that includes Medicare FFS and other payers to leverage the opportunity to transform care for oncology patients across the population. There may be differences in certain model design aspects between the subset of OCM for Medicare FFS beneficiaries and the subset for other payer beneficiaries, such as specific payment incentives. However, the approach to practice transformation is consistent across OCM. This document reflects only the methodologies that will be used for Medicare FFS beneficiaries.

OCM targets physician group practices that prescribe chemotherapy for cancer and is centered on 6-month episodes of care triggered by receipt of chemotherapy. OCM incorporates a two-part payment system for participating practices, composed of a Monthly Enhanced Oncology Services (MEOS) payment and the potential for a retrospective performance-based payment. The MEOS payment will assist participating practices with effectively managing and coordinating care for oncology patients during episodes of care, whereas the potential for performance-based payment will incentivize practices to lower the total cost of care relative to a risk-adjusted target amount and to improve the quality of care for beneficiaries. Practices will be eligible to be paid the MEOS payment monthly for each beneficiary during an episode attributed to them regardless of cancer type, unless the beneficiary enters hospice or dies. Performance-based payments will be made only for higher-volume cancer types for which it is possible to calculate accurate benchmarks. These cancer types, and the lower-volume cancer types for which we will not calculate benchmarks, are listed in the document "[OCM Cancer Type Mapping and Codes](#)" that applies for each performance period.

Episodes will initiate upon the date of service for an initial Part B chemotherapy drug claim with a corresponding cancer diagnosis on the claim, or upon the fill date for an initial Part D chemotherapy drug claim with a corresponding Part B claim for cancer on the date of, or in the 59 days preceding, the drug claim. Episodes will continue for 6 months. Beneficiaries who continue to receive chemotherapy after completing the 6-month episode will initiate a new episode. Episodes will be organized by performance periods, which are the 6-month periods of time during which a cohort of episodes terminates and is reconciled together. OCM episode expenditures will consist of all Medicare Part A and Part B expenditures and certain Part D expenditures for a beneficiary's care throughout the 6 months. These expenditures will be compared to a risk-adjusted, practice-

specific target amount, which will be based on historical expenditures trended forward to the performance period and subject to a discount (representing Medicare savings).

OCM features three possible risk arrangements: a one-sided risk arrangement with a 4 percent discount, a two-sided risk arrangement with a 2.75 percent discount (original two-sided risk), and a two-sided risk arrangement with a 2.5 percent discount (alternative two-sided risk); in either two-sided risk arrangement, the practice or pool will be eligible for higher performance-based payments. The one-sided risk arrangement will apply to all practices and all episodes initiating July 1, 2016 – January 1, 2017 (the first performance period). The original two-sided risk arrangement will be available in all following OCM performance periods for practices that have signed and uploaded the Participation Agreement Risk Arrangement Amendment. The alternative two-sided risk arrangement will be available in Performance Period 6 at the earliest for practices that have signed and uploaded the amended and restated Participation Agreement.

Practices are allowed to request a change in risk arrangement semiannually. Practices or pools that do not achieve a performance-based payment by the time of the initial reconciliation of the fourth performance period must exit the model or opt for a two-sided risk arrangement thereafter until achieving a performance-based payment. Eligibility for performance-based payments is contingent upon meeting certain quality thresholds and other requirements as articulated in the OCM Participation Agreement.

The model will run for 5 years, beginning July 1, 2016, and ending June 30, 2021, with a model closeout period after model completion. Calculation of performance-based payment will occur semi-annually and will include all episodes ending in a given 6-month period. [Table 1](#) provides the dates associated with each of the nine, 6-month performance periods, as well as the risk arrangements associated with each.

Table 1: OCM Performance Periods

Model Year	Performance Period	Episodes Beginning	Episodes Ending	Risk Arrangement
1	1	7/1/2016 - 1/1/2017	12/31/2016 - 6/30/2017	One-sided risk only
2	2	1/2/2017 - 7/1/2017	7/1/2017 - 12/31/2017	One- or Two-sided risk (original)
2	3	7/2/2017 - 1/1/2018	1/1/2018 - 6/30/2018	
3	4	1/2/2018 - 7/1/2018	7/1/2018 - 12/31/2018	
3	5	7/2/2018 - 1/1/2019	1/1/2019 - 6/30/2019	
4	6	1/2/2019 - 7/1/2019	7/1/2019 - 12/31/2019	One- or Two-sided risk (original or alternative)
4	7	7/2/2019 - 1/1/2020	1/1/2020 - 6/30/2020	
5	8	1/2/2020 - 7/1/2020	7/1/2020 - 12/31/2020	
5	9	7/2/2020 - 1/1/2021	1/1/2021 - 6/30/2021	

The following sections provide more detail on how we will calculate the performance-based payments. We calculate the target amounts using a period of baseline data with which we define a set of episodes and calculate the expenditures associated with those episodes. The method used to define those episodes is described in [Section 1](#). The method used to calculate the expenditures associated with the historical episodes is described in [Section 2](#). In [Section 3](#) we describe the method used to determine the target amount for each practice, including the benchmarking model that will be used to estimate risk-adjusted target episode prices. In [Section 4](#) we describe how we will identify episodes in each performance period, and in [Section 5](#) we describe the method used to calculate the expenditures associated with the performance period episodes. In [Section 6](#) we describe the reconciliation of performance period expenditures and the target amounts and the calculation of the performance-based payment, and in [Section 7](#) we describe how we will determine the quality score used in the calculation of the performance multiplier. Finally, in [Section 8](#) we present an example of a performance-based payment calculation.

Section 1: Determination of Baseline Episodes

The first step in determining performance-based payment is to define the set of historical episodes that will be used to develop the baseline episode expenditures on which the target amounts will ultimately be based. The historical period used to determine this set of episodes is January 2012– June 2015. All episodes included in the baseline begin between January 2012 and December 2014 and end between July 2012 and June 2015. Definition of the historical episodes consists of two major steps:

1. Identification of episodes.
2. Attribution of episodes to practices.

1.1 Episode Identification

We identify episodes by first identifying potential “trigger events” in the claims data that indicate the provision of chemotherapy, as described below in [Section 1.1.1](#). We then determine if the beneficiary meets the eligibility criteria described in [Section 1.1.2](#) for the 6 months following each trigger event. Episodes initiate on the date of the first trigger event for which the beneficiary meets all eligibility criteria in the 6 months following. Subsequent episodes may be defined in the historical period once earlier episodes have completed. Once episodes have been defined, we assign a cancer type to the episode, described in [Section 1.1.3](#).

1.1.1 Identification of Trigger Events

Each 6-month episode will begin on the date associated with a trigger event, identified as the first observed Part B chemotherapy drug claim in the historical period with a corresponding cancer diagnosis on the claim OR the first Medicare Part D chemotherapy drug claim with a corresponding Part B claim for cancer. Many chemotherapy drugs are identifiable from Healthcare Common Procedure Coding System (HCPCS) codes, which are the basis of payment for services billed under Medicare Part B. Chemotherapy drugs not covered under Part B are covered under Medicare Part D and are identifiable by National Drug Codes (NDCs). All codes associated with these drugs are referred to as “initiating cancer therapies,” and can be found in the list of “[OCM Initiating Cancer Therapies and Codes](#)” for each performance period. This list of codes will be updated periodically as new chemotherapy drugs become available.

We will identify trigger events by examining chemotherapy drug claims in the Part B (Outpatient, Carrier, and Durable Medical Equipment, Prosthetics/Orthotics, and Supplies [DMEPOS]) and Part D claims files. A Part B claim qualifies as a trigger event if it contains both an initiating cancer therapy and a cancer diagnosis included in the model, listed in the document “[OCM Cancer Type Mapping and Codes](#)” for each performance period. The Part B claim must not have a place of service code indicating an inpatient hospital setting because chemotherapy administered in a hospital does not qualify as a trigger event for OCM. When the trigger event is a Part B drug claim, the episode beginning date is the date of service on the Part B chemotherapy drug claim.

A Part D claim qualifies as a trigger event if it contains an initiating cancer therapy *and* if a Part B claim with an included cancer diagnosis in the document “[OCM Cancer Type Mapping and Codes](#)” can be found on the prescription fill date or in the 59 days preceding the fill date (because Part D

claims do not contain diagnosis codes). When the trigger event is a Part D claim, the episode beginning date is the fill date on the Part D chemotherapy drug claim.

There is no requirement that a chemotherapy-free period exist before the beginning of any episode. The existence of chemotherapy claims in the pre-episode period will be accounted for in the benchmarking process.

Once an episode has begun, it will last for 6 calendar months, except in the case of death before 6 months have passed. Such episodes are the only ones that may end before 6 months. If a beneficiary dies mid-episode, the practice will no longer be eligible to be paid the MEOS payment, but the episode will still be included in the benchmarking and performance-based payment aspects of the model. Likewise, if a beneficiary elects hospice mid-episode, the practice will no longer be eligible to be paid the MEOS payment, but the episode will still be included in the benchmarking and performance-based payment aspects of the model. Medicare expenditures incurred after hospice election will be included in benchmarking and reconciliation.

Subsequent episodes of chemotherapy may begin after earlier episodes have been completed; chemotherapy claims during an episode do not trigger new episodes. Subsequent episodes have the same requirements for trigger events as prior episodes; any amount of time may pass between the end of one episode and the beginning of the next.

1.1.2 Episode Eligibility

A beneficiary must meet the following requirements for all 6 months of the episode, or in the event the beneficiary dies prior to 6 months, until the beneficiary's death, for that episode to be eligible for inclusion in OCM:

- Beneficiary is enrolled in Medicare Parts A and B;
- Beneficiary does not receive the Medicare End Stage Renal Disease (ESRD) benefit¹;
- Beneficiary has Medicare as his or her primary payer;
- Beneficiary is not covered under Medicare Advantage or any other group health program;
- Beneficiary received chemotherapy treatment for cancer (defined above in [Section 1.1.1](#));
- Beneficiary has at least one qualifying Evaluation & Management (E&M) visit during the 6 months of the episode. A qualifying E&M visit is defined as having a HCPCS code in the ranges 99201-99205 or 99211-99215, a cancer diagnosis included in the document "[OCM Cancer Type Mapping and Codes](#)," and billed by a TIN with at least one oncology provider in the performance period. Oncology providers are those with a specialty code of Hematology/Oncology, Medical Oncology, Surgical Oncology, Radiation Oncology, and/or Gynecological/Oncology.

Episodes in which a beneficiary dies or elects hospice care before the end of 6 months are considered eligible; death will be the only case in which an episode will be shorter than 6 months.

The detailed specifications for identifying eligible episodes are located in [Appendix A](#).

¹ ESRD status will be determined using information in the Medicare Enrollment Database.

1.1.3 Assignment of Cancer Type

Each episode will be classified by cancer type (e.g., prostate, lymphoma, breast). The cancer type will be used in categorizing episodes for reporting, monitoring, and risk adjustment purposes. Cancer type will be assigned using the plurality of diagnoses on qualifying E&M visits (see the definition above in [Section 1.1.2](#)) in the carrier file that occurred during the episode. The diagnosis code corresponding to (on the same line as) each E&M visit will be mapped to a cancer type. The mapping of diagnosis code to cancer type is included in the document “[OCM Cancer Type Mapping and Codes](#)” for each performance period. This document identifies the cancer types that are reconciliation-eligible (as defined in the OCM Participation Agreement), as well as those that are not reconciliation-eligible but are still eligible for the MEOS payment. The cancer type with the most qualifying E&M visits is the one that will be assigned to the episode. In the event of a tie, we will apply tie-breakers in the following order, assigning the cancer type associated with:

1. The most recent qualifying E&M visit during the episode, then the second-most recent qualifying E&M visit, etc.;
2. The cancer type that is reconciliation-eligible;
3. The lowest last digit of the Taxpayer Identification Number (TIN) associated with the visit;
4. The highest claim ID.

The detailed specifications for assigning cancer type are included in [Appendix B](#).

1.2 Episode Attribution

Each 6-month episode will be attributed to the TIN (in the case of non-OCM practices) or OCM ID (in the case of OCM practices) associated with the most qualifying E&M visits during the 6-month episode; this is known as the plurality approach. E&M visits will be defined by the HCPCS code ranges 99201 – 99205 and 99211 – 99215. For an E&M visit to qualify and be counted toward plurality, it must be associated with (on the same line item as) one of the cancer diagnosis codes included in the document “[OCM Cancer Type Mapping and Codes](#)” and must be billed by a TIN with at least one oncology provider. Oncology providers are those with a specialty code of Hematology/Oncology, Medical Oncology, Surgical Oncology, Radiation Oncology, and/or Gynecological/Oncology. We will use the Part B Carrier file to identify qualifying E&M visits.

During the baseline period, an OCM practice is generally defined by one OCM ID and one TIN. In cases where a participating OCM practice billed under multiple TINs or changed its TIN partway through the baseline time period used to determine attribution, we will associate some or all old and new TINs with the practice during that baseline time period for the purposes of attributing episodes. This will ensure that all qualifying E&M visits are found and used to determine the baseline attribution.

In a performance period, an OCM practice is defined by one OCM ID and one TIN. If the TIN on a qualifying claim is associated with a participating OCM practice, the visit will be credited to that practice. Otherwise, the visit will be credited to the TIN on the claim, which would be that of a practice not participating in OCM. We will add up all qualifying E&M visits occurring during the episode by practice and attribute the episode to the practice with the most qualifying E&M visits, which may be a participating OCM practice or not. In the case of a tie (i.e., two different practices

having the same number of qualifying E&M visits), we will attribute the episode to the practice with the most recent qualifying E&M visit(s) in the episode. If a tie still exists we will attribute the episode to the TIN or OCM ID with the lowest last digit of the TIN, lowest second-to-last digit, etc.

1.2.1 Attribution for Pooled Participants

As described above, each episode will be attributed to an individual practice, where a participating OCM practice is represented by one OCM ID. Some practices may choose or be required to participate in the model on a partnership basis by pooling with other practices. In such cases, we will still attribute the episodes to the individual practices within the pool. We will not combine visits to all TINs in a pool when determining plurality. Episodes attributed to the individual practices in a pool will be combined (summed) for the purposes of reconciliation and quality measurement, though information on the episodes attributed to each individual practice in the pool will be available.

The detailed specifications for episode attribution are located in [Appendix C](#).

Section 2: Calculation of Baseline Episode Expenditures

Once baseline episodes have been identified and attributed to practices, we then add up the Medicare FFS expenditures incurred during each episode. Baseline episode expenditures will include expenditures for all claims where the service date is during the episode. For Inpatient and Skilled Nursing Facility (SNF) services, the service date is the date the beneficiary was admitted to the facility (the admission date on the claim). For Outpatient services, the service date is the revenue center date on the claim.² For Carrier and DMEPOS services, the service date is the line item date on the claim. For Part D claims the service date is the date the prescription was filled. For all other services (HHA, Hospice), the service date is the “from date” on the claim.

2.1 Components of Baseline Expenditures

Baseline episode expenditures include all Medicare Part A and Part B FFS expenditures (payments) and certain Part D expenditures (see [Figure 1](#) below). The Part A and Part B expenditures come from the Inpatient, SNF, Outpatient, Carrier, DMEPOS, Home Health Agency (HHA), and Hospice claims files. Medicare expenditures will be adjusted to exclude indirect medical education (IME) and disproportionate share hospital (DSH) payments, as well as inpatient pass through amounts, which include direct graduate medical education (GME), capital-related costs, and bad debt. Additional information on these adjustments is provided below. The Part D expenditures come from the Part D claims files and include only the Low-Income Cost Sharing Subsidy (LICS) amount and 80 percent of the Gross Drug Cost above the Catastrophic (GDCA) threshold. Other Part D expenditures will not be included because they are paid on a capitated basis.

The Part A and Part B expenditures will be sourced from CMS’ standardized payment files.³ These files remove geographic pricing differences and payments made from special Medicare programs that are not directly related to services provided (IME, GME, DSH) and do not include the effects of upward or downward payment adjustments related to other CMS programs, such as the Hospital Acquired Condition Reduction Program, the Electronic Health Record Incentive Program, and the Hospital Value-based Purchasing Program. These files have a “final maturity” of 12 months of claims run-out. That is, after 12 months has passed, they are no longer updated to account for additional claims or adjustments that have been submitted. Because OCM final reconciliations will include 14 months of claims run-out (see [Section 6.2](#)) there is a small possibility that some claims included in the final reconciliation (i.e., those submitted in months 13 and 14) will not have a corresponding standardized payment. In these cases, we will use the “unstandardized” payment from the claim.

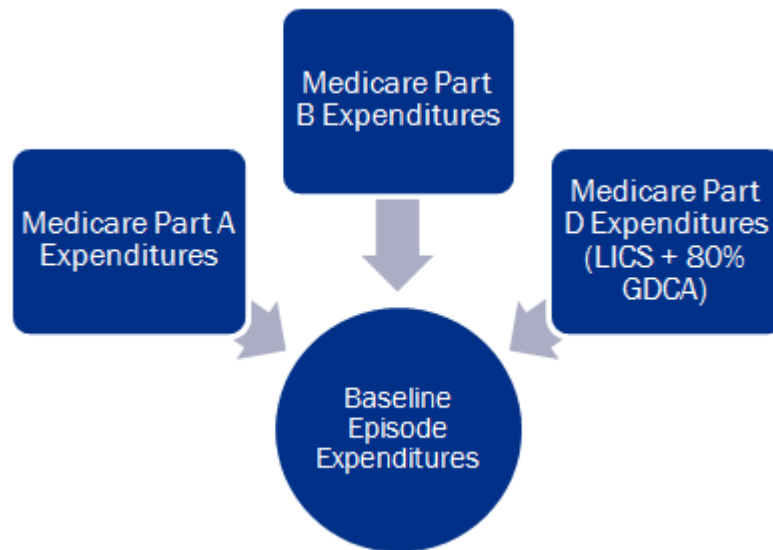
[Figure 1](#) shows the components of the baseline episode expenditures.

² Outpatient outlier amounts, which are not included in the Outpatient revenue center payments, will be included in episode expenditures based on “from date” on the claim.

³

https://www.qualitynet.org/dcs/BlobServer?blobkey=id&blobwhere=1228890829171&blobheader=multipart%2Fobject-stream&blobheadername1=Content-Disposition&blobheadervalue1=attachment%3Bfilename%3D229%2F737%2FDtdl_Price_Stndztn_Mthdly_0718.pdf&blobcol=urldata&blobtable=MungoBlobs

Figure 1: Components of Baseline Episode Expenditures



Before finalizing the baseline episode expenditures, we will apply four adjustments. The first is an adjustment to account for overlap of OCM episodes and other CMS models ([Section 2.2](#)); the second is an adjustment to remove the effects of sequestration ([Section 2.3](#)); the third is a trend adjustment ([Section 2.4](#)); and the fourth is an outlier adjustment called Winsorization ([Section 2.5](#)).

2.2 Accounting for Model Overlap in the Baseline

In the event that an OCM beneficiary was aligned with other CMS models during the baseline period, we will adjust the baseline expenditures accordingly, as described below.

Medicare Accountable Care Organizations (ACOs)

In all of the OCM actual episode expenditure calculations, we will account for any reductions in FFS payments for OCM beneficiaries aligned to Pioneer ACOs that elected population-based payments by adjusting the standardized paid amount on claims, as necessary, to reflect the amount that would have been paid in the absence of population based-payments. We will not include the Pioneer ACO's monthly payment for OCM beneficiaries aligned to Pioneer ACOs that elected population-based payments as OCM baseline expenditures.

Bundled Payments for Care Improvement Initiative (BPCI)

When a BPCI episode overlaps with an OCM episode in the baseline period, any expenditure reductions or increases will first accrue to the BPCI episode. We will prorate the BPCI reconciliation amount by the portion of the BPCI episode that overlapped with the OCM episode. This prorated BPCI reconciliation amount will be included in the baseline episode expenditures of that OCM beneficiary's care during the OCM episode.

2.3 Sequestration Adjustment

Beginning April 1, 2013, all Medicare expenditures were reduced by 2 percent due to sequestration. In the absence of sequestration, Medicare expenditures would be approximately 2 percent higher (technically $1/0.98$ or 2.041 percent higher) than they actually were. OCM baseline claims occurring on and after April 1, 2013, were covered by sequestration and reflect the 2

percent sequestration decrease, and those occurring prior to April 1, 2013, do not. To ensure that the baseline expenditures do not contain some claims with the sequestration reduction and some without, we will adjust the expenditures at the claim level, based on the date of service, to yield an amount equal to what the expenditures would have been in the absence of sequestration. The same adjustment will be made to performance period expenditures. Because any performance-based payments made under OCM will be subject to sequestration when payment is made, expenditure reductions will be calculated based on expenditures that do not reflect sequestration, so as not to double-count the sequestration reduction.

All non-DMEPOS claims with a through date of April 1, 2013, or after will be adjusted by dividing the Medicare payment by 0.98 (this reflects how sequestration was actually implemented). DMEPOS claims from April 1, 2013, or after will be adjusted by dividing the Medicare payment by 0.98. Dividing by 0.98 will increase the claim payments up to the amount that would have been paid in the absence of sequestration.

2.4 Baseline Trend

The trend adjustment will move all episode expenditures in the baseline period to the same level as the expenditures for episodes ending in the most recent 6-month historical period (January – June, 2015). We will adjust expenditures for episodes ending in the first historical period (July – December, 2012) by multiplying them by the ratio of average episode expenditures in the most recent historical period to average episode expenditures in the first historical period. A similar process will be followed for episodes ending in the second through fifth historical periods. This will bring all baseline episode expenditures forward to sixth historical period. The baseline trend factors are located in [Appendix D](#).

2.5 Winsorization

After applying the adjustments for model overlap, sequestration, and baseline trend, we apply the fourth adjustment to the baseline expenditures, which is called Winsorization. Winsorization is a two-sided truncation adjustment that will limit the impact of outliers on the average expenditures. We will Winsorize episode expenditures at the 5th and 95th percentiles of per-episode expenditures by cancer type. Specifically, episode expenditures below the 5th percentile by cancer type will be set to the 5th percentile, and episode expenditures above the 95th percentile will be set to the 95th percentile within cancer type. Winsorization thresholds will be set using all episodes defined and attributed nationally, for both OCM and non-OCM practices. The Winsorization thresholds applied in the calculation of baseline expenditures are located in [Appendix E](#).

Section 3: Calculation of Target Amounts

The target amount is a projection of what the Medicare expenditures would have been during the performance period for episodes attributed to the OCM practice or pool in the absence of OCM participation, reduced for the OCM discount; it is risk-adjusted and specific to each OCM practice. Only episodes that are assigned reconciliation-eligible cancer types, as defined by the OCM Participation Agreement, will be included in each practice's target amount. The target amount is based on baseline expenditures (see [Section 2](#)) that have been trended forward to the performance period and adjusted for the Medicare OCM discount (representing Medicare savings).

We first calculate a risk-adjusted *baseline price* for each episode. The baseline prices will be trended forward to the performance period and adjusted to reflect the costs of chemotherapy drugs that have received recent U.S. Food and Drug Administration (FDA) approval, as described in [Section 3.2](#) below. The trended and adjusted baseline price is referred to as the *benchmark price*. The benchmark price will then be reduced by a CMS discount (4 percent in the one-sided risk arrangement, 2.75 percent in the original two-sided risk arrangement, and 2.5 percent in the alternative two-sided risk arrangement). The discounted benchmark price is the *target price*. The sum of the target prices for all episodes attributed to a practice in a given performance period is equal to the *target amount* that will be compared with that practice's actual episode expenditures (defined in [Section 5](#)).

Calculating the target amount for each practice involves the following steps:

1. Determining the baseline price for each episode ([Section 3.1](#)).
2. Determining the benchmark price for each episode ([Section 3.2](#)).
3. Determining the target price for each episode ([Section 3.3](#))
4. Determining the benchmark and target amounts for each practice ([Section 3.4](#)).

In the event that a practice is participating in a pool, benchmark and target amounts will be based on episodes attributed to all practices within the pool.

3.1 Baseline Price (per Episode)

The baseline price for each episode will be calculated by first predicting the baseline expenditures associated with the specific characteristics of that episode, described below in [Section 3.1.1](#), and then adjusting the prediction to account for the practice's own experience in the baseline period, described in [Section 3.1.2](#).

3.1.1 Prediction Model

The baseline prices will be calculated using a prediction model that will be calibrated using the national set of baseline episodes described in [Section 1](#) and the baseline episode expenditures described in [Section 2](#). The prediction model will be estimated by regressing baseline episode expenditures on a list of covariates that have been determined to influence episode expenditures. The list of covariates may change over time and includes the following:

- Cancer type (those that are reconciliation-eligible, as defined in the document "[OCM Cancer Type Mapping and Codes](#)")

- Age
- Sex
- Dual eligibility for Medicaid and Medicare
- Selected non-cancer comorbidities
- Receipt of selected cancer-directed surgeries
- Receipt of bone marrow transplant
- Receipt of radiation therapy
- Type of chemotherapy drugs used during episode (for breast, prostate, and bladder cancers only)
- Institutional status
- Participation in a clinical trial
- History of prior chemotherapy use
- Episode length
- Hospital referral region

The functional form of the model will be a generalized linear model with a log link and gamma distribution. This type of model is commonly used in predicting health care expenditures and yields only positive predicted values. Because the most recent baseline year is likely to be the most important for predicting future expenditures, baseline expenditures will be weighted in the following manner: for episodes ending in the period July 2012 – June 2013, weight=0.5; for episodes ending in the period July 2013 – June 2014, weight=1.0; for episodes ending in the period July 2014 – June 2015, weight=1.5.

The coefficients from the prediction model will be used to calculate predicted baseline expenditures for each episode identified during the performance period. We will then apply an adjustment reflecting the experience of each practice or pool to each episode’s predicted baseline expenditures before calculating the final baseline price. Detailed information about the covariates used in the prediction model is available in [Appendix I](#) and the document “[OCM Prediction Model Code Lists](#),” effective July 2, 2017.

3.1.2 Experience Adjuster

Because the prediction model may not fully control for all factors that affect episode expenditures, an additional adjustment at the practice or pool level will be applied to the predicted baseline expenditures to reflect the relative costliness of each participating practice or pool during the baseline period. The experience adjuster will control for unmeasured selection at the practice or pool. The experience adjuster will be calculated by first using the prediction model to predict the expenditures of each baseline episode for each participating practice or pool, as described above in [Section 3.1.1](#). The average *actual* baseline expenditures will then be compared with the average *predicted* baseline expenditures for each practice or pool. The ratio of actual-to-predicted average baseline expenditures will form the basis for a practice- or pool-specific experience adjuster that will be applied to the predicted baseline expenditures for each episode attributed to each participating practice or pool. Because average expenditures for individual practices tend to move toward average expenditures for all practices over time (a phenomenon known as

“regression toward the mean”) the ratios of actual-to-predicted average baseline expenditures will not be applied in their entirety to the predicted baseline expenditures. Rather, a weight of 50 percent will be applied to move them closer to a value of 1.0. For example, if the ratio of actual-to-predicted average baseline expenditures for a particular practice is 1.2, we would calculate the experience adjuster for that practice to be 1.1. The formula for this adjustment is:

Experience Adjuster = 50% * 1 + 50% * ratio of actual-to-expected average baseline expenditures

Experience adjusters will be calculated for each OCM practice and pool. Should an OCM practice undergo a change in organizational structure, such as an acquisition or merger, during the model, or the composition of an OCM pool change during the model’s duration, we will recalculate the experience adjuster to reflect the baseline experience of the newly structured practice or pool. The baseline price for each episode is equal to the predicted baseline expenditures for that episode multiplied by the experience adjuster calculated for that episode’s practice or pool.

3.2 Benchmark Price (per Episode)

The benchmark price for each episode is equal to the baseline price multiplied by a trend factor and an adjustment for the use of novel cancer therapies; these adjustments are specific to each practice and pool. The trend factor will reflect underlying secular trends in episode expenditures between the baseline and performance periods. The novel therapy adjustment factor will increase the benchmark price to account for the appropriate use of newly approved oncology therapies; the novel therapy adjustment is applied only in cases where the practice’s use of specified novel therapies is greater than that of practices not participating in OCM. The calculation of the trend factor is described below in [Section 3.2.1](#). The calculation of the novel therapy adjustment is described in [Section 3.2.2](#).

3.2.1 Trend Factor

Trend factors will be derived from expenditures for all episodes attributed to oncology practices not participating in OCM. The population of non-OCM oncology practices will be defined as all TINs with at least one provider with an oncology specialty who provided an E&M visit for cancer care during the performance period.⁴ The ratio of non-participating practices’ episode expenditures in the performance period to their episode expenditures in the baseline period will constitute the basis for the trend factor. We will use regression analysis to adjust the trend factor to the case mix of each participating practice or pool in the performance period. Specifically, we will estimate separate regression models on *performance period* expenditures among non-participating oncology practices and on *baseline* expenditures among non-participating oncology practices. These regression models will use the same functional form as the prediction model used to calculate the baseline prices and will use the same set of covariates. We will use coefficients from these two models to calculate two sets of predicted expenditures for each participating practice and pool during the performance period. For a given practice or pool, the ratio of predicted performance period expenditures to predicted baseline period expenditures represents the trend factor for that practice or pool. We will multiply the baseline price by the trend factor to calculate the trended baseline price for each episode.

⁴ Oncology specialties are Hematology/Oncology, Medical Oncology, Surgical Oncology, Radiation Oncology, and Gynecology Oncology. E&M visits for cancer care are defined as they are in Section 1.1.2 for episode eligibility.

Additional adjustments to the trend factor will be made as needed to account for changes in Federal regulation or other new models.

3.2.2 Adjustment for Novel Therapies

Benchmark prices may be adjusted to reflect situations where a practice has a higher proportion of expenditures for the use of newly FDA-approved oncology drugs for the cancer types for which they are approved than what is reflected in the trended baseline prices. The FDA approves new oncology therapies each year, many of which are substantially more expensive than existing therapies.

Predicted episode expenditures based on trended historical data may not reflect the relative expense of these newly approved therapies, particularly in situations where a practice has a higher proportion of these expenditures than what is reflected in the trended baseline price. A potential adjustment may be available that will be based on the proportion of each practice's or pool's average episode expenditures for these new oncology therapies compared to the same proportion for episodes that are not part of OCM.

To qualify for adjustment, certain criteria would need to be met, including:

1. Only oncology drugs that received FDA approval after December 31, 2014, would be considered for inclusion.
2. Only practices with attributed beneficiaries who received the novel oncology therapies would be potentially impacted.
3. New oncology therapy expenditures will only be considered for adjustment if the use of the novel therapy is consistent with the FDA-approved indications.
4. Oncology drugs will be considered "new" for 2 years from FDA approval for that specific indication for the purpose of the adjustment. The "new" designation may extend past 2 years to align with the OCM reconciliation process.

For each performance period, we will calculate the percentage of actual episode expenditures associated with novel therapies for each practice and pool. As noted in #3 above, to be included in this amount, the use of the specified novel therapies must be consistent with the FDA-approved indications. For Part B drugs, the cost of new oncology drugs includes the full Medicare expenditure amount; for Part D drugs, the relevant costs include the LICS amount and 80 percent of the GDCA (as described in [Section 2.1](#)). This percentage will be compared to the percentage of actual episode expenditures associated with new oncology drugs among all episodes nationally not attributed to participating OCM practices. The population of episodes not attributed to participating OCM practices will be the same as defined for the purposes of calculating the trend factor, described in [Section 3.2.1](#) above. If a given practice's or pool's new oncology drug expenditures as a percentage of its total episode expenditures is higher than that for episodes outside OCM, then an adjustment will be made to the trended baseline prices based on 80 percent of the difference between the practice's or pool's proportion and the non-participating practices' proportion. The novel therapies adjustment may lead to a higher benchmark only; it will never lower a benchmark.

CMS may opt to adjust the calculation of the novel therapies adjustment in the future. Expenditures for certain therapies with lower clinical effectiveness may be adjusted downward

when calculating the relative proportion of novel therapy expenditures per episode. Any such adjustments would be applied no earlier than the third performance period reconciliation.

[Appendix F](#) provides an example calculation of the adjustment for the use of novel therapies.

3.3 Target Price (per Episode)

After the adjustments are applied for trend and novel therapies to produce the benchmark price, the OCM discount will be applied to obtain a target price for each episode. The OCM discount is 4 percent under the one-sided risk sharing arrangement, 2.75 percent under the original two-sided risk arrangement, and 2.5 percent under the alternative two-sided risk arrangement. The target price is equal to the benchmark price multiplied by one minus the OCM discount, or,

Target Price = Benchmark Price * (1 – OCM discount).

3.4 Benchmark and Target Amounts (per Practice)

The benchmark amount is the sum of the benchmark prices for all episodes attributed to the practice for the performance period, as described in [Section 3.2](#). The benchmark amount represents the projection of what the Medicare expenditures would have been during the performance period for episodes attributed to the OCM practice in the absence of OCM participation. The benchmark amount does not include the OCM discount.

The final target amount for each practice is equal to the sum of the target prices for all episodes attributed to the practice for the performance period.

[Appendix G](#) provides a mathematical description of the methodology for calculating target amounts in the performance period.

Section 4: Determination of Performance Period Episodes

The episodes identified and attributed for each performance period will be defined in the same way as those for the baseline period, as described in [Section 1](#). Each performance period, we will identify the national set of episodes meeting OCM criteria and will attribute them to all OCM practices as well as to non-OCM oncology practices (as defined by TIN). The episodes attributed to oncology practices not participating in OCM will be used for the development of the trend factor (see [Section 3.2.1](#)) and the adjustment for the use of novel therapies (see [Section 3.2.2](#)). The episodes attributed to each OCM practice will comprise the population for that practice and the actual episode expenditures associated with the performance period.

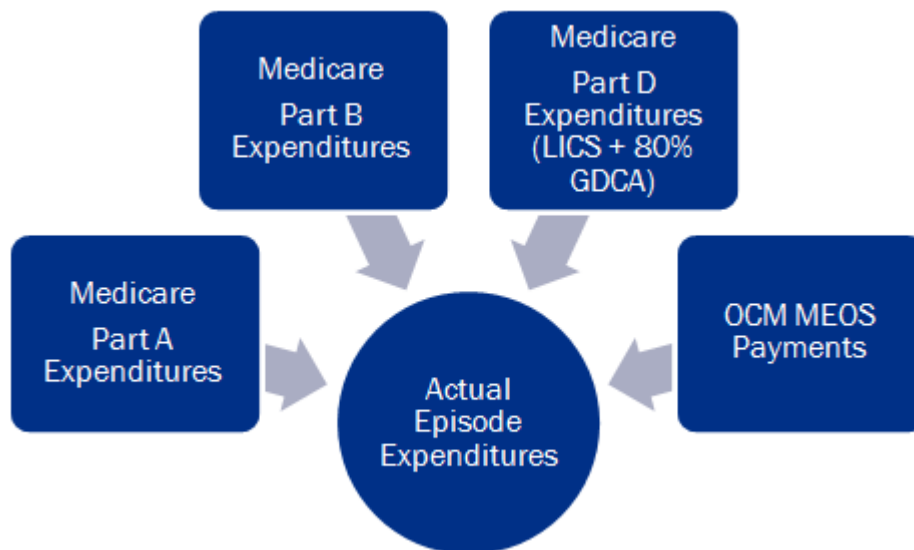
Section 5: Calculation of Actual Episode Expenditures

Once performance period episodes have been identified and attributed to practices we then add up the Medicare FFS expenditures incurred during each episode. As with the baseline expenditures, actual episode expenditures will include expenditures for all non-MEOS claims where the service date is during the episode. For Inpatient and SNF services, the service date is the date the beneficiary was admitted to the facility (the admission date on the claim). For Outpatient services, the service date is the revenue center date on the claim.⁵ For Carrier and DMEPOS services, the service date is the line item date on the claim. For Part D claims the service date is the date the prescription was filled. For all other services (HHA, Hospice), the service date is the “from date” on the claim. MEOS claims may be billed during the episode as well as during the 90 days before and after each episode. Therefore, MEOS claims will first be associated with a specific episode and then added to the episode’s expenditures, which could result in MEOS claims being included in an episode’s expenditures that did not have a service date during the episode. No more than six MEOS payments will be included in the expenditures for each episode, and each MEOS payment will only be associated with one episode.

5.1 Components of Actual Episode Expenditures

Actual episode expenditures include all Medicare Part A and Part B FFS expenditures (which will include the OCM MEOS payments), certain Part D expenditures, and payments resulting from overlapping participation in other CMS models (see [Figure 2](#) below).

Figure 2: Components of Actual Episode Expenditures



The Part A and Part B expenditures come from the Inpatient, SNF, Outpatient, Carrier, DMEPOS, HHA, and Hospice claims files. As with the baseline episode expenditures, actual Medicare expenditures will be standardized to exclude IME and DSH payments, as well as inpatient pass-through amounts. Part D expenditures come from the Part D claims files and include only the LICS

⁵ Outpatient outlier amounts, which are not included in the Outpatient revenue center payments, will be included in episode expenditures based on “from date” on the claim.

amount and 80 percent of the GDCA. Other Part D expenditures will not be included because they are paid on a capitated basis. The Part A and Part B actual expenditures will be sourced from CMS' standardized payment files (see [Section 2.1](#)).

Before finalizing the actual episode expenditures, we will apply similar adjustments as those made to the baseline expenditures—an adjustment to account for potential overlap of shared savings or performance-based payments that may be earned through participation in multiple CMS FFS models ([Section 5.2](#) below), an adjustment to remove the effect of sequestration ([Section 2.3](#)) and the Winsorization adjustment ([Section 2.5](#)). Additional adjustments to the actual episode expenditures will be made as needed to account for changes in Federal regulation or other new models.

5.2 Accounting for Model Overlap

In order to ensure that duplicative incentive payments are not made for the same savings for the same beneficiary, we will follow certain procedures depending on the additional models in which the practice participates. In the event that new CMS models begin during OCM, we will make additional adjustments as needed to account for the overlap between OCM and those new models. We will account for beneficiary overlap with the models listed below in the calculation of actual expenditures.

Medicare Accountable Care Organizations

OCM practices and practitioners and their attributed beneficiaries may participate in (or, in the case of a beneficiary, be aligned to) a Medicare Shared Savings Program (MSSP), Pioneer, or Next Generation ACO (all programs subsequently referred to as "ACOs"). In all of the OCM actual episode expenditure calculations, we will account for any reductions in FFS payments for OCM beneficiaries aligned to Medicare ACOs that have elected population-based payments by adjusting the standardized paid amount on claims, as necessary, to reflect the amount that would have been paid in the absence of population based-payments. We will not include as an expenditure in an OCM episode the ACO's monthly payment for OCM beneficiaries aligned to ACOs that have elected population-based payments.

For further accounting of ACO overlap in the performance-based payment calculation, see [Section 6.2.2](#).

BPCI and Comprehensive Care for Joint Replacement (CJR)

OCM practices, practitioners, and their beneficiaries may participate (or, in the case of a beneficiary, be included) concurrently in BPCI and/or CJR. When a BPCI episode overlaps with an OCM episode, any reductions or increases in expenditures will first accrue to the BPCI episode. After BPCI performs its reconciliation calculations, we will prorate the BPCI reconciliation amount, a non-claims-based payment or recoupment, by the portion of the BPCI episode that overlapped with the OCM episode. This prorated BPCI reconciliation amount will be included in the actual episode expenditures of that OCM beneficiary's care during the OCM episode. This amount will be added to the OCM actual episode expenditures prior to the application of Winsorization. The same approach will be taken in the event of contemporaneous attribution of a beneficiary to both an OCM episode and a CJR episode.

Medicare Care Choices (MCCM)

OCM practices, practitioners, and beneficiaries may participate (or, in the case of a beneficiary, be included) concurrently in MCCM. MCCM per beneficiary per month (PBPM) payments will be included in the actual episode expenditures of the OCM beneficiary's care during the OCM episode. No explicit adjustment will be required to be made to the actual expenditures, as the MCCM PBPM payments will appear as individual records in the claims data used to determine the actual episode expenditures.

Section 6: Calculation of Performance-Based Payments

Performance-based payments will be calculated separately for each OCM practice and pool for each of the nine performance periods defined in [Table 1](#). For each performance period, we will calculate each practice's target amount as described in [Section 3](#) and each practice's actual episode expenditures as described in [Section 5](#). In this section, we describe how we will compare the actual episode expenditures with the target amount to determine if there were expenditure reductions in the performance period and how we will determine the amount of the eligible performance-based payment associated with any expenditure reductions. This process is called reconciliation. We also describe three post-hoc adjustments that will be made to the performance-based payment. Two of these adjustments, geographic variation and sequestration, will apply to all practices and pools. One of them, an adjustment for ACO overlap, will potentially apply to only those OCM participants who are also ACOs. Finally, we discuss the frequency with which the reconciliation process will occur.

6.1 Requirements for Receiving a Performance-Based Payment

In order to receive a performance-based payment, the following requirements must be met:

- The practice's target amount exceeds the actual episode expenditures of the episodes attributed to the practice, or, in the case of a pool, the sum of the target amounts for the practices comprising the pool exceeds the sum of the actual episode expenditures of the episodes attributed to the practices in the pool.
- The practice or pool achieves an Aggregate Quality Score (AQS) that meets or exceeds the minimum performance threshold of 30 percent (out of 100 percent). The AQS is equal to the total quality points earned divided by the maximum quality points in the performance period. Information on the quality measures and how quality points are determined is located in [Section 7](#).
- The practice, or, in the case of a pool, each practice in the pool, reports to the OCM Data Registry on all of the required practice-reported quality measures for the performance period, as identified in [Section 7.1, Table 2](#).
- The practice, or, in the case of a pool, each practice in the pool, implements all of the Practice Redesign Activities.

6.2 Reconciliation

To determine whether a performance-based payment may be made to an individual practice, we will first compare the practice's actual episode expenditures with its target amount (which reflects the OCM discount) for the performance period. If the actual episode expenditures are lower than the target amount, a performance-based payment may be made, contingent upon quality performance. In this case, we would first determine if the OCM "stop-gain" provision would be triggered. The stop-gain provision limits the reduction in expenditures to which the performance multiplier will be applied. In the one-sided and original two-sided risk arrangements, the reduction in expenditures is limited to no more than 20 percent of the practice's benchmark amount. If the reduction in expenditures is greater than 20 percent of the benchmark amount, it will be set equal to 20 percent of the benchmark amount. In the alternative two-sided risk arrangement, the

reduction in expenditures is limited to 16 percent of the “Total Part B Revenue” for the practice or pool. “Total Part B Revenue” is defined as the sum of (1) all Part B revenue for services billed under the practice’s TIN during the 12-month time period spanned by a given Performance Period and (2) any additional Part B payments for chemotherapy drugs (as defined on the most current initiating therapies list at the time) and their administration for all episodes attributed to the practice or pool for the Performance Period. If the reduction in expenditures is greater than 16 percent of the Total Part B Revenue, it will be set equal to 16 percent of the Total Part B Revenue.

The performance-based payment in all risk arrangements will be equal to the difference between the actual episode expenditures (as modified by the stop-gain provision, if applicable) and the target amount, multiplied by the performance multiplier, adjusted for geographic variation (see [Section 6.2.1](#)), and reduced for sequestration (required by law), as shown in this formula:

$$\text{PBP} = (\text{Target} - \text{Actual}) * \text{PM} * \text{GA} * \text{S}, \text{ where}$$

PBP = performance-based payment

Target - Actual = target amount minus actual episode expenditures, modified by stop-gain

PM = performance multiplier

GA = geographic variation adjustment

S = sequestration (equal to 0.98)

The performance multiplier will be 0 percent, 50 percent, 75 percent, or 100 percent, depending on the practice’s or pool’s AQS for the performance period. The method for determining the performance multiplier is described in [Section 7](#).

In the one-sided risk arrangement, if the actual expenditures are greater than the target amount, no performance-based payment will be made.

If the practice is in the original two-sided risk arrangement and the actual expenditures are greater than the *target* amount, the practice must pay CMS back the difference (called a recoupment), subject to a maximum repayment of 20 percent of the benchmark amount, adjusted for geographic variation and reduced for sequestration.

If the practice is in the alternative two-sided risk arrangement and the actual expenditures are greater than the *benchmark* amount, the practice must pay CMS back the difference between the actual expenditures and the benchmark (called a recoupment), subject to a maximum repayment of 8 percent of the Total Part B Revenue (as defined above), adjusted for geographic variation and reduced for sequestration.

The performance multiplier will not be applied to any recoupment amounts.

6.2.1 Geographic Variation Adjustment

Before calculating the final performance-based payments, we will include an adjustment to account for differences in costs due to geographic location. As described in [Section 2.1](#), we initially remove the effects of geographic variation in the calculation of the target amounts and the

actual episode expenditures by using standardized payments, which include adjustments for the CMS Geographic Practice Cost Index (GPCI) and the Hospital Wage Index (HWI), among others. During reconciliation, the geographic variation will be reintroduced by multiplying PBPs by the ratio of actual to standardized payments for the reconciliation-eligible episodes attributed in each performance period, for each practice or pool. This approach directly reverses the effects of standardization, thereby reintroducing the original geographic variation in payments.

6.2.2 Adjustment for ACO Overlap

OCM MEOS payments, performance-based payments, and recoupments will be eligible for inclusion in ACO shared savings calculations in the event that an OCM beneficiary is also aligned to an entity participating as an ACO. However, shared savings calculations for ACOs will not take into account OCM discount amounts, which represent Medicare savings. Thus, CMS will perform separate calculations to identify these amounts. If a portion of the OCM discount is paid out as shared savings to an ACO under the same TIN as an OCM practice, CMS will recover that portion from the OCM practice. The amount to be recovered will be equal to the ACO's shared savings percentage multiplied by the OCM discount amount associated with the overlapping beneficiaries' episodes. See [Appendix J](#) for more details regarding the calculation of the ACO Overlap amount.

Whenever possible, the recoupment amount will be subtracted from the performance-based payment for the current reconciliation. There may be cases where the calculation is unable to be made until after any performance-based payment has been made for the third reconciliation (described below in [Section 6.2.3](#)), in which case the practice would return the amount directly to CMS in the form of an external recoupment.

6.2.3 Frequency and Timing

We will carry out the calculations for each 6-month performance period three times. Each reconciliation will use more claims run-out (that is, claims submitted after the end of the performance period) than the one prior. The first reconciliation will include 2 months of claims run-out, the second reconciliation will include 8 months of claims run-out, and the third and final reconciliation will include 14 months of claims run-out. The results of the second and third reconciliations will be compared with those of the previous reconciliations, possibly resulting in changes to the performance-based payment or recoupment. Differences between the current and previous reconciliations will be added to or subtracted from the current reconciliation amount. If the revised performance-based payment exceeds the original performance-based payment, CMS will make an additional payment to the practice or pool. If the revised performance-based payment is less than the original performance-based payment, the practice or pool will be required to pay back the difference (under one-sided risk, the performance-based payment for a given performance period will never be less than zero).

Calculations for each reconciliation will begin once the last month of run-out for the reconciliation has been received, usually within 6 weeks after the end of the last month of run-out. In general, results of the first reconciliation will be communicated by the eighth month after the end of each performance period. The results of the second and third reconciliations will be communicated 6 and 12 months later, respectively.

6.3 Performance-Based Payments for Pools

The actual expenditures for each pool will be the sum of the actual expenditures for all episodes attributed to the practices in the pool. The quantity to which a pool's actual expenditures will be compared will be the sum of the target amounts for all practices comprising the pool. Likewise, the performance multiplier will be based on the combined experience of all episodes attributed to the practices in the pool, as described in [Section 7.5](#). We will calculate one performance-based payment for the pool, and it will be paid to the pool's designated recipient as specified in the OCM Participation Agreement.

Performance-based payments for pools will be calculated in generally the same manner as described above for individual practices. To determine whether a performance-based payment may be made to a pool, we will first compare the pool's actual episode expenditures with the sum of the target amounts for the performance period for all practices in the pool. If the actual episode expenditures are lower than the sum of the practice target amounts, a performance-based payment may be made, contingent upon quality performance. In this case, we would first determine if the OCM stop-gain provision would be triggered. In the one-sided and original two-sided risk arrangements, if the reduction in expenditures is greater than 20 percent of the sum of the benchmark amounts for all practices in the pool, it will be set equal to 20 percent of the sum of the benchmark amounts. The performance-based payment will be equal to the difference between the actual episode expenditures (as modified by the stop-gain provision, if applicable) and the sum of the target amounts, multiplied by the performance multiplier, adjusted for geographic variation, and reduced for sequestration (as required by law). The performance multiplier will be 0 percent, 50 percent, 75 percent, or 100 percent, depending on the pool's AQS for the performance period. The method for determining the performance multiplier is described in [Section 7](#).

If the actual expenditures are greater than the sum of the target amounts, no performance-based payment will be made.

If the pool is in the original two-sided risk arrangement for the performance period and the actual expenditures are greater than the *target* amount, the pool must pay CMS back the difference (called a recoupment), subject to a maximum repayment of 20 percent of the sum of the benchmark amounts, adjusted for geographic variation and reduced for sequestration.

If the pool is in the alternative two-sided risk arrangement for the performance period, and the actual expenditures are greater than the *benchmark* amount, the pool must pay CMS back the difference (called a recoupment), subject to a maximum repayment of 8 percent of the sum of the Total Part B Revenue for all practices in the pool, adjusted for geographic variation and reduced for sequestration.

The performance multiplier will not be applied to any recoupment amounts.

Section 7: Quality Measures and the Performance Multiplier

As described above in [Section 6](#), the final calculation of performance-based payment requires the application of a performance multiplier. This multiplier will determine the percentage of eligible performance-based payment (0 percent to 100 percent) that may be paid to each practice or pool. The multiplier will be based on the AQS constructed from each practice’s or pool’s performance on the quality measures. In [Section 7.1](#), we describe the OCM quality measures and how they contribute to the determination of the performance multiplier. In [Section 7.2](#) we describe the approach for calculating the measure performance rates. In [Section 7.3](#), we describe the methods that will be used to assign quality points to each measure and to calculate the AQS. In [Section 7.4](#) we address cases of inapplicable measures and measures with insufficient denominators. Finally, in [Section 7.5](#) we address scoring for pooled practices.

7.1 Quality Measures and Quality Points

The performance multiplier will be based on a set of 14 measures that fall into four domains, shown in [Table 2](#).⁶ These measures were chosen after an extensive literature review, a review by a Technical Expert Panel, discussions with CMS, and consideration of alignment with other quality reporting efforts, including the Physician Quality Reporting System (PQRS). Measures are derived from claims, the OCM Data Registry (as reported by practices), and a patient experience of care survey that a CMS contractor will field.

Table 2: Measures to Be Used in OCM Performance Multiplier

Measure Name	OCM Measure Number	Measure Source
Communication and Care Coordination		
Risk-adjusted proportion of patients with all-cause hospital admissions within the 6-month episode ¹	OCM-1	Claims
Risk-adjusted proportion of patients with all-cause emergency department visits or observation stays that did not result in a hospital admission within the 6-month episode	OCM-2	Claims
Proportion of patients who died who were admitted to hospice for 3 days or more	OCM-3	Claims
Care Plan ²	OCM-24	Registry (practice-reported)
Closing the Referral Loop: Receipt of Specialist Report ²	OCM-30	Registry (practice-reported)
Person- and Caregiver-Centered Experience and Outcomes		

⁶ OCM-7 was retired effective with the March 2018 reporting period and will only be used in the quality scoring for Performance Period 1. OCM-8 through OCM-11 were retired effective with the March 2019 reporting period and will only be used in the quality scoring for Performance Periods 1 – 3. OCM-24 and OCM-30 were added effective with the March 2019 reporting period and will only be used in the quality scoring for Performance Period 4. OCM-1, OCM-12, OCM-24, and OCM-30 were retired effective with Performance Period 5.

Measure Name	OCM Measure Number	Measure Source
Pain Assessment and Management Composite ³	OCM-4	Registry (practice-reported)
Preventive Care and Screening: Screening for Depression and Follow-Up Plan (CMS 2v6.3, NQF 0418)	OCM-5	Registry (practice-reported)
Patient-Reported Experience of Care	OCM-6	Survey
Clinical Quality of Care		
Prostate Cancer: Adjuvant Hormonal Therapy for High or Very High Risk Prostate Cancer (PQRS 104, NQF 0390) ⁴	OCM-7	Registry (practice-reported)
Adjuvant chemotherapy is recommended or administered within 4 months (120 days) of diagnosis to patients under the age of 80 with AJCC III (lymph node positive) colon cancer (NQF 0223) ⁵	OCM-8	Registry (practice-reported)
Combination chemotherapy is recommended or administered within 4 months (120 days) of diagnosis for women under 70 with AJCC T1cN0M0, or Stage IB - III hormone receptor negative breast cancer (NQF 0559) ⁵	OCM-9	Registry (practice-reported)
Trastuzumab administered to patients with AJCC stage I (T1c) - III and human epidermal growth factor receptor 2 (HER2) positive breast cancer who receive adjuvant chemotherapy (NQF 1858) ⁵	OCM-10	Registry (practice-reported)
Breast Cancer: Hormonal Therapy for Stage I (T1b)-IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer (CMS 140v5.0, NQF 0387) ⁵	OCM-11	Registry (practice-reported)
Patient Safety		
Documentation of Current Medications in the Medical Record (CMS 68v6.1, NQF 0419) ⁶	OCM-12	Registry (practice-reported)

1. OCM-1 was retired effective with Performance Period 5.
2. OCM-24 and OCM-30 were added effective with the March 2019 reporting period and retired with the September 2019 reporting period.
3. The composite measure, OCM-4, is comprised of two measures: OCM-4a, Oncology: Medical and Radiation – Pain Intensity Quantified (PQRS 143, NQF 0384), and OCM-4b, Oncology: Medical and Radiation – Plan of Care for Pain (PQRS 144, NQF 0383).
4. OCM-7 was retired effective with the March 2018 reporting period.
5. OCM-8 – OCM-11 were retired effective with the March 2019 reporting period.
6. OCM-12 was retired effective with the September 2019 reporting period.

[Table 3](#) summarizes the approach for phasing in the measures. In the first five performance periods there will be a mix of pay-for-reporting (P4R) and pay-for-performance (P4P) measures. P4R measures require only that each practice report data on a sufficient number of beneficiaries for the practice or pool to receive quality points. P4P measures are assigned quality points based on the practice or pool's performance as compared to set thresholds, called quality benchmarks. For episodes ending in the first performance period, the three claims-based measures are P4P and five practice-reported measures (OCM-7 – OCM-11) are P4R. Note that the patient-reported experience of care measure (OCM-6) and five of the practice-reported measures (OCM-4, OCM-5, OCM-12, OCM-24, and OCM-30) *are not included* in the first performance period scoring.

For episodes ending in the second performance period, the three claims-based measures are P4P and seven practice-reported measures (OCM-4, OCM-5, and OCM-8 – OCM-12) are P4R (OCM-7 is retired as of the second performance period). The patient-reported experience of care measure (OCM-6) is not included in the second performance period scoring, nor are OCM-24 and OCM-30, which are effective in the fourth performance period.

For episodes ending in the third performance period, the three claims-based measures are P4P, the patient-reported experience of care measure (OCM-6) is P4P, and seven practice-reported measures are P4R (OCM-4, OCM-5, OCM-8 – OCM-12); however, OCM-8 – OCM-12 are optionally P4R. If OCM-8 – OCM-12 are reported, the maximum number of points available in the denominator in the third performance period is greater. OCM-24 and OCM-30 are not included in the third performance period and are effective in the fourth performance period.

For episodes ending in the fourth performance period, the three claims-based measures and the patient-reported experience of care measure (OCM-6) are P4P and five practice-reported measures are P4R (OCM-4, OCM-5, OCM-12, OCM-24, and OCM-30); however, OCM-12, OCM-24, and OCM-30 are optionally P4R. If any of OCM-12, OCM-24, or OCM-30 are reported, the maximum number of points available in the denominator in the fourth performance period is greater. OCM-8 – OCM-11 are retired as of the fourth performance period.

For episodes ending in the fifth performance period, two claims-based measures (OCM-2 and OCM-3) and the patient-reported experience of care measure (OCM-6) are P4P and two practice-reported measures (OCM-4 and OCM-5) are P4R. OCM-1, OCM-12, OCM-24, and OCM-030 are retired as of the fifth performance period.

For episodes ending in the sixth and subsequent performance periods, there will be five measures (OCM-2 – OCM-6), and all measures are P4P.

In [Table 3](#), “R” indicates only reporting of the measure will be required for the performance period, and “P” indicates the measure will be scored by comparison with a threshold (described in [Section 7.3](#) below) for the performance period.

Table 3: OCM Measure Phase-in

OCM Measure Number	PP1	PP2	PP3	PP4	PP5	PP6+
OCM-1	P	P	P	P	--	--
OCM-2	P	P	P	P	P	P
OCM-3	P	P	P	P	P	P
OCM-4	--	R	R	R	R	P
OCM-5	--	R	R	R	R	P
OCM-6	--	--	P	P	P	P
OCM-7	R	--	--	--	--	--
OCM-8	R	R	R*	--	--	--
OCM-9	R	R	R*	--	--	--
OCM-10	R	R	R*	--	--	--

OCM Measure Number	PP1	PP2	PP3	PP4	PP5	PP6+
OCM-11	R	R	R*	--	--	--
OCM-12	--	R	R	R*	--	--
OCM-24	--	--	--	R*	--	--
OCM-30	--	--	--	R*	--	--
# Measures	8	10	7 - 11	6 - 9	5	5

*Optionally reported.

[Table 4](#) shows the maximum number of points available for each measure in each performance period.

Table 4: Maximum Points per Measure per Performance Period

OCM Measure Number	PP1	PP2	PP3	PP4	PP5	PP6+
OCM-1	10	10	10	10	--	--
OCM-2	10	10	10	10	10	10
OCM-3	10	10	10	10	10	10
OCM-4	--	2.5	2.5	2.5	2.5	10
OCM-5	--	2.5	2.5	2.5	2.5	10
OCM-6	--	--	10	10	10	10
OCM-7	2.5	--	--	--	--	--
OCM-8	2.5	2.5	2.5*	--	--	--
OCM-9	2.5	2.5	2.5*	--	--	--
OCM-10	2.5	2.5	2.5*	--	--	--
OCM-11	2.5	2.5	2.5*	--	--	--
OCM-12	--	2.5	2.5	2.5*	--	--
OCM-24	--	--	--	2.5*	--	--
OCM-30	--	--	--	2.5*	--	--
Total	42.5	47.5	47.5 - 57.5	45 - 52.5	35	50

*Optionally reported.

All P4P measures will have a maximum of 10 points available for each, and all P4R measures will have a maximum of 2.5 points available for each.

In the first performance period, there will be a maximum of 42.5 points available, 30 of which will come from P4P measures and 12.5 of which will come from P4R measures. Scoring in the first performance period will be calculated as follows:

- Maximum of 30 points for P4P measures (3 measures * 10 points each).
- Maximum of 12.5 points for P4R measures (5 measures * 2.5 points each).
- Maximum of 42.5 points total.

In the second performance period, there will be a maximum of 47.5 points available, 30 of which will come from P4P measures and 17.5 of which will come from P4R measures. Scoring in the second performance period will be calculated as follows:

- Maximum of 30 points for P4P measures (3 measures * 10 points each).
- Maximum of 17.5 points for P4R measures (7 measures * 2.5 points each).
- Maximum of 47.5 points total.

In the third performance period, there will be a maximum of 57.5 points available, 40 of which will come from P4P measures and 17.5 of which will come from P4R measures. Scoring in the third performance period will be calculated as follows:

- Maximum of 40 points for P4P measures (4 measures * 10 points each).
- Maximum of 17.5 points for P4R measures (7 measures * 2.5 points each).
- Maximum of 57.5 points total.

In the fourth performance period there will be a maximum of 52.5 points available, 40 of which will come from P4P measures and 12.5 of which will come from P4R measures. Scoring in the fourth performance period will be calculated as follows:

- Maximum of 40 points for P4P measures (4 measures * 10 points each).
- Maximum of 12.5 points for P4R measures (5 measures * 2.5 points each).
- Maximum of 52.5 points total.

In the fifth performance period there will be a maximum of 35 points available, 30 of which will come from P4P measures and 5 of which will come from P4R measures. Scoring in the fifth performance period will be calculated as follows:

- Maximum of 30 points for P4P measures (3 measures * 10 points each).
- Maximum of 5 points for P4R measures (2 measures * 2.5 points each).
- Maximum of 35 points total.

In the sixth and subsequent performance periods there will be a maximum of 50 points available. At this point, the two practice-reported P4R measures transition to P4P and all measures are weighted equally. Therefore, the scoring for the sixth and subsequent performance periods will be calculated as follows:

- Maximum of 50 points (5 measures * 10 points each)

In each performance period, we will calculate the AQS for each practice and pool, expressed as a percent ranging from 0 to 100, which will equal the sum of the points earned on all applicable measures divided by the maximum number of points available, where in the third and fourth performance periods the maximum number of points available may vary depending on which measures were reported. The performance multiplier will depend upon the AQS. [Section 7.2](#) describes how performance rates are calculated for each measure, and [Section 7.3](#) describes

how the reporting and performance rates determine the number of points earned for each measure.

7.2 Performance Rates

Performance rates on P4P measures will be calculated according to the specifications for each measure. Performance rates for claims-based measures (OCM-1 – OCM-3) will be calculated using Medicare administrative data only. Performance rates for the patient-reported experience of care measure (OCM-6) will be calculated using the survey data collected by the Evaluation Contractor and a methodology agreed upon by the Evaluation Contractor, the Implementation Contractor, and CMS. Performance rates for practice-reported measures (OCM-4 and OCM-5) will be calculated using data submitted to the OCM Data Registry by OCM practices.

Because certain measures may not generate denominators that are high enough to calculate stable performance rates in one 6-month performance period, we will use the average episode-weighted performance rate over two performance periods to calculate the quality score for all quality measures. Each calculation will cover the current performance period and the prior one. We will add the denominators and numerators from the current and prior performance periods and calculate one performance rate for each measure. This should help reduce the number of cases where a measure denominator is too low to calculate a statistically reliable performance rate with only 6 months of data. For all measures except OCM-6, the required denominator size is 20 (i.e., 20 episodes, 20 visits, etc.) in the two performance periods combined. For OCM-6, the required “denominator” is 100 survey responses over two performance periods. See [Section 7.4](#) for the treatment of measures where the denominator does not meet the minimum requirement. Only the claims-based measures will be scored based on performance in the first performance period, where there is no prior performance period with which to average. In this case, the performance rate will include episodes terminating during the first half of 2016 as well as those terminating during the first performance period (first half of 2017).⁷

Since the model measures financial performance during 6-month episodes of chemotherapy, quality performance will also be based on 6-month episodes to the extent possible. As written above, each quality performance calculation will average the performance rates of the current performance period with the performance rates of the previous performance period. As such, measure calculations will include the applicable patients with episodes in those two performance periods and will include events for those patients occurring during their 6-month episodes, again, to the extent possible. In the context of this paper, “applicable patients” refers to the patients who qualify for a particular measure (for example, the breast cancer measures do not apply to patients who do not have breast cancer).

⁷ Ideally, we would average episodes ending in the first half of 2017 with those ending in the last half of 2016, to use consecutive performance periods. However, this would cause significant overlap in episodes used, double-counting the same experience, since episodes will be defined anew for the first performance period. If the set of episodes that is averaged with those in the first performance period is limited to those ending in the first half of 2016 (rather than the second half), we avoid this potential for double-counting.

7.3 Measure Scoring and Aggregate Quality Score

The process of assigning quality points to each measure, called “scoring,” will be based on practices’ reporting and/or quality performance relative to set thresholds. Reporting performance is based on whether the practice reported data to the OCM Data Registry.

Performance thresholds will be determined based on the best data available for each type of measure. If national data are available, they will be employed first to set performance thresholds. If national data are not available (e.g., the patient-reported experience of care measure, for which there is no national data at this time) we will use other sources of information to set the thresholds. In the sections below ([Section 7.3.1](#), [Section 7.3.2](#), and [Section 7.3.3](#)) we describe the scoring approach for each measure type (claims-based, practice-reported, and patient-reported).

7.3.1 Claims-Based Measure Scoring

Performance thresholds for claims-based measures were determined using national historical Medicare claims data for OCM participating and non-participating practices. We developed a distribution of performance for all practices nationally to which episodes were attributed, following the same episode identification and attribution specifications defined in [Section 1](#). The six performance periods covered by the OCM 3-year baseline time frame were aggregated into three 12-month periods, called “practice-years.” Each practice-year contributed to the threshold calculations if at least a minimum number of episodes was attributed to it – a minimum of 100 episodes for OCM-1 and OCM-2 and a minimum of 20 episodes ending in death for OCM-3. Using this distribution, we set performance thresholds at each quintile. These quintiles determine the number of points awarded for each measure.

See [Table 5](#) for the point structure that applies to each claims-based measure. For OCM-3, a higher rate on the performance measure results in a higher number of points being assigned. However, it is important to note that OCM-1 and OCM-2 have a reverse scoring structure, where a lower rate on the performance measure indicates better quality and therefore results in a higher number of points being assigned. This reverse scoring structure is reflected in the performance thresholds in the document “[OCM Claims Based Quality Measure Benchmarks](#),” available on healthcarecommunities.org.

Table 5: Scoring of Claims-Based Measures

OCM-1 and OCM-2: Quality Performance Rate (P)	OCM-1 and OCM-2: Points Assigned	OCM-3: Quality Performance Rate (P)	OCM-3: Points Assigned
$P \leq 20^{\text{th}}$ Percentile	10	$P \geq 80^{\text{th}}$ Percentile	10
20^{th} Percentile $< P \leq 40^{\text{th}}$ Percentile	7.5	60^{th} Percentile $\leq P < 80^{\text{th}}$ Percentile	7.5
40^{th} Percentile $< P \leq 60^{\text{th}}$ Percentile	5	40^{th} Percentile $\leq P < 60^{\text{th}}$ Percentile	5

OCM-1 and OCM-2: Quality Performance Rate (P)	OCM-1 and OCM-2: Points Assigned	OCM-3: Quality Performance Rate (P)	OCM-3: Points Assigned
60 th Percentile < P ≤ 80 th Percentile	2.5	20 th Percentile ≤ P < 40 th Percentile	2.5
P > 80 th Percentile	0	P < 20 th Percentile	0

7.3.2 Practice-Reported Measure Scoring

In the first through fifth performance periods, the practice-reported measures (five measures in the first performance period, seven measures in the second, up to seven measures in the third performance period, up to five measures in the fourth performance period, and two measures in the fifth performance period) will be P4R. In the sixth and subsequent performance periods, all practice-reported measures will be P4P measures. Below we describe the approach we will use to score practice-reported measures when they are P4R and when they are P4P.

Pay-for-reporting

In all performance periods in which the OCM FFS Beneficiary and Practice-Level (All Payer) measures (OCM-4, OCM-5, OCM-7 – OCM-12, OCM-24, and OCM-30) are P4R, practices will receive the maximum number of reporting points (2.5) for those measures, as long as they have reported the measure, except in cases where the practice has no attributed OCM episodes for a Practice-Level (All Payer) measure’s (OCM-7 – OCM-11) cancer type. For example, if a practice has no colon cancer episodes, OCM-8 will be inapplicable for that practice and will be excluded from scoring (see [Section 7.4](#) for more information). Please note that CMS may reduce or eliminate a practice’s reporting points in the event that an audit of a practice’s medical records demonstrates that the quality measure data reported were not complete or accurate. For more information on the Practice-Level (All Payer) and OCM FFS Beneficiary measures, see the OCM Quality Measures Guide.

Pay-for-performance

P4P measures (OCM-4 and OCM-5, beginning in the sixth performance period) will be scored based on the practice’s performance on the measures as compared to set quality thresholds. At the beginning of OCM, there were no reliable national data available for the OCM practice-reported measures, as they were developed specifically for OCM. We have used the data reported by the OCM practices to calculate performance thresholds for these measures. These thresholds are reflected in the document called “[OCM Practice-Reported Measure Benchmarks](#),” available on OCM Connect and healthcarecommunities.org.

Please note that CMS may reduce or eliminate a practice’s performance points, regardless of their performance rates as compared to the established thresholds for each measure, in the event that an audit of a practice’s medical records demonstrates that the quality measure data reported were not complete or accurate.

The AQS for each performance period will be based on the applicable OCM FFS Beneficiary and Practice-Level (All Payer) measure results reported by each respective reporting deadline. Neither

the OCM FFS Beneficiary measures nor the Practice-Level (All Payer) measures will be updated after attribution is received or in the first or second true-up of each performance period.

[Table 6](#) shows which registry data will be used in the scoring of the practice-reported measures for each performance period. Note that beginning with Performance Period 6, when the practice-reported measures become P4P, the quality scores will be determined using two measurement periods of data rather than one, per the description above whereby quality scores for each performance period will be calculated as the average of the scores for the current and previous performance periods.

Table 6: Registry Data Used in Scoring Practice-Reported Measures, by Performance Period

Performance Period	Measurement Period(s)	Reporting Deadline(s)
1	January – June, 2017	October 2017
2	July – December, 2017	April 2018
3	January – June, 2018	September 2018
4	July – December, 2018	March 2019
5	January – June, 2019	September 2019
6	January – June, 2019 July – December, 2019	September 2019, March 2020
7	July – December, 2019 January – June, 2020	March 2020, September 2020
8	January – June, 2020 July – December, 2020	September 2020, March 2021
9	July – December, 2020 January – June, 2021	March 2021, October 2021

7.3.3 Patient Experience of Care Scoring

A multi-item survey to assess patient experience with chemotherapy care will be administered to a sample of patients at each practice. Twenty-six of the survey items will be based on the first Consumer Assessment of Healthcare Providers and Systems (CAHPS) for Cancer Care field test report and will center on five composites and one overall measure of patient experience.⁸ In its current form, the CAHPS for Cancer Care composites include “Exchanging Information with Patients” (four scored items), “Access” (six scored items), “Shared Decision Making” (composite not scored), “Enabling Self-Management” (eight scored items), and “Affective Communication” (four scored items). Additional survey items will be drawn from various validated instruments (e.g., CAHPS for Cancer Care, CanCORS), but these items will not be used for scoring purposes.

We will use the responses to all composite-related items to create summary scores for each composite, except for the Shared Decision Making composite. Field tests to date have indicated that the Shared Decision Making composite is not sufficiently reliable for benchmarking and payment purposes. We will collect these data for monitoring purposes and may score this

⁸ <https://www.advisory.com/-/media/Advisory-com/Research/OR/Blog/2014/Cancer-CAHPS-Update.pdf>

composite in the patient experience measure in future performance periods (not earlier than the third). We will also score the overall measure of patient experience. One aggregate “patient experience” score will then be calculated from the five scores (four composite scores and one summary item scores).

First, each beneficiary’s responses to the individual survey items will be assigned point values ranging from 0 to 10. Then we will determine the average point value over all survey items in each composite as the sum of the points assigned to each survey item divided by the number of survey items in the composite. This is done at the beneficiary level. Next, we will calculate average composite point values over all surveyed beneficiaries in each practice or pool. Average composite values will be risk-adjusted to account for the characteristics of the episodes in the practice or pool. Covariates used in the risk adjustment will include characteristics that are predictive of patient experience such as age, sex, Medicaid status, cancer type, education level, self-reported health status, and HCC categories. Many of these variables are also used in the expenditure prediction model. Finally, we will calculate the aggregate patient experience of care score for each practice or pool as the average of the five scores. [Appendix H](#) lists the scored survey items in each of the four composites and in the overall measure of patient experience as well as the point values that will be assigned to each response.

As with several of the practice-reported measures, there are currently no external data available for the OCM patient experience of care measure. We have used the data from the surveys fielded during the early months of the model among all participants to calculate performance thresholds for this measure. These thresholds are reflected in the document called “[OCM Patient Experience Measure Benchmarks](#),” available on healthcarecommunities.org.

The patient experience survey will be administered each quarter to a sample of the beneficiaries who received cancer care at each OCM practice in a 6-month period. Each administration of the survey is referred to as a “wave.” The survey waves overlap. For example, Wave 1 was administered to beneficiaries who received cancer care at OCM practices between January and June of 2016 and Wave 2 was administered to beneficiaries who received cancer care at OCM practices between April and September of 2016. No beneficiary will be surveyed more than one time in a 12-month period. [Table 7](#) shows the survey waves that will be used in the scoring for each performance period. Note that because the performance rate for OCM-6 will be based on data from the current performance period and the one prior, the final performance rate for each performance period will be based on five survey waves (due to the overlap of survey waves described above).

Table 7: Survey Waves Used in Scoring OCM-6, by Performance Period

Performance Period	Survey Waves	Dates Beneficiaries Received Care
1	n/a	n/a
2	n/a	n/a
3	Wave 4 – Wave 6 Wave 6 – Wave 8	October 2016 – September 2017 April 2017 – March 2018

Performance Period	Survey Waves	Dates Beneficiaries Received Care
4	Wave 6 – Wave 8 Wave 8 – Wave 10	April 2017 – March 2018 October 2017 – September 2018
5	Wave 8 – Wave 10 Wave 10 – Wave 12	October 2017 – September 2018 April 2018 – March 2019
6	Wave 10 – Wave 12 Wave 12 – Wave 14	April 2018 – March 2019 October 2018 – September 2019
7	Wave 12 – Wave 14 Wave 14 – Wave 16	October 2018 – September 2019 April 2019 – March 2020
8	Wave 14 – Wave 16 Wave 16 – Wave 18	April 2019 – March 2020 October 2019 – September 2020
9	Wave 16 – Wave 18 Wave 18 – Wave 20	October 2019 – September 2020 April 2020 – March 2021

7.3.4 Aggregate Quality Score

After points have been determined for each measure, all earned points will be summed and divided by the practice’s or pool’s total possible points to calculate the AQS. Practices or pools will then be awarded performance-based payments by comparing their AQS to a payment scale to determine the performance multiplier (in the case where the target amount exceeds the average episode expenditures in the performance period). [Table 8](#) shows a mapping of the AQS to the performance multiplier.

Table 8: Aggregate Quality Score Translated into Performance Multiplier

Aggregate Quality Score (% of maximum points)	Performance Multiplier
75% – 100%	100%
50% – 74%	75%
30% – 49%	50%
Less than 30%	0%

In order to receive a performance-based payment, practices must have reported all applicable measures for the performance period to the OCM Data Registry, per the OCM Participation Agreement. Note that in the third and fourth performance periods, the optional measures need not be reported for a practice or pool to be eligible for a performance-based payment. A practice or pool that scores above the 30 percent minimum in [Table 8](#), but does NOT report sufficiently to the OCM Data Registry, will not receive a performance-based payment.

In [Table 9](#), we show two examples of the quality score calculation, one for the third performance period and one for the sixth performance period.

Performance Period 3 Example: Assume that a practice reports all P4R measures in Performance Period 3, including the optional measures OCM-8 – OCM-11, as in the “Performance Period 3 Example” columns in [Table 9](#). The practice receives the maximum number of points for the P4R measures ($2.5 * 7 = 17.5$ points). The practice also earns 7.5 quality points for each P4P measure ($7.5 * 4 = 30$ points). The sum of all quality points is 47.5 and the AQS is 82.6 percent (equal to 47.5 divided by 57.5). The practice would earn 100 percent of the eligible performance-based payment (if actual expenditures are lower than the target amount) for that performance period.

Performance Period 6 Example: Assume that a practice earns points for each measure as in the “Performance Period 6 Example” columns in [Table 9](#) and that it reported all measures in the performance period. The sum of all quality points is 30 and the AQS is 60 percent (equal to 30 divided by 50). The practice would earn 75 percent of the eligible performance-based payment (if actual expenditures are lower than the target amount) for that performance period.

Table 9: Illustrative Quality Scoring Examples

OCM Measure Number	Perf. Period 3 Example, Points Earned	Perf. Period 3 Example, Maximum Points	Perf. Period 6 Example, Points Earned	Perf. Period 6 Example, Maximum Points
OCM-1	7.5	10	--	--
OCM-2	7.5	10	7.5	10
OCM-3	7.5	10	7.5	10
OCM-4	2.5	2.5	2.5	10
OCM-5	2.5	2.5	5	10

OCM Measure Number	Perf. Period 3 Example, Points Earned	Perf. Period 3 Example, Maximum Points	Perf. Period 6 Example, Points Earned	Perf. Period 6 Example, Maximum Points
OCM-6	7.5	10	7.5	10
OCM-8	2.5	2.5	--	--
OCM-9	2.5	2.5	--	--
OCM-10	2.5	2.5	--	--
OCM-11	2.5	2.5	--	--
OCM-12	2.5	2.5	--	--
OCM-24	--	--	--	--
OCM-30	--	--	--	--
P4R Points	17.5	17.5	NA	NA
P4P Points	30	40	30	50
Total Points	47.5	57.5	30	50
AQS	82.6%	--	60%	--
Performance Multiplier	100%	--	75%	--

7.4 Inapplicable Measures and Measures with Insufficient Denominator Size

We anticipate that OCM will include practices of varying sizes and specialties. As such, there may be practices that either 1) do not have enough episodes in the performance rate calculation to provide a statistically reliable denominator, or 2) do not treat patients with the type of cancer for which a measure is defined. For example, urology practices may not have breast or colon cancer episodes attributed, yet in some performance periods OCM includes four quality measures that are specific to breast and colon cancers.

If a practice or pool has no beneficiaries that meet the criteria for inclusion in the denominator of a practice-reported measure, we will exclude that measure from the calculation of the AQS for that performance period. Using the third performance period and a urology practice that sees no breast or colon cancer patients as an example, rather than having a maximum of 57.5 points available, the practice would have a maximum of 52.5 points available. Scoring on all other measures would remain as described previously.

If a practice or pool chooses not to report the optional measures in the third or fourth performance period, we will exclude those measures from the calculation of the AQS.

In the same way, if a practice or pool does not have enough episodes in the calculation of the two-performance period average to comprise a minimum denominator of 20, we will exclude that measure from the calculation of that practice's or pool's AQS for that performance period.

Similarly, the patient experience of care measure must be based on a sufficient number of survey responses to provide a statistically reliable performance score. If a practice or pool does not have at least 100 survey responses over two performance periods, we will exclude the patient

experience of care measure from the calculation of that practice's or pool's AQS for that performance period.

7.5 Scoring for Pooled Practices

OCM pools that are made up of more than one practice will have all of their episodes treated as if they belong to one practice for the purposes of quality scoring. This means we will sum the numerators and denominators for each practice in the pool before calculating pooled performance rates for each measure. For the patient experience of care measure, which is calculated at the practice level, we will calculate a weighted average of aggregate patient experience of care scores across all practices in the pool. The number of episodes in each practice during the performance period will serve as the weight. These methods implicitly or explicitly weight the performance for each practice in the pool by the number of episodes attributed to the practice in the performance period. The points for each pooled performance rate will be assigned and summed to produce the AQS in the same way as for individual practices.

Section 8: Example

The following example illustrates the calculation of the performance based payment under the one-sided and two-sided risk arrangements. The example is for illustrative purposes only and does not necessarily reflect the experience expected during any given performance period.

In this example, the sum of baseline episode prices is calculated as \$2.5 million for a practice with approximately 100 episodes. After application of a trend factor of 1.02 and an adjustment for novel therapies of 1.01, the benchmark amount is \$2.576 million. After application of the OCM discount rate, the target amount is \$2,472,480 for the performance period for the one-sided risk arrangement (4 percent discount), \$2,504,674 for the original two-sided risk arrangement (2.75 percent discount), and \$2,511,113 for the alternative two-sided risk arrangement (2.5 percent discount). The practice's actual episode expenditures for the performance period are \$2.3 million and the performance multiplier is 75 percent. The performance multiplier is multiplied by the difference between the target amount and the actual episode expenditures to arrive at the performance-based payment for the practice. Finally, a geographic adjustment of 1.03 and the sequestration adjustment of 2 percent are applied to calculate the final performance-based payment of \$130,576 under the one-sided risk arrangement, \$154,948 under the original two-sided risk arrangement, and \$159,823 under the alternative two-sided risk arrangement.

Table 10: Example Performance-Based Payment Calculation

		One-Sided Risk	Original Two-Sided Risk	Alternative Two-Sided Risk
A	Sum of Baseline Episode Prices	\$2,500,000	\$2,500,000	\$2,500,000
B	Adjustment for Trend	1.02	1.02	1.02
C	Adjustment for Novel Therapies	1.01	1.01	1.01
D	Benchmark Amount (A * B * C)	\$2,575,500	\$2,575,500	\$2,575,500
E	OCM Discount Rate	4.00%	2.75%	2.5%
F	OCM Discount Amount (D * E)	\$103,020	\$70,826	\$64,388
G	Target Amount (D - F)	\$2,472,480	\$2,504,674	\$2,511,113
H	Actual Episode Expenditures	\$2,300,000	\$2,300,000	\$2,300,000
I	Difference (Target less Actual; G - H)	\$172,480	\$204,674	\$211,113
J	Performance Multiplier	75%	75%	75%
K	Performance-Based Payment (I * J)	\$129,360	\$153,505	\$158,334
L	Final Performance-Based Payment, after Geographic Adjustment and Sequestration (K * 1.03 * 0.98)	\$130,576	\$154,948	\$159,823

Section 9: OCM Resources

OCM Connect: <https://app.innovation.cms.gov/OCMConnect> (for model participants only)

CMS OCM Website: <https://innovation.cms.gov/initiatives/Oncology-Care>

OCM Participant Portal: <https://app.innovation.cms.gov/ocmpost>

OCM Support: OCMSupport@cms.hhs.gov

1-844-711-2664 (1-844-711-CMMI), Option 2

Appendix A: Specifications for Episode Identification

Below are the detailed specifications for identifying initial and subsequent episodes in a performance period. Performance periods will be defined as in [Table 1](#).

- Step 1: Identify all possible claims that could trigger an episode ending in the performance period.
 - Carrier, DMEPOS (identification at the line level):
 - The claim must contain a line item HCPCS code indicating an included chemotherapy drug (initiating cancer therapy) in any line item.
 - The chemotherapy drug line item must have a “line first expense date” in the appropriate 6 month “Episodes Beginning” period in [Table 1](#), inclusive of end dates.
 - The chemotherapy drug line item must not be denied (line allowed charge >0).
 - The chemotherapy drug line place of service must not be an inpatient hospital (21).
 - The chemotherapy drug claim must contain an included cancer diagnosis code (see “[OCM Cancer Type Mapping and Codes](#)”) either:
 - 1) In any non-denied line item on the same claim (does not have to be same line as HCPCS code above) OR
 - 2) Anywhere in the claim header AND contains ICD10 code Z51.11 or Z51.12 or ICD9 code V58.11 or V58.12 as the principal diagnosis in the claim header.
 - The trigger date is the line first expense date on the qualifying chemotherapy drug line.
 - Outpatient (identification at the revenue center level):
 - The claim must contain a HCPCS code indicating an included chemotherapy drug (initiating cancer therapy) in any revenue center.
 - The “revenue center date” on the same revenue center in which the HCPCS code is found must be in the appropriate 6 month “Episode Beginning” period in [Table 1](#), inclusive of end dates.
 - The claim must not be denied (Medicare non-payment reason code is not blank).
 - The revenue center in which the HCPCS code is found must not be denied (“revenue center total charge amount” minus “revenue center non-covered charge amount” > 0).
 - The claim header must contain an included cancer diagnosis code (see “[OCM Cancer Type Mapping and Codes](#)”).
 - The trigger date is the revenue center date.
 - Part D (identification at the claim level):
 - The claim must contain an included chemotherapy drug (initiating cancer therapy) NDC code.
 - The claim “fill date” must be in the appropriate 6 month “Episode Beginning” period in [Table 1](#), inclusive of end dates.

- A non-denied Carrier (line allowed charge >0) or Outpatient (Medicare non-payment reason code is not blank) claim with an included cancer diagnosis code (see “[OCM Cancer Type Mapping and Codes](#)”) in any line item (Carrier) or in the header (Outpatient) can be found on the fill date or in the 59 days preceding the fill date. Use line first expense date on the Carrier claims and from date on the Outpatient claims to determine if the claim occurred on the fill date or in the 59 days prior.
 - The trigger date is the fill date on the PDE claim.
- Step 2: Identify potential episodes
 - For each potential trigger claim identified in Step 1, flag whether the 6 months following the trigger date meet the three criteria below. Episodes will be end-dated 6 calendar months after the trigger date, even in the case of death before 6 months. A trigger claim initiates an episode only when all of the below criteria are met.
 - For all performance periods, the potential episode trigger date must not be included in any episode defined for a prior performance period.⁹ Potential trigger claims occurring inside a previously defined episode cannot trigger a new episode.
 - The 6 month period beginning with the trigger date must contain a non-denied Carrier claim with a qualifying E&M visit (HCPCS code 99201 – 99205, 99211 – 99215), an included cancer diagnosis code (see “[OCM Cancer Type Mapping and Codes](#)”), and be billed by a TIN with at least one oncology provider (see specifications below) on the same line item.
 - The beneficiary must meet the criteria below for the entire 6 month period (or until death) beginning with the trigger date, inclusive of end dates:
 - Beneficiary is enrolled in Medicare Parts A and B;
 - Beneficiary does not receive the Medicare ESRD benefit, as determined by the Medicare Enrollment Database;
 - Beneficiary has Medicare as his or her primary payer;
 - Beneficiary is not covered under Medicare Advantage or any other group health program.
- Step 3: Identify final set of episodes.
 - For each unique beneficiary, identify the first potential episode from Step 2 meeting all three criteria.
 - Apply the following hierarchy if there is more than one trigger claim on the same day from different types of service: Outpatient, Carrier, DMEPOS, Part D
 - If there is still more than one trigger claim on the same day within the same type of service, choose the claim with the first claim ID.

This is the episode for the current performance period, and could be the beneficiary’s first episode in OCM or an episode subsequent to an episode defined for a prior performance period. Identify the beginning and ending dates of the episode.

⁹ The model will only define episodes that began on or after July 1, 2016.

Below are the specifications for determining whether a TIN has at least one oncology provider during the performance period. These specifications require access to all Medicare claims data in a performance period.

- Step 1: Identify all Carrier claim lines that:
 - Have a “line first expense date” occurring between the earliest episode beginning date and the latest episode ending date for the performance period (i.e., between 7/2/2017 and 6/30/2018 for performance period 3);
 - Have a HCPCS code in the range 99201 – 99205 or 99211 – 99215;
 - Have “line allowed charge” > 0;
 - Have a diagnosis code in the list of included cancer diagnoses (see “[OCM Cancer Type Mapping and Codes](#)”);
 - Have a provider specialty code of 83 (Hematology/Oncology), 90 (Medical Oncology), 91 (Surgical Oncology), 92 (Radiation Oncology), 98 (Gynecology Oncology).
- Step 2: Identify the TIN on each of the claim lines identified in Step 1. The unique list of these TINs constitutes the list of TINs with an oncology provider in the performance period.

Appendix B: Specifications for Assignment of Cancer Type

- Step 1: Identify all visits that count toward the assignment of a cancer type. Qualifying visits:
 - Appear in the Carrier claims file (i.e., have been billed on the CMS-1500 or electronic equivalent);
 - Are identified at the line item level (because visits on different days may be billed on a single claim);
 - Have a “line first expense date” occurring between the episode beginning and ending dates, inclusive of begin and end dates;
 - Have a HCPCS code in the range 99201 – 99205 or 99211 – 99215, which indicates an E&M service;
 - Have “line allowed charge” > 0, indicating that the line service was not denied by Medicare;
 - Have a diagnosis code in the list of included cancer diagnoses (see “[OCM Cancer Type Mapping and Codes](#)”) on the same line as the E&M visit.
 - Are billed by a TIN with at least one oncology provider (see specifications in [Appendix A](#)).
- Step 2: Identify unique visits and count the number of visits associated with each cancer type.
 - Map the diagnosis code on the E&M line to a cancer type as defined in the document “[OCM Cancer Type Mapping and Codes](#).”
 - For the purposes of assigning a cancer type to the episode, a visit is defined by the unique combination of beneficiary ID, TIN, line first expense date, and cancer type associated with the diagnosis code on the line.
 - The TIN is the taxpayer identification number on the same line as the qualifying E&M visit.
 - This step should result in a file of visit counts by unique beneficiary-cancer type combinations.
- Step 3: Assign the episode the cancer type that has the most visits.
 - In the event of a tie, apply tie-breakers in the order below. Assign the cancer type associated with:
 - The most recent visit in the episode, second most recent visit, third most recent visit, etc.;
 - The cancer type that is reconciliation-eligible;
 - The lowest last digit of the TIN;
 - The highest claim ID.

Appendix C: Specifications for Episode Attribution

- Step 1: Identify all visits that count toward attribution. Qualifying visits:
 - Appear in the Carrier claims file (i.e., have been billed on the CMS-1500 or electronic equivalent);
 - Are identified at the line item level (because visits on different days may be billed on a single claim);
 - Have a “line first expense date” occurring between the episode beginning and ending dates, inclusive of begin and end dates;
 - Have a HCPCS code in the range 99201 – 99205 or 99211 – 99215, which indicates an E&M service;
 - Have “line allowed charge” > 0, indicating that the line service was not denied by Medicare;
 - Have a diagnosis code in the list of included cancer diagnoses (see [“OCM Cancer Type Mapping and Codes”](#)) on the same line as the E&M visit.
 - Are billed by a TIN with at least one oncology provider (see specifications in [Appendix A](#)).
- Step 2: Count the number of qualifying visits to each TIN.
 - A visit is defined by the unique combination of beneficiary ID, TIN, and line first expense date.
 - Assign the visit to the TIN on the same line as the qualifying E&M visit. A TIN will either be associated with an OCM ID or it will not.
 - Sum the number of visits by beneficiary and TIN (in the case of non-OCM practices) or OCM ID (in the case of OCM practices). In the baseline period, in cases where an OCM ID has more than one TIN (i.e., a current and legacy TIN), sum the visits over all TINs associated with the OCM ID. (In a performance period, an OCM practice is always defined by one OCM ID and one TIN.)
 - This step results in a file of visit counts by unique beneficiary-TIN/OCM ID combinations.
- Step 3: Attribute the episode to the TIN or OCM ID with the most qualifying visits.
 - In the event of a tie, apply tie-breakers in the order below. Attribute the episode to the TIN/OCM ID with:
 - The most recent visit in the episode, second most recent visit, third most recent visit, etc.
 - The lowest last digit of the TIN, second lowest digit, etc.
 - In cases where practices have pooled together for the purposes of reconciliation, continue to attribute episodes to the individual OCM IDs within the pool. Do not combine visits across the OCM IDs in the pool for the purposes of determining plurality.

Appendix D: Baseline Trend Adjustments

The baseline trend adjustments were created to move all episode expenditures to the same level as the expenditures for episodes ending in the most recent 6-month baseline period (1/1/2015 – 6/30/2015). The adjustments reflect the impact of inflation and any changes in episode expenditures due to evolving patterns of care, Medicare payment policies, etc. during the baseline period. The adjustment factor for a given period was calculated by dividing average, un-Winsorized expenditures for episodes ending in the period 1/1/2015 – 6/30/2015 by the average, un-Winsorized expenditures for episodes ending in the period to be adjusted. The adjustment factor was then applied to the expenditures of each episode in the period undergoing adjustment. This brought all baseline episode expenditures forward to the latest 6-month baseline period. The baseline trend adjustments are shown below.

Table D-1: Baseline Trend Adjustments

Episode Ending Dates	Number of Episodes	Average Episode Expenditures ¹	Baseline Trend Adjustment
7/1/2012 - 12/31/2012	466,605	\$25,009.02	1.0813338607
1/1/2013 - 6/30/2013	390,517	\$25,611.27	1.0559060338
7/1/2013 - 12/31/2013	416,439	\$25,973.30	1.0411881779
1/1/2014 - 6/30/2014	391,010	\$26,181.15	1.0329224139
7/1/2014 - 12/31/2014	420,311	\$26,793.53	1.0093144046
1/1/2015 - 6/30/2015	401,605	\$27,043.10	1.0000000000

¹ Standardized, un-Winsorized dollars

Appendix E: Baseline Winsorization Adjustments

Winsorization is a two-sided truncation adjustment that limits the impact of outliers on predicted and actual expenditures, as explained in [Section 2.5](#). Baseline episode expenditures are Winsorized at the 5th and 95th percentiles by cancer type. Specifically, episode expenditures below the 5th percentile by cancer type were set to the 5th percentile, and episode expenditures above the 95th percentile were set to the 95th percentile within cancer type. The Winsorization adjustments occur after baseline trending.

Winsorization thresholds for the 5th and 95th percentiles are listed in Table E-1 by cancer type.

Table E-1: Winsorization Thresholds

Cancer type	5 th Percentile of Episode Expenditures ¹	95 th Percentile of Episode Expenditures ¹
Acute Leukemia	\$8,254.37	\$151,268.63
Anal Cancer	\$8,069.98	\$81,512.63
Bladder Cancer	\$2,066.46	\$61,703.01
Breast Cancer	\$461.09	\$53,642.05
CNS Tumor	\$9,185.23	\$97,356.83
Chronic Leukemia	\$4,317.93	\$90,063.21
Endocrine Tumor	\$7,838.61	\$72,814.59
Female GU Cancer other than Ovary	\$2,324.35	\$65,449.71
Gastro/Esophageal Cancer	\$8,135.86	\$91,478.86
Head and Neck Cancer	\$7,179.33	\$92,646.06
Kidney Cancer	\$4,980.39	\$83,580.51
Liver Cancer	\$7,398.50	\$80,274.83
Lung Cancer	\$7,626.05	\$85,206.23
Lymphoma	\$7,936.91	\$97,294.36
MDS	\$11,056.27	\$108,103.78
MEOS, no PBP ²	\$837.68	\$75,525.40
Malignant Melanoma	\$3,759.67	\$171,644.46
Multiple Myeloma	\$11,202.91	\$98,156.68
Ovarian Cancer	\$3,932.29	\$72,450.97
Pancreatic Cancer	\$7,027.21	\$76,767.31
Prostate Cancer	\$1,406.69	\$60,034.30
Small Intestine / Colorectal Cancer	\$6,332.27	\$85,498.09

¹ Standardized, trended dollars

² The “MEOS, no PBP” cancer type is not used in reconciliation.

Appendix F: Specifications for the Novel Therapies Adjustment

The adjustment for the use of novel therapies will be calculated based on the proportion of each practice's or pool's average episode expenditures for specified new oncology drugs compared to the same proportion for episodes that are not part of OCM. The method is described below.

- Step 1: Calculate Proportion of Episode Expenditures for Specified Novel Therapies at the Practice or Pool
 - A = the actual episode expenditures for all services for all episodes attributed to the practice or pool during the same performance period.
 - B = the actual episode expenditures associated with the new oncology therapies for all episodes attributed to a practice or pool where the cancer type assigned to the episode is the same as the cancer type for which the FDA has approved the new therapy.
 - C = the expenditures associated with the new oncology chemotherapy drugs as a proportion of actual episode expenditures. C equals B divided by A.
- Step 2: Calculate Proportion of Episode Expenditures for Specified Novel Therapies at All Non-Participating Practices
 - Perform the same calculations in Step 1 for the non-participating practices for the same time period. This is the amount that should already be incorporated into the overall trend factor for the specific therapies.
- Step 3: Compare Relative Proportions and Calculate Difference
 - Compare the proportions in Steps 1 and 2. If the proportion calculated for the non-participating practices is greater than that for the practice or pool, no adjustment will be made to the baseline prices. If the reverse is true, then the practice or pool had a higher proportion of expenditures for the new therapies than was the case at the non-participating practices and will qualify for an adjustment based on 80 percent of the difference in relative expenditures.
- Step 4: Calculate Adjustment and Apply to Baseline Prices
 - If the proportion of episode expenditures for novel therapies at the practice or pool exceeds the proportion for the non-participating practices then the adjustment can be calculated as shown in the example in [Table F-1](#) below. In this example, the practice's actual episode expenditures are \$2.3 million and the practice's expenditures associated with novel therapies are \$149,500. The corresponding proportion of expenditures associated with novel therapies for this practice is 6.5 percent ($\$149,500 / \2.3 million). The analogous proportion for all practices not participating in OCM is 4 percent. We first determine the practice's additional expenditures on novel therapies in the performance period beyond what is reflected in the national non-OCM experience; this is equal to the practice's actual episode expenditures (\$2.3 million) multiplied by the difference between the practice's novel therapy proportion and the national non-OCM novel therapy proportion, which is 2.5 percent (6.5 percent - 4 percent). These additional expenditures are \$57,500 ($\$2.3 \text{ million} * 0.025$). Next, we multiply the additional expenditures by a policy factor of 80 percent ($\$57,500 * 0.8 = \$46,000$), and divide the reduced additional expenditures by

the sum of the practice’s trended baseline prices (\$2.5 million in the example) to calculate the novel therapy adjustment. In this example, the adjustment is 1.84 percent (\$46,000 / \$2.5 million). We will increase each trended baseline price by this percentage to determine the benchmark price. Every episode attributed to a practice will receive the same novel therapies adjustment.

Table F-1: Example: Application of Adjustment for Use of Novel Therapies

Row	Item	Amount
A	Practice’s Actual Episode Expenditures	\$2,300,000
B	Practice’s Expenditures for Novel Therapies	\$149,500
C	Practice’s Proportion of Actual Episode Expenditures Due to Novel Therapies (B/A)	6.50%
D	National Proportion of Actual Episode Expenditures Due to Novel Therapies	4.00%
E	Practice’s Additional Proportion of Novel Therapy Use Beyond National non-OCM Trend (C - D)	2.5%
F	Practice’s Additional Expenditures for Novel Therapy Use Beyond National non-OCM Trend (E * A)	\$57,500
G	Practice’s Additional Expenditures for Novel Therapy Use Beyond National non-OCM Trend, Reduced by Policy Factor (F * 0.8)	\$46,000
H	Sum of Practice’s Trended Baseline Prices	\$2,500,000
I	Adjustment for Novel Therapies (G/H)	1.84%
J	Practice’s Benchmark Amount (H + H*I)	\$2,546,000

Appendix G: Mathematical Description of the Methodology for Establishing Target Amounts

The target amount for a given practice is the sum of the target prices of all episodes attributed to the practice in the performance period. The target price for a given episode i in the performance period can be represented by:

$$TP_i = BP_i * TF * ND * (1 - Discount), \text{ where}$$

TP_i = Target price for a given episode

BP_i = Baseline price for episode i in the performance period

TF = trend factor for the practice

ND = Novel therapies adjustment for the practice (see [Appendix F](#))

Discount = OCM discount (0.04 for one-sided risk, 0.0275 for original two-sided risk, 0.025 for alternative two-sided risk)

The quantity $BP_i * TF * ND$ is referred to as the benchmark price for episode i .

The baseline price for episode i treated by a given practice in the performance period can be expressed as:

$$BP_i = \exp(X_i \beta) * EA, \text{ where}$$

BP_i = Baseline price of the i^{th} episode

X_i = Characteristics of the i^{th} episode (e.g., age, sex, cancer type, etc.)

β = Vector of coefficients from the expenditure prediction model based on all episodes treated by all practices (participating and non-participating) in the baseline period

EA = experience adjuster for the practice based on relative costliness in the baseline period

The trend factor for a given practice can be expressed by:

$$TF = \frac{\sum_j \exp(X_j \gamma)}{\sum_j \exp(X_j \delta)}, \text{ where}$$

TF = Trend factor for the practice

X_j = Characteristics of the j^{th} episode in the performance period

γ = Vector of coefficients from the expenditure prediction model based on performance period episodes attributed to non-participating practices

δ = Vector of coefficients from the expenditure prediction model based on baseline episodes attributed to non-participating practices.

The experience adjuster for a given practice can be expressed as:

$$EA = 0.5 + 0.5 * \frac{\sum_k C_k}{\sum_k \exp(X_k \beta)}, \text{ where}$$

EA = Experience adjuster for the practice

C_k = Actual expenditures for the k^{th} episode attributed to the practice in the baseline period

X_k = Characteristics of the k^{th} episode in the performance period

β = Vector of coefficients from the expenditure prediction model based on all episodes treated by all practices (participating and non-participating) in the baseline period

Appendix H: Patient Experience of Care Measure Composites and Scoring

In Table H-1, there are four different response schemes for individual survey items. The points associated with each response are shown below.

1. **Never; Sometimes; Usually; Always**
 Never = 0 points
 Sometimes = 3 1/3 points
 Usually = 6 2/3 points
 Always = 10 points
2. **Never; Sometimes; Usually; Always – INVERSE SCORE**
 Never = 10 points
 Sometimes = 6 2/3 points
 Usually = 3 1/3 points
 Always = 0 points
3. **No; Yes**
 No = 0 points
 Yes = 10 points
4. **No; Yes, somewhat; Yes, definitely**
 No = 0 points
 Yes, somewhat = 5 points
 Yes, definitely = 10 points

Table H-1: Patient Experience of Care Measure Composites and Survey Items

Item/Composite	Responses
Overall Rating	
Using any number from 0 to 10, where 0 is the worst Cancer Therapy Team possible and 10 is the best Cancer Therapy Team possible, what number would you use to rate your Cancer Therapy Team over the last 6 months?	0, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10
Affective Communication Composite	
In the last 6 months, how often did your Cancer Therapy Team show respect for what you had to say?	Never; Sometimes; Usually; Always
In the last 6 months, how often did your Cancer Therapy Team listen carefully to you?	Never; Sometimes; Usually; Always
In the last 6 months, how often was your Cancer Therapy Team direct and straightforward when talking with you about your cancer and chemotherapy or hormonal therapy?	Never; Sometimes; Usually; Always
In the last 6 months, how often did your Cancer Therapy Team spend enough time with you?	Never; Sometimes; Usually; Always
Enabling Self-Management Composite	

Item/Composite	Responses
In the last 6 months, did you and your Cancer Therapy Team talk about pain related to your cancer, or related to your chemotherapy or hormonal therapy?	No; Yes
In the last 6 months, did your Cancer Therapy Team advise you about or help you deal with this pain (if pain was identified as a problem)?	No; Yes, somewhat; Yes, definitely
In the last 6 months, did you and your Cancer Therapy Team talk about any changes in your energy levels related to your cancer or your chemotherapy or hormonal therapy?	No; Yes
In the last 6 months, did your Cancer Therapy Team advise you about or help you deal with changes in your energy levels? (if energy levels were identified as a problem)	No; Yes, somewhat; Yes, definitely
In the last 6 months, did you and your Cancer Therapy Team talk about any emotional problems, such as anxiety or depression, related to your cancer or your chemotherapy or hormonal therapy?	No; Yes
In the last 6 months, did your Cancer Therapy Team advise you about or help you deal with these emotional problems (if emotional problems were identified)?	No; Yes, somewhat; Yes, definitely
In the last 6 months, did you and your Cancer Therapy Team talk about additional services to manage your cancer care at home, such as home health care, special medical equipment, or special supplies?	No; Yes
In the last 6 months, did you and your Cancer Therapy Team talk about things you can do to maintain your health during cancer treatment, such as what to eat and what exercises to do?	No; Yes, somewhat; Yes, definitely
Exchanging Information Composite	
Since it was decided that you would have chemotherapy or hormonal therapy to treat your cancer, did your Cancer Therapy Team clearly explain how this treatment could affect your normal daily activities?	No; Yes, somewhat; Yes, definitely
In the last 6 months, did your Cancer Therapy Team tell you what the next steps in your chemotherapy or hormonal therapy would be?	No; Yes, somewhat; Yes, definitely
In the last 6 months, how often did your Cancer Therapy Team explain test results in a way that was easy to understand?	Never; Sometimes; Usually; Always
In the last 6 months, did your Cancer Therapy Team explain what that medicine was for in a way that was easy to understand (if medicine was prescribed that you had not taken before)?	No; Yes, somewhat; Yes, definitely
Access Composite	
After it was decided that you would have chemotherapy or hormonal therapy, did your Cancer Therapy Team encourage you to contact them with questions between visits?	No; Yes, somewhat; Yes, definitely

Item/Composite	Responses
Did your Cancer Therapy Team tell you to call them immediately if you have certain symptoms or side effects?	No; Yes, somewhat; Yes, definitely
Did your Cancer Therapy Team give you clear instructions about how to contact them outside of regular office hours?	No; Yes, somewhat; Yes, definitely
How often were these office visits scheduled at times that were convenient for you (if visits occurred in the last 6 months)?	Never; Sometimes; Usually; Always
How often were the blood tests, x-rays, scans, or other procedures scheduled to be done as soon as you or your doctor thought you needed (if blood tests, x-rays, scans, or other procedures were done)?	Never; Sometimes; Usually; Always
In the last 6 months, how often did you have to wait longer for your test results than you expected?	Never; Sometimes; Usually; Always (inversely scored)

Appendix I: OCM Prediction Model

This appendix describes the definition and form of the covariates that are incorporated into the OCM prediction model. The covariates are listed below and are described in more detail in the subsequent sections. Some covariates may be refined over the course of OCM to improve the accuracy of the prediction model.

OCM Prediction Model Covariates:

1. Age/Sex
2. Cancer type
3. Chemotherapy drugs taken/administered during the episode (breast, bladder and prostate cancers only)
4. Receipt of cancer-related surgery
5. Part D eligibility and dual eligibility for Medicare and Medicaid
6. Receipt of radiation therapy
7. Receipt of bone marrow transplant
8. Clinical trial participation
9. Comorbidities
10. History of prior chemotherapy use
11. Institutional status
12. Episode length
13. Geographic location/Hospital Referral Region

These covariates are summarized with brief descriptions in [Table I-1](#) at the end of this appendix. Covariates that serve as reference groups in the prediction model are noted.

Age and Sex

Age is calculated as of the first day of the episode. Ten age/sex categories are included in the model:

FEMALE_AGE_18_64	MALE_AGE_18_64
FEMALE_AGE_65_69 (reference group)	MALE_AGE_65_69
FEMALE_AGE_70_74	MALE_AGE_70_74
FEMALE_AGE_75_79	MALE_AGE_75_79
FEMALE_AGE_80+	MALE_AGE_80+

Cancer Type

There are 21 cancer types eligible for reconciliation, defined by specific diagnosis codes. The reconciliation-eligible cancer types are:

Acute Leukemia	Kidney Cancer
Anal Cancer	Liver Cancer
Bladder Cancer	Lung Cancer
Breast Cancer	Lymphoma
Chronic Leukemia	Malignant Melanoma

Central Nervous System (CNS) Tumor	Multiple Myeloma
Endocrine Tumor	Myelodysplastic Syndrome (MDS)
Female Genitourinary (GU) Cancer other than Ovarian	Ovarian Cancer
Gastro/Esophageal Cancer	Pancreatic Cancer
Head and Neck Cancer	Prostate Cancer
Small Intestine / Colorectal Cancer	

Specific variable names are provided in the section below on “Receipt of Cancer-Related Surgery.” Information on the specific diagnosis codes that correspond to each of the reconciliation-eligible cancer types and how a cancer type is assigned to an episode is included in the document “[OCM Cancer Type Mapping and Codes.](#)”

Chemotherapy Drugs Taken/Administered During the Episode (Breast, Prostate, and Bladder Cancers Only)

Additional considerations apply to breast cancer, bladder cancer, and prostate cancer episodes. Many breast cancer episodes represent women who are on long-term oral endocrine therapy such as tamoxifen or an aromatase inhibitor. Breast cancer episodes involving only long-term oral endocrine therapy tend to be much less costly than breast cancer episodes that include other therapies. Therefore, the OCM prediction model designates breast cancer episodes containing only long-term oral endocrine chemotherapy (receipt of anastrozole, exemestane, letrozole, and/or tamoxifen without any other chemotherapy) as low-risk and all other breast cancer episodes as high-risk.

Treatment of bladder and prostate cancer, as with other cancers, may have widely varying costs based on differences in treatment for different types of disease. CMS has noted that some oncology specialists may care for a greater proportion of low-risk bladder and low-intensity prostate cancer patients, while other oncology specialists may care for a greater proportion of high-risk bladder and high-intensity prostate cancer patients. CMS has observed significant differences in episode costs between these different types of cancer. Therefore, the OCM prediction model distinguishes between high- and low-risk bladder cancers and low-intensity and high-intensity prostate cancers.

For the purposes of establishing a target price, low-risk bladder cancer will be designated by the receipt of BCG (Bacillus Calmette-Guerin) and/or mitomycin **without any other chemotherapy**. High-risk disease will be designated by the receipt of chemotherapy other than these two designated drugs.

Similarly, for the purposes of establishing a target price, low-intensity prostate cancer will be designated by the receipt of either androgen deprivation and/or anti-androgen therapy **without any other chemotherapy**. High-intensity disease will be designated by the receipt of chemotherapy other than, or in addition to, androgen deprivation or anti-androgen therapy. The list of androgen deprivation and anti-androgen therapy drugs is contained in the document “[OCM Prediction Model Code Lists,](#)” effective July 2, 2017.

Specific variable names for these covariates are provided in the section below on “Receipt of Cancer-Related Surgery.” The specifications for identifying breast cancer episodes that contain only long-term oral endocrine chemotherapy in the Medicare claims data are as follows:

- **Step 1: For all breast cancer episodes, identify all chemotherapy claims that occurred during the episode.** Chemotherapy for these purposes are:
 - Carrier and DME lines where all criteria in Step 1 of [Appendix A](#) are met, with the exception that the line first expense date is during the episode (inclusive of start and end dates);
 - Outpatient revenue centers where all criteria in Step 1 of [Appendix A](#) are met, with the exception that the revenue center date is during the episode (inclusive of start and end dates); and
 - PDE claims where the fill date is during the episode (inclusive of start and end dates) and the claim contains an included chemotherapy drug (initiating cancer therapy) NDC.
- **Step 2: Flag each chemotherapy claim found in Step 1 as long-term oral endocrine therapy or not.** Long-term oral endocrine therapy claims are those found in the PDE claims file with NDCs for anastrozole, exemestane, letrozole, and/or tamoxifen. All other claims are not long-term oral endocrine therapy.
- **Step 3: Set the breast cancer “low risk” and “high risk” variables.**
 - If the episode had any claims flagged as long-term endocrine therapy and NO claims flagged otherwise, the corresponding “low risk” breast cancer variable (with or without surgery, as appropriate) is set to one and the corresponding “high risk” breast cancer variable is set to zero.
 - Otherwise, the corresponding “high risk” breast cancer variable (with or without surgery, as appropriate) is set to one and the corresponding “low risk” breast cancer variable is set to zero.

The specifications for identifying high- and low-risk bladder cancer episodes in the Medicare claims data are as follows:

- **Step 1: For all bladder cancer episodes, identify all chemotherapy claims that occurred during the episode.** Chemotherapy for these purposes are:
 - Carrier and DME lines where all criteria in Step 1 of [Appendix A](#) are met, with the exception that the line first expense date is during the episode (inclusive of start and end dates);
 - Outpatient revenue centers where all criteria in Step 1 of [Appendix A](#) are met, with the exception that the revenue center date is during the episode (inclusive of start and end dates); and
 - PDE claims where the fill date is during the episode (inclusive of start and end dates) and the claim contains an included chemotherapy drug (initiating cancer therapy) NDC.
- **Step 2: Flag each chemotherapy claim found in Step 1 as BCG (Bacillus Calmette-Guerin) and/or mitomycin or not.**

- **Step 3: Set the bladder cancer “low risk” and “high risk” variables.**
 - If the episode had any chemotherapy claims flagged as BCG (bacillus calmette-guerin) live vax, intravesical), BCG LIVE VAX, intravesical, BCG (intravesical) per instillation, and/or mitomycin and NO claims flagged otherwise, the corresponding “low risk” bladder cancer variable (with or without surgery, as appropriate) is set to one and the corresponding “high risk” bladder cancer variable is set to zero.
 - Otherwise, the corresponding “high risk” bladder cancer variable (with or without surgery, as appropriate) is set to one and the corresponding “low risk” bladder cancer variable is set to zero.

The specifications for identifying low-intensity and high-intensity prostate cancer episodes in the Medicare claims data are as follows:

- **Step 1: For all prostate cancer episodes, identify all chemotherapy claims that occurred during the episode.** Chemotherapy for these purposes are:
 - Carrier and DME lines where all criteria in Step 1 of [Appendix A](#) are met, with the exception that the line first expense date is during the episode (inclusive of start and end dates);
 - Outpatient revenue centers where all criteria in Step 1 of [Appendix A](#) are met, with the exception that the revenue center date is during the episode (inclusive of start and end dates); and
 - PDE claims where the fill date is during the episode (inclusive of start and end dates) and the claim contains an included chemotherapy drug (initiating cancer therapy) NDC.
- **Step 2: Flag each chemotherapy claim found in Step 1 as androgen deprivation and/or anti-androgen therapy or not.** The list of androgen deprivation and anti-androgen therapy drugs is as follows (codes are contained in the document “[OCM Prediction Model Code Lists](#),” effective July 2, 2017): bicalutamide, degarelix, flutamide, goserelin, histrelin, leuprolide, nilutamide, triptorelin
- **Step 3: Set the prostate cancer “low-intensity” and “high-intensity” variables.**
 - If the episode had any chemotherapy claims flagged as androgen deprivation or anti-androgen therapy and NO claims flagged otherwise, the corresponding “low-intensity” prostate cancer variable (with or without surgery, as appropriate) is set to one and the corresponding “high-intensity” prostate cancer variable is set to zero.
 - Otherwise, the corresponding “high-intensity” prostate cancer variable (with or without surgery, as appropriate) is set to one and the corresponding “low-intensity” prostate cancer variable is set to zero.

Receipt of Cancer-Related Surgery

Thirteen of the cancer types have cancer-related surgeries that are controlled for in the OCM prediction model if the surgeries occur during an episode. The specific surgeries are listed in the document “[OCM Prediction Model Code Lists](#),” effective July 2, 2017, and are different for each cancer type. Each of the thirteen cancer types with cancer-related surgeries is represented by two variables in the model: one for episodes in which a cancer-related surgery was performed and one for episodes in which no cancer-related surgery was performed. Each cancer type that does not have a specific surgery adjustment is represented by a single variable in the model.

For breast and bladder cancers, we define four variables based on the presence of a surgery flag and risk level (low vs. high risk). The four variables denote: low-risk episodes with surgery; low-risk episodes without surgery; high-risk episodes with surgery; high-risk episodes without surgery. Similarly, for prostate cancer, we define four variables denoting: low-intensity episodes with surgery; low-intensity episodes without surgery; high-intensity episodes with surgery; high-intensity episodes without surgery.

The variables representing cancer types, surgery status, risk level, and intensity are summarized below:

Breast cancer

- BREAST_WITH_SURGERY_LOW_RISK
- BREAST_WITHOUT_SURGERY_LOW_RISK (reference group)
- BREAST_WITH_SURGERY_HI_RISK
- BREAST_WITHOUT_SURGERY_HI_RISK

Bladder Cancer

- BLADDER_WITH_SURGERY_LOW_RISK
- BLADDER_WITHOUT_SURGERY_LOW_RISK
- BLADDER_WITH_SURGERY_HI_RISK
- BLADDER_WITHOUT_SURGERY_HI_RISK

Prostate Cancer

- PROSTATE_WITH_SURGERY_LOW
- PROSTATE_WITHOUT_SURGERY_LOW
- PROSTATE_WITH_SURGERY_HIGH
- PROSTATE_WITHOUT_SURGERY_HIGH

Other cancer types with cancer-related surgeries

ANAL_WITH_SURGERY	ANAL_WITHOUT_SURGERY
FEMALE_GU_WITH_SURGERY	FEMALE_GU_WITHOUT_SURGERY
GASTRO_WITH_SURGERY	GASTRO_WITHOUT_SURGERY
HEAD_NECK_WITH_SURGERY	HEAD_NECK_WITHOUT_SURGERY
INTESTINAL_WITH_SURGERY	INTESTINAL_WITHOUT_SURGERY
LIVER_WITH_SURGERY	LIVER_WITHOUT_SURGERY
LUNG_WITH_SURGERY	LUNG_WITHOUT_SURGERY
OVARY_WITH_SURGERY	OVARY_WITHOUT_SURGERY
PANCREAS_WITH_SURGERY	PANCREAS_WITHOUT_SURGERY
KIDNEY_WITH_SURGERY	KIDNEY_WITHOUT_SURGERY

Cancer Types without cancer-related surgeries

ACUTE_LEUKEMIA	CHRONIC_LEUKEMIA	CNS
ENDOCRINE	LYMPHOMA	MDS
MELANOMA	MYELOMA	

The specifications for identifying cancer-related surgery in the Medicare claims data are as follows:

- **Step 1: Identify cancer-related surgery from the INPATIENT file by identifying inpatient claims for each episode where:**
 - The claim contains an ICD procedure code in the SurgeryCodes tab of the “[OCM Prediction Model Code Lists](#)” document;
 - The claim admission date falls between the first and last dates of the episode, inclusive;
 - The Medicare nonpayment reason code on the claim is blank; and,
 - The claim contains a diagnosis code that maps to the cancer type associated with the procedure code in the SurgeryCodes table OR the cancer type assigned to the episode is the same as the cancer type associated with the procedure code in the SurgeryCodes table.
- **Step 2: Identify cancer-related surgery from the OUTPATIENT file by identifying outpatient claims for each episode where**
 - The claim contains an ICD procedure code OR a HCPCS procedure code in the SurgeryCodes tab of the “[OCM Prediction Model Code Lists](#)” document;
 - If a HCPCS code is found in the revenue centers, the revenue center date falls between the first and last dates of the episode, inclusive, AND the revenue center is not denied (revenue center total charge amount minus revenue center non covered charge amount > \$0);
 - If an ICD procedure code is found in the claim header, the corresponding procedure date falls between the first and last dates of the episode, inclusive;
 - The claim is not denied (Medicare nonpayment reason code is blank); and,

- The claim contains a diagnosis code that maps to the cancer type associated with the procedure code in the SurgeryCodes table OR the cancer type assigned to the episode is the same as the cancer type associated with the procedure code in the SurgeryCodes table.
- **Step 3: Identify cancer-related surgery from the CARRIER file by identifying carrier claims for each episode where:**
 - The claim contains a line item with a HCPCS procedure code in the SurgeryCodes tab of the “[OCM Prediction Model Code Lists](#)” document;
 - The line first expense date falls between the first and last dates of the episode, inclusive;
 - The line item is not denied (line allowed charge >0); and,
 - The claim contains a header diagnosis code that maps to the cancer type associated with the procedure code in the SurgeryCodes table OR the cancer type assigned to the episode is the same as the cancer type associated with the procedure code in the SurgeryCodes table.
- **Step 4: Set the cancer type-specific surgery variables.**
 - If any claim is found meeting the criteria above, the corresponding cancer type variable “with surgery” is set to one and the corresponding cancer type variable “without surgery” is set to zero.
 - Otherwise, the corresponding cancer type variable “without surgery” is set to one and the corresponding cancer type variable “with surgery” is set to zero.

Part D Eligibility and Dual Eligibility for Medicare and Medicaid

Dual eligibility refers to beneficiaries who are enrolled in both Medicare and Medicaid. Full dual eligibility refers to eligibility for full Medicaid benefits; these beneficiaries are normally entitled to Part D enrollment with a low income subsidy (LIS). Beneficiaries with partial Medicaid benefits and other low income beneficiaries without Medicaid may also qualify for Part D and the LIS. The following set of variables defines eligibility for full Medicaid benefits and Part D (measured at the beginning of the episode) in the OCM prediction model:

- FULL_DUAL – Has full Medicaid benefits (including Part D and LIS)
- PART_D_LIS – Does not have full Medicaid benefits but does have Part D with LIS
- PART_D_NO_LIS – Has Part D enrollment but no LIS
- NO_PART_D – Has no Part D enrollment (reference group)

These categories are mutually exclusive and exhaustive.

Receipt of Radiation Therapy

A single variable indicates whether radiation therapy was provided during the episode or not. The ICD and HCPCS procedure codes used to identify radiation therapy are contained in the document “[OCM Prediction Model Code Lists](#),” effective July 2, 2017. The codes are restricted to those indicating the delivery of radiation therapy, and do not include planning or preparation for

radiation therapy. If any claim during an episode had one of the procedure codes listed for radiation delivery, the RADIATION variable was assigned a value of 1 (otherwise 0).

The specifications for identifying radiation therapy in the Medicare claims data are as follows:

- **Step 1: Identify radiation from the INPATIENT file by identifying inpatient claims for each episode where:**
 - The claim contains at least one of the ICD or HCPCS procedure codes in the Radiation tab of the [“OCM Prediction Model Code Lists”](#) document;
 - The claim admission date falls between the first and last dates of the episode, inclusive; and,
 - The claim is not denied (Medicare nonpayment reason code is blank).

- **Step 2: Identify radiation from the OUTPATIENT files by identifying outpatient claims for each episode where:**
 - The claim contains a HCPCS or ICD procedure code in the Radiation tab of the [“OCM Prediction Model Code Lists”](#) document;
 - If a HCPCS code is found in the revenue centers, the revenue center date falls between the first and last dates of the episode, inclusive, and the revenue center is not denied (revenue center total charge amount minus revenue center non covered charge amount > \$0)
 - If an ICD procedure code is found in the claim header, the corresponding procedure date falls between the first and last dates of the episode, inclusive;
 - The claim is not denied (Medicare nonpayment reason code is blank).

- **Step 3: Identify radiation from the PHYSICIAN files by identifying physician claims for each episode where:**
 - The claim contains a line item with a HCPCS code in the Radiation tab of the [“OCM Prediction Model Code Lists”](#) document;
 - The line first expense date falls between the first and last dates of the episode, inclusive; and
 - The line item is not denied (line allowed charge > 0).

- **Step 4: If a claim is found meeting the criteria above, RADIATION = 1, otherwise, RADIATION = 0.**

Receipt of Bone Marrow Transplant

Two bone marrow transplant (BMT) variables are calculated: one for allogeneic BMTs (BMT_ALLOGENEIC) and one for autologous BMTs (BMT_AUTOLOGOUS). BMTs will be counted for five cancer types: Acute Leukemia, Chronic Leukemia, Lymphoma, Multiple Myeloma, and MDS. If both types of BMT appear in a given episode, the allogeneic BMT will take precedence. BMT procedures are identified by the codes included in the document [“OCM Prediction Model Code Lists,”](#) effective July 2, 2017. The claim with the BMT procedure code or DRG must contain a diagnosis code for the same cancer type as the episode.

The specifications for identifying bone marrow transplants in the Medicare claims data are as follows:

- **Step 1: Identify BMTs from the INPATIENT file by identifying inpatient claims for each episode where:**
 - The claim contains a DRG or ICD code listed in the BMT tab of the “[OCM Prediction Model Code Lists](#)” document (the list identifies which codes are autologous and which are allogeneic);
 - The claim admission date falls between the first and last dates of the episode, inclusive;
 - The Medicare nonpayment reason code on the claim is blank; and,
 - The episode’s cancer type is Acute Leukemia, Chronic Leukemia, Lymphoma, Multiple Myeloma, or MDS.

- **Step 2: Identify BMTs from the OUTPATIENT files by identifying outpatient claims for each episode where:**
 - The claim contains a HCPCS or ICD procedure code in the BMT tab of the “[OCM Prediction Model Code Lists](#)” document;
 - If a HCPCS code is found in the revenue centers, the revenue center date falls between the first and last dates of the episode, inclusive, and the revenue center is not denied (revenue center total charge amount minus revenue center non covered charge amount > \$0);
 - If an ICD procedure code is found in the claim header, the corresponding procedure date falls between the first and last dates of the episode, inclusive; and,
 - The claim is not denied (Medicare nonpayment reason code is blank);
 - The episode’s cancer type is Acute Leukemia, Chronic Leukemia, Lymphoma, Multiple Myeloma, or MDS.

- **Step 3: Flag the appropriate BMT variable.**
 - If a claim meeting the criteria above for an allogeneic BMT is found, BMT_ALLOGENEIC = 1, otherwise BMT_ALLOGENEIC = 0.
 - If a claim meeting the criteria above for an autologous BMT is found AND no claims meeting the criteria for an allogeneic BMT was found, BMT_AUTOLOGOUS = 1, otherwise BMT_AUTOLOGOUS = 0.

Clinical Trial Participation

A single variable (CLINICAL_TRIAL) indicates whether the beneficiary participated in a clinical trial during the episode. An ICD 9 diagnosis code of V70.7 or an ICD10 diagnosis code of Z00.6 must appear on a claim that also contains a cancer diagnosis and has a service date within the 6-month episode.

The specifications for identifying clinical trial participation in the Medicare claims data are as follows:

- **Step 1: Identify clinical trials from the INPATIENT file by identifying inpatient claims for each episode where:**

- The claim contains an ICD 9 diagnosis code of V70.7 or an ICD 10 diagnosis code of Z00.6;
 - The claim admission date falls between the first and last dates of the episode, inclusive;
 - The claim is not denied (Medicare nonpayment reason code is blank); and,
 - The claim contains a qualifying cancer diagnosis.
- **Step 2: Identify clinical trials from the OUTPATIENT file by identifying outpatient claims for each episode where:**
 - The claim contains an ICD 9 diagnosis code of V70.7 or an ICD 10 diagnosis code of Z00.6;
 - The claim from date or claim through date¹⁰ falls between the first and last dates of the episode, inclusive;
 - The claim is not denied (Medicare nonpayment reason code is blank); and,
 - The claim contains a qualifying cancer diagnosis.
- **Step 3: Identify clinical trials from the PHYSICIAN and DME files by identifying physician and DME claims for each episode where:**
 - The claim contains an ICD 9 diagnosis code of V70.7 or an ICD 10 diagnosis code of Z00.6 in the line item diagnoses or in the header diagnoses;
 - If the diagnosis code is found in a line item, the line first expense date falls between the first and last dates of the episode and the line item is not denied (line allowed charge >0);
 - If the diagnosis code is not found in a line item but appears in the claim header, the claim from date or claim thru date falls between the first and last dates of the episode, inclusive;
 - The claim is not denied (carrier claim payment denial code is one of: 1-9, A, B); and,
 - Claim contains a qualifying cancer diagnosis in the line or header diagnoses.
- **Step 4: If any claim is found meeting the criteria above, CLINICAL_TRIAL = 1, otherwise CLINICAL_TRIAL = 0.**

Comorbidities

Comorbidities are measured through a subset of the CMS Hierarchical Condition Category (HCC) flags. These flags are created by CMS on a calendar year basis and indicate treatment for 70 different conditions in the prior calendar year. The number of HCC flags that are “turned on” in the calendar year in which the episode started is incorporated in the model because episode expenditures increase with higher numbers of pre-existing comorbidities. Condition flags related to cancer are not counted in the OCM prediction model because all beneficiaries in OCM episodes have cancer. Also, flags associated with opportunistic infections, protein-calorie malnutrition, severe hematological disorders, disorders of immunity, and coagulation defects and other specified hematological disorders are not counted because these conditions are often

¹⁰ This can't be the revenue center date (as with procedures) because there is no revenue center diagnosis code. This may result in the same claiming turning on the clinical trial participation flag for two separate episodes.

preventable or are a recognized aspect of the specified cancer, and are therefore already incorporated into baseline episode expenditures. The HCC-related variables are as follows:

- HCC_0 – No HCC flags turned on (reference group)
- HCC_1 – One HCC flag turned on
- HCC_2 – Two HCC flags turned on
- HCC_3 – Three HCC flags turned on
- HCC4_5 – Four or five HCC flags turned on
- HCC6_OR_MORE – Six or more HCC flags turned on
- NEW_ENROLLEE – No HCC flags because the enrollee was new to Medicare

The HCC categories used in the OCM model are listed in the document “[OCM Prediction Model Code Lists](#),” effective July 2, 2017. Note that some of the categories are hierarchical, consistent with the hierarchies established for Medicare Advantage payment policy. If flags for a more severe and a less severe version of a specific condition are present then only the flag associated with the more severe version of the condition is counted.

History of Prior Chemotherapy Use

Episodes where the beneficiary has a history of chemotherapy use often tend to be less expensive than those without such a history. The episode start date minus the date of the most recent chemotherapy claim before the episode start date is referred to as the “clean period.” There are three variables related to length of the clean period:

- CLEAN_1_61 – Clean period between 1 and 61 days
- CLEAN_62_730 – Clean period between 62 and 730 days
- CLEAN_731+ – Clean period over 730 days or no prior chemo claims (reference group)

Beneficiaries with recent Medicare enrollment have little or no Medicare claims history and will be categorized in the CLEAN_731+ group if they have no observable prior chemotherapy use. These beneficiaries will be distinguished in the model by the NEW_ENROLLEE variable described in the “Comorbidities” section above.

The specifications for identifying prior chemotherapy use in the Medicare claims data are as follows:

- **Step 1: Identify all possible qualifying chemotherapy claims in the two-year period prior to the episode start date.**
 - Qualifying chemotherapy claims meet the same criteria in Step 1 of [Appendix A](#).
- **Step 2: Calculate the clean period as the difference between the chemotherapy claim date and the episode beginning date.**
 - For Physician and DME claims the chemotherapy claim date is the line first expense date.
 - For Outpatient claims the chemotherapy claim date is the revenue center date.
 - For PDE claims the chemotherapy claim date is the fill date.
- **Step 3: Set the clean period flag according to the clean period calculated in Step 2.**
 - Clean_1_61 = 1 if $0 < \text{clean period} < 62$; 0 otherwise
 - Clean_62_730 = 1 if $61 < \text{clean period} < 731$; 0 otherwise

- Clean_731+ = 1 if clean period > 730 OR there were no chemotherapy claims before the episode began; 0 otherwise.

Institutional Status

The variable INSTITUTIONAL_STATUS measures whether the beneficiary had been institutionalized in a long term care facility for more than 90 days as of the month in which the episode started. This variable is obtained from CMS' HCC files, which contain monthly indicators for residence in a long term care facility. CMS derives these monthly indicators from the Minimum Data Set (MDS), which contains assessment information collected from skilled nursing facilities.

Episode Length

Episodes have a fixed length of 6 calendar months, which results in a variable number of days (181 – 184 days) depending on which calendar months are included in the episode. The variable EP_183_184 represents episodes with a length of 183 or 184 days compared to those with a length of 181 or 182 days.

Geographic Location/Hospital Referral Region

A geographic adjustment will be made to distinguish episodes occurring in high- and low-cost areas. The geographic unit will be hospital referral region (HRR). There are 307 such areas defined by the Dartmouth Institute for Health Policy and Clinical Practice to reflect regional healthcare markets for tertiary hospital care.¹¹ Beneficiary zip codes were mapped to the HRRs for purposes of assigning a specific HRR to each episode. The average baseline episode cost in each HRR was divided by the average baseline cost of all episodes to obtain a relative episode cost for each HRR. The geographic adjustment was then operationalized as:

$$\text{HRR_RELATIVE_COST} = [(\text{Average episode cost for the HRR}/\text{Average episode cost across all HRRs}) - 1] * 100.$$

By subtracting one from the ratio of average costs the variable is anchored at zero. Episodes in HRRs with higher than average costs will see an increase in predicted costs and episodes in HRRs with lower than average costs will see a decrease in predicted costs. The variable captures the percentage difference in average episode costs between a given HRR and all HRRs. This variable is continuous.

Prediction Model Variable Names

The table below lists all of the variables used in the OCM prediction model and their descriptions. All variables take values of either zero or one except for the HRR_RELATIVE_COST, which is a continuous variable. Model coefficients and other regression output are summarized in the document "[OCM Prediction Model Code Lists](#)," effective July 2, 2017.

Table I-1: OCM Prediction Model Variables

Variable Name	Description (if value=1)
FEMALE_AGE_18_64	Female, age 18 to 64
FEMALE_AGE_65_69	Female, age 65 to 69 (reference group)

¹¹ Dartmouth Institute for Health Policy and Clinical Practice. The Dartmouth Atlas of Health Care. Available at <http://www.dartmouthatlas.org/>.

Variable Name	Description (if value=1)
FEMALE_AGE_70_74	Female, age 70 to 74
FEMALE_AGE_75_79	Female, age 75 to 79
FEMALE_AGE_80+	Female, age 80 or greater
MALE_AGE_18_64	Male, age 18 to 64
MALE_AGE_65_69	Male, age 65 to 69
MALE_AGE_70_74	Male, age 70 to 74
MALE_AGE_75_79	Male, age 75 to 79
MALE_AGE_80+	Male, age 80 or greater
BREAST_WITH_SURGERY_LOW_RISK	Breast cancer, low risk episodes with surgery
BREAST_WITHOUT_SURGERY_LOW_RISK	Breast cancer, low risk episodes without surgery (reference group)
BREAST_WITH_SURGERY_HI_RISK	Breast cancer, high risk episodes with surgery
BREAST_WITHOUT_SURGERY_HI_RISK	Breast cancer, high risk episodes without surgery
BLADDER_WITH_SURGERY_LOW_RISK	Bladder cancer, low risk episodes with surgery
BLADDER_WITHOUT_SURGERY_LOW_RISK	Bladder cancer, low risk episodes without surgery
BLADDER_WITH_SURGERY_HI_RISK	Bladder cancer, high risk episodes with surgery
BLADDER_WITHOUT_SURGERY_HI_RISK	Bladder cancer, high risk episodes without surgery
PROSTATE_WITH_SURGERY_LOW	Prostate cancer, low-intensity with surgery
PROSTATE_WITHOUT_SURGERY_LOW	Prostate cancer, low-intensity without surgery
PROSTATE_WITH_SURGERY_HIGH	Prostate cancer, high-intensity with surgery
PROSTATE_WITHOUT_SURGERY_HIGH	Prostate cancer, high-intensity without surgery
ANAL_WITH_SURGERY	Anal cancer, with surgery
ANAL_WITHOUT_SURGERY	Anal cancer, without surgery
FEMALE_GU_WITH_SURGERY	Female GU cancer other than ovary, with surgery
FEMALE_GU_WITHOUT_SURGERY	Female GU cancer other than ovary, without surgery
GASTRO_WITH_SURGERY	Gastro/Esophageal cancer, with surgery
GASTRO_WITHOUT_SURGERY	Gastro/Esophageal cancer, without surgery
HEAD_NECK_WITH_SURGERY	Head and neck cancer, with surgery
HEAD_NECK_WITHOUT_SURGERY	Head and neck cancer, without surgery
INTESTINAL_WITH_SURGERY	Small Intestine / Colorectal cancer, with surgery
INTESTINAL_WITHOUT_SURGERY	Small Intestine / Colorectal cancer, without surgery
KIDNEY_WITH_SURGERY	Kidney cancer, with surgery
KIDNEY_WITHOUT_SURGERY	Kidney cancer, without surgery
LIVER_WITH_SURGERY	Liver cancer, with surgery
LIVER_WITHOUT_SURGERY	Liver cancer, without surgery
LUNG_WITH_SURGERY	Lung cancer, with surgery
LUNG_WITHOUT_SURGERY	Lung cancer, without surgery
OVARY_WITH_SURGERY	Ovarian cancer, with surgery
OVARY_WITHOUT_SURGERY	Ovarian cancer, without surgery
PANCREAS_WITH_SURGERY	Pancreatic cancer, with surgery
PANCREAS_WITHOUT_SURGERY	Pancreatic cancer, without surgery
ACUTE_LEUKEMIA	Acute leukemia
CHRONIC_LEUKEMIA	Chronic leukemia
CNS	CNS tumor
ENDOCRINE	Endocrine tumor

Variable Name	Description (if value=1)
LYMPHOMA	Lymphoma
MDS	Myelodysplastic Syndrome
MELANOMA	Malignant melanoma
MYELOMA	Multiple myeloma
FULL_DUAL	Enrolled in Part D, full dual, LIS
PART_D_LIS	Enrolled in Part D, partial dual or LIS applicant, LIS
PART_D_NO_LIS	Enrolled in Part D, no LIS
NO_PART_D	Not enrolled in Part D (reference group)
RADIATION	Received radiation therapy during episode
BMT_ALLOGENEIC	Received allogeneic BMT during episode
BMT_AUTOLOGOUS	Received autologous BMT during episode
CLINICAL_TRIAL	Participated in a clinical trial for cancer during episode
HCC_0	No HCC flags turned on (reference group)
HCC_1	One HCC flag turned on
HCC_2	Two HCC flags turned on
HCC_3	Three HCC flags turned on
HCC4_5	Four or five HCC flags turned on
HCC6_OR_MORE	Six or more HCC flags turned on
NEW_ENROLLEE	New Medicare enrollee (no HCC flags turned on)
CLEAN_1_61	Clean period between 1 and 61 days
CLEAN_62_730	Clean period between 62 and 730 days
CLEAN_731+	Clean period over 730 days or no prior chemo claims (reference group)
INSTITUTIONAL_STATUS	Was institutionalized for more than 90 days as of the month the episode began
EP_183_184	Episode length 183 - 184 days
HRR_RELATIVE_COST	Episode expenditures in beneficiary's HRR relative to average episode expenditures in all HRRs

Appendix J: Calculation of Adjustment for Overlapping ACO and OCM Payments

The following steps are taken in the calculation of the ACO overlap adjustment:

Identify patients who have reconciliation-eligible episodes attributed to an OCM practice and who were also aligned with an ACO during the episode.

1. Identify the subset of episodes from Step 1 whose attributed practice's TIN was also an ACO participant for any part of the OCM performance period.
2. Determine the percentage of each episode that overlaps with the ACO performance year by dividing the number of days of overlap by the length of the episode.
3. Calculate the prorated benchmark price for each episode by multiplying the overlap percentage calculated in Step 3 by the episode's benchmark price.
4. Calculate the prorated benchmark amount for each practice or pool by summing the prorated benchmark prices calculated in Step 4.
5. Determine whether the OCM participant's ACO received a shared savings payment in the ACO performance year overlapping with the current OCM performance period AND if the OCM participant has a PBP calculated for the current performance period.
 - If either is not true, there is no ACO overlap adjustment.
 - If both are true, go to Step 7.
6. Calculate the overlapping discount amount by multiplying the prorated benchmark amount by the OCM discount (4% in one-sided risk).
7. Multiply the overlapping discount amount by the ACO's sharing percentage. The result is the Adjustment for Overlapping Payments.

Note that some OCM performance periods overlap with one ACO performance year (i.e., a calendar year) and some OCM performance periods overlap with two ACO performance years. In the case where an OCM performance period overlaps with two ACO performance years, two separate calculations are performed, one for each ACO performance year, and the resulting adjustments are summed before subtracting from the OCM PBP.

See below for an example calculation. This example assumes the OCM practice is in the one-sided risk arrangement, with a 4% OCM discount.

OCM-999

Total Episodes		1,200
Benchmark Amount		\$40,000,000
Target Amount	Benchmark * (1 - 0.04)	\$38,400,000
Actual Expenditures		\$38,000,000
Savings over Benchmark	Benchmark Amount - Actual Expenditures	\$2,000,000
Savings over Target	Target Amount - Actual Expenditures	\$400,000
Percentage Savings over Benchmark	Savings over Benchmark / Benchmark Amount	5%
Percentage Savings over Target	Savings over Target / Target Amount	1%

GoodHealth ACO

Total ACO Beneficiaries		67,250
ACO Benchmark		\$690,000,000
ACO Actual Expenditures		\$683,100,000
ACO Savings	ACO Benchmark - ACO Actual Expenditures	\$6,900,000
ACO Percentage Savings	ACO Savings / ACO Benchmark	1%
ACO Sharing Rate		70%
ACO Shared Savings Payment	ACO Sharing Rate * ACO Savings	\$4,830,000

Prorated OCM Discount Amount is savings that is a subset of the ACO's savings.

Overlap between OCM-999 and GoodHealth ACO

Overlapping Episodes		120
Prorated Benchmark Amount (Steps 1-2)		\$4,000,000
Prorated OCM Discount Amount (Steps 3-5, 7)	4% * Prorated Benchmark Amount	\$160,000
Adjustment for Overlapping ACO Shared Savings Payments* (Step 8)	ACO Sharing Rate * Prorated OCM Discount	\$112,000

*The adjustment for overlapping ACO shared savings payments is subtracted from the OCM practice's PBP.

Because OCM-999 saved over its target, it also saved the prorated OCM discount amount for the overlapping episodes, \$160,000. This is \$160,000 in OCM savings that will not be paid to the OCM practice as part of its OCM PBP, because in OCM CMS keeps the OCM discount amount. With no adjustment, GoodHealth ACO will have received a shared savings payment that includes a portion of the OCM savings (70% of \$160,000, or, \$112,000) that ought to have been retained by CMS.

HEALTH NEWS

✓ Fact Checked

The Value and Cost of Immunotherapy Cancer Treatments

Written by Ann Pietrangelo on October 12, 2016



Your body's first-line defense against foreign invaders is your own immune system.

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Some forms of cancer can trick the immune system into seeing cancer cells as healthy cells. Hiding in plain sight, they are free to grow and reproduce.

That's where immunotherapy comes in.

Immunotherapy is a way to stimulate the immune system to attack cancer cells. It's already being used to treat some forms of cancer, and more in the future.

"Immunotherapy for cancer treatment is exploding," said Dr. David Chan, program director for oncology at Torrance Memorial Medical Center in California. "It's the current big thing in cancer research."

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He also noted it's one of the reasons for rising healthcare costs, particularly in cancer treatment.

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While immunotherapy is nothing short of a miracle for some cancer patients, it doesn't work for everyone.

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The potential of immunotherapy

We're only beginning to scratch the surface of the potential of immunotherapy to treat cancer.

In an interview with Healthline, Chan said most of the recent interest in immunotherapy has to do with a class of drugs known as immune checkpoint inhibitors.

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recognizing cancer cells. Rather than attack, the T cells allow cancerous cells to grow.

Chan said cancer researchers have been trying to harness the immune system for 30 years.

“About a decade ago, they started developing antibodies to treat HER2-positive breast cancer,” he said. “It’s a very aggressive form of breast cancer. It had higher recurrence and fatality rates than other breast cancers. It was very difficult to treat prior to immunotherapy.”

Until a drug called Herceptin came along.

Herceptin binds to HER2 receptors and blocks them from growth signals. At the same time, it stimulates the immune system to destroy cancer cells.

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Chan said Herceptin has dramatically improved the cure rate for HER2-positive breast cancer. Some of his patients have been in remission for 10 years or more.

“When that pathway is interrupted, it unmask the cancer so T cells recognize it and activate. The result is a significant reduction in cancer and prolonged survival,” he said.

He noted there are currently four FDA-approved drugs that work through

this kind of pathway.

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Malignant melanoma, non-small cell lung cancer (NSCLC), kidney, bladder, and head and neck cancers can all be treated with immune checkpoint inhibitors.

According to Chan, one quarter to one third of patients treated with immune checkpoint inhibitors show signs of regression or remission.

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He added that, for the most part, immunotherapy is fairly well-tolerated and can continue indefinitely. Unlike chemotherapy and radiation, immunotherapy leaves healthy cells unscathed.

However, sometimes the immune system overreacts to the therapy. That means treatment must be stopped while side effects are addressed. Chan said during that time, the cancer often remains in check.

A severe immune system overreaction is potentially fatal.

Not all patients respond to immunotherapy.

“It’s not a cure-all. When it works, it works really well. But the majority of patients won’t respond to checkpoint inhibitors,” said Chan. “If we use immunotherapy for a typical approved cancer, one of three patients will benefit.”

Currently, there’s no way to know in advance which category patients will fall into

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“Not every antibody is the same, not every cancer is the same. The difficult part is trying to identify, molecularly, which patients will benefit. Through research, we’ll have to figure it out cancer by cancer and drug by drug,” said Chan.

Combining immunotherapies with other cancer treatments may offer promise, but Chan explained that it’s a complicated issue.

“It’s not going to be a simple thing where there’s a single way to treat cancer. But without question, it will improve cure rates and quality of life,” he said.

Dr. Mark Faries, director of the Donald L. Morton, M.D., Melanoma Research Program, and director of therapeutic immunology at the John Wayne Cancer Institute at Providence Saint John’s Health Center in California, agrees.

He told Healthline it’s still too soon to say how safe and effective combination therapy will be.

“We know that some combinations of immunotherapies are better than one immunotherapy by itself,” he said. “There are clinical trials to evaluate combining these medications with other types of treatments including chemotherapy, targeted therapies, and radiation. We have also had good experiences with patients who have had immunotherapy and surgery. But the complete answer to this question will come through multiple clinical trials over the next several years.”

[Read more: Treating breast cancer without chemotherapy »](#)

The problem of cost

Immunotherapy is expensive.

“We’re talking about treatments that cost over \$100,000 per year,” said Chan. “Combine drugs and it’s over \$200,000 per year.”

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Immunotherapy is often covered by health insurance, but patients still have to deal with rising out-of-pocket costs. Surgery and other cancer treatments add still more to the financial burden.

According to Chan, cost is a big problem.

“We’ve got to try to make these treatments available at a lower cost. The United States pays far higher costs for drugs than other countries. We’re the only ones who don’t take cost into account before approving a drug. We don’t negotiate costs with drug companies. Americans are bearing the price of drug research for the entire world,” he said.

Faries also looks at the potential long-term benefits.

“If the therapy is curative, the total cost of therapy might be less than would be the case for repeated courses of less expensive, but less effective treatments such as chemotherapy,” he explained.

“One of the main potential advantages of immune therapy relative to other cancer medical treatments is the durability of the responses. Some patients who have good responses seem to maintain them for many years, possibly forever. While there can be side effects to the treatments, even severe or life-threatening side effects, quality of life is frequently quite good and side effects are generally able to be controlled,” said Faries.

“A long-term, durable remission might allow patients to return to work and productivity. But given the price of these drugs, cost effectiveness analysis will be an important component of future research,” said Faries.

[Read more: First wave of biosimilar drugs may save billions for patients and insurers »](#)



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EVALUATION OF THE ONCOLOGY CARE MODEL

Performance Period One



Final

December 2018

Contract #HHSM-500-2014-000261 T0003

SUBMITTED BY:

Abt Associates

Andrea Hassol, Project Director
6130 Executive Boulevard
Rockville, MD 20852

PREPARED FOR:

Susannah Cafardi

Center for Medicare & Medicaid Innovation
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

IN PARTNERSHIP WITH

The Lewin Group
Harvard Medical School
GDIT
Geisel School of Medicine at Dartmouth



The statements contained in this report are solely those of the authors and do not necessarily reflect the views or policies of the Centers for Medicare & Medicaid Services. Abt Associates assumes responsibility for the accuracy and completeness of the information contained in this report.

AUTHORS:

Abt Associates: Andrea Hassol, Qian Gu, T.J. Christian, Gabriella Newes-Adeyi, Sean McClellan, Giulia Norton, Patricia Rowan, Brenda Karkos, Rebecca Freeman-Slade,

The Lewin Group: Carol Simon, Shalini Jhatakia, Donna Spencer, Amanda Tripp, Sara Kizer, Richard Svoboda, Inna Cintina, Madison Davidson, Chloe Mitchell

Harvard Medical School: Nancy Keating, Mary Beth Landrum, Lauren Riedel, Michael Liu, Robert Wolf

Geisel School of Medicine at Dartmouth: Gabriel Brooks

General Dynamics Information Technology: Colleen Kummet, Van Doren Hsu

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Abt Associates: Olivia Jung, Seyoun Kim, Samuel Dastrup, Claire Hoffman

The Lewin Group: Desiree Froshaug, David Zhang, Laura Schmiel, Stephen Muldoon, Jonathan van Arneman, Theodore Kirby

Harvard Medical School: Barbara McNeil, Nancy Beaulieu, Michael Chernew, Anupam Jena, Joyce Lii

GDIT: Glenda Martens, Yishu He

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Executive Summary

Introduction

In February 2015, the Centers for Medicare and Medicaid Services (CMS) invited oncology physician group practices to participate in the Oncology Care Model (OCM), an episode-based alternative payment model (APM) for cancer care. OCM tests whether additional funding for enhanced services and financial incentives to improve the quality and appropriateness of care provided to Medicare Fee-For-Service (FFS) beneficiaries, can improve quality and reduce Medicare spending for patients undergoing chemotherapy for cancer. CMS invited other payers to operate similar models for their insured patients served by OCM oncology practices. The Model launched on July 1, 2016 with nearly 200 oncology group practices and 17 payers participating.

The OCM evaluation uses a difference-in-differences (DID) approach, in which a matched comparison group is used to estimate what would have happened in the absence of OCM. The *First Annual Report from the Evaluation of the Oncology Care Model: Baseline Period*¹ explored the construction of an evaluation comparison group, and the trends during a multi-year baseline period for both the OCM and comparison groups.

The current report, *Evaluation of the Oncology Care Model: Performance Period One*, measures program implementation and outcomes for six-month chemotherapy treatment episodes that began between July 1, 2016 and January 1, 2017, and ended by June 30, 2017 (hereafter referred to as Performance Period One or PP1). During PP1, many participating practices were hiring staff, enhancing oncology services, improving electronic health record systems, establishing new care processes and workflows, and learning to analyze the feedback reports and data provided by CMS. The mixed methods evaluation uses claims data to measure episode-level impacts on utilization, cost, and clinical treatment outcomes, survey data to measure patient- and family-reported care experiences, reporting from the participating practices to understand care delivery changes they are implementing, and qualitative data from case studies and interviews to understand how participants are redesigning care delivery and the context surrounding observed impacts. Claims data are from PP1 and data from surveys, practice reporting, case studies, and interviews are from July 1, 2016 – June 30, 2017.

Model Overview

OCM is a five-year model consisting of six-month episodes that began in mid-2016. The goals of OCM include improving care coordination and access to care for Medicare beneficiaries receiving chemotherapy for cancer. OCM leverages a two-pronged approach to incentivize the provision of high-quality care. It includes a \$160 Monthly Enhanced Oncology Services (MEOS) per-beneficiary per-month payment and the potential to earn performance-based payments (PBPs). Enhanced oncology services include the following:

¹ Abt Associates. First Annual Report from the Evaluation of the Oncology Care Model: Baseline Period. Prepared for the Centers for Medicare and Medicaid Services in partnership with the Lewin Group, Harvard Medical School, GDIT, and Dartmouth College. Bethesda, MD: Abt Associates; February 1, 2018. Available from <https://downloads.cms.gov/files/cmmi/ocm-baselinerreport.pdf>.

- 24/7 patient access to an appropriate clinician who has real-time access to the patient’s medical records
- Core functions of patient navigation
- A documented Care Plan for every OCM patient that contains 13 components recommended by the Institute of Medicine (IOM)
- Cancer treatment that is consistent with nationally recognized clinical guidelines

OCM applies to FFS beneficiaries with all types of cancer who are undergoing chemotherapy treatment.² OCM combines attributes of medical homes with financial incentives for providing these services efficiently, and with high quality.³

Summary of Key Findings

Characteristics of Participating Practices and the Episodes of Care They Provided

OCM and comparison practices were well matched in the baseline period. The balance of the two samples and the degree to which these practices are similar to the national sample are discussed in the Baseline Report. This current report focuses on PP1, relative to the baseline period. In general, both the OCM and comparison practices experienced similar changes in practice structure and episode mix during PP1.

Affiliation with hospitals/health systems increased for both OCM and comparison practices,⁴ likely reflecting broader industry consolidation. There was little change for OCM or comparison practices in the demographics of beneficiaries they served or the type and severity of cancer episodes.

Use of immunotherapies and Part D (oral) chemotherapy increased in both OCM and comparison practices, reflecting national trends in the rapid adoption of newly-approved treatments. We found no evidence that OCM restricted use of immunotherapies, despite the high cost of these treatments.

Episode Utilization and Cost

Among the anticipated effects of the OCM Model and the increased use of enhanced services are better coordination of care and access to the oncology care team, and thus reduction of unnecessary utilization and lower costs. We compared changes between the baseline and PP1 in the OCM group with changes in the comparison group. During PP1, while magnitudes were small and only use of intensive care units and emergency department (ED) visits reached the level of statistical significance, all five hospital utilization measures (any inpatient hospitalizations, number of inpatient hospitalizations, number of ICU admissions, number of inpatient days per episode, or 30-day readmissions per episode) declined more for OCM episodes than for comparisons, as did visits to EDs. This consistent pattern may be an early signal of OCM impact in reducing use of hospital-based services. Total episode cost of care (TCOC) without MEOS declined in both groups, but slightly more (although not statistically significant) for OCM episodes than for comparisons (\$173 greater decline for OCM episodes than comparisons), which is consistent with the small reduction in service utilization observed. This change in TCOC represents a 0.6 percent reduction since the baseline.

² Chemotherapy is defined for OCM purposes as cytotoxic chemotherapy, immunotherapy, or hormonal therapy for cancer.

³ More information about OCM can be found at: <https://innovation.cms.gov/initiatives/oncology-care/>

In the first performance period (PP), OCM did not yet have a detectable impact on any distinct component of cost, with the exception of Part D chemotherapy costs, which increased more for OCM episodes than for comparisons (\$294 or 6.3 percent) reflecting an increase in use of oral chemotherapy, as noted above.

Enhanced Oncology Services

After a three-month start-up period, OCM practices were required to offer four enhanced oncology services: 24/7 patient access to an appropriate clinician with real-time access to the practice's medical records, a Care Plan containing 13 elements recommended by the Institute of Medicine,⁵ core functions of patient navigation, and treatment with therapies consistent with nationally recognized clinical guidelines. Participating practices may bill CMS for monthly MEOS payments in order to support development or expansion of these enhanced services, to meet individual patient needs.

Based on data from progress reports OCM practices submitted to CMS and on 12 case studies we conducted during the first year of OCM, most OCM practices offered 24/7 clinician access and followed evidence-based guidelines before OCM began. During the first year, most hired and/or trained staff to enhance patient navigation services. OCM practices struggled to create all Care Plan elements recommended by the IOM, especially estimating beneficiary out-of-pocket costs.

Quality of Care

The evaluation examined the impact of OCM on the quality of care provided to beneficiaries, to detect improvements as well as any possible reductions in quality arising from inappropriate utilization reductions. We also examined patient-reported care experiences, and use of guideline-recommended supportive care, and changes between baseline and PP1.

The OCM and comparison groups were well matched on most measures of patient-reported care experiences before OCM began, and respondents to the patient survey rated their oncology care teams very highly on most measures of care coordination, communication, access, and symptom management. Survey respondents indicated room to improve on shared decision making.

During 12 case studies, OCM practices told us they were working to improve supportive care (e.g., better nausea and pain management), with the goal of reducing ED visits and subsequent hospitalizations. However there was not yet a measurable impact of OCM on use of antiemetic (anti-nausea) therapy according to guidelines for high, moderate, or low-risk or nausea chemotherapy agents, or on reducing ED visits or hospitalizations for chemotherapy-associated complications.

OCM encourages appropriate end-of-life care and respondents to the baseline survey indicated room to improve in this regard. In PP1, there was a small impact of OCM in reducing hospital-based care near the end of life, including fewer inpatient admissions and ICU stays in the last month of life but no impact on

⁵ CMS requires OCM practices to develop all 13 components of the Care Plan and to document these items in the electronic health record (EHR). CMS encourages clinicians to share a hard copy of the care plan with patients; however, this is not a requirement. The 13 components are: patient information (e.g., name, date of birth, medication list, and allergies), diagnosis, prognosis, treatment goals, initial plan for treatment and proposed duration, expected response to treatment, treatment benefits and harms, information on quality of life and a patient's likely experience with treatment, who will take responsibility for specific aspects of a patient's care, advance care plans, estimated total and out-of-pocket costs of cancer treatment, a plan for addressing a patient's psychosocial health needs, and a survivorship plan.

the rate of hospice use or timing of hospice entry. In the baseline survey, proxy respondents for deceased OCM patients were less likely to report that hospice started “at the right time” than were proxy respondents for deceased comparison patients, and there was no change over time for OCM practices on this measure.

Secondary Impacts: Other Payers’ Experiences

Private payers expressed great interest in using OCM to implement or expand oncology value-based purchasing. The models they implemented aligned broadly with OCM, but differed in many details, mainly due to administrative and technical feasibility issues. In addition, most had established signed agreements with just one or two OCM practices, with small numbers of cancer patients, which made it difficult for the payers to establish stable benchmarks and measure significant change.

1. OCM Background and Evaluation Overview

1.1 OCM Background

Half of newly diagnosed cancer patients are over age 65,⁶ making Medicare the single largest payer of oncology care in the U.S. CMS is operating the Oncology Care Model (OCM) to foster coordinated, high-quality, cost-effective cancer care. OCM applies to Medicare Fee-For-Service (FFS) beneficiaries with cancer who are undergoing chemotherapy treatment.⁷ OCM combines attributes of medical homes^{8,9} (patient-centeredness, accessibility, evidence-based guidelines,¹⁰ and continuous monitoring for improvement opportunities) with financial incentives for providing these services efficiently, and with high quality.

OCM features a two-pronged financial incentive strategy. First, participating practices may bill Medicare a \$160 Monthly Enhanced Oncology Service (MEOS) fee for up to six months per episode for FFS Medicare beneficiaries, which is intended to support enhanced oncology services, including the following:

1. 24/7 patient access to an appropriate clinician who has real-time access to the patient's medical records
2. Core functions of patient navigation
3. A documented Care Plan for every OCM patient that contains 13 components recommended by the Institute of Medicine¹¹
4. Cancer treatment that is consistent with nationally recognized clinical guidelines

Second, although participating OCM practices are paid under Medicare's FFS billing rules, all Medicare-covered services that their chemotherapy patients receive are combined in six-month episodes. Participating practices may earn a PBP if they reduce Medicare episode expenditures as compared with historic benchmarks (less a discount retained by CMS). These payments are adjusted to reflect performance on several practice-reported quality measures, other quality measures derived from Medicare

⁶ National Cancer Institute website. Retrieved on April 11, 2018 from <https://www.cancer.gov/about-cancer/causes-prevention/risk/age>.

⁷ Chemotherapy is defined for OCM purposes as systemic therapies including cytotoxic chemotherapy, hormonal therapy, biologic therapy, immunotherapy, and combinations of these therapies.

⁸ Demartino, J. K. & Larsen, J. K. Equity in Cancer Care: Pathways, Protocols, and Guidelines. JNCCN, vol. 10, Supplement 1: S1-S9.

⁹ Page, R. D., Newcomer, L. N., Spradino, J. D., et al. The Patient-Centered Medical Home in Oncology: From Concept to Reality. 2015 ASCO Educational Book. Retrieved on June 7, 2016 from <http://meetinglibrary.asco.org/content/11500082-156>.

¹⁰ Demartino, J.K. & Larsen, J.K. Equity in Cancer Care: Pathways, Protocols, and Guidelines. JNCCN, vol. 10, Supplement 1: S1-S9.

¹¹ Delivering High Quality Cancer Care: Charting a New Course for a System in Crisis. Committee on Improving the Quality of Cancer Care: Addressing the Challenges of an Aging Population; Board on Health Care Services; Institute of Medicine. 2013. Retrieved on June 7, 2016 from: <http://nap.edu/18359>.

claims, and patient-reported ratings of care experiences measured through a survey. TCOC estimates for PP1 do not include PBPs distributed to the practices.

The five-year OCM began with six-month episodes that started on July 1, 2016; it will operate through nine consecutive semi-annual PPs, with the last six-month episodes ending on June 30, 2021. This report focuses on episodes that began during PP1: episodes that began between July 1, 2016 and January 1, 2017 and ended by June 30, 2017.

Participating OCM practices may voluntarily adopt two-sided risk, in which expenditures above the target are repaid to CMS. Accepting two-sided risk meets the Quality Payment Program's criteria for being an Advanced Alternative Payment Model. Practices will be required to move to two-sided risk (or end their participation in OCM) if, as of the initial reconciliation of the fourth PP (estimated summer 2019), they have not yet achieved a PBP at least once.

Additional details about the OCM Model and methodology are available on the CMS website.¹²

1.2 Evaluation Overview

The OCM evaluation focuses on how care delivery evolves under OCM and the contextual factors affecting Model success. The evaluation will measure impacts of the five-year OCM on characteristics of participating practices and their patients, and the impact of OCM on use of services, Medicare spending, quality of care, and patient satisfaction. The OCM evaluation is examining care provided by practices that volunteered to participate in OCM, and comparing changes over time in this group with changes in a carefully selected comparison group. This difference-in-differences (DID) design measures whether changes over the five-year demonstration period are different in the OCM intervention group than in the comparison group.

Baseline Report. As described in the *First Annual Report from the Evaluation of the Oncology Care Model: Baseline Period* (Baseline Report),¹³ we used propensity score matching to select a group of oncology physician group practices. The Baseline Report demonstrates that OCM practices and selected comparison practices¹⁴ were much alike in the baseline period (episodes that began between January 2, 2014 and July 1, 2015 and ended between July 1, 2014 and December 31, 2015), as were the beneficiaries they served and the services these beneficiaries used during their treatment episodes, which reflected national patterns on most dimensions. The similarities in the two groups, and the parallel trends demonstrated over a multi-year baseline period, enhance confidence that program impacts measured with econometric models will be a result of OCM. The Baseline Report also showed that a few very large OCM practices contributed to some baseline differences between the two groups on measures such as average practice size and average practice volume, because there are no comparably large comparison practices in the nation to include in the evaluation comparison group. In addition, the two groups differed in the baseline period in the proportion of episodes for dually eligible patients (which was lower in OCM

¹² <https://innovation.cms.gov/initiatives/oncology-care/>.

¹³ <https://downloads.cms.gov/files/cmmti/ocm-baselinerreport.pdf>.

¹⁴ Comparison practices are defined as individual tax ID numbers (TINs), as described in detail in the Baseline Report. A TIN is a billing unit, and may not perfectly map to an entire physician group practice, which can comprise multiple TINs.

practices than for comparison practices in the baseline period). Our impact analyses take these differences into account. On dozens of other practice characteristics, patient characteristics, and utilization and cost characteristics, the two groups were quite similar in the baseline period, before OCM began.

Performance Period One Report. The primary objectives of this *Evaluation of the Oncology Care Model: Performance Period One* (PP1 Report) include:

1. ***Describe how participating OCM practices are implementing Model requirements for enhanced services and using MEOS funds to improve care delivery and lower costs of care.*** We describe the OCM and comparison practices in PP1, and differential changes since the baseline period between the two groups. We also describe strategies participating oncology practices told us they employed to meet OCM requirements, and challenges that different types of practices faced as they worked to improve evidence-based care and patients' care experiences, and reduce episode costs. We further describe how participating practices are using MEOS revenue and their own resources to hire new staff, improve electronic information systems, analyze data, coordinate care, identify high-risk patients and manage their symptoms and psychosocial needs, and ensure that end-of-life (EOL) care is consistent with patient preferences. This information provides context for evaluation impact results.
2. ***Describe impacts of OCM on use of Medicare-covered services and on episode costs of care.*** Participating practices may find different ways to reduce episode costs, for example, by offering urgent care hours for symptom management (to avoid ED visits), using lower-cost but equally efficacious treatments, or discontinuing aggressive treatment at the end of life in favor of hospice or other less-intensive care. OCM encourages adherence to national oncology clinical guidelines for cancer treatment, and encourages effective management of cancer- and treatment-related symptoms. We explore early OCM impacts on many different components of utilization and cost, especially those that practices told us they were focusing on first, those that are important drivers of episode costs, and those that may indicate improved symptom management and quality of care.
3. ***Describe impacts of OCM on patient care experiences and satisfaction with cancer care.*** OCM has an explicit goal of helping patients navigate the complexities of having cancer such as treatment schedules, psychosocial impacts, side effects of treatment, depression, and out-of-pocket (OOP) cost burden. OCM also emphasizes better access for patients to their cancer care team, ongoing patient education and communication between patient and providers, and better advance care planning to ensure that providers understand each patient's goals and preferences. Improvement in these areas is expected to also improve patient-reported care experiences. We use survey data to understand the impact of OCM in these areas and whether overall satisfaction with cancer care is improving over time, both for patients who are alive at the time of the survey sampling and—as reported by family members—for those who die during or soon after their treatment episode.

To measure impacts, and the underlying changes driving these impacts, the evaluation uses data from many sources including: Medicare administrative data systems, applications completed by volunteer practices and payers, case studies and interviews, practice-reported progress in meeting OCM requirements, surveys completed by patients and family members, and clinician surveys. The evaluation also takes advantage of inputs and data from the OCM Data Registry and annual Practice Transformation Plans submitted by participants.

1.3 Organization of This Report

In Chapter 2, we describe the data and methods used in evaluation data collection and analyses. Chapter 3 presents evaluation findings for utilization, cost, practice transformation and enhanced oncology services, and quality (supportive care, EOL care, patient experiences). For each topic, we synthesize data from multiple sources to provide a multifaceted understanding of early changes and impacts of OCM. We provide a brief conclusion in Chapter 4. Throughout the report, we refer to appendices containing additional detail that may be of interest.

This report includes information about six-month episodes that began and ended during the first PP (i.e., began July 1, 2016–January 1, 2017, all of which ended by June 30, 2017). The report includes information about OCM participants and impacts in that period. It also includes surveys of patients whose episodes began and ended during the first Model year, qualitative data we collected during the first Model year, and program data reported by participants during that year. Subsequent changes in programmatic requirements, participants, and impacts will be addressed in future reports.

2. Methods

This chapter of the report describes secondary and primary data, and the methods used to analyze data and measure the impacts of OCM. In addition to analyzing Medicare claims, we surveyed patients (and family members of deceased patients) to understand care experiences. We visited 12 OCM participating practices in the first year, to understand practice transformation and changes in care delivery motivated by OCM requirements and incentives. For more detailed information about the data and methods used in this report, see Appendix A.

2.1 Secondary Data and Analytic Methods

2.1.1 Secondary Data Sources

We used several sources of data to construct the episode files used in our analyses. We used Part A and B Medicare Claims files and Part D Prescription Drug Event (PDE) files to construct measures of health care utilization and cost. In addition, we leveraged several files for beneficiary enrollment and coverage information, beneficiary characteristics, and beneficiary alignment to other CMS initiatives.

Other secondary data sources added key county-level and practice-level information. These included the CMS Health Professional Shortage Area (HPSA) files, the SK&A Office-Based Physician File,¹⁵ academic medical school affiliation data from Welch and Bindman (2016),¹⁶ and the Area Health Resource File (AHRF).

The full set of data sources used in the claims analyses are shown in Appendix A.

2.1.2 Secondary Data File Creation

Observation Period

OCM began July 1, 2016 and is structured with six-month episodes of care triggered by chemotherapy, for FFS Medicare beneficiaries with continuous Parts A and B enrollment. The Model is organized in semi-annual PPs, for which CMS retrospectively reconciles costs and performance for participating practices. The five-year Model test has nine PPs. The first PP includes episodes that started between July 1, 2016 and January 1, 2017, and ended between December 31, 2016 and June 30, 2017. The last PP will include episodes starting between July 2, 2020 and January 1, 2021, all of which will end by June 30, 2021.

The baseline period used in the evaluation includes six-month episodes that began January 2, 2014 through July 1, 2015 and ended by December 31, 2015. Practices submitted applications to participate in OCM in June 2015, and CMS notified practices of acceptance into the Model in April 2016. The intervention period for this report includes all episodes that occurred during the Model's first PP (PP1). We applied a "hold-out" period that did not allow episodes to begin between July 2, 2015 and June 30, 2016, so that any changes that practices began between applying to participate and before the official start of the Model did not affect the baseline period. If episodes had been defined, those that would have

¹⁵ <http://www.skainfo.com/databases/physician-data>

¹⁶ Welch, P. and Bindman, A.B. (2016). Town and gown differences among the largest medical groups in the US. *Journal of Academic Medicine*, July, 91(7):1007–14.

initiated in the last PP of the hold-out period were especially important to exclude, because they would have ended during the intervention period. The specific episode start and end dates that map to each PP in the baseline and intervention period are outlined in Appendix A.

Identification of Episodes and Attribution of Episodes to Practices

OCM focuses on six-month episodes of care, each triggered by a Part B claim for chemotherapy along with a relevant cancer diagnosis code, or by a Part D chemotherapy prescription filled within 59 days of or on the same day as a Part B claim with a relevant cancer diagnosis. Episodes have a fixed length of six calendar months, which can vary between 181 to 184 days depending on which calendar months are included in the episode. CMS attributes each episode to the physician practice (based on Tax ID Number, or TIN) that has the plurality of cancer-related Evaluation and Management (E&M) services during the episode.

Identification of Episodes

We identified episodes for the baseline and intervention periods on a PP basis based on the first date of chemotherapy administration or prescription fill observed in each PP, assuming it does not overlap with a prior episode. The baseline is composed of three PPs during which episodes could be triggered, and the intervention period is currently comprised of PP1 (thus far, for this report). After identifying a Part B or Part D trigger event, we examined cancer-related E&M services from the Part B carrier claims, and considered an episode to be eligible if the beneficiary had at least one cancer-related E&M service during the six months following the chemotherapy trigger event. In addition, during the entire episode, the beneficiary needed to have: continuous Medicare Parts A and B enrollment; coverage under Medicare FFS (not Medicare HMO, Medicare Advantage, or the United Mine Workers of America program); Medicare as the primary payer; and no Medicare benefit due to End-Stage Renal Disease (ESRD).

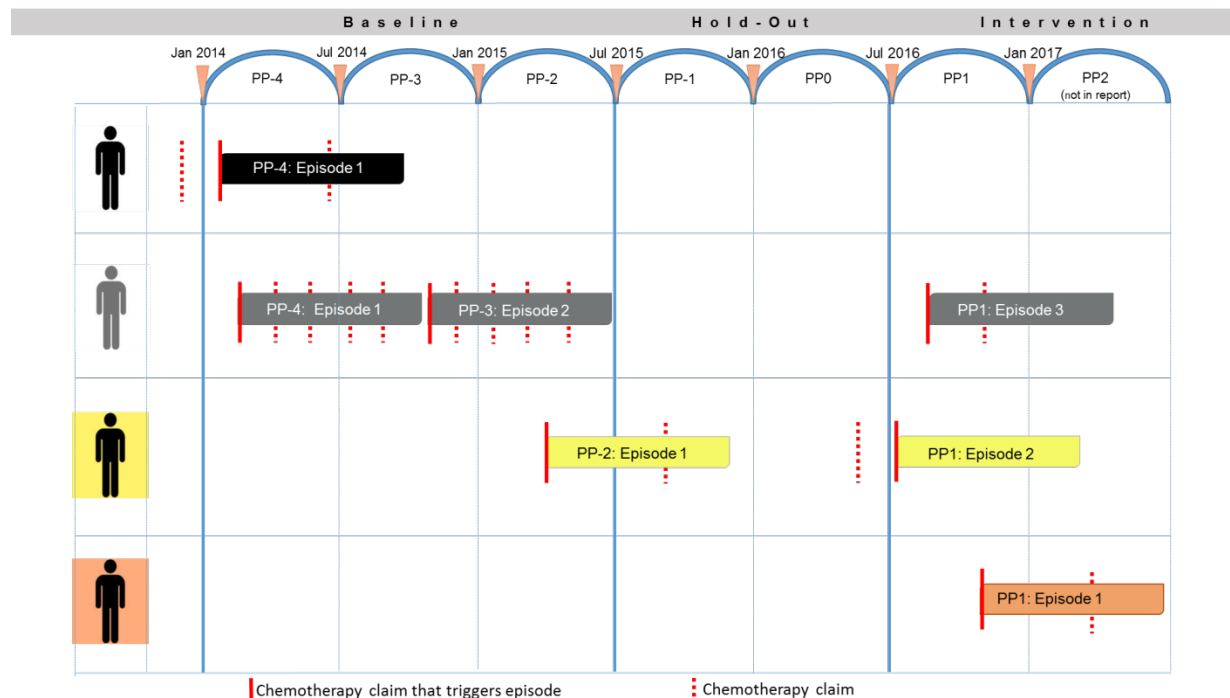
Per the OCM methodology for episode identification, we implemented the following:

- All Part A, B, and D claims that occurred during the six-month period following a triggering claim were included as part of the episode.
- If a beneficiary had a subsequent qualifying chemotherapy claim that did not overlap with the prior episode, that claim would trigger a new episode (if the episode met the eligibility criteria specified above).
- A chemotherapy-free period was not required between one episode and the next, but a subsequent episode did not trigger until the prior episode (i.e., six months) ended.
- An episode could only end earlier than six months if the beneficiary died.

Episodes were identified for the baseline and intervention periods independently, with the identification process restarted for the intervention period. **Exhibit 1** illustrates several important features of episode identification. First, episodes were assigned to a period based on the baseline PP (denoted by a negative PP to indicate it is a pre-performance period) or intervention PP in which they began, and there was a hold-out period between the baseline and intervention periods. For this reason, as shown by *PP-2:Episode 1* in the third row of the exhibit, an episode that triggered in the last (third) PP of the baseline period was included as a baseline episode, even though the episode concluded during the hold-out period. Second, a beneficiary can have more than one episode, and those episodes may exist during the baseline period, the intervention period, or both time periods. For example, in the second row of the exhibit, the beneficiary

had three episodes, two episodes in the baseline period (*PP-4:Episode 1* and *PP-3:Episode 2*) and one episode in the intervention period (*PP1:Episode 3*). Third, once an episode begins, subsequent claims for chemotherapy do not trigger a new episode until after the six-month episode ends (as shown in *PP-4:Episode 1* and *PP-3:Episode 2* in the second row).

Exhibit 1: Identification of Episodes



Source: Figure produced by report authors.

Notes: PP-4 through PP-2 refer to the three PPs in the baseline period, PP-1 through PP0 refer to the two PPs in the hold-out period, and PP1 refers to the first PP of the intervention period. Episodes that start in PP2 will be included in the intervention period in subsequent reports.

As **Exhibit 1** demonstrates, the episode identification algorithm yields a different mix of episodes in the first PP of both the baseline and the intervention than in subsequent periods. Because the OCM methodology does not require an initial chemotherapy-free period, a beneficiary’s first eligible chemotherapy claim in the first PP of the baseline period, or in the first PP of the intervention period, triggered an episode—even when the beneficiary had a chemotherapy claim within the prior six months. (For example, *PP-4:Episode 1* for the beneficiary in the first row and *PP1:Episode 2* for the beneficiary in the third row of the exhibit both do not include claims that occur outside the OCM time periods.) As a result, the first baseline PP included a higher proportion of beneficiaries with ongoing chemotherapy (prevalent cases) than new chemotherapy (incident cases). In subsequent baseline PPs, new episodes were identified if there was no trigger in the prior PP or if a previous episode had ended and a new trigger occurred, and this yielded a clearer distinction between prevalent and incident cases¹⁷. The number of

¹⁷ A prevalent case reflects an episode for which a beneficiary has been receiving on-going chemotherapy treatment prior to the start of the episode. An incident case reflects an episode for which a beneficiary has newly begun chemotherapy treatment at the start of the episode.

episodes identified in the first baseline PP was higher than the number of episodes identified in the subsequent baseline PPs. The same is true for the intervention period (i.e., more episodes, and more prevalent cases, in PP1 than in subsequent periods).

Another artifact of the episode attribution algorithm pertains to long-term hormonal therapies (e.g., a patient taking a daily tamoxifen pill after breast cancer surgery). Some beneficiaries on long-term hormonal therapies have infrequent cancer E&M services, as few as one or two office visits each year. Because the OCM methodology requires a cancer E&M service to identify an episode, and defines episodes as six months in duration, beneficiaries whose cancer E&M services take place more than six months apart may not trigger consecutive episodes even if they are on continuous treatment. This results in beneficiaries who were actually in ongoing (prevalent) chemotherapy treatment in the first PP not being identified as having episodes until the next PP, due simply to the timing of their E&M services. This may lead to an understatement of the beneficiaries whose care is being overseen by the practice at any point in time. This artifact of episode triggering will gradually moderate, as prevalent users of long-term hormonal therapy return for cancer E&M visits on schedules that even out over the months of the year.

Section 3.1.1 provides more information about the number and characteristics of episodes identified in the baseline and intervention periods.

Episode Attribution

Per the OCM attribution methodology, we assigned all eligible episodes to the practice that provided the plurality of cancer-related E&M services during the episode. A practice is defined as the TIN listed on the E&M claim. A TIN is a billing unit, and it may or may not represent the structure of a physician group practice; some oncology practices use multiple TINs, and some oncology practices share a single TIN with a larger multi-specialty organization. For OCM, CMS requires that participating practices each use a single TIN, and that all OCM practitioners in the practice submit claims under that TIN. Participating OCM practices that experienced billing or business changes during the baseline or intervention period provided CMS with any “legacy” (i.e., older) TINs, which were replaced by the active TIN used for OCM participation, and we used these legacy TINs to attribute episodes to OCM practices in the baseline period. Because legacy TINs were not available for practices not participating in OCM, we were unable to track TIN changes for these practices and instead attributed episodes to individual TINs.

Comparison Group Selection

We selected a comparison group of practices using propensity score matching (PSM). The objective of PSM is to identify a comparison group that is statistically similar to the treatment group, based on observable factors. We chose a subset of non-participant practices that are relevant for OCM, taking into consideration (a) patterns of billing cancer-related E&Ms for chemotherapy patients, (b) eligibility to participate in OCM based on Model rules, and (c) similarity to OCM practices in terms of key characteristics.

The propensity score is defined as the probability of participating in OCM, conditional on a set of observed characteristics. PSM aims to balance the distributions of important characteristics between the OCM group and the comparison group, improving the quality of inferences that can be made about the impact of the intervention. The key advantage of PSM over other methods is that by using a combination of characteristics to compute a single score, it balances the treatment and comparison groups on a large

number of factors, without eliminating comparators that may be good matches (i.e., similar) on average, to OCM practices.

PSM yielded strong evidence that the selected comparison group of 539 practices is statistically similar to the group of OCM practices overall, and on most key characteristics. More information about the comparison group selection is provided in Appendix A in this report and in the Baseline Report.¹⁸

2.1.3 Secondary Data Analyses

OCM practices that withdrew from the Model before the end of PP1 were retained in the analysis, because we are using an Intent-to-Treat evaluation approach. This is necessary to avoid measuring impact only for those that successfully implement the Model, and also because some practice transformation may continue after withdrawal (e.g., improved patient education materials, improved phone triage processes) with potential ongoing impacts.

Claims-Based Outcome Measures

We compared health care utilization and costs, as well as end-of-life (EOL) care quality, for the OCM and comparison samples during the baseline and intervention periods. All outcome measures are calculated at the episode level, not the practice/TIN level. Findings with $p < 0.10$ are considered statistically significant.

The utilization measures presented in this report address inpatient care, emergency department (ED) visits, Part A post-acute services (e.g., skilled nursing facility and home health agency services), selected Part B outpatient services (e.g., imaging and radiation therapy services), and Part B and D chemotherapy and drug fills. We also measure ED visits and inpatient hospitalizations due to complications from chemotherapy. We constructed utilization process and outcome measures of EOL and hospice care, in three domains: hospital-based care and chemotherapy at the end of life, hospice use and timing, and place of death. (See Appendix A for measure specifications.)

Cost measures include total cost of care (TCOC), comprised of Part A, Part B, and Part D costs. In addition, we report Part A costs for inpatient care and post-acute and long-term care, institutional and non-institutional Part B costs, and Part B and D costs for cancer-related services and drugs. We also present total beneficiary deductible and coinsurance costs for Parts A, B, and D.

The costs we report throughout this report reflect Medicare payments. The reported Part A and B costs are based on standardized payments, which exclude geographic differences in labor costs and practice expenses and also remove payment variation resulting from other CMS program reductions/additions (e.g., for programs including bundled payment). The reported Part D costs are not standardized and include low-income cost-sharing and reinsurance payments. Calculated costs do not include MEOS bills submitted by OCM practices because full MEOS billing data for PP1 were not available in time for inclusion in this report.

Descriptive and DID Impact Analyses

For this PP1 Report, we compared OCM and comparison practices on a number of episode- and practice-level characteristics. We used DID regression analyses to estimate the impact of OCM on utilization, cost, supportive therapy, and EOL quality, controlling for other factors unrelated to OCM that could influence outcomes. DID is a statistical technique that compares changes in an outcome for the OCM group with

¹⁸ <https://downloads.cms.gov/files/cmml/ocm-baselinerreport.pdf>

changes in that outcome for the comparison group, from the baseline period before OCM began, to the implementation period (after July 1, 2016). The DID models used in this report estimate the average impact of OCM on an outcome of interest, over the duration of the intervention period thus far, PP1.

For a subset of key outcomes, we estimated impacts for core cancer subgroups where there appeared to be differences, and for which we had adequate statistical power (i.e., sufficient episode volume) in PP1 to detect meaningful differences. The first set of subgroup analyses focused on the 10 most prevalent cancer bundles. We derived episode cancer bundles based on the cancer types assigned to each episode (see Appendix A for details). A separate set of subgroups were defined according to episodes for low-risk and high-risk cancer bundles. Low-risk cancer bundles were composed of breast cancer episodes using only hormonal therapies, and prostate and bladder cancer episodes using only low-risk chemotherapy regimens. Appendix A contains more information about the statistical methods used.

Probability Estimation

In addition to the DID impact analyses, we estimated the *probability* of OCM impacts (e.g., the probability of reduced costs or utilization under OCM) for four key outcomes, specifically: (1) the number of inpatient stays, (2) the number of ED visits not resulting in an inpatient stay, (3) the number of ED visits resulting in an inpatient stay, and (4) total costs of care per episode. These measures were selected because of their relevance to the cost and quality goals of OCM and to the OCM PBP methodology. In addition, the utilization measures may be important early indicators of the potential impacts of enhanced services under OCM.

More information about the estimation methodology is shown in Appendix A.

2.1.4 Clinical Analyses

Guideline-Recommended Use of Prophylactic Antiemetics during Intravenous Chemotherapy

Many patients undergoing chemotherapy experience nausea, and antiemetic therapy is an important element of supportive care. The incentive to deliver high-value care under OCM could lead practices to systematically reduce overuse of costly antiemetic (anti-nausea) drugs, in situations where similarly effective and less expensive alternatives are available. Conversely, the incentive to prevent ED visits and costly hospitalizations could lead practices to adopt more high-intensity antiemetic regimens, with the goal of reducing use of acute care. We therefore studied the use of guideline-recommended prophylactic antiemetic supportive therapy, and also the use of high-intensity antiemetics in situations where less potent and costly options might suffice. Specifically, we used national guidelines for supportive therapy from the National Comprehensive Cancer Network (NCCN) and the American Society of Clinical Oncology (ASCO), and identified patients starting intravenous chemotherapy regimens, stratified by the emetogenicity risk of the chemotherapy regimen (high, moderate, or low risk of causing nausea and vomiting). These guidelines specify drugs that should be used prophylactically—before chemotherapy infusions—to prevent nausea. We defined prophylactic antiemetic supportive therapy as prescription or in-office administration of guideline-recommended antiemetic drugs within 14 days before through one day after the first chemotherapy infusion. Criteria for identifying guideline-recommended antiemetic regimens are shown in Appendix A. We considered any use of potent antiemetics for patients receiving only low-risk chemotherapy agents to be non-guideline care.

In addition to assessing guideline-recommended antiemetic use, we evaluated “high-intensity” patterns of guideline-recommended antiemetic use among patients receiving chemotherapy with moderate and low emetogenic risk. For example, use of a 5-HT₃ receptor antagonist with or without an NK1 receptor

antagonist is guideline-recommended antiemetic prophylaxis for moderate emetogenic risk chemotherapy. We classified combination antiemetic treatment with both a 5-HT3 receptor antagonist and an NK1 receptor antagonist as high-intensity. Analyses of “high-intensity” drug use assess whether OCM influenced patterns of antiemetic use for patients already receiving guideline-recommended antiemetic therapy.

Hospitalizations and ED Visits for Patients Undergoing Chemotherapy

We adapted a CMS measure originally developed to assess hospitalizations and ED visits for patients undergoing chemotherapy in hospital-based outpatient departments.¹⁹ We examined chemotherapy episodes in OCM comparison practices that included at least one chemotherapy-associated hospitalization or ED visit.

In Appendix F, we also separately report ED visits that do, and those that do not, result in an inpatient stay.

While there are some limitations of these measures, all of these limitations apply equally to OCM and comparison practices, and in both the baseline and intervention periods; we do not expect them to differentially influence our DID estimates of OCM impact. Rather, these issues help to inform interpretation of the findings and of differences between findings for this measure and other measures of inpatient and ED use.

2.1.5 Practice Transformation Plans

CMS asks participating OCM practices to submit annual Practice Transformation Plans (PTPs). These are structured self-assessments of their practice transformation activities during the prior year, and their plans for the future. The reporting template contains primarily close-ended questions covering several domains.²⁰ OCM practices have submitted two PTPs to date, early in Model Year One (Fall 2016) and early in Year Two (Fall 2017). This report focuses on PTP responses provided in Fall 2017, because the Fall 2016 PTPs reflected only three months of OCM activity. We coded PTP responses into binary measures reflecting consistent use of care processes. Descriptive analyses explored the percentage of OCM practices using a given approach or care process, and bivariate analyses stratified PTP measures by practice characteristics and compared changes in PTP reports between 2016 and 2017. Appendix A shows how analytic measures are defined, and Appendix E includes all results from these analyses.

¹⁹ Mathematica Policy Research. Admissions and Emergency Department Visits for Patients Receiving Outpatient Chemotherapy Measure Technical Report. Prepared for Centers for Medicare & Medicaid Services; March 2016. Available from: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html>.

²⁰ The 2017 PTPs included the following domains: Respondent information; Access and continuity; Care coordination; Care planning and management; Patient and caregiver engagement; Team-based care; Data-driven quality improvement; Evidence-based medicine; Strategic plan; and Practice redesign priorities for the next 6 to 12 months.

2.2 Primary Data Collection and Analysis

2.2.1 Patient Survey

This report compares survey responses from OCM and comparison patients receiving cancer care just as OCM began (April through September 2016); for the purposes of the survey, we consider this survey wave to be the baseline. This report also presents trends in the OCM group from the baseline through intervention survey wave 1 (July through December 2016), intervention survey wave 2 (October 2016 through March 2017), and intervention survey wave 3 (January through June, 2017). The surveys are administered by mail.

Survey Data Collection

The OCM patient survey measures perspectives about a number of cancer care experiences. We designed and administered three distinct survey instruments:

1. The **main** questionnaire is sent to cancer patients we believe to be alive at the time of survey mailing. It contains questions about care experiences and current health status, but does not ask about EOL care because these patients are (to the best of our knowledge) alive.
2. A tailored **alternative** questionnaire is sent to the family proxies of cancer patients who had died by the time the survey was mailed (i.e., died during or soon after their six-month care episode). It asks the same care experience questions as the main survey, and also asks about EOL care, but it does not ask about current health status (because patients are deceased).
3. A **decedent** questionnaire is sent to the family proxies of patients who were alive for the initial survey mailing (whether or not they responded), but who died during the subsequent year. It asks about EOL care.

Appendix A contains more details about the differences between these three instruments. These three instruments and populations together offer a complete picture of care and satisfaction as experienced by patients who survive, those who die during or soon after their six-month treatment episodes, and those who die months later.

Both the main and alternative questionnaires are based on a questionnaire that was developed and tested in the first Consumer Assessment of Healthcare Providers and Systems (CAHPS) for Cancer Care chemotherapy (drug therapy) module, with additional insight from its use in a National Committee for Quality Assurance study.²¹ We revised the instrument to address all types of cancer treatment included in OCM (chemotherapy, immunotherapy, and hormonal therapy). We also augmented the instrument to add items that are of interest to OCM, including presence of treatment-related symptoms (e.g., nausea, neutropenia, constipation) and management of these symptoms, quality of life, health status, understanding of the purpose of treatment, and (for the alternative and decedent questionnaires) EOL care. The three patient survey instruments are included in Appendix G of this report.

The evaluation uses a baseline survey wave timed just as OCM began, followed by 19 quarterly intervention-period survey waves. In each survey wave we send the main survey to sampled patients we

²¹ The final version of CancerCAHPS was not available in time for our baseline survey, and we wanted to use the same questionnaire for the baseline and subsequent survey waves, to ensure comparability.

believe to still be alive, and the alternative survey to family members (proxies) of sampled patients we believe are deceased. Three survey waves include a parallel sample of matched comparison group patients: the baseline survey (episodes starting April through September 2016), intervention survey wave 9 (episodes starting July through December 2018), and intervention survey wave 19 (episodes starting January through June 2021). Two waves include the decedent survey: baseline and intervention survey wave 9.

In each survey wave we sample patients who received chemotherapy²² in the previous six months, and assign each to the TIN that billed the most E&M visits between the episode triggering date and the date we draw the sample.²³ We do not select the same patient more than once in a year, even from the smaller practices, to reduce respondent burden. In survey waves that include a sample of comparison patients, we select comparison patients by matching to OCM patients on selected beneficiary and practice characteristics.

The baseline wave was the first of three survey waves for which we will sample both OCM and comparison beneficiaries. We selected beneficiaries who received chemotherapy in April through September 2016, which we consider the baseline for the survey.²⁴

Appendix A shows the starting sample size and response rate for each survey wave. Response rates in each wave were higher for the main survey than for the alternative survey or the decedent survey. For example, the response rate among OCM patients in the baseline wave was 48.3 percent for the main survey, 39.0 percent for the (proxy) alternative survey, and 40.9 percent for the (proxy) decedent survey, and response rates were similar for the comparison sample. Response rates for the OCM sample declined slightly in each subsequent wave for the main and alternative surveys, possibly related to the changing composition of the survey sample (i.e., different mix of cancer types in each survey wave).

Survey Outcome Measures

In each wave of survey analysis, we calculate six patient experience composite scores, as follows: Access (six survey questions), Affective Communication (four questions), Enabling Patient Self-Management (eight questions), Exchanging Information (four questions), Shared Decision Making (four questions),

²² Chemotherapy is defined for OCM and for the patient survey as chemotherapy, immunotherapy, and/or hormonal therapy.

²³ We draw a new survey sample every quarter, looking back six months for a trigger drug event. For most in the sample we therefore do not have a full six months of claims, and cannot attribute an episode to a TIN using the full six months of E&M visits. Waiting for six months of post-trigger claims to accumulate would delay the survey and increase the potential for recall bias.

²⁴ Note that the baseline period for claims analysis ends a year before OCM began; that year is “held out” to ensure that any changes in preparation for OCM do not affect the baseline. The baseline survey, in contrast, took place just as OCM began, because it was not possible to collect data a year earlier.

and Symptom Management (eight questions).²⁵ In addition, there is a single survey question that asks patients for their overall rating of their cancer therapy team. Appendix A describes the component questions for each composite.

Each composite score is calculated as the average score across all component questions within a composite, with each non-missing question assigned an equal weight. All composite scores and the overall rating range from 0 (worst experience possible) to 10 (best experience possible). We also analyzed selected individual survey questions, including the individual questions that comprise the composites, and other questions that are not grouped into a composite.²⁶

Survey Analytic Methods

For this report we conducted two survey analyses. The first analysis compares care experiences reported by OCM respondents with those reported by a matched sample of comparison respondents, at baseline (April through September 2016). That baseline survey wave used both the main and alternative surveys, and also the decedent survey, for OCM and comparison respondents. The second analysis examines trends in care experiences reported by OCM respondents from the baseline wave through intervention survey wave 3 (January through June 2017). (We have not yet collected data from a comparison sample in the intervention period, and have not yet repeated the decedent survey in the intervention period).

For both analyses, we combined responses to the main survey and the alternative survey to understand care received by patients who survived and those that did not, except for EOL care questions which are not asked in the main survey. For questions about EOL care we combined the alternative survey and the decedent survey to compare the OCM and comparison samples at baseline.²⁷ For the trend analysis of EOL care (OCM group only), we used the alternative survey for EOL care measures, because the baseline decedent survey has not yet been repeated.

For both analyses, we used an Ordinary Least Square (OLS) regression if the outcome measure was a continuous variable and a logistic regression if the outcome measure was a dichotomous variable. Respondents reported their annual OOP expenses related to cancer care in six expense categories, and we used an ordered logit regression to estimate the risk-adjusted share of respondents reporting each expense

²⁵ The enabling patient self-management composite includes three questions about whether care providers talked with the patient about three cancer-related symptoms: pain, change in energy level, and emotional problems. It also includes questions about whether care providers helped patients deal with these symptoms (if patients did experience them), as well as two questions about additional services to help patients manage care and maintain health at home. The symptom management composite includes eight questions about whether care providers helped patients deal with symptoms: one for each of the eight symptoms, including the three symptoms in the enabling patient self-management composite and five additional symptoms. Thus, three of the symptom management questions are repeated in both of these composites.

²⁶ For each individual question, we created a dichotomous variable that takes a value of 1 for the most positive response and 0 otherwise. For example, responses of “Always” to the question asking “How often tests and procedures were done as soon as you needed?” are assigned a value of 1, and any other answer to that question is assigned a value of 0.

²⁷ The comparison group survey and decedent survey will be repeated in intervention wave 9; the comparison group survey will be repeated again in intervention wave 19.

category. We report the 90 percent confidence intervals for all estimates of interest. We adjusted all analyses with sampling and nonresponse weights, and clustered the standard errors at the practice level.

For all survey analyses, we included both patient and practice characteristics in risk adjustment for composite scores and for individual questions, to control for differences that may be unrelated to OCM. In addition to analyzing all respondents as a group, we estimated the risk-adjusted survey results for key patient subgroups.

2.2.2 Year One Case Studies

Data Collection

We conducted 12 in-person case studies with participating practices during Model Year One, one each month starting in July 2016. We selected practices with a range of different attributes including size, ownership, geographic location, and pre-OCM average per beneficiary cost of care. We initially developed and continuously updated both the interview protocols and the codebook based on the findings from case studies. Depending on the practice size and other characteristics, interviewees for each case study included:

- Clinical and administrative leaders
- Medical oncologists and specialty oncologists
- Palliative medicine specialists
- Physician assistants and nurse practitioners
- Nurses
- Patient navigators and care coordinators
- Medical assistants
- Business/finance directors
- Patient financial advocates/counselors
- Directors of performance improvement
- IT staff (e.g., electronic health records)
- Pharmacists
- Staff involved in data management and analytics

Exhibit 2 shows characteristics of the 12 OCM practices we visited during Year One.

Cross-Case Analysis

After each case study visit, the team coded themes using NVivo software and updated the codebook to include new themes as appropriate. We identified themes found in at least two of the 12 case studies, and important insights that emerged from one case study in contrast with the others.

In reporting the findings from the cross-case analysis, we note practice characteristics that appear to be associated with an observed theme, where applicable. Specifically, we looked for differences that may be related to practice size or ownership (independent versus health system-owned). We also categorized case study themes based on whether we visited early in the first OCM Model year (between July and December 2016) or later in the year (January through May 2017). Since this qualitative analysis includes only 12 case studies, we cannot examine differences by multiple characteristics at the same time. As with other findings in this report, we caution that case study material reflects early Model experience, during the first year of OCM implementation.

Exhibit 2: Characteristics of 12 Year One Case Study Practices

Practice	Location	Ownership	Size*	Oncology Only or Multi-Specialty	Baseline Episode Average Monthly Cost ²⁸ (as Compared with National Averages)	Time of Site Visit
Year 1A	Northeast	Health system-owned	Large	Multispecialty	Average	Jul.–Dec. 2016 (early case studies)
Year 1B	Midwest	Health system-owned	Very large	Multispecialty	High	
Year 1C	South	Independent	Medium	Oncology only	Average	
Year 1D	West	Independent	Medium	Oncology only	Low	
Year 1E	Mid-Atlantic	Independent	Small	Oncology only	Average	
Year 1F	Southwest	Independent	Medium	Oncology only	High	Jan.–May 2017 (later case studies)
Year 1G	West	Health system-owned	Small	Oncology only	Low	
Year 1H	Midwest	Independent	Medium	Oncology only	Low	
Year 1I	Mid-Atlantic	Health system-owned	Medium	Multispecialty	Average	
Year 1J	Southeast	Independent	Very large	Oncology only	Average	
Year 1K	West	Independent	Very large	Oncology only	Average	
Year 1L	South	Independent	Small	Oncology only	Low	

* Practice size categories: small=fewer than 12 medical oncologists; medium=between 12 and 24 medical oncologists; large=between 25 and 49 medical oncologists; very large=50 or more medical oncologists.

2.2.3 Other Payer Interviews and Exit Interviews

During 2016, 17 payers signed an OCM Memorandum of Understanding (MOUs) with CMS to implement oncology alternative payment models aligned with OCM, and try to enroll OCM practices with which the payers have contracts. One payer terminated shortly after the Model began. We reviewed the applications and implementation updates from the 16 remaining payers, and interviewed them in January and February 2017 by telephone. Descriptive analysis explored payment model features and alignment with OCM features, practices participating in these payers’ models, and payer implementation successes and challenges.

Throughout the course of Year One, eight practices withdrew from OCM. We used a structured interview guide to interview representatives from practices that withdrew from the OCM, to understand reasons for withdrawing and perspectives about the value of their abbreviated participation.

²⁸ The OCM Implementation and Monitoring contractor developed preliminary Medicare beneficiary/month cost averages in the baseline period. We used these averages to categorize each practice’s Medicare costs as being close to the national average of all practices (OCM and others), below the national average, or above the national average.

3. Findings

Chapter 3 contains detailed findings from multiple data sources, organized by domain. Section 3.1 describes early changes in the characteristics of participating OCM practices, the patients they served, and the episodes of care they provided. Section 3.2 presents results about the impact of OCM on utilization of Medicare-covered services. Section 3.3 presents results about the impact of OCM on episode costs, and 3.4 shows the probability of various levels of cost savings to Medicare. Section 3.5 addresses practices' efforts to offer enhanced oncology services, and Section 3.6 presents findings about quality of care. Section 3.7 contains information about the experience of other payers who agreed to align their oncology alternative payment models with OCM. Each section begins with a summary of key findings.

3.1 Changes in Episode and Practice Characteristics

Summary of Findings on Changes in Episode and Practice Characteristics, Between Baseline and Intervention Periods

OCM practices and comparison practices were well matched in the baseline period, and there was little change in the types of beneficiaries served or the type and severity of cancer episodes in PP1. It is important to monitor practice characteristics and case mix to understand any potential impacts of OCM program incentives.

- The proportion of both OCM practices and comparison practices affiliated with hospitals or health systems increased between the baseline and intervention periods, and both OCM and comparison practices increased in size.
- There was an increase in the share of providers who were nurse practitioners and physician assistants, for both OCM practices and comparison practices.
- Per episode Part D chemotherapy use increased among OCM and comparison beneficiaries who were enrolled in Part D.
- Use of immunotherapies corresponded to the U.S. Food and Drug Administration (FDA) approval of drugs and indicated uses.
 - In the baseline period, few immunotherapies had been approved, and immunotherapies were used in less than one percent of OCM episodes. Immunotherapy use increased similarly for both OCM and comparison episodes in the intervention period.

In the Baseline Report,²⁹ we described the characteristics of OCM practices prior to the implementation of the model, and compared their attributes to those of the Taxpayer Identification Numbers (TINs) selected for the evaluation comparison group. Overall, comparison practices were similar to OCM practices across most episode and practice characteristics. Comparison practices, however, were smaller than OCM practices on average, with respect to the number of attributed episodes, number of oncologists, and number of practice sites. With data from PP1, we explored whether OCM or comparison practices have changed since the baseline in terms of key episode and practice characteristics such as cancer mix, beneficiary demographics, practice size, and organizational structure. Changes in practice and episode attributes over time can influence treatments, outcomes, and costs. Understanding these changes provides

²⁹ <https://downloads.cms.gov/files/cmmt/ocm-baselinerreport.pdf>

context for the impact findings described later in this report. Moreover, if OCM practices are changing their mix of beneficiaries or organizational structure in response to OCM Model incentives, the types and magnitude of changes is important to understand as these may affect decisions about scalability of the Model.

3.1.1 Changes in Beneficiary and Episode Characteristics from Baseline to Intervention Periods

We examined how cancer bundle mix, beneficiary demographics and risk, and the use of Part D chemotherapy, immunotherapy and novel therapy changed among OCM and comparison episodes, between the baseline and the intervention periods, because these changes can influence episode-level outcomes and cost. As noted in Chapter 2, the intervention period covered in this report was comprised of six-month episodes that began during the PP1 of OCM (July 1, 2016 to January 1, 2017), while the baseline period was comprised of six-month episodes that began between January 2, 2014 and July 1, 2015.

Episode Attribution Algorithm

As described in Section 2.1.2, the OCM algorithm that identifies and attributes episodes yielded a different mix of episodes in the first PP of the baseline period and the first PP of the intervention period, than in subsequent PPs, yielding a larger proportion of prevalent cases with on-going chemotherapy. However, the episode algorithm impacts the first PP data for both OCM and comparison episodes equally; we therefore believe the DID impact estimates presented in this report are not affected. While we anticipate the algorithm's effect will diminish in future PPs, it is important to account for these measurement issues when interpreting trends, especially early in the Model.

Cancer Bundle Mix

We examined changes in the cancer bundle mix between the baseline and intervention periods (**Exhibit 3**), because changes in the cancer bundle mix will affect average episode cost. For both the baseline and intervention periods, the volume of episodes varied considerably by cancer bundle, indicating that aggregate outcome measures of cost and utilization are heavily influenced by specific cancer bundles.

- Hormonal only and non-hormonal breast cancer represented the largest share of episodes, comprising 35 percent of OCM and comparison episodes followed by low-risk and high-risk prostate cancer (12 percent) and lung cancer (9 percent).
- Liver cancer, malignant melanoma, low-risk bladder cancer, central nervous system (CNS) tumors, acute leukemia, and anal cancer together represented five percent of all OCM and comparison episodes.

Exhibit 3: Cancer Bundle Mix among OCM and Comparison Episodes from Baseline to Intervention (PP1)

Cancer Bundle	Baseline Period Episodes Initiating: (1/2/14-7/1/15)		Cumulative Intervention Period Episodes Initiating: (7/1/16-1/1/17)	
	OCM N=349,681	COMP N=415,483	OCM N=140,029	COMP N=164,195
	%	%	%	%
Hormonal Only Breast Cancer	23.6%	23.2%	24.8%*	23.5%*
Non-Hormonal Only Breast Cancer	10.6%	9.5%	10.1%*	9.2%*
Lung Cancer	9.6%	9.0%	9.5%	9.2%*
Low-Risk Prostate Cancer	8.0%	11.2%	8.1%*	10.8%*
Lymphoma	7.0%	6.1%	6.5%*	5.7%*
Colorectal/Small Intestine Cancer	6.4%	6.0%	5.6%*	5.4%*
Multiple Myeloma	5.4%	5.0%	5.6%*	5.2%*
Non-Reconciliation Eligible Cancer ³⁰	3.9%	4.5%	4.6%*	5.5%*
Chronic Leukemia	3.5%	3.5%	3.5%	3.4%
High-Risk Prostate Cancer	3.6%	3.8%	3.5%	3.6%*
Pancreatic Cancer	2.3%	2.2%	2.2%	2.3%
Ovarian Cancer	2.2%	2.3%	1.9%*	2.0%*
Gastro/Esophageal Cancer	1.7%	1.6%	1.5%*	1.6%
Endocrine Tumor	1.3%	1.1%	1.5%*	1.4%*
Myelodysplastic Syndrome (MDS)	1.7%	1.4%	1.5%*	1.3%*
Head and Neck Cancer	1.5%	1.4%	1.4%	1.3%*
Female GU Cancer Other Than Ovary	1.3%	1.4%	1.4%*	1.5%*
High-Risk Bladder Cancer	1.4%	1.3%	1.2%*	1.2%*
Kidney Cancer	0.8%	0.9%	1.1%*	1.1%*
Liver Cancer	1.0%	1.0%	1.0%	1.1%
Malignant Melanoma	0.6%	0.6%	0.9%*	0.9%*
Low-Risk Bladder Cancer	0.7%	1.3%	0.7%	1.2%*
Central Nervous System (CNS) Tumor	0.8%	0.7%	0.7%*	0.7%*
Acute Leukemia	0.7%	0.6%	0.7%	0.7%*
Anal Cancer	0.3%	0.3%	0.3%	0.3%

Source: Episode analytic files, 2014–2017.

Notes: * Denotes a statistically significant difference from baseline estimates to intervention estimates at $p \leq 0.10$. Due to the precision of the values reported, some results that are statistically significantly different may appear to be identical; however, they are different when including more precision on the point estimate.

OCM: OCM intervention group; COMP: Comparison group.

Beneficiary Characteristics

The characteristics (i.e., gender, age, race/ethnicity, Medicaid dual status) of beneficiaries with attributed episodes changed very little from the baseline to the intervention period for both OCM and comparison episodes (see Appendix B).

Part D Chemotherapy Use

The proportion of episodes triggered by a Part D chemotherapy drug (i.e., prescribed oral therapy rather than infused chemotherapy) increased between the baseline and intervention periods for both OCM and

³⁰ The non-reconciliation eligible cancer bundle comprises a set of cancer types identified by CMS to be very rare with small samples sizes. As a result, episodes assigned with these cancer types are not eligible for CMS’s performance based payment, although are eligible to receive MEOS payments.

comparison episodes (see Appendix B). While there were underlying changes occurring in the availability and use of chemotherapy drugs, OCM practices were not appreciably different from comparisons in this dimension. This is important to continue monitoring as OCM and comparisons may differ in terms of substitution from Part B infused chemotherapy to oral Part D chemotherapy, or in the uptake of Part D novel therapies.

The proportion of OCM episodes triggered by a Part D chemotherapy drug increased slightly from 38.5 percent in the baseline period to 41.6 percent in the intervention period (see Appendix B). The proportion of comparison episodes triggered by a Part D chemotherapy drug increased similarly.

We examined Part D chemotherapy use for the subset of beneficiaries who were enrolled in Part D throughout all months of the episode (while alive).

- Part D chemotherapy drug use during episodes increased from 55.4 percent in the baseline period to 57.3 percent in the intervention period for OCM episodes.
- The proportion of comparison episodes with Part D chemotherapy drugs also increased, from 55.6 percent in the baseline period to 56.5 percent in the intervention period.

There was an increase in use of Part D chemotherapy for the majority of cancer bundles between baseline and intervention periods (**Exhibit 4**). The largest increases were for breast cancer episodes (nine percentage point increase) where treatment involves more than hormonal therapy only (driven by increasing use of palbociclib—a Part D medication—in this patient population), and for chronic leukemia episodes (eight percentage point increases). In contrast, Part D chemotherapy use decreased in both OCM and comparison episodes in kidney cancer, malignant melanoma, and high-risk prostate cancer. Decreases in use of Part D chemotherapy for these cancers is consistent with publicized changes in cancer treatment (e.g., increasing use of intravenous immunotherapies for treatment of kidney cancer and melanoma, substituting for Part D oral therapies).

Immunotherapy Use

As of PP1, there is no differential use of immunotherapy between OCM and comparison practices. Understanding immunotherapy use among OCM episodes relative to comparison episodes is important because OCM practices may be incentivized to use costly immunotherapies at different rates than their comparison counterparts.³¹ The National Cancer Institute defines immunotherapy as: “A type of therapy that uses substances to stimulate or suppress the immune system to help the body fight cancer, infection, and other diseases. Some types of immunotherapy only target certain cells of the immune system. Others affect the immune system in a general way. Types of immunotherapy include cytokines, vaccines, bacillus Calmette-Guerin (BCG), and some monoclonal antibodies.”³² In this report, the term “immunotherapy” generally refers to the new class of monoclonal antibody therapies that includes nivolumab and pembrolizumab, among other agents. These therapies are typically very expensive, sometimes exceeding \$100,000 in per-episode costs, which heavily influences the total episode cost of

³¹ Since immunotherapies were not widely available in the baseline period, it is difficult to assess changes in immunotherapy utilization within a DID framework. We therefore examine descriptive changes in immunotherapy use in this report.

³² National Cancer Institute. NCI dictionary of cancer terms [homepage on the internet]. Posted May 15, 2015. Available from <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/immunotherapy>.

care. Few immunotherapies were approved by the FDA during the OCM baseline period (i.e., before July 1, 2016), but the pace of FDA approvals is accelerating during the OCM intervention period. While OCM provides a novel therapies adjustment, it also incentivizes use of lower-cost treatments, which could impact adoption and use of immunotherapies. We therefore reviewed the availability and uptake of immunotherapies from the baseline period to intervention period, in the OCM and comparison groups.

Exhibit 4: Part D Chemotherapy Utilization among OCM and Comparison Episodes from Baseline to Intervention, by Cancer Bundle

Cancer Bundle	Baseline Period Episodes Initiating: (1/2/14-7/1/15)				Intervention Period Episodes Initiating: (7/1/16-1/1/17)			
	OCM N= 278,676		COMP N = 335,421		OCM N = 115,294		COMP N = 136,081	
	N	%	N	%	N	%	N	%
Hormonal Only Breast Cancer	82,407	100.0%	95,990	100.0%	34,656	100.0%	38,387	100.0%
Non-Hormonal Only Breast Cancer	27,855	45.4%	30,646	47.2%	11,155	54.6%*	12,173	55.5%*
Lung Cancer	24,118	22.5%	27,831	23.5%	9,931	19.0%*	11,526	20.9%*
Low-Risk Prostate Cancer	17,152	40.1%	29,651	38.0%	7,427	37.7%*	11,856	36.6%*
Lymphoma	17,138	16.3%	18,116	17.5%	6,695	20.7%*	7,110	22.3%*
Colorectal/Small Intestine Cancer	15,856	11.1%	18,269	11.8%	5,741	11.3%	6,601	11.4%
Multiple Myeloma	15,616	69.7%	17,355	71.2%	6,619	74.3%*	7,293	76.3%*
Non-Reconciliation Eligible Cancer	10,810	49.8%	14,881	49.8%	5,317	52.0%*	7,466	53.2%*
Chronic Leukemia	10,705	74.9%	12,549	76.6%	4,520	82.8%*	5,129	84.2%*
High-Risk Prostate Cancer	10,622	83.7%	13,681	84.2%	4,198	78.9%*	5,156	78.7%*
Pancreatic Cancer	5,657	6.2%	6,744	6.3%	2,258	5.5%	2,833	5.0%*
Ovarian Cancer	5,682	17.1%	7,152	18.6%	1,984	18.4%	2,646	22.6%*
Gastro/Esophageal Cancer	4,067	6.3%	4,717	8.1%	1,525	7.6%*	1,881	7.5%
Endocrine Tumor	3,441	19.2%	3,581	26.5%	1,599	21.1%	1,800	26.8%
Myelodysplastic Syndrome (MDS)	4,267	28.0%	4,315	31.2%	1,596	29.6%	1,643	30.9%
Head and Neck Cancer	3,558	6.7%	4,092	7.6%	1,429	7.9%	1,594	7.7%
Female GU Cancer Other Than Ovary	3,350	27.1%	4,519	26.1%	1,542	28.2%	2,017	28.1%*
High-Risk Bladder Cancer	3,159	12.1%	3,725	10.4%	1,227	8.1%*	1,410	10.9%
Kidney Cancer	2,577	80.5%	3,400	80.1%	1,272	62.5%*	1,477	63.3%*
Liver Cancer	2,762	34.4%	3,428	34.7%	1,171	34.5%	1,410	33.0%
Malignant Melanoma	1,723	38.8%	2,006	39.1%	902	23.2%*	1,132	21.5%*
Low-Risk Bladder Cancer	1,653	0.7%	3,534	1.0%	758	0.7%	1,348	1.0%
Central Nervous System (CNS) Tumor	1,955	10.4%	2,260	11.6%	743	11.2%	918	10.9%
Acute Leukemia	1,740	26.0%	2,062	27.2%	712	30.1%*	937	28.2%
Anal Cancer	806	5.3%	917	7%	317	7.9%	338	5.9%

Source: Episode analytic files, 2014–2017.

Notes: * Denotes a statistically significant difference from baseline estimates to intervention estimates at $p \leq 0.10$.

OCM: OCM intervention group; COMP: Comparison group.

Use of immunotherapies for treatment of specific cancers generally corresponded to the U.S. Food and Drug Administration (FDA) approval of drugs and indicated uses. In the baseline period, overall use of immunotherapies was less than one percent. The proportion of episodes with immunotherapy use increased 4.5 percentage points from the baseline period to the intervention period for both OCM and comparison practices (**Exhibit 5**). The cancer bundles with the largest statistically significant increase in immunotherapy use from the baseline to intervention period, were the following which had new immunotherapies approved after 2014 (e.g., checkpoint inhibitors such as pembrolizumab and nivolumab):

- Lung cancer: Immunotherapy use increased by 29 percentage points among both OCM and comparison episodes.
- Head and neck cancer: Immunotherapy use increased by 18 percentage points for OCM episodes and by 21 percentage points for comparison episodes.
- Kidney cancer: Immunotherapy use increased by 48 percentage points for OCM episodes and by 44 percentage points for comparison episodes.
- Malignant melanoma: Immunotherapy use increased by 28 percentage points for OCM episodes and 26 percentage points for comparison episodes. More than 80 percent of episodes for malignant melanoma involved immunotherapy use in the intervention period, for both groups.

The increase in immunotherapy use for these specific cancer bundles aligns with the timing of the FDA approval and indicated use³³ of the following immunotherapies:

- Pembrolizumab (approved August 2016 for head and neck cancer; approved October 2016 for lung cancer)
- Nivolumab (approved December 2014 for malignant melanoma; approved November 2015 for kidney cancer; approved November 2016 for head and neck cancer).

Low rates of immunotherapy use in other cancer bundles may reflect off-label use; or beneficiaries having a second cancer for which the immunotherapy was approved; or FDA approval of a drug near the end of a performance period, which may affect treatment patterns more in subsequent PPs.

The rapid increase in immunotherapy among episodes for kidney cancer and malignant melanoma aligns with the decrease in Part D chemotherapy utilization for those two cancer bundles, suggesting a substitution from Part D chemotherapies in the baseline period to Part B immunotherapies in the intervention period. Exploring this change further as more data accrues, will highlight whether the OCM incentives for use of lower-cost treatment impacts the adoption and use of immunotherapies.

³³ U.S. Food and Drug Administration. Hematology/oncology (cancer) approvals and safety notifications [homepage on the internet]. Last updated 02/27/2018. Available from <https://www.fda.gov/Drugs/InformationOnDrugs/ApprovedDrugs/ucm279174.htm>.

Exhibit 5: Immunotherapy Utilization among OCM and Comparison Episodes from Baseline to Intervention (PP1), by Cancer Bundle

Cancer Bundle	Baseline Period Episodes Initiating: (1/2/14-7/1/15)				Intervention Period Episodes Initiating: (7/1/16-1/1/17)			
	OCM N= 349,681		COMP N = 415,483		OCM N = 140,029		COMP N = 164,195	
	N	%	N	%	N	%	N	%
Hormonal Only Breast Cancer	82,658	0.0%	96,267	0.0%	34,769	0.0%	38,517	0.0%
Non-Hormonal Only Breast Cancer	37,055	0.0%	39,525	0.0%	14,109	0.2%*	15,149	0.4%*
Lung Cancer	33,578	0.7%	37,396	1.4%	13,300	30.5%*	15,066	30.0%*
Low-Risk Prostate Cancer	27,808	0.0%	46,651	0.0%	11,365	0.0%	17,742	0.0%
Lymphoma	24,587	0.0%	25,218	0.0%	9,122	0.7%*	9,393	0.8%*
Colorectal/Small Intestine Cancer	22,488	0.0%	25,111	0.0%	7,843	0.6%*	8,815	0.6%*
Multiple Myeloma	18,899	0.0%	20,774	0.0%	7,837	0.3%*	8,511	0.2%*
Non-Reconciliation Eligible Cancer	13,525	0.4%	18,495	0.9%	6,425	7.9%*	8,959	7.6%*
Chronic Leukemia	12,410	0.1%	14,344	0.1%	4,965	0.2%*	5,540	0.2%*
High-Risk Prostate Cancer	12,529	0.0%	15,745	0.1%	4,899	0.4%*	5,934	0.8%*
Pancreatic Cancer	8,085	0.1%	9,339	0.0%	3,135	0.3%*	3,748	0.3%*
Ovarian Cancer	7,746	0.0%	9,399	0.0%	2,613	0.7%*	3,346	0.8%*
Gastro/Esophageal Cancer	5,922	0.1%	6,627	0.1%	2,144	1.1%*	2,570	1.5%*
Endocrine Tumor	4,611	0.1%	4,677	0.0%	2,124	1.2%*	2,305	1.0%*
Myelodysplastic Syndrome (MDS)	6,050	0.0%	5,830	0.0%	2,122	0.1%*	2,119	0.2%*
Head and Neck Cancer	5,184	0.8%	5,777	0.9%	1,994	18.5%*	2,176	21.6%*
Female GU Cancer Other Than Ovary	4,392	0.1%	5,792	0.2%	1,950	0.7%*	2,525	1.7%*
High-Risk Bladder Cancer	4,810	0.0%	5,467	0.1%	1,731	3.5%*	2,009	3.5%*
Kidney Cancer	2,899	0.4%	3,777	0.5%	1,539	48.3%*	1,725	44.1%*
Liver Cancer	3,607	0.1%	4,343	0.1%	1,451	1.4%*	1,781	2.1%*
Malignant Melanoma	2,235	53.3%	2,642	56.4%	1,247	81.0%*	1,509	82.4%*
Low-Risk Bladder Cancer	2,445	0.0%	5,368	0.0%	1,037	0.0%	1,992	0.0%
Central Nervous System (CNS) Tumor	2,669	0.2%	3,032	0.1%	965	1.0%*	1,125	0.9%*
Acute Leukemia	2,391	0.0%	2,700	0.1%	935	0.3%*	1,174	0.1%
Anal Cancer	1,098	0.5%	1,187	0.8%	408	2.7%*	465	3.4%*
TOTAL	349,681	0.5%	415,483	0.6%	140,029	5.1%*	164,195	5.0%*

Source: Episode analytic files, 2014–2017.

Notes: * Denotes a statistically significant difference from baseline estimates to intervention estimates at $p \leq 0.10$.

OCM: OCM intervention group; COMP: Comparison group.

Novel Therapy Use

As with immunotherapies, other novel therapies tend to be more expensive than the drugs they replace, and this can materially impact total episode costs, as well as utilization and patient outcomes. Per OCM Model rules, a drug is considered a novel therapy for an indicated cancer type for two years from the date of FDA approval. We examined the use of novel therapies among OCM and comparison episodes in the intervention period,³⁴ by cancer bundle (**Exhibit 6**). This analysis includes use of immunotherapies meeting the novel therapy designation.

- The proportion of OCM episodes with novel therapy use (12.4 percent) was higher and statistically significantly different from the proportion of comparison episodes with novel therapy use (12.0 percent), although the magnitude of the difference is small.
- Use of novel therapies differed between OCM and comparison episodes for some cancer bundles:
 - Novel therapy use was more common among OCM episodes than comparison episodes for kidney cancer, chronic leukemia, and non-reconciliation-eligible cancers.
 - Novel therapy use was more common among comparison episodes than OCM episodes for pancreatic cancer, head and neck cancer, and liver cancer.

With only one PP of data, it is too early to determine if these differential patterns of novel therapy use between OCM and comparison episodes will persist, and we will continue to monitor use of novel therapies to evaluate whether OCM is influencing their use.

³⁴ CMS did not designate novel therapy status during the baseline period. Therefore, the results in this report focus on novel therapy use in the intervention period only.

Exhibit 6: Novel Therapy Utilization among OCM and Comparison Episodes in the Intervention Period (PP1)

Cancer Bundle	Intervention Period Episodes Initiating: (7/1/16-1/1/17)			
	OCM N = 140,029		COMP N = 164,195	
	N	%	N	%
Hormonal Only Breast Cancer	34,769	0.0%	38,517	0.0%
Non-Hormonal Only Breast Cancer	14,109	16.9%	15,149	17.4%
Lung Cancer	13,300	34.0%	15,066	34.7%
Low-Risk Prostate Cancer	11,365	0.0%	17,742	0.0%
Lymphoma	9,122	2.2%	9,393	2.3%
Colorectal/Small Intestine Cancer	7,843	4.4%	8,815	4.3%
Multiple Myeloma	7,837	63.3%	8,511	64.3%
Non-Reconciliation Eligible Cancer	6,425	6.4%	8,959	5.6%*
Chronic Leukemia	4,965	3.6%	5,540	2.9%*
High-Risk Prostate Cancer	4,899	0.0%	5,934	0.0%
Pancreatic Cancer	3,135	1.9%	3,748	3.2%*
Ovarian Cancer	2,613	30.2%	3,346	30.5%
Gastro/Esophageal Cancer	2,144	12.5%	2,570	11.9%
Endocrine Tumor	2,124	28.0%	2,305	26.2%
Myelodysplastic Syndrome (MDS)	2,122	0.0%	2,119	0.0%
Head and Neck Cancer	1,994	18.4%	2,176	21.3%*
Female GU Cancer Other Than Ovary	1,950	12.3%	2,525	10.8%
High-Risk Bladder Cancer	1,731	3.1%	2,009	3.1%
Kidney Cancer	1,539	54.1%	1,725	48.9%*
Liver Cancer	1,451	0.1%	1,781	0.6%*
Malignant Melanoma	1,247	88.0%	1,509	89.5%
Low-Risk Bladder Cancer	1,037	0.0%	1,992	0.0%
Central Nervous System (CNS) Tumor	965	0.0%	1,125	0.0%
Acute Leukemia	935	0.0%	1,174	0.0%
Anal Cancer	408	0.0%	465	0.0%
TOTAL	140,029	12.4%	164,195	12.0%*

Source: Episode analytic files, 2014–2017.

Notes: * Denotes a statistically significant difference from OCM episode point estimates at $p \leq 0.10$.

OCM: OCM intervention group; COMP: Comparison group.

3.1.2 Changes in Practice Characteristics from Baseline to Intervention

Patient characteristics and care delivery can vary across health care settings due to practice attributes such as size, specialty mix of providers, and affiliations with health systems. We examined how OCM and comparison practices changed along these dimensions between the baseline and intervention periods, because structural changes could impact care delivery, patient experiences, and other outcomes.

Practice Size

We used the number of chemotherapy episodes attributed to the practice or TIN in each PP quarter as a measure of practice size that is directly relevant to providing oncology services. The number of episodes is a conservative reflection of a practice’s actual volume of Medicare FFS cancer patients, because an episode is only attributed to a practice if the beneficiary receives the plurality of his/her cancer E&M services at the practice.

On average, the number of attributed episodes per practice increased about 20 percent for both OCM and comparison practices, between the baseline period and the intervention period, as seen in **Exhibit 7**. It will be important to monitor whether episode volume remains higher, on average, as the Model progresses, and whether this differs for the OCM and comparisons, because practice size may influence many aspects of care delivery (e.g., electronic health record selection, new staff positions, stability of performance metrics).

Another measure of size is the number of NPIs providing cancer services. Based on this measure, we again find that OCM and comparison practices increased in size between the baseline and intervention periods, comparing the first six months of the baseline with the first PP of the intervention period. On average, the number of NPIs per practice increased from 35 to 41 for OCM practices and increased from 19 to 23 NPIs for comparison practices (**Exhibit 7**). The median number of NPIs did not increase at the same rate, suggesting that data are skewed by a few practices with very large increases over time in the number of NPIs serving cancer patients.

Exhibit 7: Practice Size among OCM and Comparison Practices from Baseline to Intervention (PP1)

Statistic	Baseline Period Episodes Initiating: (1/2/14-7/1/14)		Intervention Period Episodes Initiating: (7/1/16-1/1/17)	
	OCM N = 190	COMP N = 539	OCM N = 190	COMP N = 527
Number of Episodes				
Median	198	91	215	98
Mean	337	140	368	156
Std Dev	679	337	714	368
Number of NPIs				
Median	18	8	22	10
Mean	35	19	41	23*
Std Dev	51	35	60	41

Source: Practice analytic file, 2014–2017.

Notes: * Denotes a statistically significant difference from baseline to intervention estimates at $p \leq 0.10$.

OCM: OCM intervention group; COMP: Comparison group.

In their 2017 PTPs, 90 percent of practices reported using revenue from OCM to hire additional staff. This did not vary significantly by practice size, ownership, academic affiliation, or between 2016 and 2017. During Year One case studies, over half of practices reported using MEOS payments to hire additional staff, such as NPs, patient navigators, care coordinators, social workers, financial counselors, or quality leads.

Practice Specialty Mix

We examined provider specialty (oncologist, urologist, NP/PA) of the NPIs delivering cancer services and assessed whether the increase, and practices' specialty/staffing mix, changed over time. Although the number of physician oncologist NPIs³⁵ increased, the proportion of NPIs who are oncologists decreased by two percentage points for both OCM and comparison practices from the baseline period to PP1. This decline was offset by an increase in the proportion of NP/PAs, which increased 3.5 percentage points among OCM practices and about 1.5 percentage points among comparison practices (**Exhibit 8**).

Exhibit 8: Practice Specialty Mix among OCM and Comparison Practices from Baseline to Intervention (PP1)

	Baseline Period Episodes Initiating: (1/2/14-7/1/14)		Intervention Period Episodes Initiating: (7/1/16-1/1/17)	
	OCM N = 190	COMP N = 539	OCM N = 190	COMP N = 527
Proportion of Specialties Per Practices				
Oncology (all sub-specialties)	64.3%	62.9%	62.2%	61.1%
NP/PA	11.1%	9.4%	14.6%*	10.8%*
Urology	4.6%	6.5%	4.5%	6.1%
Proportion of Oncology Specialties Per Practice				
Hematology/Oncology, Medical Oncology	82.3%	84.0%	82.5%	83.3%
Surgical Oncology	2.3%	1.9%	2.6%	2.0%
Radiation Oncology	11.1%	10.6%	11.0%	11.4%
Gynecologic Oncology	4.4%	3.5%	3.9%	3.3%
Proportion of Oncology-Specialty Practices				
Oncology-Specialty†	34.7%	44.0%	34.5%	42.9%

Source: Practice analytic file, 2014–2017.

Notes: * Denotes a statistically significant difference from baseline estimates to intervention estimates at $p \leq 0.10$.

† Denotes practices that contain only oncology-specialty physicians and/or NPs/PAs, as opposed to multi-specialty groups.

OCM: OCM intervention group; COMP: Comparison group.

There was no change in sub-specialties (e.g., radiation oncology, surgical oncology) among OCM and comparison practices from the baseline to intervention period. In addition, the proportion of practices that

³⁵ We coded NPIs as oncologists if they specialized in hematology/oncology or medical oncology, surgical oncology, radiation oncology, or gynecologic oncology.

were oncology only (not multi-specialty)³⁶ changed little for OCM and comparison practices, between the baseline and intervention periods.

Findings from Year One case studies support the results above that indicate a small increase in NPs and/or PAs as a proportion of all NPIs in OCM practices. Five of the 12 practices we visited in Year One told us they had hired, or were planning to hire, additional NP/PA practitioners to support OCM care process redesign initiatives.

Practice Structure and Affiliation

The proportion of OCM and comparison practices owned by a hospital or affiliated with a health system increased by more than six percentage points for the OCM practices (43.4 percent to 50.0 percent), and five percentage points for the comparison practices (54.6 percent to 59.8 percent). The latter change for comparison practices between baseline and PP1 was statistically significant.³⁷ The increase in health system affiliation/ownership over time aligns with the broader national trend toward greater vertical integration of hospitals and oncology physician practices in recent years.³⁸

In summary, although there were some changes in cancer mix, Part D chemotherapy use, novel therapy use, and practice size and affiliation since the baseline period, it is too early to know whether these changes will persist as the Model progresses, or what impact they may have. Furthermore, some of the observed changes may be influenced by the OCM episode algorithm during PP1. We will continue monitoring these and other practice and episode characteristics as the Model progresses.

3.1.3 Practices that Withdrew During Year One

During the first Model year, six of the 196 practices that signed participation agreements voluntarily exited OCM, and three others merged together. We contacted the six practices requesting a brief conversation about their reasons for terminating. Two practices did not respond to our requests for an interview. Of these, one terminated mid-year and the other quite late in the year. We interviewed the remaining four practices that exited OCM.³⁹ Their primary reasons for termination included:

- Eligibility requirements. One practice did not understand until after OCM launched that having an oncologist overseeing chemotherapy treatment for patients at a critical access hospital (CAH) would render it ineligible to participate in OCM.⁴⁰
- Resource constraints. One small practice (a single medical oncologist) did not have adequate staff or budget to hire additional staff to track patients, upload data, and perform financial analyses.

³⁶ We classified a practice or TIN as oncology-only specialty if all of its NPIs have an oncology specialty or a NP/PA specialty.

³⁷ Practice-level affiliation with a health system and hospital ownership were constructed using practice site-level information from the SK&A data. SK&A extracts from August 2016 and 2017 were used for the intervention period, while a historical extract from July 2015 was used to construct affiliations for the baseline period. Note that the August 2016 SK&A extract was used for the baseline period reported in the “First Annual Report from the Oncology Care Model Evaluation: Baseline Period.”

³⁸ Alpert A, Hsi H, Jacobson M. Evaluating the role of payment policy in driving vertical integration in the oncology market. *Health Affairs*. 2017;36(4):680-688.

³⁹ The content of outreach emails and the interview guide were both approved by the Institutional Review Board.

⁴⁰ CAHs have a separate cost-report reconciliation that does not align with OCM’s payment methodology.

- Closure. One practice sold all its assets and transferred its employees to a health system which intends to “use the practice as a springboard for the development of an extensive oncology service line” across its nine hospitals.

None of the withdrawn practices expressed concerns that OCM could have unintended consequences deleterious to patient care, and none reported resistance among oncologists. All three mentioned beneficial aspects of their abbreviated tenure in OCM:

- One practice’s sole physician increased his use of the EHR, recording more information in structured fields, and discussed treatment topics more thoroughly with patients.
- A representative from another practice offered that CMS webinars provided the opportunity for “a lot of learning and relationship building. It was very beneficial to hear from others about having their EHR system accommodate the OCM.”
- Feedback reports comparing a practice to other OCM participants were “surprising” and will be used to guide future practice activities.

3.2 Program Effectiveness: Utilization

Summary of Findings on Program Effectiveness: Utilization

In this early phase of OCM, all hospital utilization measures declined more for OCM practices than for comparison practices, and two of the declines were statistically significant: ICU stays and ED visits. This consistent pattern suggests a potential early impact of OCM on use of hospital services.

- Participating practices report using strategies such as extended hours and patient navigation in the attempt to reduce hospitalizations and emergency department visits.
- ICU admissions during the six month episode period decreased by 7 admissions per 1,000 episodes, and ED visits decreased by 15 visits per 1,000 among OCM episodes relative to comparison episodes.

OCM requires participating practices to implement enhanced services that are intended to improve access, communication, patient education, and care coordination. These improvements are expected to improve quality of care, reduce unnecessary care, such as the duplication of tests, and minimize treatment complications that can result in potentially avoidable ED visits and hospitalizations. In this chapter, we present strategies (from case studies) that practices are employing to reduce utilization, and the estimated DID impact of OCM on utilization for episodes that began during PP1. Utilization measures include hospital inpatient hospitalizations, ICU admissions, and ED visits, as well as use of chemotherapy, other drugs, post-acute care, imaging, and other Part B services. Information in this chapter comes from OCM practices’ annual PTPs, case studies, and Medicare claims. All claims-based results are at the episode level and are based on DID analyses, which compare the early changes for OCM episodes with those of comparison episodes, between the baseline and intervention periods. For more information about methods, see Appendix A.

3.2.1 Use of Hospital-Based Services

OCM practices are working to identify improvements that will reduce inappropriate or potentially avoidable use of services, especially high-cost services such as ED visits, inpatient hospitalization, and ICU admissions.

Strategies to Reduce Emergency Department Use and Inpatient Admissions

The practices we visited in Year One for case studies implemented several specific strategies to manage patient symptoms in a timely manner and reduce ED use and inpatient admissions, as summarized in Exhibit 9.

Exhibit 9: Strategies to Address Patients' Urgent Care Needs and Reduce ED Use, Based on 12 Year One Case Studies

Strategy	Number of Practices Currently Employing Strategy*	Challenges
Extended hours on nights or weekends for supportive therapy	5	Three additional practices tried this, but discontinued the extended hours due to low use by patients.
Proactive outreach to high-risk patients	6	
Same-day and walk-in appointments	8	Three other hospital-based practices lacked the capacity for same-day appointments, either because they did not have enough space or because they did not control infusion center capacity or scheduling.
Arrangement with nearby hospital outpatient department for same-day supportive therapy on weekends	3 (1 only by appointment)	Hospital outpatient departments are generally not open for supportive therapy at night.
Arrangement with nearby urgent care center for same-day/same-night supportive therapy (e.g., hydration)	2	

Note: * Practices may implement multiple strategies summarized in this table.

During Year One case studies, many interviewees noted an early focus on improving symptom management and access for supportive therapy, particularly for high-risk patients. Many practices with this focus tried to identify the subset of OCM patients at high risk using factors such as diagnosis, highly toxic treatment, comorbidities, social circumstances (e.g., lacking social support), and patient demographics. Having identified patients at special risk, practices used proactive outreach and more frequent contacts, to recognize and address emerging problems. For example, nurse navigators may call these patients following each chemotherapy infusion, to address symptom management issues that could lead to an ED visit. In some practices, this process of identifying high risk patients and making more contacts with them is systematized via sophisticated algorithms in the EHR and automatic call scheduling. In other practices identification of high risk patients is more ad hoc, with nurses and navigators keeping their own lists of patients who need extra attention. For more information, please see Section 3.6.3.

Another area of improvement several practices considered, but few had yet implemented, was expanding urgent care services and clinic hours. Several described challenges in expanding urgent care services. For example, the four hospital-based practices we visited told us that they are space-constrained and at capacity; they cannot offer same-day urgent care visits in their current space and have no ability to expand. One hospital-based practice's internal data indicate that most cancer patients' ED visits take place during weekday hours, not evenings or weekends, but they told us that their clinics are completely filled and same-day visits are not possible. In addition, hospital-based practices often do not control scheduling or staffing of infusion centers. Clinicians in such practices told us that they have no choice but to send patients with urgent needs to the ED. We observed somewhat more flexibility among independent practices to expand space, alter schedules, and shift staff assignments to extend clinic hours and accommodate more patients for urgent care needs. In their 2017 PTPs, most OCM practices (95 percent)

reported using same-day appointments as a strategy to better address patients' urgent care needs, but fewer than 40 percent of practices offered evening and weekend clinic hours for supportive therapy, consistent with findings from case studies.

Estimated OCM Impact on Hospital Inpatient Utilization

Inpatient Hospitalizations

Nationally, the number of inpatient hospitalizations among Medicare beneficiaries declined between 2012 and 2015.⁴¹ This trend was also evident in our OCM and comparison groups. From the baseline period to the intervention period, the proportion of episodes with an inpatient stay, and the average number of inpatient hospitalizations per episode, decreased for both OCM and comparison episodes. In addition, the proportion of episodes with a 30-day readmission and the average number of readmissions per episode decreased for both OCM and comparison episodes.

Findings from the DID impact analyses include:

- As shown in **Exhibit 10**, while impact estimates were negative, OCM had no statistically significant impact on the occurrence of inpatient hospitalizations, the number of inpatient hospitalizations, the number of inpatient days per episode, or 30-day readmissions per episode.
- Relative to comparison episodes, the number of ICU admissions decreased significantly by 0.007 admissions ($p \leq 0.05$) for OCM episodes. This represents a reduction of approximately 7 ICU admissions per 1,000 episodes, and a 5.3 percent change from the average OCM baseline ICU admissions per episode.
- The direction and magnitude of the DID impact estimates reported for hospital inpatient utilization are aligned with corresponding cost results reported in Section 3.3.1, below. We estimate that relative albeit non-statistically significant reductions in inpatient utilization among OCM episodes led to lower inpatient costs, even in this very early phase of OCM.

⁴¹ US Department of Health and Human Services, Centers for Medicare and Medicaid Services, Office of Enterprise Data and Analytics. 2016 CMS statistics. CMS Pub. No. 03513, March 2017. Available from https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/CMS-Statistics-Reference-Booklet/Downloads/2016_CMS_Stats.pdf.

Exhibit 10: Estimated OCM Impact for Hospital Inpatient Utilization per Episode, PP1

Measure	# of Episodes		OCM		COMP		Impact Estimates			
	OCM	COMP	Baseline Mean	Int. Mean	Baseline Mean	Int. Mean	DID	90% LCL	90% UCL	Percent Change
Occurrence of IP Stay	489,710	579,678	27.3%	26.2%	25.7%	24.8%	-0.2%	-0.6%	0.2%	-0.8%
# of IP Hospitalizations	489,710	579,678	0.428	0.408	0.398	0.382	-0.004	-0.012	0.004	-0.9%
# of ICU Admissions	489,710	579,678	0.123	0.118	0.116	0.118	-0.007**	-0.011	-0.002	-5.3%
# of IP Days	132,708	147,179	8.574	8.368	8.459	8.285	-0.032	-0.168	0.103	-0.4%
Occurrence of 30-Day Readmission	126,476	140,010	22.3%	21.9%	21.6%	21.4%	-0.2%	-0.8%	0.3%	-1.0%
# of All 30-Day Readmissions	489,710	579,678	0.103	0.097	0.093	0.089	-0.003	-0.006	0.001	-2.8%
Occurrence of 30-Day Unplanned Readmission	126,476	140,010	20.9%	20.3%	20.2%	19.9%	-0.3%	-0.8%	0.3%	-1.3%
# of 30-Day Unplanned Readmissions	489,710	579,678	0.093	0.087	0.084	0.081	-0.003	-0.006	0.001	-3.0%

Source: Episode analytic file, 2014–2017.

Notes: All measures were calculated at the episode level. Means and DID impact estimates are regression-adjusted. DID impact estimates for “occurrence” outcomes represent a percentage point change. LCL and UCL refer to lower confidence limit and upper confidence limit, respectively. Percent change was calculated by dividing the DID estimate by the OCM baseline mean.

OCM: OCM intervention group; COMP: Comparison group.

Int.: Intervention period

*p≤0.10, **p≤0.05, ***p≤0.01

Inpatient Hospitalizations by Cancer Subgroup

We evaluated the number of inpatient hospitalizations per episode for the 10 most prevalent cancer bundles and for low- and high-risk cancer bundles⁴² to assess whether findings by subgroups differ from overall findings. There was no statistically significant impact on the number of inpatient hospitalizations per episode for any subgroup (see Appendix C for these results). Small sample sizes at this point may limit our ability to detect significant changes.

Estimated OCM Impact on Use of Emergency Departments

A primary goal of OCM programmatic requirements and incentives is to reduce the incidence of adverse events and treatment complications that result in costly hospital utilization, much of which originates in the ED.⁴³ OCM practices we visited in Year One all told us that reducing ED use was an important early focus. In their 2017 PTPs, many practices reported offering same-day appointments (95 percent), extending hours into the evening (38 percent) or during the weekend (36 percent), stratifying patients into actionable risk cohorts (45 percent), and using OCM revenue to hire additional staff (90 percent).

ED Visits

The DID impact estimated in **Exhibit 11** shows that the number of ED visits decreased significantly by 0.015 visits ($p \leq 0.01$) among OCM episodes relative to comparisons, representing a reduction of approximately 15 ED visits per 1,000 episodes and a 2.3 percent change from the average OCM baseline value. Much of this decrease was due to a decline in ED visits that resulted in an inpatient stay, which decreased by 0.011 visits ($p \leq 0.01$) among OCM episodes relative to comparison episodes, representing a reduction of approximately 11 visits per 1,000 episodes and a 3.7 percent change from the OCM baseline value. This finding is consistent with the non-significant decline in inpatient hospitalizations reported above. There was no statistically significant change in ED visits that did not result in an inpatient stay. Section 3.6 on Supportive Care examines ED visits and hospitalizations specifically related to chemotherapy and its side effects.

ED Visits by Cancer Subgroup

We estimated the impact of OCM on the number of ED visits resulting in an inpatient stay, and the number of ED visits not resulting in an inpatient stay, for the most prevalent cancer bundles and for low- and high-risk cancer bundles (see Appendix C). For most cancer subgroups, there was no statistically significant impact of OCM, but several statistically significant findings did emerge, including:

- For a number of high-cost cancer bundles (lung cancer, colorectal cancer, lymphoma and multiple myeloma), the DID impact estimates indicate a decrease in ED visits resulting in an inpatient stay among OCM episodes relative to comparison episodes. This was because these ED visits, on average, declined for OCM episodes, but rose for comparison episodes.

⁴² Low-risk cancer bundles were composed of breast cancer episodes using only hormonal therapies and of prostate and bladder cancer episodes using only low-risk chemotherapy regimens. Episodes in the remaining 22 cancer bundles were combined into the high-risk cancer bundle subgroup.

⁴³ Gonzalez Morganti, K., Bauhoff, S., Blanchard, J. C., et al. (2013). The Evolving Role of Emergency Departments in the United States. Santa Monica, CA: RAND Corporation. https://www.rand.org/pubs/research_reports/RR280.html.

- These declines in ED utilization may be a result of specific changes in care delivery, or signal targeted efforts by OCM practices to reduce utilization within high cost cancer bundles. We will continue to monitor these patterns in use within cancer bundles.

3.2.2 Use of Post-Acute and Outpatient Services

OCM promotes efficient use of health care services. One way this could be operationalized by the OCM practices is by optimizing post-acute and outpatient services, and care coordination. This section explores the extent to which there is an impact of OCM on utilization of several post-acute and outpatient services, including skilled nursing, home health, cancer-related E&M services, imaging, radiation, and outpatient therapy services.

Estimated OCM Impact on Post-Acute Services

None of the 12 practices we visited in Year One mentioned an explicit focus on opportunities to standardize or reduce post-acute care. In their 2017 PTPs, nearly all OCM practices reported providing and/or referring to hospice services (99 percent of OCM practices) and coordinating care with home health agencies (95 percent). Many practices also reported communicating with other care settings, including post-acute care: 73 percent of practices reported using structured communications (such as forms or standard reports) to communicate across care settings, 41 percent reported sharing data with clinical stakeholders outside the practice in an effort to improve care and patient experiences, and reduce cost; and 30 percent reported instituting written agreements with care partners.

Exhibit 11: Estimated OCM Impact for Emergency Department Utilization per Episode, PP1

Measure	# of Episodes		OCM		COMP		Impact Estimates			
	OCM	COMP	Baseline Mean	Int. Mean	Baseline Mean	Int. Mean	DID	90% LCL	90% UCL	Percent Change
Occurrence of ED Visit Not Resulting in IP Stay	489,710	579,678	23.2%	23.7%	23.8%	24.4%	-0.1%	-0.5%	0.2%	-0.5%
# of ED Visits	489,710	579,678	0.658	0.657	0.643	0.657	-0.015***	-0.024	-0.006	-2.3%
# of ED Visits Not Resulting in IP Stay	489,710	579,678	0.352	0.361	0.365	0.376	-0.002	-0.009	0.005	-0.6%
# of ED Visits Resulting in IP Stay	489,710	579,678	0.304	0.295	0.277	0.279	-0.011***	-0.018	-0.005	-3.7%

Source: Episode analytic file, 2014–2017.

Notes: All measures were calculated at the episode level. Means and DID impact estimates are regression-adjusted. DID impact estimates for “occurrence” outcomes represent a percentage point change. LCL and UCL refer to lower confidence limit and upper confidence limit, respectively. Percent change was calculated by dividing the DID estimate by the OCM baseline mean.

OCM: OCM intervention group; COMP: Comparison group.

Int.: Intervention period

*p≤0.10, **p≤0.05, ***p≤0.01

Skilled Nursing Facility (SNF) Utilization

There was a general decline in SNF use from 2010 to 2015 among all Medicare beneficiaries.⁴⁴ While average per episode utilization of skilled nursing services declined from the baseline period to the intervention period for both OCM and comparison episodes, DID estimates were not statistically significant, indicating no impact of OCM for episodes in PP1 (see Appendix C).

Home Health Agency (HHA) Utilization

Average HHA utilization declined from the baseline period to the intervention period for both OCM and comparison episodes, a trend that was consistent with HHA utilization among all Medicare beneficiaries from 2010 to 2015.⁴⁵ There was no DID impact of OCM on either HHA utilization measure, for episodes in PP1 (see Appendix C).

Estimated OCM Impact on Part B Outpatient Services

Cancer-Related E&M Service Utilization

Improved access to appropriate and timely care in the outpatient setting including doctor's offices, such as E&M services and other contact between patients and their care team (e.g., remote monitoring, telehealth, telephone calls, email communication), may improve care continuity and patient care experiences.

Improved access may manifest as increased cancer E&M services per episode, if practices emphasize in-person services, or as decreased E&M services if telephone and other communication replaces some in-person services. It is also possible that there will be no change in outpatient E&M services if increased remote/telephonic contact (which generates no claims) enhances, but does not replace, in-person services. There may also be unintended consequences of OCM if practices increase visits for breast cancer patients on long-term hormonal therapy in order to trigger more episodes.

There was no significant OCM impact on the number of cancer E&M services in the first PP. Between the baseline and intervention periods, there were similar downward trends in the use of cancer E&M services for both OCM and comparison episodes, which decreased 5.1 percent among OCM episodes between the baseline period and intervention period, and 4.2 percent among comparison episodes. See Appendix C for results.

⁴⁴ US Department of Health and Human Services, Centers for Medicare and Medicaid Services, Office of Enterprise Data and Analytics. 2016 CMS statistics. CMS Pub. No. 03513, March 2017. Available from https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/CMS-Statistics-Reference-Booklet/Downloads/2016_CMS_Stats.pdf.

⁴⁵ US Department of Health and Human Services, Centers for Medicare and Medicaid Services, Office of Enterprise Data and Analytics. 2016 CMS statistics. CMS Pub. No. 03513, March 2017. Available from https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/CMS-Statistics-Reference-Booklet/Downloads/2016_CMS_Stats.pdf.

Use of Part B Imaging Services

Improved care coordination and communication among all providers involved in a patient's care could improve efficient use of services, such as reducing the number of duplicate images (e.g., x-rays), reducing the frequency of routine imaging, or using lower-cost images that are reasonable substitutes for high-cost images.

The majority of both OCM and comparison episodes (86 to 88 percent) included at least one imaging service (advanced, standard, or other) in the baseline and intervention periods. DID analysis shows no OCM impact on the occurrence or number of standard/other or advanced imaging services (see Appendix C). The average number of imaging services (all types) per episode declined by nearly 0.4 services from the baseline period to PP1 (400 services per 1,000 episodes), for both OCM and comparison episodes. This change was entirely due to a reduction in the number of standard and other imaging services, while the number of advanced imaging services did not change.

Although these results indicate no statistically significant OCM impact thus far in use of imaging services among OCM episodes relative to comparison episodes, five of the 12 practices we visited in Year One told us that OCM spurred them to consider strategies to reduce imaging and related costs. These strategies included monitoring oncologists' ordering patterns, altering timing of imaging in treatment regimens, and reviewing costs of freestanding imaging centers to which they refer patients. The changes they described may take more time to become evident in claims-based measures. For example, a health system-owned practice told us that historically, images were ordered at each visit (each cycle) for many patients, but they now encourage oncologists to order images only when the results could affect a patient's treatment plan, which they expect will reduce the frequency of imaging. An independent practice described difficulty obtaining patients' comprehensive records from other providers, resulting in redundant imaging; they anticipate that better EHR interoperability in the future may reduce the number of redundant tests. Two independent practices refer their patients to external/freestanding imaging centers that they know to be high-cost. One of these practices is opening its own imaging center on site and plans to charge less than competitors, but the other will continue to use the preferred freestanding imaging center which they feel is exceptionally high quality.

Use of Radiation Therapy Services

Improved communication among clinicians, and adherence to national clinical guidelines, may also lead to more-appropriate use of radiation therapy services. For example, short-course radiation treatment is appropriate for some breast cancer patients.⁴⁶ The number of radiation services per episode decreased by 14.5 percent among OCM episodes from the baseline period to the intervention period, and by 14.0 percent among comparison episodes (see Appendix C).⁴⁷ Despite these changes in utilization, our DID analyses found no impact on the number of radiation therapy services among OCM episodes. As reported in Section 3.3.1 below, radiation therapy costs per episode also decreased between the baseline and intervention periods, for both OCM and comparison episodes.

⁴⁶ NCCN Guideline for radiation treatment in breast cancer available at: <https://www.tri-kobe.org/nccn/guideline/breast/english/breast.pdf>, accessed on March 16, 2018.

⁴⁷ The occurrence of radiation therapy was also evaluated, but baseline trends for OCM and comparison episodes were not statistically parallel. Results are omitted from the report as the assumptions for the DID analysis were not met.

Use of Outpatient Rehabilitation Therapy Services

The use of outpatient rehabilitation services⁴⁸ increased from the baseline period to the intervention period for both OCM and comparison episodes, but the DID impact estimates indicate no significant differences between OCM and comparison episodes (Appendix C).

3.2.3 Chemotherapy and Other Drug Utilization

We examined chemotherapy and other drug utilization because OCM may, over time, affect the types of chemotherapy used (oral or infused), or the settings in which chemotherapy is delivered (in-office, in-hospital, at home). Further, OCM may influence a practice's adherence to national clinical guidelines, use of supportive care drugs, and efforts to improve patient adherence to prescribed oral treatments. This section presents information about the impact of OCM on Part B and Part D drug use and services. We remind the reader that for OCM, chemotherapy includes cytotoxic treatment, hormonal therapy, and immunotherapy.

As reported in Section 3.1, the unadjusted proportion of episodes triggered by Part D chemotherapy and using Part D chemotherapy⁴⁹ increased for both OCM and comparison episodes from the baseline period to the intervention period. Part D (oral) chemotherapy appears to be increasing in importance, in cancer treatment. The risk-adjusted proportion of episodes that included any Part D chemotherapy drug also increased for both OCM and comparison episodes, as shown in **Exhibit 12**. While reliance on Part D chemotherapy increased over time, for both intervention and comparison episodes, OCM had no estimated DID impact on the occurrence of Part D chemotherapy, the number of Part D 30-day equivalent prescription fills per episode, the number of Part D fills per episode, or the number Part B drug services.⁵⁰ Based on the first PP, it appears that OCM is not impeding adoption of oral chemotherapies, or having any corresponding impact on the volume of Part B services. In future reports, we will explore utilization and cost of Part B and Part D chemotherapies further, to identify any emerging trends.

⁴⁸ Use of outpatient rehabilitation services is measured as the proportion of episodes with at least one outpatient therapy service, and also as the number of outpatient therapy services per episode.

⁴⁹ The proportion of episodes triggered by Part D chemotherapy drugs (i.e., prescribed oral therapy rather than infused chemotherapy) or proportion of episodes using Part D chemotherapy (i.e., Part D prescription drug event, or PDE, filled during the episode) is limited to episodes for beneficiaries enrolled in Part D.

⁵⁰ The number of Part B chemotherapy services was evaluated, but omitted from this report because trends in the two groups were statistically different in the baseline period and the parallel trend assumption for the DID analyses was not met.

Exhibit 12: Estimated OCM Impact for Drug Utilization per Episode, PP1

Measure	# of Episodes		OCM		COMP		Impact Estimates			
	OCM	COMP	Baseline Mean	Int. Mean	Baseline Mean	Int. Mean	DID	90% LCL	90% UCL	Percent Change
Part D Drugs										
Occurrence of Part D Chemo Use	393,970	471,502	55.4%	56.7%	55.7%	56.8%	0.1%	-0.3%	0.5%	0.3%
# of Part D Fills	393,970	471,502	23.581	23.098	23.400	22.981	-0.063	-0.212	0.086	-0.3%
# of Part D 30-Day Equivalent	393,970	471,502	29.279	30.169	29.365	30.329	-0.074	-0.229	0.081	-0.3%
Part B Drugs										
# of Part B Drug Services	489,710	579,678	19.808	19.590	19.196	19.081	-0.104	-0.438	0.231	-0.5%

Source: Episode analytic file, 2014–2017.

Notes: All measures were calculated at the episode level. Means and DID impact estimates are regression-adjusted. DID impact estimates for “occurrence” outcomes represent a percentage point change. LCL and UCL refer to lower confidence limit and upper confidence limit, respectively. Percent change was calculated by dividing the DID estimate by the OCM baseline mean.

OCM: OCM intervention group; COMP: Comparison group.

Int.: Intervention period

3.3 Program Effectiveness: Cost of Care

Summary of Findings on Program Effectiveness: Cost of Care

While current results do not yet show meaningful savings (without MEOS or PBP included in the calculations), the direction of the cost impact estimates correspond to their related utilization measures and efforts made by OCM practices in the first performance period.

- There was no statistically significant impact of OCM on TCOC, Part A and B costs, or Part D costs per episode. Also no significant OCM impact on Part B chemotherapy costs.
- Part D chemotherapy costs increased for OCM by \$294 per episode relative to the comparison group, representing a 6.3 percent increase from baseline.
 - Part D chemotherapy beneficiary cost-sharing increased by \$31 (8.0 percent change) for OCM six-month episodes relative to comparison episodes.
- About half of OCM and comparison respondents reported spending less than \$500 out-of-pocket in the prior year for cancer-related costs.
- All 12 practices we visited now advise their Medicare patients about OOP costs. This was a new activity for five of the 12 practices, started because of OCM.

OCM aims to improve the quality of cancer care while maintaining, if not reducing, associated Medicare health care costs. This section addresses two important cost questions: did total episode cost of care change, and did associated beneficiary cost-sharing change, for costs incurred during episodes that began in the PP1 of OCM? As in the previous sections, all results presented are at the episode level.

This section begins with a descriptive summary of the Medicare cost categories that comprise OCM and comparison episodes; data in this summary are not regression-adjusted. Next, DID results are presented, estimating the early impact of OCM by comparing changes in costs for OCM episodes to changes in costs for comparison episodes, between the baseline and intervention periods. The estimated DID impact of OCM is shown for several cost measures, specifically: Medicare episode total costs of care (TCOC), total costs for Part A and B claims, and total costs for Part D claims. We then break out health care costs for Part A acute care and post-acute and long-term care services, Part B services, and chemotherapy and cancer-related services. This section ends with estimated OCM impacts on beneficiary cost-sharing, and patient survey results on OOP spending. For more information about the analytic methods used, see Appendix A.

We examine the costs of care using Medicare payments. Part A and B costs are based on standardized cost variables. These costs exclude geographic differences in labor costs and practice expenses. Part D costs, however, are not standardized. We did not winsorize or trim extreme cost values, and we also did not adjust costs for inflation between 2014 and 2017, for either the OCM or comparison group. These costs also *exclude* PBP and MEOS payments billed under Part B by OCM practices in the intervention period, because billing data for PP1 were not available in time for inclusion in this report.

3.3.1 Composition of Health Care Costs

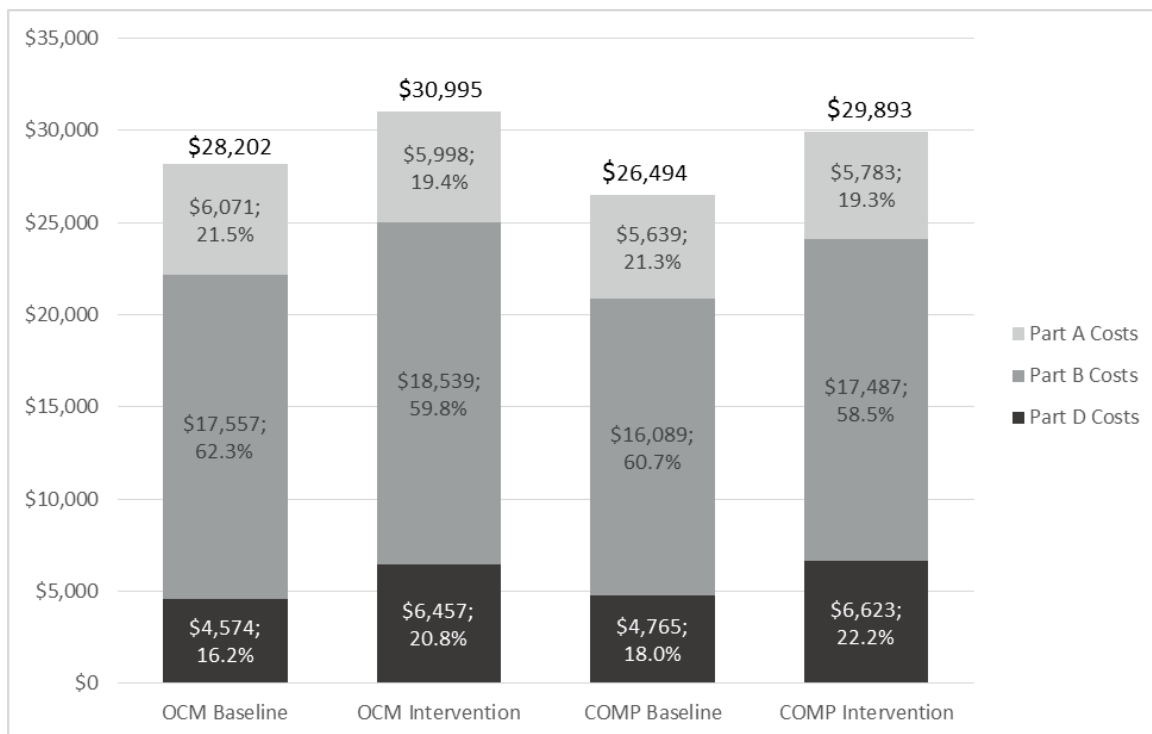
Examining the composition of episode-level costs, and how shares of each cost component change over time, can help identify areas where reductions might be expected to have the most impact on overall

episode costs. **Exhibit 13** shows the components of TCOC for OCM and comparison episodes along with the shares of the respective cost components.

Looking first at unadjusted changes in cost levels (i.e., not regression-adjusted), TCOC for OCM episodes increased from \$28,202 in the baseline period to \$30,995 in the intervention period, a change of almost 10 percent. Average TCOC for comparison episodes was lower than the OCM mean in the baseline period (\$26,494), but rose to \$29,893, an increase of almost 13 percent.

In terms of composition of overall costs, Part B costs represented the majority (nearly 60 percent) of all Medicare costs incurred for both OCM and comparison episodes in the intervention period; Part A costs and Part D costs constituted a similar share of the remaining balance—19 percent and just over 20 percent, respectively. There were shifts in the composition of costs over time, as Part D costs increased as a proportion of TCOC by about four percentage points from the baseline to the intervention period for both OCM and comparison episodes.

Exhibit 13: Unadjusted Average TCOC per Episode, Baseline and PP1



Source: Episode analytic file, 2014–2017.

Exhibit 14 presents episode-level Part A, B, and D costs for OCM and comparison episodes. Key findings include:

- Part B costs represented approximately 60 percent of TCOC during the intervention period. Part B drug costs were the largest driver of increases in overall Part B costs between the baseline and the intervention period. Costs for Part B drugs (chemotherapy and other drugs) represented over 60 percent of overall Part B costs for both OCM and comparison episodes.

- Chemotherapy drugs accounted for over 70 percent of Part B *drug* costs. The proportion of Part B costs attributed to chemotherapy drugs increased by about 2 percentage points for both OCM and comparison episodes.
- Part A costs represented about 20 percent of TCOC during the intervention period. Inpatient costs represented over 60 percent of all Part A costs for both OCM and comparison. The majority of the remainder were SNF costs and HHA costs, each of which amounted to just over 10 percent of Part A costs.
 - There was a slight increase in the proportion of Part A costs attributed to inpatient costs between the baseline and intervention period for both OCM and comparison episodes.
- Part D costs represented just over 20 percent of TCOC during the intervention period. Costs for chemotherapy drugs amounted to over 80 percent of Part D costs for both OCM and comparison episodes. The proportion of Part D costs for chemotherapy drugs increased by 4.2 percentage points for OCM episodes and by 2.7 percentage points for comparison episodes, from the baseline to the intervention period.
- Overall, the combined costs of Part B drugs and Part D drugs accounted for almost 60 percent of TCOC for both OCM and comparison episodes in the intervention period.

Exhibit 14: Unadjusted Components of Episode Costs, Baseline and PP1, OCM vs. Comparison Episodes

Payment Category	OCM Baseline			OCM Intervention			COMP Baseline			COMP Intervention		
	Mean	% of Part	% of TCOC	Mean	% of Part	% of TCOC	Mean	% of Part	% of TCOC	Mean	% of Part	% of TCOC
Part A, B, and D TCOC	\$28,202		100.0%	\$30,995		100.0%	\$26,494		100.0%	\$29,893		100.0%
Part A Costs	\$6,071	100.0%	21.5%	\$5,998	100.0%	19.4%	\$5,639	100.0%	21.3%	\$5,783	100.0%	19.3%
Inpatient (IP) Costs	\$3,855	63.5%	13.7%	\$3,866	64.5%	12.5%	\$3,508	62.2%	13.2%	\$3,631	62.8%	12.1%
SNF Costs	\$654	10.8%	2.3%	\$624	10.4%	2.0%	\$627	11.1%	2.4%	\$615	10.6%	2.1%
Home Health Agency Costs	\$698	11.5%	2.5%	\$660	11.0%	2.1%	\$604	10.7%	2.3%	\$590	10.2%	2.0%
IP Rehab Costs	\$230	3.8%	0.8%	\$240	4.0%	0.8%	\$150	2.7%	0.6%	\$167	2.9%	0.6%
Long Term Care Costs	\$127	2.1%	0.5%	\$98	1.6%	0.3%	\$115	2.0%	0.4%	\$84	1.5%	0.3%
Hospice Costs	\$455	7.5%	1.6%	\$468	7.8%	1.5%	\$413	7.3%	1.6%	\$428	7.4%	1.4%
Other Part A Costs	\$52	0.9%	0.2%	\$42	0.7%	0.1%	\$222	3.9%	0.8%	\$268	4.6%	0.9%
Part B Costs	\$17,557	100.0%	62.3%	\$18,539	100.0%	59.8%	\$16,089	100.0%	60.7%	\$17,487	100.0%	58.5%
Imaging Costs	\$841	4.8%	3.0%	\$804	4.3%	2.6%	\$813	5.1%	3.1%	\$801	4.6%	2.7%
Lab Costs	\$503	2.9%	1.8%	\$503	2.7%	1.6%	\$406	2.5%	1.5%	\$415	2.4%	1.4%
Radiation Therapy Costs	\$832	4.7%	3.0%	\$783	4.2%	2.5%	\$836	5.2%	3.2%	\$834	4.8%	2.8%
Chemo Drug Costs	\$7,830	44.6%	27.8%	\$8,593	46.4%	27.7%	\$6,942	43.1%	26.2%	\$7,936	45.4%	26.5%
Non-Chemo Drug Costs	\$2,920	16.6%	10.4%	\$3,320	17.9%	10.7%	\$2,406	15.0%	9.1%	\$2,839	16.2%	9.5%
Chemo Administration Costs	\$640	3.6%	2.3%	\$622	3.4%	2.0%	\$699	4.3%	2.6%	\$679	3.9%	2.3%
Cancer-Related E&M Costs	\$438	2.5%	1.6%	\$403	2.2%	1.3%	\$367	2.3%	1.4%	\$344	2.0%	1.2%
Other E&M Costs	\$903	5.1%	3.2%	\$882	4.8%	2.8%	\$797	5.0%	3.0%	\$803	4.6%	2.7%
Other Non-Institutional Costs	\$1,309	7.5%	4.6%	\$1,242	6.7%	4.0%	\$1,154	7.2%	4.4%	\$1,104	6.3%	3.7%
Other Institutional Costs	\$1,340	7.6%	4.8%	\$1,386	7.5%	4.5%	\$1,671	10.4%	6.3%	\$1,733	9.9%	5.8%
Part D Costs	\$4,574	100.0%	16.2%	\$6,457	100.0%	20.8%	\$4,765	100.0%	18.0%	\$6,623	100.0%	22.2%
Chemo Drug Costs	\$3,728	81.5%	13.2%	\$5,531	85.7%	17.8%	\$3,854	80.9%	14.5%	\$5,534	83.6%	18.5%
Other Drug Costs	\$847	18.5%	3.0%	\$926	14.3%	3.0%	\$911	19.1%	3.4%	\$1,089	16.4%	3.6%

Source: Episode analytic file, 2014–2017.

Notes: OCM: OCM intervention group; COMP: Comparison group; Int.: Intervention period

3.3.2 Impact of OCM on Cost of Care

Estimated OCM Impact on Total Episode Cost of Care

OCM incentivizes practices to manage episode costs by providing them with a semi-annual PBP if they achieve savings relative to a target amount.⁵¹ For this reason, monitoring the impact of OCM on TCOC is a key evaluation focus. Below we present results from the DID trend analysis for three core measures of overall Medicare expenditures:

- TCOC, defined as total Part A costs, B costs (not including MEOS payments or PBP), and D costs of care during an episode
- Part A costs and B costs (not including MEOS payments) per episode, reflecting payments for services received specifically under these benefits
- Part D costs per episode, measured as the sum of the low-income cost-sharing amount (LICS) and reinsurance, or 80 percent of the gross drug cost above the OOP threshold (GDCA)⁵²

All tables in this section provide regression-adjusted means along with the DID impact estimates.

Exhibit 15 presents key findings about TCOC:

- Average model-adjusted TCOC per episode increased similarly for both OCM and comparison practices between the baseline and intervention periods (from a mean of over \$27,000 to a mean of approximately \$30,000). The increase in average costs over time was evident for Parts A and B, and for Part D.
- There was no statistically significant impact of OCM on TCOC, Part A and B costs, or Part D costs per episode during the intervention period.

⁵¹ PBP amounts are not included in this annual report because they were not available at the time of the analyses.

⁵² Part D costs were restricted to episodes for the subset of beneficiaries enrolled in Part D for all months of the episode. Separate results are provided for Part D Costs and Part D Gross Drug Costs (GDC). GDC includes payments made by all parties (including the health plan and beneficiaries in addition to Medicare), and is calculated as the sum of ingredient costs, dispensing fee, sales tax, and vaccine administration fee.

Exhibit 15: Estimated OCM Impact for Total Costs per Episode, PP1

Measure	# of Episodes		OCM		COMP		Impact Estimates			
	OCM	COMP	Baseline Mean	Int. Mean	Baseline Mean	Int. Mean	DID	90% LCL	90% UCL	% Change
TCOC (Part A, B, and D Costs)	489,710	579,678	\$27,484	\$30,313	\$27,204	\$30,206	-\$173	-\$446	\$100	-0.6%
Part A & B Costs	489,710	579,678	\$22,709	\$24,099	\$22,374	\$23,968	-\$204	-\$448	\$39	-0.9%
Part D Costs	393,970	471,502	\$5,881	\$7,703	\$5,911	\$7,636	\$96	-\$18	\$210	1.6%
Part D Gross Drug Costs	393,970	471,502	\$9,119	\$11,366	\$9,250	\$11,463	\$34	-\$136	\$204	0.4%

Source: Episode analytic file, 2014–2017.

Notes: All measures were calculated at the episode level. Means and DID impact estimates are regression-adjusted. LCL and UCL refer to lower confidence limit and upper confidence limit, respectively. Percent change was calculated by dividing the DID estimate by the OCM baseline mean. OCM: OCM intervention group; COMP: Comparison group. Int.: Intervention period

TCOC by Cancer Subgroup

To assess whether overall findings varied for different cancer bundles, we analyzed episode-level TCOC for the 10 most prevalent cancer bundles, and separately by high-risk vs. low-risk cancer bundles.⁵³ See Appendix D for these results.

- For most cancer bundles, the DID impact estimates were not statistically significant, indicating that, as with the overall finding, OCM episode costs for different cancer types did not change relative to comparison episodes.
- There was a decline in TCOC for OCM episodes relative to comparisons, for two cancer bundles: breast cancer episodes treated with other than hormonal-only therapies, and lymphoma episodes.
- There was no impact on TCOC for low- or high-risk cancer bundles.

Estimated OCM Impact on Episode Part A Cost Components

As described earlier, practices participating in OCM are required to implement enhanced services and quality improvement efforts designed to improve care coordination, and are incentivized to reduce use of inappropriate or potentially avoidable services. OCM promotes efficient use of high-cost services (such as hospitalization) as well as appropriate use of post-acute and outpatient services. This section examines changes between the baseline and intervention period in Part A acute care costs, post-acute, and long-term care costs for OCM and comparison practices. Trends and DID impact estimates are presented.

Overall, there was no impact of OCM on Part A acute care costs during the intervention period. For both OCM and comparison episodes, average inpatient and readmission costs changed little between the baseline and intervention periods. There was also no impact on Part A post-acute and long-term care costs, per episode. It is worth noting that, while not statistically significant, many of the Part A cost impact point estimates were negative (costs declined), which is consistent with OCM goals. The complete results of these analyses are included in Appendix D. The DID results for Part A cost components are also consistent with the utilization findings presented earlier.

Inpatient Costs by Cancer Subgroup

We examined whether impacts on episode-level inpatient costs varied for the most prevalent cancer bundles, or by cancer bundle risk (see Appendix D). The lack of impact on inpatient costs overall held true for both low- and high-risk cancer bundles, and all cancer bundles except episodes for beneficiaries with chronic leukemia for whom we identified a statistically significant decrease of \$394 in average inpatient costs for OCM episodes between the baseline and intervention period.

Estimated OCM Impact on Episode Part B Costs

Under OCM, expanded care coordination and communication among providers are expected to improve efficiency in health care delivery and reduce costs. This may manifest as reductions in unnecessary or low-value services and increased use of effective but less costly therapies and services.

⁵³ Low-risk cancer bundles included breast cancer episodes using only hormonal therapies, and prostate and bladder cancer episodes using only low-risk chemotherapy regimens. Episodes in the remaining 22 cancer bundles were combined into the high-risk cancer bundle subgroup.

DID impact estimates for the components of standardized Part B costs (not including MEOS payments to OCM practices) suggest no OCM impact on most Part B cost components (see Appendix D). While we show that both cancer-related E&M utilization and cancer-related E&M costs did not change statistically (**Exhibit 16** below), we identified a small but statistically significant decrease of \$31 in overall E&M costs for OCM episodes ($p \leq 0.01$, 2.4 percent change from the average baseline value) relative to comparison episodes (see Appendix D).

The overall findings for Part B costs are in the same direction as the Part B utilization results presented earlier in this report. However, the reduction in E&M costs is not consistent with case study findings (see Section 3.6.3 below) indicating that practices are striving to bring patients into the office for supportive care such as hydration (i.e., more E&M services) to avoid the need for ED visits. It is possible that the two findings will align over time, as practices continue redesigning care processes to improve supportive care.

Estimated OCM Impact on Episode Chemotherapy Costs and Other Cancer-Related Costs

We examined chemotherapy and non-chemotherapy cancer-related costs. These costs are especially relevant for OCM, and, as shown earlier in **Exhibit 14**, represent a sizeable proportion of overall drug costs for Medicare beneficiaries with cancer. OCM may affect use of different types of chemotherapy, or the settings in which chemotherapy is delivered (in-office, in-hospital, at home). Further, OCM may influence a practice's adherence to evidence-based guidelines, use of supportive care drugs, and patient education about medication adherence. Any such shifts in cancer care have implications for associated health care costs under OCM.

Exhibit 16 presents the DID impact estimates for measures of chemotherapy and other cancer-related costs. OCM had no impact on total chemotherapy (Part B and D), Part B chemotherapy, or Part B cancer-related E&M costs. There was, however, an increase in Part D chemotherapy costs for OCM episodes relative to comparison episodes.

Exhibit 16: Estimated OCM Impact for Chemotherapy and Other Cancer-Related Costs per Episode, PP1

Measure	# of Episodes		OCM		COMP		Impact Estimates			
	OCM	COMP	Baseline Mean	Int. Mean	Baseline Mean	Int. Mean	DID	90% LCL	90% UCL	Percent Change
Chemotherapy Drug Costs										
Part B and Part D Chemo Costs	489,710	579,678	\$11,252	\$13,734	\$11,160	\$13,534	\$108	-\$131	\$348	1.0%
Part B Chemo Costs	489,710	579,678	\$7,423	\$8,334	\$7,266	\$8,203	-\$27	-\$281	\$227	-0.4%
Part D Chemo Costs	393,970	471,502	\$4,702	\$6,760	\$4,754	\$6,518	\$294 ***	\$171	\$418	6.3%
Part D Chemo Gross Drug Costs	393,970	471,502	\$6,822	\$9,417	\$6,874	\$9,239	\$230 **	\$42	\$418	3.4%
Hormonal Only or Low-Risk Chemo Costs	489,710	579,678	\$179	\$191	\$181	\$192	\$1	-\$4	\$7	0.7%
Other Cancer-Related Costs										
Part B Chemo Admin Costs	489,710	579,678	\$641	\$660	\$681	\$692	\$8	-\$9	\$24	1.2%
Part B Radiation Therapy Costs	489,710	579,678	\$808	\$732	\$883	\$825	-\$18	-\$40	\$4	-2.2%
Part B Cancer-Related E&M Costs	489,710	579,678	\$423	\$390	\$381	\$353	-\$6	-\$15	\$3	-1.4%

Source: Episode analytic file, 2014–2017.

Notes: All measures were calculated at the episode level. Part D chemotherapy costs and Part D chemotherapy gross drug costs were restricted to episodes for the subset of beneficiaries enrolled in Part D for all months of the episode. Means and DID impact estimates are regression-adjusted. LCL and UCL refer to lower confidence limit and upper confidence limit, respectively. Percent change was calculated by dividing the DID estimate by the OCM baseline mean.

OCM: OCM intervention group; COMP: Comparison group.

Int.: Intervention period

*p≤0.10, **p≤0.05, ***p≤0.01

Between the baseline and intervention periods, mean total chemotherapy costs (Part B and Part D combined) increased at the same rate for both OCM and comparison episodes, resulting in no statistically significant impact on costs for OCM episodes. For Part B chemotherapy, trends in costs were also similar for the two groups, and the DID impact estimate was not statistically significant. These findings suggest no early impact of OCM on Part B, or combined Part B and D, chemotherapy costs. In contrast, while average Part D chemotherapy costs increased for both OCM and comparison episodes, the increase was greater for OCM episodes, resulting in an estimated overall DID increase of \$294 for OCM episodes relative to comparisons ($p \leq 0.01$, 6.3 percent change from the average baseline value).

Trends in other cancer-related services varied. Average Part B chemotherapy administration costs increased for both OCM and comparison episodes between the baseline and average periods, while average Part B cancer-related E&M service and radiation therapy costs decreased for both groups. For all of these outcome measures, cost trends were similar for the two groups, and we estimate no OCM impact. These results correspond to the results from our analyses of cancer-related health care utilization presented in Section 3.2.

Part D Chemotherapy Costs by Cancer Subgroup

Due to the statistically significant impact estimates for Part D chemotherapy costs, we estimated the DID impact of OCM on Part D chemotherapy costs for the most prevalent cancer bundles, and for low- and high-risk cancer bundles, to understand whether these results are due to specific types or risk levels. The complete results of these analyses are in Appendix D. Here, we highlight cancer types for which we identified a significant impact of OCM on Part D chemotherapy costs, in both low- and high-risk cancer bundles.⁵⁴

- For low-risk cancer bundles, the estimated increase in Part D chemotherapy costs was \$10 ($p \leq 0.05$, 26.9 percent change from the average OCM baseline value) for OCM episodes, relative to comparisons. We also observed small, but significant impact estimates for Part D chemotherapy costs within two of the primary low-risk cancer bundles—breast cancer episodes treated with hormonal therapy (\$3, 9.1 percent change) and low-risk prostate cancer episodes (\$40, 57.7 percent change). For beneficiaries with these cancers, average Part D chemotherapy costs decreased for comparison episodes between the baseline and intervention periods, but increased on average for OCM episodes.
- An increase in Part D chemotherapy costs was also observed for high-risk cancer bundle episodes; the estimated increase in Part D chemotherapy costs was \$368 ($p \leq 0.01$, 4.9 percent change) for OCM episodes, relative to comparisons. This finding was a result of large increases in Part D chemotherapy costs within two high risk cancer bundles. Relative to comparison episode costs, OCM costs for high-risk prostate cancer episodes increased by \$813 ($p \leq 0.10$, 4.5 percent change from the average OCM baseline value), and OCM costs for chronic leukemia episodes increased by \$1,438 ($p \leq 0.01$, 7.5 percent change).

Changes in per-episode Part D chemotherapy costs (and differences between OCM and comparison episodes) may be due to a number of factors, including availability of Part D chemotherapies, changes in beneficiary medication adherence, shifts in treatment regimens and/or duration of chemotherapy, or changes in the types of patients who are treated. Additional PPs are needed to draw conclusions about Part D chemotherapy costs.

⁵⁴ See footnote 49.

Practice's Strategies to Control Financial Risk Due to High Drug Costs

Part B drugs are not only a large share of Medicare's episode costs; maintaining the necessary inventory is also a substantial operating cost for oncology practices due to the high cost of many infused chemotherapy drugs. Practices are also at financial risk if a patient who requires a costly infused drug lacks insurance for the 20 percent Part B copayment. During Year One case studies, some interviewees described reliance on 340B hospitals to reduce the financial risk arising from under-insured patients who require costly infusions, and a few described strategies to minimize waste of costly drugs.

340B Hospital Infusion Services for Under-Insured Patients

Hospitals that are eligible to participate in the 340B Drug Pricing Program pay reduced prices for drugs.⁵⁵ Independent oncology practices are not eligible to participate in this program. OCM practices affiliated with or owned by a health system that has a hospital with 340B status, can send under-insured patients to that hospital for their chemotherapy infusions. Even practices without such affiliations may schedule their patients' infusions at a nearby 340B hospital as this may be financially advantageous for both the practice (avoiding potential losses) and the patient (lower OOP costs).

All oncologists we interviewed in independent practices prefer to infuse patients in their own outpatient infusion centers so that they can oversee the quality of care provided and attend to any unexpected problems. They also explained that care is more complicated, and adherence potentially impaired, when a patient must come to the oncologist's office for pre-infusion lab work, and then go to a hospital (whether nearby or far away) for their infusion. The four health system-owned practices we visited could accommodate patients without secondary insurance, since all are non-profit and provide uncompensated (charity) care—one of these also participates in the 340B program. Three independent practices we visited in the early months of OCM occasionally send under-insured patients elsewhere for chemotherapy infusions due to drug costs. For example, one independent practice is located more than 20 miles from the nearest 340B hospital, but schedules infusions there for under-insured patients who need very costly drugs (i.e., drugs for which the uncovered 20 percent copayment would be a substantial financial loss for the practice and/or an untenable debt for the patient). Oncologists at the five independent practices we visited later in the year did not report referring under-insured patients to 340B hospitals for infusion of high cost drugs.

Minimizing Drug Wastage

Staff at two practices told us about new efforts since the start of OCM to reduce drug waste, by revising prescribing guidelines to avoid opening a second vial of an infusion drug if only a small amount will be used (e.g., dose rounding down). Many practices have dispensing pharmacies and ship oral drug refills to their patients. A very large independent practice has a team of pharmacy technicians who call every patient regularly to ask about adherence and side effects before mail shipping the next oral medication refill. This strategy was implemented long before OCM began, in an effort to avoid sending expensive medications to patients who do not yet need them.

3.3.3 Beneficiary Cost-Sharing

In all 12 practices we visited, financial counselors meet with patients who are concerned about OOP costs to identify sources of financial assistance (e.g., from private foundations). This was a new activity for five of the 12 practices, started because of OCM. (See also discussion in Section 3.5.2 on estimating OOP

⁵⁵ <https://www.hrsa.gov/opa/faqs/index.html>.

costs as part of the Care Plan.) Whether or not practices previously estimated OOP on a routine basis, all told us that they strive to find financial assistance for all who request it. Private foundations are important sources of copay support for cancer patients. One challenge practices encounter is that foundations typically have annual budgets, and their resources are often depleted before the end of December. Patients who begin treatment late in the calendar year may therefore not have access to this assistance. Many hospitals and health systems have their own philanthropic foundations, from which oncology patients in affiliated practices may also receive assistance.

Five of the 12 practices we visited help underinsured patients enroll in secondary insurance plans or obtain other government benefits. One small practice refers patients to the Area Agency on Aging for help locating secondary insurance or applying for government benefits, and four practices offer this assistance in house. One practice asks patients to bring their tax returns to their appointment with a financial counselor to help determine whether the patient is eligible for Medicaid in addition to Medicare. For Medicare patients without a Part D plan, the five practices will recommend a plan and help a patient enroll. If a patient's Part D plan does not include the necessary drug(s) on its formulary, the practice may recommend changing Part D plans during the next open enrollment period.

For some high-cost drugs, pharmaceutical companies offer Patient Assistance Programs (PAPs) to cover copays and gaps in a patient's private insurance coverage. Medicare beneficiaries, and those dually eligible for Medicare and Medicaid, cannot use both their Part D/Medicaid coverage and these PAPs.⁵⁶ One practice reported that it works with low-income patients to determine whether it would be more financially beneficial for the patient to use his or her insurance coverage or to enroll in the PAP, depending on the generosity of the PAP. None of the 12 practices we visited reported that this prohibition on the use of PAP in conjunction with Medicare/Medicaid creates an access or affordability problem for patients, because their financial advocates are always able to locate other financial assistance.

We have two sources of information about beneficiary OOP costs: Medicare claims and the patient survey. Claims analysis shows a slight impact of OCM in increasing OOP costs, largely related to Part D drug costs, while survey results show no change over time. The increase measured by claims was likely too small to be reflected in survey responses.

Beneficiaries with cancer have some of the highest OOP costs in Medicare. Excluding monthly premiums, Medicare beneficiaries' costs include deductibles and coinsurance, unless a beneficiary has a supplemental source of health insurance coverage that covers these costs (e.g., Medigap secondary insurance, Medicaid, or a retiree health plan).^{57,58,59} To monitor beneficiary cost-sharing under OCM, we

⁵⁶ <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PAPData.html>.

⁵⁷ Noe-Miller, C.L. Medicare beneficiaries' out-of-pocket spending for health care. Insight on the Issues: Washington, DC: AARP Policy Research Institute, October 2015. Available from <https://www.aarp.org/content/dam/aarp/ppi/2015/medicare-beneficiaries-out-of-pocket-spending-for-health-care.pdf>.

⁵⁸ Under Part A, beneficiaries are responsible for an annual deductible for hospitalizations, coinsurance for hospital stays beyond 60 days, and coinsurance for days 21 through 100 in SNFs. Under Part B, all beneficiaries pay an annual deductible and then beneficiaries typically pay 20 percent coinsurance for certain services. Beneficiary cost-sharing requirements for the standard Part D benefit vary by the stage of the coverage (i.e., initial coverage, coverage gap or "donut hole," and catastrophic coverage). Generally, Plan D coverage includes an initial beneficiary deductible and a coinsurance for drug costs during the initial coverage period. A beneficiary is then responsible for a higher rate of coinsurance during the coverage gap and a small copay/co-

calculated total beneficiary deductible and coinsurance costs for Parts A, B, and D per episode, as well as for Part B and D chemotherapy. Since overall cost-sharing levels were similar for OCM and comparison episodes in the baseline period, any differential change in cost-sharing over time will be due to differences in episode characteristics (controlled for to the extent we can in impact analyses) or differences in service use, including type and cost of drugs.

Exhibit 17 presents regression-adjusted means and the estimated OCM impact for beneficiary cost-sharing, including deductibles and coinsurance. Average beneficiary costs per episode increased between the baseline and PP1 for both OCM and comparison episodes. While OCM had no impact on Part B cost-sharing, it did have an impact on beneficiary cost-sharing for Part A and Part D. Relative to comparison episodes, OCM Part A beneficiary cost-sharing per episode decreased by \$9 ($p < 0.05$, -2.1 percent change from the average baseline value) while OCM Part D beneficiary cost-sharing per episode increased by \$17 ($p \leq 0.05$, 2.6 percent change). Beneficiary episode cost-sharing for Part D chemotherapy also increased for OCM episodes relative to the comparison group (\$31, $p \leq 0.01$, 8.0 percent change), which corresponds to the observed increase in OCM Medicare Part D chemotherapy costs reported earlier in **Exhibit 16**.

In the OCM patient surveys, respondents self-reported their OOP expenses during the past year for cancer care or medications, using one of six expense categories: “less than \$100,” “\$100-\$499,” “\$500-\$999,” “\$1,000-\$1,999,” “2,000-\$4,999” and “\$5,000 or more.” In the baseline survey, about half of OCM and comparison respondents reported spending less than \$500 out-of-pocket and there was no statistically significant difference between OCM and comparison respondents across the six expense categories. Self-reported OOP expenses among OCM respondents increased slightly in the first two intervention survey waves, and then returned to the baseline level in the third intervention survey wave (see Appendix E), yielding no statistically significant trend from the baseline through the first three intervention waves (the comparison group will be surveyed again in Year Three).

insurance during the catastrophic benefit phase. In these analyses, Part D beneficiary costs are measured as the sum of patient pay amount and other True Out of Pocket (TrOOP) amount (does not include low income cost-sharing amounts).

⁵⁹ In 2010, approximately 86 percent of all Medicare beneficiaries had some source of supplemental coverage (<https://www.kff.org/report-section/a-primer-on-medicare-what-types-of-supplemental-insurance-do-beneficiaries-have/>). After removing beneficiaries with Medicare Advantage, this amounts to 82 percent of Medicare FFS beneficiaries with some type of supplemental coverage.

Exhibit 17: Estimated OCM Impact for Beneficiary Cost-Sharing per Episode, PP1

Measure	# of Episodes		OCM		COMP		Impact Estimates			
	OCM	COMP	Baseline Mean	Int. Mean	Baseline Mean	Int. Mean	DID	90% LCL	90% UCL	Percent Change
Cost-Sharing for all Services										
Part A Beneficiary Cost-Sharing Amount	489,710	579,678	\$455	\$443	\$439	\$436	-\$9*	-\$18	-\$1	-2.1%
Part B Beneficiary Cost-Sharing Amount	489,710	579,678	\$4,442	\$4,702	\$4,388	\$4,680	-\$31	-\$87	\$25	-0.7%
Part D Beneficiary Cost-Sharing Amount	393,970	471,502	\$661	\$735	\$664	\$721	\$17**	\$4	\$30	2.6%
Cost-Sharing for Chemotherapy Drugs										
Part B Chemo Beneficiary Cost-Sharing Amount	489,710	579,678	\$1,995	\$2,134	\$1,935	\$2,105	-\$31	-\$99	\$37	-1.6%
Part D Chemo Beneficiary Cost-Sharing Amount	393,970	471,502	\$393	\$471	\$394	\$441	\$31***	\$19	\$43	8.0%

Source: Episode analytic file, 2014–2017.

Notes: All measures were calculated at the episode level. Part D cost-sharing overall and for chemotherapy was restricted to episodes for the subset of beneficiaries enrolled in Part D for all months of the episode. Means and DID impact estimates are regression-adjusted. LCL and UCL refer to lower confidence limit and upper confidence limit, respectively. Percent change was calculated by dividing the DID estimate by the OCM baseline mean. Many beneficiaries had no Part A cost-sharing.

OCM: OCM intervention group; COMP: Comparison group.

Int.: Intervention period

*p≤0.10, **p≤0.05, ***p≤0.01

3.4 Program Effectiveness: Probability of Select Cost and Utilization Impacts

Summary of Findings on Probability of Impacts

Early results about total Medicare spending show promise, indicating an 85 percent probability that OCM is achieving some level of savings; however savings are not enough to cover projected payments to practices (MEOS and PBP), which are not yet incorporated in the analyses.

- The likelihood that Medicare savings totaled at least \$452 or half of the possible maximum MEOS payments was less than 5 percent, and there was no chance that the savings were enough to cover the maximum possible MEOS.
- There was an 80 percent probability of any decrease in the number of inpatient stays and a 69 percent probability of any decrease in the number of ED visits, but these decreases were likely small.

We calculated probabilities for four key outcomes: TCOC per episode (not including MEOS payments), the number of inpatient hospitalizations per episode, the number of ED visits not resulting in an inpatient stay per episode, and the number of ED visits resulting in an inpatient stay per episode. These were selected for probability analysis because of their fundamental relevance to the cost and quality goals of OCM. In addition, these utilization measures may be important early indicators of the potential impacts of enhanced oncology services under OCM.

We report below the probability that each of these four measures decreased for OCM episodes, relative to changes in these outcomes for comparison episodes, between the baseline and intervention periods. Using the main DID result for each of the four measures, we estimated the probability that the impact was a particular value (e.g., fell above or below zero), and also the probability that any savings were sufficient to cover the maximum possible MEOS payments that practices could have billed.⁶⁰ More information about the estimation methodology is provided in Appendix A.

3.4.1 Probability Estimates for TCOC

In Section 3.3, we reported no statistically significant DID impact on TCOC per episode. The DID impact estimate, representing an average change in TCOC (not including MEOS payments) for OCM episodes relative to comparison episodes, was negative (-\$173) and amounts to a 0.6 percent reduction in TCOC relative to average OCM baseline costs (**Exhibit 15** in Section 3.3.2). The \$173 decrease in TCOC (not including MEOS) was not statistically significant at the 10 percent level.

An alternative way to look at the findings is to estimate the likelihood of observing relevant changes in key measures. The probability that TCOC decreased by *any* amount for OCM episodes (i.e., that there were savings for Medicare, without MEOS payments) was 85.1 percent (**Exhibits 18 and 19**), and the likelihood that Medicare savings (without including MEOS payments) totaled at least \$100 per episode was 66.9 percent.

There was, however, zero probability that the per episode savings to Medicare were sufficient to offset the maximum possible MEOS payments. If the maximum MEOS amount had been billed by all OCM practices for PP1, these estimated costs would range from \$891 to \$934 per episode (depending on type of

⁶⁰ MEOS payments only apply to OCM episodes during the intervention period, not the baseline.

cancer), for an average of \$904 per episode (Appendix D).⁶¹ As shown in **Exhibits 18 and 19**, there was zero probability that the savings achieved per episode was at least the maximum possible MEOS payment per episode, and a 4.6 percent probability that the savings were enough to offset at least half of the maximum MEOS of \$452.

Exhibit 18: Probability Estimates for Changes in TCOC per Episode, PP1

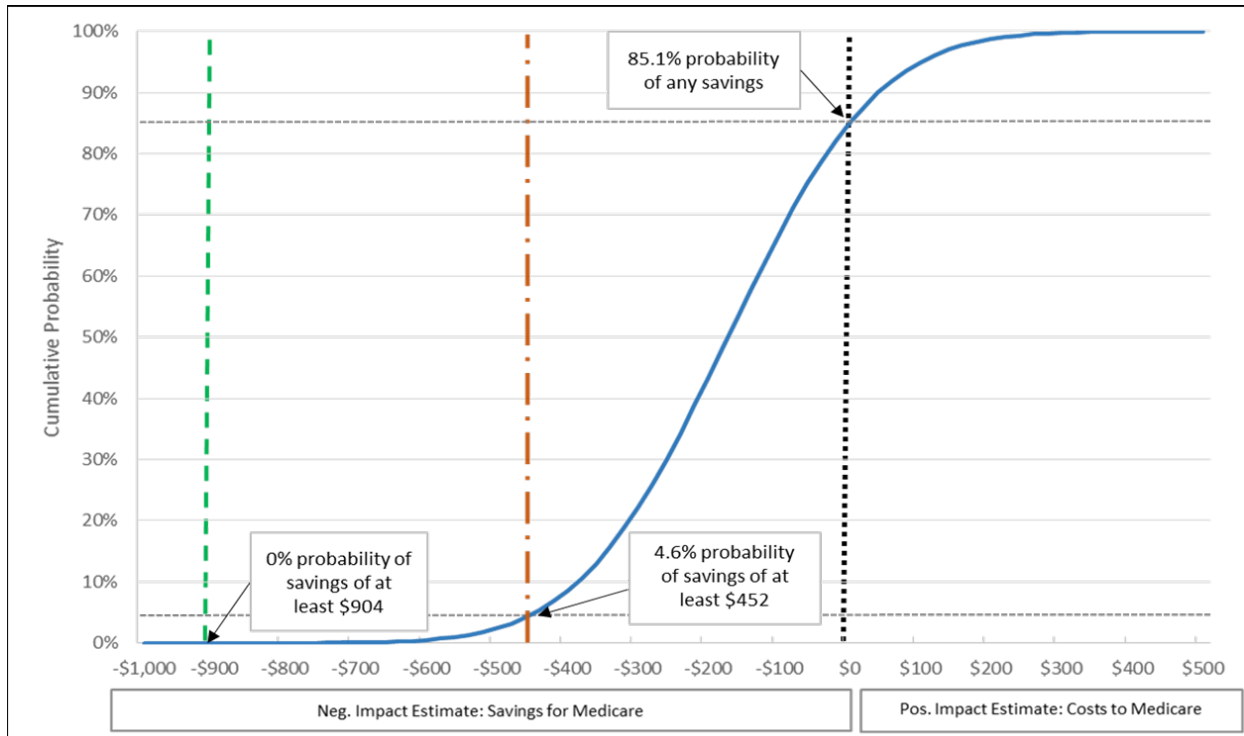
Savings Category	Probability
Any amount of increase in costs to Medicare per episode	14.9%
Any amount of savings for Medicare per episode	85.1%
Savings of at least \$100 per episode	66.9%
Savings of at least \$200 per episode	43.4%
Savings of at least \$300 per episode	22.1%
Savings of at least \$452 to offset half of maximum MEOS per episode	4.6%
Savings of at least \$904 to offset maximum MEOS per episode	0.0%

Source: Episode analytic file, 2014–2017.

Notes: TCOC excludes costs for MEOS payments billed by OCM practices. The maximum MEOS amount accounts for Medicare sequestration, hospice entry, and death.

⁶¹ OCM practices may submit claims for a MEOS payment of \$160 per month for each six-month episode attributed to the practice, for a maximum of \$960 per six-month episode (less sequestration). Practices may not submit MEOS claims after a patient enters hospice or dies. The estimated maximum MEOS payments averaged less than \$960 per episode because the Medicare sequestration adjustment applies to MEOS payments, and also due to hospice entry or death. The estimated maximum MEOS averaged \$904, and ranged between \$891 and \$934 because rates of hospice entry and beneficiary death vary by cancer bundle.

Exhibit 19: Cumulative Probability Estimates for Changes in TCOC per Episode, PP1



Source: Episode analytic file, 2014–2017.

3.4.2 Probability Estimates for Inpatient and Emergency Department Utilization

In addition to the DID impact estimates above, we estimated the probability that OCM was associated with a decrease in the number of inpatient hospitalizations and ED visits among OCM episodes, relative to episodes in the comparison group, between the baseline and intervention periods. During PP1, there was an average of about 4,080 inpatient hospitalizations per 10,000 OCM episodes and an average of 6,570 ED visits per 10,000 OCM episodes.

Several recent studies indicate that as many as 20 percent of hospitalizations for cancer patients are potentially avoidable.^{62,63,64} As reported in Section 3.2 above, there was no statistically significant impact of OCM on the number of inpatient hospitalizations. The DID impact estimate of -0.004 represents a reduction of 40 hospitalizations per 10,000 episodes, only a 0.9 percent reduction relative to the OCM baseline value (**Exhibit 10** in Section 3.2.1). Although the DID estimate was not statistically significant, we estimate that there was an 80 percent probability of *any* decrease in the number of inpatient hospitalizations for OCM episodes (**Exhibit 20**). This decrease was likely small. For example, the probability that the decrease represented even a two percent reduction from baseline for OCM episodes (a

⁶² Brooks, G. A., Abrams, T. A., & Meyerhardt, J. A., et al. (2014). Identification of potentially avoidable hospitalizations in patients with GI cancer. *J Clin Oncol*, 32(6), 496–503.

⁶³ Brooks, G. A., Jacobson J. O., & Schrag D. (2015). Clinician perspectives on potentially avoidable hospitalizations in patients with cancer. *JAMA Oncol*, 1(1),109.

⁶⁴ Meisenberg, B.R., Hahn, E., Binner, M., et al. (2016). ReCAP: Insights into the potential preventability of oncology readmissions. *J Oncol Pract*, 12(2),153–154; e149–156.

reduction of approximately 86 inpatient visits per 10,000 episodes) was 15.8 percent, and the probability that the decrease represented a five percent reduction (or 214 visits per 10,000 episodes) was zero.

Exhibit 20: Probability Estimates for Reductions in the Number of Inpatient Hospitalizations per Episode, PP1

Reduction in IP Hospitalizations	Number of Hospitalizations (per 10,000 Episodes) Associated with Reduction	Probability
Any reduction in the number of IP hospitalizations per episode	>0	80.0%
Reduction of at least 1%	43 or more	46.9%
Reduction of at least 2%	86 or more	15.8%
Reduction of at least 3%	128 or more	2.7%
Reduction of at least 4%	171 or more	0.2%
Reduction of at least 5%	214 or more	0.0%

Source: Episode analytic file, 2014–2017.

In Section 3.2, we similarly reported a negative but not statistically significant impact (point estimate = - 0.002) on the number of ED visits that did not result in a hospitalization for OCM episodes relative to comparison episodes, which represents a reduction of 20 visits per 10,000 episodes, a 0.6 percent reduction from the average OCM baseline value. We estimate that there was a 69 percent probability of *any* decrease in the number of ED visits not resulting in a hospitalization (**Exhibit 21**). Again, this decrease was likely small. For example, the likelihood that the decrease represented a two percent reduction from baseline for OCM episodes (a reduction of approximately 70 ED visits not resulting in an inpatient stay, per 10,000 episodes) was 13.7 percent, and the probability that the decrease represented a five percent reduction (or 176 visits per 10,000 episodes) was zero.

Exhibit 21: Probability Estimates for Reductions in the Number of ED Visits Not Resulting in an Inpatient Stay per Episode, PP1

Reduction in ED Visits Not Resulting in IP Stay	Number of Visits (per 10,000 Episodes) Associated with Reduction	Probability
Any Reduction in the Number of ED Visits Not Resulting in IP Stay per Episode	>0	69.4%
Reduction of at least 1%	35 or more	38.4%
Reduction of at least 2%	70 or more	13.7%
Reduction of at least 3%	106 or more	2.9%
Reduction of at least 4%	141 or more	0.3%
Reduction of at least 5%	176 or more	0.0%

Source: Episode analytic file, 2014–2017.

The DID impact estimate indicates that OCM episodes had 0.011 fewer ED visits that resulted in hospitalization ($p \leq 0.01$), relative to comparison episodes (**Exhibit 11** in Section 3.2.1). This represents a 3.7 percent reduction from the average OCM baseline level of utilization, or 110 fewer visits per 10,000 episodes. The probability estimates show that there was a nearly 100 percent probability of *any* decrease in ED visits resulting in an inpatient stay. (**Exhibit 22**). This is consistent with the level of statistical significance of the DID impact estimate; the probabilities of reductions in ED visits resulting in hospitalization were higher than the probabilities of reductions in ED visits not resulting in a hospitalization. For example, the likelihood of a reduction in ED visits resulting in hospitalization of at least two percent (or a decrease of 61 per 10,000 episodes) was 89.9 percent, and the likelihood of a reduction of at least five percent (or 152 per 10,000 episodes) was 16.9 percent.

Exhibit 22: Probability Estimates for Reductions in the Number of ED Visits Resulting in an Inpatient Stay per Episode, PP1

Reduction in ED Visits Resulting in IP Stay	Number of Visits (per 10,000 Episodes) Associated with Reduction	Probability
Any Reduction in the Number of ED Visits Resulting in IP Stay per Episode	>0	99.7%
Reduction of at least 2%	61 or more	89.8%
Reduction of at least 4%	122 or more	41.5%
Reduction of at least 5%	152 or more	16.9%
Reduction of at least 7%	213 or more	0.7%
Reduction of at least 10%	304 or more	0.0%

Source: Episode analytic file, 2014–2017.

3.5 Program Effectiveness: Enhanced Oncology Services

Summary of Findings on Enhanced Oncology Services

Many OCM practices were meeting some of the OCM requirements for enhanced oncology services before the Model began, and during PP1, practices continued to work to provide additional enhanced services.

24/7 Access

- Practices used a number of strategies to improve access to care for their patients.
 - Most OCM practices offered same day appointments before OCM began (95 percent). Evening and weekend clinic hours for urgent care were offered by fewer than 40 percent of OCM practices.
- Surveyed patients rated access to providers very highly for both OCM and comparison practices.

Care Plans with 13 Elements Recommended by the Institute of Medicine

- Comprehensive Care Plans were new for all 12 practices we visited in Year One, and EHR technology did not support easily compiling all necessary information.
- Most elements of Care Plans were straightforward for practices to document, but the following were more challenging: prognosis, OOP cost estimates, identifying and meeting psychosocial needs, and survivorship plans.

Core Functions of Patient Navigation

- Practices offered multiple patient navigation functions, shared among multiple staff members; some also took advantage of nurse navigators at nearby or affiliated hospitals.

Use of Evidence-Based Treatment Guidelines

- All 12 practices we visited in Year One followed clinical guidelines from the National Comprehensive Cancer Network (NCCN) prior to OCM, and used the same guidelines for OCM and non-OCM patients.
- Some practices use pathways software programs to guide oncologists' treatment decisions, but these are often not integrated with computerized order entry.
- Oncologists are permitted to deviate from guidelines and/or pathways, but practices we visited vary greatly in the extent of oversight or approval required for any deviation.

Participating OCM practices are required to offer four enhanced oncology services for patients with OCM episodes: 1) 24/7 patient access to an appropriate clinician with real-time access to the practice's medical records, 2) a Care Plan containing the 13 components in the Institute of Medicine Care Management Plan,⁶⁵ 3) core functions of patient navigation, and 4) treatment with therapies consistent with nationally

⁶⁵ CMS requires clinicians at OCM practices to develop all 13 components of the Care Plan and to document these items in the EHR. CMS encourages clinicians to share a hard copy of the Care Plan with patients, however this is not a requirement. The 13 components are: patient information (e.g., name, date of birth, medication list, and allergies), diagnosis, prognosis, treatment goals, initial plan for treatment and proposed duration, expected response to treatment, treatment benefits and harms, information on quality of life and a patient's likely experience with treatment, who will take responsibility for specific aspects of a patient's care, advance care plans, estimated total and out-of-pocket costs of cancer treatment, a plan for addressing a patient's psychosocial health needs, and a survivorship plan.

recognized clinical guidelines. CMS offers participating practices the opportunity to bill monthly MEOS payments to ensure that these enhanced services are available to meet individual patient needs. OCM also requires practices to use data for continuous quality improvement, and to use electronic health record systems (EHRs) certified by the Office of the National Coordinator of Health IT. This section presents survey, case study, and PTP findings about enhanced oncology services and other OCM programmatic requirements, as well as clinician experiences and perceptions about the impact of these changes.

3.5.1 Providing 24/7 Access to Clinicians

Prior to OCM, all 12 practices we visited in Year One were already providing 24/7 access for all patients to oncology clinicians who were able to access patients' EHRs, and patient survey responses in the Access to Care composite were not statistically different between OCM and comparison beneficiaries at baseline. Among OCM survey respondents, composite responses in the OCM Patient survey did not change statistically over time (see Appendix E). The comparison group will be surveyed again in Year Three.

Eleven of 12 practices we visited during used a nurse triage line during business hours and an answering service after hours. Triage nurses respond to patient questions directly and consult with an oncologist when necessary. After hours, answering services route patients' clinical calls to the appropriate on-call oncologist. All nurses and oncologists who take patient calls have access to the patient's EHR both during the day and via home computers and mobile devices after hours. At the time of our visit, these 11 practices were satisfied with these approaches and did not plan any changes. The twelfth practice relies on its hospital's 24-hour call-in line. This line is staffed by non-clinicians and the practice leaders were aware that oncology patients' concerns were not always addressed in a timely fashion. The practice planned to revise its triage process to route all patient calls about oncology questions and concerns directly to an on-call oncologist.

3.5.2 Care Plans

OCM practices are required to document 13 Care Plan elements in their EHRs, and CMS encourages them to share this information with patients. All 12 practices we visited in Year One recorded at least some of the 13 components in their EHRs prior to OCM, but the extent and accessibility of this information differs, and depends greatly on EHR functionality. Prior to OCM, none of the practices were completing Care Plans that captured all 13 components in a consistent manner and printing them for patients, but practices told us that completing most of the components of the Care Plan has been straightforward.

Some of the 13 Care Plan components were formatted in discrete fields in the leading EHRs of the 12 practices we visited (e.g., medication list, treatment plan, goals of therapy), but other components had no structured EHR fields. Some practices customized their EHRs to add fields for missing elements, and trained clinicians to use these new fields. Others manually extract information from oncologists' text notes. In seven of the 12 practices we visited, oncologists are responsible for improving their EHR documentation and entering formatted data rather than using text notes for important information such as prognosis, disease stage, and expected response to treatment. In the other five practices, oncologists were not asked to change their workflow and staff such as nurses, nurse practitioners, or data entry staff pull information from the oncologist's notes to complete the Care Plan. Some information, such as total and OOP costs, or pathology results for disease staging and prognosis, exist in different information systems altogether (e.g., billing, tumor registry) and may not be easily accessible or extractable.

Three of the 12 practices we visited, all independently owned, told us that they complete Care Plans for all of their patients, regardless of insurance coverage. The other nine practices focus their Care Plan efforts on OCM patients only, at least to start, although there may be some spillover in documentation for non-OCM patients. Several practices plan to create Care Plans for all their patients in the future.

Most of the Care Plan elements were straightforward for OCM practices, but the following were described by interviewees as being especially challenging:

OOP Cost Estimates for Patients. CMS asks OCM practices to document estimates of OOP cost for all cancer treatment (not limited to chemotherapy) and share this information with patients. Three of the 12 practices we visited provided some OOP cost information for patients prior to OCM, but providing comprehensive estimates of OOP costs is a new exercise for all 12. They all told us this is difficult, especially for independent practices that do not provide surgery, radiation therapy, or other services that contribute to total and OOP costs. Even practices owned by health systems that provide these other services could not determine the costs of this care until after the fact, because their billing departments do not generate estimates in advance. The multiple inputs for cost calculations (treatment regimen, cost of drugs not dispensed/infused by the practice, imaging, lab tests, secondary insurance) make such computations complex, labor-intensive, and prone to error. Ten of the 12 practices told us that they estimate OOP costs only for the drugs prescribed for the initial treatment regimen, and lab tests performed in the office; they do not estimate OOP costs for imaging, radiology, surgery, or other services patients receive elsewhere.

One health system-owned practice we visited tries to include all cancer-related costs (or a range of costs) by diagnosis, based on its own cost/billing experience with oncology patients, but acknowledged this is inaccurate for services provided outside its own health system. One independent practice provides the OOP cost estimate after the first chemotherapy cycle, when they have a better sense of the exact cost of the patient's medications and supportive therapies.

Although most interviewees agreed that OOP cost information helps patients with financial planning, several raised concerns about providing even an estimate up front that may eventually prove to be incorrect. Response to treatment may be suboptimal, requiring additional lines of therapy, for example, and this cannot be known in advance. A few practices address this by updating OOP estimates with each change in treatment.

Prognosis and Treatment Intent/Goals. Many oncologists we interviewed are wary about specifying prognosis at the start of treatment. They told us that prognosis for many cancers and treatments is imprecise and poorly understood by patients, and a poor initial prognosis can affect patient morale (and possibly adherence to treatment). Many also told us that response to treatment is unpredictable and they feel it is best to address prognosis as disease and treatment progress. Five of the 12 practices we visited worked with their oncologists to define and implement standard definitions of prognosis. For example, one categorizes prognosis as "fair" or "good," while another defines prognosis as treatment intent of "cure" versus "living longer with my disease." The other seven practices allow oncologists to define prognosis in whatever way they prefer, and share this information with patients whenever they think best. While the oncologists we interviewed in OCM practices generally know that documenting prognosis is an OCM requirement, practices do not necessarily monitor whether oncologists share this information with patients.

Identifying and Meeting Psychosocial Needs. Systematic screening for psychosocial needs is new under OCM for four of the 12 practices we visited. Three of these practices instituted standardized screening for depression after the start of OCM, and one started screening for both depression and distress. The other eight practices were informally assessing patients’ emotional and psychosocial needs before OCM, but now use standardized screening tools to make this process more systematic and routine. Some of the independent practices raised concerns that the screeners are identifying needs that they are unable to meet for many patients, due to financial barriers or inadequate community-based resources (e.g., no transportation services in rural areas). A few independent practices compiled lists of community resources, such as transportation, that they offer to patients with needs identified through the new screening process. Health system-owned practices described having more resources to meet patient psychosocial needs, and the oncology team frequently refers patients to the health system’s social workers, dietitians, and other resources. Some independent practices that are located adjacent to a local hospital also refer patients to the hospital’s social workers and dietitians for support. Two of the independent practices considered hiring social workers for OCM, but decided the level of need among their patients (as revealed by screening) does not justify the expense; a third hired social workers for the first time, to work exclusively with OCM patients.

Survivorship Plans. One of the 13 Care Plan components is a survivorship plan, summarizing the treatment received and a schedule for follow-up/surveillance after treatment is complete. Five of the 12 practices we visited created survivorship plans for their patients prior to OCM, and were improving these—for example, creating standard follow-up plans for each type and stage of cancer, or incorporating the survivorship plan into the EHR instead of using a paper document. Written survivorship plans for patients are entirely new for the other seven practices we visited, to meet OCM requirements. Three OCM practices added new survivorship “clinics,” usually staffed by a nurse practitioner, to see patients for surveillance follow-up (e.g., routine scans) in the years following successful treatment. In these practices, the impetus for adding the survivorship clinic was to reduce follow-up sessions with oncologists, who would then have more time in their schedules for new patients. Two practices routinely send survivorship plans to patients’ primary care providers at the end of treatment, and others encourage patients to share the paper survivorship plan with their other providers.

3.5.3 Core Functions of Patient Navigation

OCM requires practices to provide the core functions of patient navigation. At the time of our case study visits, all 12 practices offered some patient navigation functions, even if they did not have designated “navigators.”⁶⁶ In their 2017 PTPs, participating practices reported how frequently they use each of 11 core patient navigation activities to meet patient needs.⁶⁷ Of the 11 core patient navigation activities, 10

⁶⁶ Although OCM practices are required to offer the functions of patient navigation, practices do not need to have designated patient navigators.

⁶⁷ The PTP Plans ask about: 1) coordinating appointments with clinicians inside and outside the practice to ensure timely delivery of diagnostic and treatment services, 2) maintaining communication with patients and their families across the care continuum, 3) ensuring that appropriate medical records are available at scheduled appointments, 4) arranging language translation or interpretation services, 5) facilitating connections to follow-up services, 6) providing access to clinical trials, 7) building partnerships with local agencies and groups (e.g., referrals to other services and/or cancer survivor support groups), 8) facilitating financial support (e.g., counseling, or payments from foundations or drug companies), 9) arranging transportation, 10) arranging child or elder care, 11) helping with paper work (e.g., living wills, financial support forms).

were offered to all or nearly all patients who needed them (as far as the practices were aware of the need). Twenty-five percent of OCM practices reported on the PTP that they consistently arrange child care or elder care for patients having that need. Larger practices were more likely than smaller practices to arrange language translation or interpretation services ($p<0.05$) for patients with this need, and hospital- or health system-owned practices were more likely than independent practices to arrange transportation for patients who need it ($p<0.05$). Practices with academic affiliation were less likely than non-academic practices to report that they coordinate appointments with outside clinicians, ensure that appropriate medical records are available at appointments, or assist patients with locating financial support ($p<0.05$ for all three). In 2017, more practices reported coordinating appointments with clinicians inside and outside the practice than in 2016 (75 percent in 2016 vs. 85 percent in 2017, $p<0.05$) but there were no other significant changes reported over Year One.

Exhibit 23 summarizes how each of the 12 practices we visited approaches the OCM requirement for patient navigation. Several practices rely at least in part on nurse navigators (e.g., breast cancer navigators) at an affiliated or neighboring hospital where the patient had initial surgery. This is most common for patients undergoing multi-modal treatment (radiation, surgery, chemotherapy) because they have complicated treatment scheduling. Practice staff assist other patients who do not qualify for the hospital navigators' services.

Two independent practices increased their patient navigation/care coordination staff for OCM. One very large practice hired dozens of care coordinators who work remotely and follow their assigned patients throughout treatment—proactively calling to follow up on any specific issues noted by the oncologists, helping with navigation, and linking patients to other resources as needed. A second very large independent practice hired its first four nurse navigators for OCM, who rotate among the practices' many clinics, meeting new patients in person whenever possible and following them with telephone check-ins.

Clinical and non-clinical staff share navigation functions at most practices we visited. For example, administrative staff follow the prescribed regimen to schedule lab work and chemotherapy sessions, and help patients schedule appointments outside the practice, such as for radiation treatment. Oncologists or nurses may refer patients to other support services (e.g., social workers, dieticians, transportation support, and support groups) available in an affiliated health system or in the community. Several practices employ patient advocates/financial counselors to focus on financial and insurance counseling and assistance. At some practices, the patient advocates also arrange for translators during appointments, and refer patients to non-clinical community resources (transportation, support groups, etc.). One medium-sized practice has a cadre of cancer survivors who volunteer as peer navigators, spending time with patients in the infusion room and telling them about community resources.

Exhibit 23: Use of Patient Navigators

Practice Visited	Ownership	Size	Employs Dedicated Navigators	Refers Patients to Hospital Navigators
Year 1A	Health system-owned	Large	✓	
Year 1B	Health system-owned	Very large	✓	
Year 1C	Independent	Medium		✓
Year 1D	Independent	Medium	✓	
Year 1E	Independent	Small		✓
Year 1F	Independent	Medium		✓
Year 1G	Health system-owned	Small		✓
Year 1H	Independent	Medium	✓	✓
Year 1I	Health system-owned	Medium	✓	
Year 1J	Independent	Very large	✓	
Year 1K	Independent	Very large	✓	
Year 1L	Independent	Small	✓	

3.5.4 Use of Evidence-Based Treatment Guidelines

OCM requires evidence-based care, which in turn may encourage greater attention to standardization, and increased monitoring of deviation from guidelines. This section explores the use of guidelines, regimens, and order sets programmed in EHRs; use of pathways software programs; and how these may be changing in response to OCM incentives.

All 12 practices we visited in Year One follow clinical guidelines from the National Comprehensive Cancer Network (NCCN) or the American Society of Clinical Oncology (ASCO), and use the same guidelines for OCM and non-OCM patients. Most practices have a process through which oncologists review new published literature and national guidelines and reach consensus about the preferred regimens they agree to use. The preferred or recommended regimens are sometimes compiled into a paper or web-based document, and in all but one practice the regimens are programmed into order sets in the EHR. Four of the 12 practices regularly review and remove obsolete regimens and order sets. Two others recently “cleaned house” and discarded obsolete regimens, prompted at least in part by OCM participation. Six practices currently use pathway software programs to guide oncologists toward the best-value regimen. The six others use standard regimens based on guidelines, but do not employ pathways software. Of these, two independent practices were considering purchasing pathways software programs in the coming year. In their annual PTPs, the proportion of practices reporting electronic clinical decision support integrated with the EHR increased substantially, from 38 percent of practices in 2016 to 66 percent of practices in 2017 ($p < 0.01$).

The number of regimens adopted by practices varies widely and does not seem to correlate with practice size. The smallest practice we visited was building over 300 regimens into its new EHR; conversely, a medium-sized practice we visited has distilled a concise set of standard regimens for each cancer type and stage, and these are programmed into the EHR and printed in an easy-reference pocket-size “booklet” for oncologists.

In all 12 practices we visited, oncologists are permitted to deviate from the care pathway or preferred regimen if they consult with colleagues, cite published literature demonstrating the efficacy of the

alternative regimen, and note the deviation in the EHR. The practices vary considerably in the extent of oversight or approval required for any deviation. The smallest of the 12 practices, which has over 300 treatment regimens and no pathways software, has no process for reviewing—much less approving—deviations. A medium-sized practice that also does not use pathways software emphasizes oncologists’ autonomy and has no formal process for reviewing or approving deviations. The medium-sized practice with the pocket reference booklet described above requires prior approval from its medical director before an oncologist prescribes a regimen that deviates materially from the standard regimen. Practices with care pathways software appear to discourage deviation from guidelines more than those without pathways, and one oncologist at such a practice emphasized that “it is very difficult to deviate from the [programmed] pathways.”

None of the 12 practices we visited select their treatment regimens based explicitly on cost, and oncologists have no ability to compare the actual cost of alternative drug regimens before prescribing. Leaders at three practices told us that they support inclusion of cost considerations when oncologists are prescribing (e.g., generics), but the oncologists we interviewed in these practices did not all agree. Leaders at three practices told us about strategies to raise oncologists’ awareness of lower cost treatment options. The pharmacist at one practice reviews drug costs regularly and suggests alternatives to oncologists if the drugs they order are not more effective than lower-cost options. One practice implemented a clinical pathways software program after the start of OCM that prioritizes lower-cost drugs of equivalent efficacy, and another uses a similar program that rank orders equally efficacious regimens according to cost (lowest to highest). None of the practices we visited that use pathways software programs reported that they had evidence yet that these programs were affecting prescribing patterns or drug costs.

Section 3.6.3 below describes the impact of OCM on adherence to guidelines for prophylactic antiemetic supportive therapy.

3.5.5 Certified EHRs and Using Data for Continuous Quality Improvement (CQI)

All the OCM practices we visited in Year One adopted certified EHRs prior to the start of OCM. Several were planning upgrades and improvements in information technology, and considered OCM requirements in making these decisions.

OCM practices are required to use data (e.g., clinical EHR data, CMS feedback reports, claims data, patient surveys) for continuous quality improvement. Practices report progress toward meeting this requirement in their annual PTPs, and we asked about this during case studies.

In their 2017 PTPs, over three quarters of practices reported reviewing data about quality of care, utilization, and patient-reported experiences on at least a quarterly basis. Hospital- or health system-owned practices were more likely than independent practices to review data on patient-reported care experiences on at least a quarterly basis (85 percent vs. 73 percent, $p < 0.05$), perhaps reflecting their greater resources for surveying patients.

Many of the 12 practices we visited repurposed CQI processes from previous initiatives (e.g., Meaningful Use, PQRS). As shown in **Exhibit 24**, some practices regularly provide feedback to individual oncologists about their performance, while others review performance data at the practice level but do not share individual physician-level data. The larger practices tend to have more-robust CQI activities, with staff dedicated to collecting and analyzing performance data and developing data-driven improvement

initiatives. In two of the four health system-owned practices we visited, the health system assigned performance improvement staff to spend at least a portion of their time supporting OCM.

Exhibit 24: Types and Uses of Performance Data among 12 Case Study Practices

Type of Data Reviewed	Number of Practices Employing Approach*	Who Reviews	Notes
Review practice-level performance metrics	11	<ul style="list-style-type: none"> 7 practices share with oncologists to discuss improvement strategies 4 practices share only with practice executives to discuss improvement strategies 	<ul style="list-style-type: none"> The twelfth practice visited had not yet begun reviewing these data at the time of the visit, but planned to begin using an OCM Analytics module they purchased from their new EHR vendor.
Review physician-level performance metrics	10	<ul style="list-style-type: none"> 6 practices share performance metrics with individual oncologists 3 practices share only patient satisfaction survey (e.g., Press Ganey) results with individual oncologists 2 practices share performance metrics only with practice executives to discuss improvement strategies 	<ul style="list-style-type: none"> One practice is considering tying oncologist performance metrics to their physician compensation model.
Participate in the Quality Oncology Practice Initiative (QOPI)	4		<ul style="list-style-type: none"> Practices noted that participation in QOPI informed their performance monitoring for OCM; however, some indicated limited utility of QOPI metrics because OCM uses different measures.

* Total is more than 12 since some practices implement more than one approach.

3.5.6 Provider Experiences and Satisfaction

Staff in a number of practices we visited stated that OCM has added new tasks to their workflow—for example, medical assistants in at least one practice administer the distress screener—but also feel strongly that these new tasks improve quality of care by helping to ensure that patient needs are identified and promptly addressed. New tasks, such as making proactive outreach calls to high-risk patients, take time, but several nurses told us that they feel enhanced job satisfaction in identifying and meeting patients’ needs early. In at least one practice, clinicians told us that proactive outreach to high-risk patients reduces call volume to the on-call oncologist at night and on the weekend, improving physician satisfaction (and rest).

During Year One case studies, several oncologists expressed concern that increasing documentation, especially recording information in structured EHR fields rather than free text notes, is time-consuming and reduces the time they spend with patients. A few mentioned that increased documentation requirements could also lead to oncologist and staff dissatisfaction and burnout. While OCM is not the only factor contributing to documentation burden, oncologists in several practices mentioned completing and documenting Care Plan components (an OCM requirement) as new and burdensome.

Lack of adequate EHR tools for creating Care Plans and software systems that do not interoperate affect provider burden and satisfaction. Even advanced EHRs do not fully support OCM requirements, and awkward work-arounds are common. For example, standardizing treatment regimens and adhering to national guidelines has prompted several practices to adopt clinical pathways software programs that are not integrated with their EHRs. In this circumstances, oncologists use two separate systems: one to identify the correct pathway, and the other to select the order set that matches the pathway. For another example, none of the oncology EHRs are designed to automatically extract the 13 Care Plan components and assemble them into a single document, without additional work by practice staff.

We will conduct a comprehensive clinician survey in Year Three to measure satisfaction with OCM and perceived impact of the Model.

3.6 Program Effectiveness: Quality

Summary of Findings on Quality

The intervention and comparison groups were well matched at baseline on most measures of patient-reported quality, and there is not yet a measurable impact of OCM on quality. There is early indication of less aggressive care at the end of life for OCM patients.

- Surveyed cancer patients were highly satisfied with their cancer teams and care before OCM began, and ongoing surveys of OCM beneficiaries did not identify any significant changes.
- There are some early indications of less aggressive care at the end of life for beneficiaries served by OCM practices, compared to those served by non-participating practices, including fewer inpatient admissions and ICU stays in the last month of life.
- OCM practices are working to improve patient education, follow evidence-based guidelines, and proactively managing chemotherapy symptoms such as nausea and dehydration, all with the goal of avoiding unnecessary ED visits and costly hospitalizations.

This section of the report presents findings about overall patient ratings and experiences with care coordination, communication, access, and shared decision making, all important components of overall quality from the patient's perspective. This section also presents findings about quality of supportive care and EOL care.

3.6.1 Overall Patient Ratings of Their Cancer Therapy Team

The OCM patient survey asks respondents for an overall rating of their cancer therapy team on a scale of 0 (worst cancer therapy team possible) to 10 (best cancer therapy team possible). In the baseline, there was no statistically significant difference in overall rating between OCM and comparison respondents (see Appendix E). Both OCM and comparison respondents gave their cancer therapy team very high marks (approximately 9.3 out of 10), and among the OCM group there was little room to improve and no statistically significant change over time. This suggests that OCM did not improve or impair overall patient ratings of their cancer care team.

3.6.2 Care Coordination and Communication

This section explores care coordination and communication processes that may be affected by OCM, as well as practices' efforts to comply with OCM requirements. Overall, practices we visited told us that activities related to coordination were of high priority, although they experience challenges in receiving

timely notification when their patients visit EDs. Overall, both OCM and comparison survey respondents gave their care teams high ratings for care coordination.

Care Coordination

In their 2017 PTPs, OCM practices report on several activities related to care coordination, and the patient survey includes three questions about care coordination.⁶⁸ Additionally, the 12 practices we visited during Year One were all exploring how to make better use of their EHRs to coordinate care.

The percentage of practices reporting use of care coordination approaches in 2017 in the PTP ranged from 61 percent of all OCM practices conducting medication reconciliation with outside clinicians, to 93 percent of practices conducting medication reconciliation with patients during care transitions. No variation in care coordination activities was observed by practice size, ownership, or academic affiliation, and no significant differences between the first and second PTPs.

There was no statistically significant difference between OCM and comparison survey respondents to the baseline survey, on any of the three care coordination measures. Both OCM and comparison practices were rated highly by their patients on care coordination (see Appendix E). At baseline, approximately 90 percent of both OCM and comparison respondents reported that their cancer therapy team never delayed treatment due to missing tests or reports, and that they never received conflicting information about care from different members of their cancer therapy team. Seventy-two percent of both OCM and comparison respondents reported their cancer therapy team always knew important information about their medical history.

Over time, fewer OCM respondents reported that their cancer therapy team always knew the important information about their medical history, a decline from 71.9 percent in the baseline wave to 67.8 percent in the intervention wave 3 ($p \leq 0.05$). This decline was more pronounced among OCM respondents who were treated with long-term hormonal therapy only, without other chemotherapy—patients who have infrequent contact with their oncology care team. For breast cancer patients with hormonal therapy only, the rate declined from 70.9 percent in the baseline to 63.1 percent in the intervention wave 3 ($p \leq 0.10$). For prostate cancer patients with hormonal therapy only, the rate declined from 68.0 percent in the baseline to 59.7 percent in the intervention wave 3 ($p \leq 0.10$). There was no statistically significant trend in the other two care coordination measures among OCM survey respondents. We will continue to monitor this downward trend in the OCM group over time, and in Year Three will determine whether the same decline occurred among comparison respondents.

Data collected during case studies focused mainly on the ability of the practice to utilize EHRs to improve documentation and communication across health care providers, and the practices' ability to obtain notifications when patients are receiving care outside of their practice. Three of the 12 practices we visited transitioned to new or upgraded EHRs during the early months of the Model and considered OCM requirements when making the change/upgrade. Two practices purchased their EHR vendor's OCM module as an add-on. While these EHR enhancements may help practices implement and monitor key

⁶⁸ These three measures are (1) how often the cancer therapy team seemed to know important information about the patient's medical history, (2) how often the cancer therapy team delayed the patient's treatment or a treatment decision due to missing test results or reports from other providers, and (3) how often patients received conflicting information from different members of the cancer therapy team.

components of OCM, they do not necessarily contain additional features that help facilitate coordination with entities outside the practice.

Oncologists want to know as soon as possible when their patients receive care elsewhere, especially if patients visit an ED or are admitted to the hospital, as this may alter the treatment plan going forward. Two practices we visited are owned by integrated health systems that use enterprise EHRs, which means that all of the care a patient receives, anywhere in the health system, exists in a single record that can be accessed by oncologists and nurses. This is not the case at the other two health system-owned practices, where the practice and its parent health system have different EHRs. Oncologists at these two practices, like those at the eight independent practices, have some capability to view portions of their patients' records in the affiliated hospitals' EHRs, but the reverse is usually not possible. That is, a hospital's EHR may have a provider portal through which the oncologist can view portions of a patient's hospital record, but the practice's oncology EHR has no similar portal through which hospital staff (and other external physicians) can view the patient's oncology record.

Real-time notification when a patient visits the ED could help oncologists communicate with ED physicians, reduce unnecessary tests performed in the ED, and potentially avert inpatient admissions, but many oncologists only learn about ED visits from the patient. Health Information Exchanges (HIEs) offer the possibility of better coordination between oncology practices and nearby hospitals, but HIE utility is only as good as the extent of membership and timeliness of information sharing. One health system-owned practice we visited participates in the local HIE and is notified whenever one of its patients is seen at any other local hospital that is also in the HIE, but not all local hospitals are HIE members. Another practice we visited receives a report from the regional HIE every 12 hours about ED visits by any of its patients, which is helpful but usually not timely enough for oncologists to intervene before a patient is admitted from the ED to the hospital. A third practice is in the process of joining its state HIE, to which most hospitals belong. After this is complete, nurse navigators at the practice will be notified in real time if one of their patients is in an ED, and can work with ED staff to avert an inpatient admission. This practice told us it is costly to link its EHR to the HIE, and it will take 18 months to complete the necessary contracting and IT connections.

Patient-Provider Communication

In their 2017 PTPs, most OCM practices reported that they offer online patient portals and on-call clinicians to facilitate communication between patients and their oncology team. Of the different composites on the patient survey that assess patient-provider communication, composite scores were highest for affective communication and lowest for shared decision making. There were no statistically significant differences at baseline between intervention and comparison groups on these composites, and no changes in the OCM group over time.

In their annual PTPs, practices indicated how they use technology to facilitate patient-provider communication. Nearly 95 percent of practices use an EHR patient portal, and 11 percent of practices offer two-way, real-time, video visits. Use of these technologies did not vary by practice size, ownership, or academic affiliation and did not change between 2016 and 2017.

Telephone access is described in Section 3.5, and every practice we visited includes 24/7 telephonic access to a clinician who can access the patient's electronic record. Leaders at several practices we visited in Year One mentioned that they are implementing and/or enhancing tools for communicating with their patients, at least in part to succeed in OCM. All 12 practices we visited installed EHR patient portals prior

to OCM through which patients can securely message their care teams and review posted test results. Of the 12 practices, six now give patients copies of their Care Plans and upload the document to the patient portal. One independent practice invested in new software that sends automated text message reminders to patients about appointments, and adherence reminders for oral chemotherapy. In the future, this practice intends to use the software to identify patients experiencing adverse side effects and proactively engage with them to improve symptom management.

Communication technologies and strategies, along with enhanced navigation and care coordination, may improve patient experiences of communicating with their oncology care teams. Other OCM requirements enumerated in the Care Plans (see Section 3.5.2) are intended to ensure that patients understand their treatment plan and goals of therapy, to support shared decision making and advance care planning. The patient survey includes many questions about communication between patients and providers, in three domains: Affective Communication, Exchanging Information, and Shared Decision Making. We created one composite for each domain.

Over the three intervention waves, the adjusted mean composite scores for Affective Communication and Exchanging Information were very high, and declined slightly among OCM respondents (**Exhibit 25**), from 9.01 in the baseline to 8.92 in the intervention wave 3 ($p \leq 0.01$) for Affective Communication, and from 8.51 to 8.41 for Exchanging Information ($p \leq 0.05$). We will survey comparison patients again in Year 3 to understand whether these declines were present in comparators as well.

We note that the magnitude of identified changes over time was quite small, and that the reason for statistical significance is primarily the large sample size of our survey. These small changes may not be clinically meaningful or related to overall patient ratings of care, which remained unchanged over time (see Section 3.6.1).

Exhibit 25: Adjusted Measures on Patient-Provider Communication, by OCM Patient Survey Wave (OCM Respondents Only)

Measure	Adjusted Mean				Linear Time Trend Estimates		
	Baseline Wave	Int. Wave 1	Int. Wave 2	Int. Wave 3	Point Estimate	90% CLs	
	(Apr. 16–Sep. 16)	(Jul. 16–Dec. 16)	(Oct. 16–Mar. 17)	(Jan. 17–Jun. 17)		LCL	UCL
Affective Communication							
Composite score: affective communication (on a scale of 0–10)	9.01	8.96	8.93	8.92	-0.03***	-0.04	-0.01
Cancer therapy team always showed respect for what patient had to say	81.1%	79.4%	79.0%	80.1%	-0.4%	-0.9%	0.1%
Cancer therapy team always listened carefully to the patient	79.0%	77.9%	78.5%	78.5%	-0.1%	-0.4%	0.2%
Cancer therapy team was always direct and straightforward when talking with patient about cancer and drug therapy	77.5%	76.1%	74.2%	75.0%	-1.0%**	-1.6%	-0.3%
Cancer therapy team always spent enough time with the patient	72.7%	71.9%	70.3%	70.5%	-0.8%***	-1.3%	-0.3%
Exchanging Information							
Composite score: exchanging information (on a scale of 0–10)	8.51	8.42	8.38	8.41	-0.04**	-0.06	-0.01
Cancer therapy team definitely clearly explained how drug treatment could affect the patient's normal daily activities	74.3%	72.8%	74.7%	72.6%	-0.3%	-0.8%	0.1%
Cancer therapy team definitely told patient what the next steps in drug therapy would be	69.4%	68.4%	65.8%	68.4%	-0.6%*	-1.1%	-0.1%
Cancer therapy team always explained test results in a way that was easy to understand	75.5%	74.2%	74.0%	74.5%	-0.3%	-0.8%	0.1%
Cancer therapy team definitely explained what new medicine was for in a way that was easy to understand (if patient was prescribed new medicine in the last 6 months)	88.6%	89.2%	88.3%	90.2%	0.4%	-0.5%	1.3%
Shared Decision Making							
Composite score: shared decision making (on a scale of 0–10)	7.45	7.38	7.31	7.44	-0.01	-0.04	0.02
Cancer therapy team definitely talked with patient about the reasons patient might want to have drug therapy	85.7%	85.5%	84.7%	84.2%	-0.5%*	-1.0%	-0.04%
Cancer therapy team definitely talked with patient about the reasons patient might not want to have drug therapy	44.9%	41.7%	41.5%	44.0%	-0.3%	-0.9%	0.2%

Measure	Adjusted Mean				Linear Time Trend Estimates		
	Baseline Wave	Int. Wave 1	Int. Wave 2	Int. Wave 3	Point Estimate	90% CLs	
	(Apr. 16–Sep. 16)	(Jul. 16–Dec. 16)	(Oct. 16–Mar. 17)	(Jan. 17–Jun. 17)		LCL	UCL
Cancer therapy team definitely asked for patient’s opinion about whether or not to have drug therapy	61.3%	60.9%	60.9%	62.7%	0.4%	-0.2%	1.0%
Cancer therapy team definitely involved patient in decisions about drug therapy as much as the patient wanted	74.8%	74.1%	72.8%	75.3%	-0.0002%	-0.3%	0.3%

Source: OCM patient survey.

Notes: Int.: Intervention period

*p≤0.10, **p≤0.05, ***p≤0.01

3.6.3 Quality of Supportive Care

An important aspect of cancer care is effective supportive care to address symptoms related to cancer and its treatment. Improving supportive care may help to improve patient experiences and reduce preventable ED visits and hospitalizations.⁶⁹ OCM practices we visited are working to improve symptom management for their patients, through proactive outreach to high-risk patients to assess symptoms, urgent/same-day appointments to address symptoms (including on weekends), and educating patients about seeking care from the oncology practice rather than in EDs. In addition, the OCM requirement to follow evidence-based guidelines may lead practices to adhere more closely to guidelines for prophylactic antiemetic supportive therapy, to prevent nausea and vomiting due to toxic chemotherapy. This section describes changes practices are implementing to better support patients undergoing chemotherapy, adherence to evidence-based guidelines for antiemetic therapy, patient-reported experiences receiving assistance managing symptoms from cancer and chemotherapy, and chemotherapy-related hospitalizations and ED visits.

Practice Efforts to Identify High-risk Patients

Some chemotherapeutic regimens are especially toxic, and patients require additional support to tolerate side effects and complete treatment. All 12 practices we visited in Year One acknowledged the benefit of identifying high-risk patients for proactive outreach and symptom management, although not all were using standard processes to categorize risk, or recording patient risk status in their EHRs. Three practices instituted formal tools to identify high-risk patients: one records practice-calculated risk scores in the EHR, the other two maintain separate lists of high-risk patients because their EHRs have no field to record this information. At the time of our visit, only one of these three practices was systematically acting on the information about risk status, by using its list to review specific patient needs in weekly OCM care coordination huddles. Three other practices hoped to add risk assessment functionality within their new EHRs or with a separate tool, but had not yet implemented this at the time of our visit. In the remaining six practices, clinical staff told us that they identify high-risk patients in an ad hoc fashion based on patient characteristics (e.g., age, caregiver support needed), treatment regimen, psychosocial

⁶⁹ <https://www.fredhutch.org/en/news/releases/2017/many-cancer-patients-emergency-department-visits-appear-preventable.html>; accessed on March 5, 2018.

factors, comorbidities, or other factors identified from “knowing our patients.” Having identified such patients in these practices, however, follow-up is sporadic and not standardized across the practice.

The annual PTPs ask about use of risk scores/risk cohorts to target patients for proactive outreach and enhanced supportive care. The percent of OCM practices stratifying patients into actionable risk cohorts increased from 30 percent in 2016 to 46 percent in 2017 ($p < 0.05$).

Side effects from chemotherapy can cause patients to skip doses of oral medication, sometimes without communicating with their oncology care team. Better communication about side effects, and assistance in managing those side effects, may improve patient adherence to the prescribed medication/schedule. Several practices told us they proactively contact patients on oral therapies to monitor adherence and check for side effects. Nurses at three practices told us that as a direct result of OCM they now routinely call oral therapy patients, especially those taking more-toxic or costly medications, to monitor adherence. Pharmacy technicians do the same at a fourth very large independent practice, but this began before OCM. A fifth practice planned to start oral adherence calls soon after our visit. One practice purchased software that will generate text reminders to patients about adhering to the schedule for their oral medications.

Guideline-Recommended Use of Prophylactic Antiemetics for Patients Undergoing Intravenous Chemotherapy

The incentive to deliver high-value care under OCM could lead practices to systematically reduce overuse of costly antiemetic drugs (which prevent nausea and vomiting), in situations where similarly effective and less expensive alternatives are available. Conversely, the incentive to prevent costly ED visits and hospitalizations could lead practices to adopt more high-intensity antiemetic regimens, administered prior to toxic chemotherapy, with the goal of reducing acute care utilization.

Rates of guideline-recommended antiemetic use in the baseline period were similar for OCM and comparison practices, although OCM practices had a slightly higher rate of guideline-recommended antiemetic use for patients on high emetogenic risk chemotherapy regimens (75.4 percent vs. 72.2 percent, see **Exhibit 26**). There was no DID estimated OCM impact on use of guideline-recommended antiemetics for any emetogenic risk group, for episodes that began during PP1, although the rate increased for both groups.

Among patients who received guideline-recommended chemotherapy, we assessed the extent to which patients received higher-intensity (and more costly) versus appropriate lower-intensity regimens that might be a suitable first strategy for patients starting chemotherapy. There was no significant OCM impact on the intensity of antiemetics used, among the guideline-recommended antiemetic regimens (**Exhibit 27**).

Exhibit 26: Guideline Recommended Use of Antiemetics

Measure	# of Episodes		OCM		COMP		Impact Estimates			
	OCM	COMP	Baseline Mean	Int. Mean	Baseline Mean	Int. Mean	DID	90% LCL	90% UCL	Percent Change
Guideline-Recommended Use of Antiemetics										
High emetogenic risk episodes	6,620	8,235	75.4%	81.1%	72.2%	78.4%	-1.6%	-4.8%	1.6%	-2.2%
Moderate emetogenic risk episodes	41,301	47,846	96.6%	96.0%	96.5%	95.9%	0.8%	-0.2%	1.7%	0.8%
Low emetogenic risk episodes	35,946	42,400	85.3%	87.0%	86.9%	88.5%	-0.6%	-2.3%	1.1%	-0.7%

Source: Episode analytic file (2014–2017).

Notes: OCM: OCM intervention group; COMP: Comparison group. Int.: Intervention period

Exhibit 27: Use of Higher versus Lower-Intensity Guideline-Recommended Antiemetic Regimens

Measure	# of Episodes		OCM		COMP		Impact Estimates			
	OCM	COMP	Baseline Mean	Int. Mean	Baseline Mean	Int. Mean	DID	90% LCL	90% UCL	Percent Change
Use of Antiemetics										
Moderate emetogenic risk episodes with high-intensity antiemetic patterns	40,019	45,943	24.3%	29.4%	23.1%	28.0%	0.1%	-2.8%	2.9%	0.3%
Low emetogenic risk episodes with high-intensity antiemetic patterns	30,637	37,202	37.8%	33.9%	38.3%	34.4%	1.6%	0.0%	3.2%	4.2%

Source: Episode analytic file (2014–2017).

Notes: OCM: OCM intervention group; COMP: Comparison group. Int.: Intervention period

Patient-Reported Symptom Management

Efforts by OCM practices to better support patients during chemotherapy (e.g., prophylactic antiemetic therapy, expanded clinic hours, same-day appointments) may improve patient-reported care experiences, especially symptom management. In their 2017 PTPs, OCM practices reported offering same day appointments (95 percent), and extended evening clinic hours (38 percent) or weekend hours (36 percent).

The OCM patient survey contains multiple questions about patients' experiences communicating with their care providers about symptoms related to cancer and treatment, and receiving assistance to manage those symptoms.

We created two composite scores to measure symptom management. The first—the Enabling Patient Self-Management—is one of the five composites used to adjust the performance-based payments that practices may be eligible to receive and contains eight questions, including:

- Questions about whether patients talked with their cancer therapy team about three symptoms related to cancer and chemotherapy, including pain, changes in energy levels, and emotional problems such as anxiety or depression
- Questions about whether the cancer therapy team tried to help patients deal with those symptoms, if patient experienced them
- Questions about whether the cancer therapy team provided additional services to help patients, including additional services to manage cancer care at home, such as home health care, special medical equipment, or special supplies; and things patient can do for themselves to maintain health during cancer treatment, such as diet and exercise.

There was no difference between intervention and comparison survey respondents in the baseline survey on the composite score for Enabling Patient Self-Management, which was 6 out of a possible 10 in both groups. This suggests that our comparison group resembled the OCM group before the Model began and in both groups, practices have room to improve.

The second composite—Symptom Management—contains questions about whether the cancer therapy team tried to help patients deal with eight symptoms, if the patient experienced any of those symptoms. The Symptom Management composite is important to measure whether practices' symptom management efforts are improving patient experiences. The eight symptoms include the three symptoms that are also in the Enabling Patient Self-Management composite (pain, changes in energy levels, and emotional problems), as well as five additional symptoms that clinical experts advise are especially relevant for chemotherapy patients: nausea/vomiting, difficulty breathing, coughing, constipation/diarrhea, and neuropathy. The Symptom Management composite is not used to adjust PBP payments. There was no baseline difference between intervention and comparison survey respondents in the composite score for Symptom Management (7.4 out of 10 in both groups).

We surveyed OCM patients in three intervention survey waves during Model Year One (comparison patients will be surveyed again in Year Three). There was no statistically significant trend over time in either composite score related to symptom management (**Exhibit 28**). There were, however, a few trends over time in the OCM group for individual survey questions within the composites dealing with emotional problems, definitely talking about things the patient could do to maintain health during cancer treatments, and talking about additional services to manage care at home.

Exhibit 28: Adjusted Measures on Symptom Control, by OCM Patient Survey Wave (OCM Respondents Only)

Measure	Adjusted Mean				Linear Time Trend Estimates		
	Baseline Wave	Int. Wave 1	Int. Wave 2	Int. Wave 3	Point Estimate	90% CLs	
	(Apr. 16–Sep. 16)	(Jul. 16–Dec. 16)	(Oct. 16–Mar. 17)	(Jan. 17–Jun. 17)		LCL	UCL
Composite Score							
Composite score: enabling patient self-management (on a scale of 0–10)	5.96	5.86	5.99	5.96	0.01	-0.02	0.04
Composite score: symptom management (on a scale of 0–10)	7.29	7.14	7.32	7.28	0.01	-0.02	0.05
Individual Question: Talked about Symptoms							
Cancer therapy team talked with patient about pain related to cancer or chemotherapy or hormonal therapy	71.1%	69.5%	70.3%	69.6%	-0.4%	-1.2%	0.4%
Cancer therapy team talked with patient about changes in energy levels related to cancer or chemotherapy or hormonal therapy	78.7%	77.8%	79.6%	77.6%	-0.2%	-0.6%	0.3%
Cancer therapy team talked with patient about emotional problems related to cancer or chemotherapy or hormonal therapy	53.7%	54.2%	54.8%	54.6%	0.3%	-0.1%	0.7%
Individual Question: Helped Deal with Symptoms							
Cancer therapy team definitely tried to help patient deal with pain (if patient had this symptom from cancer or drug therapy in the last 6 months)	74.7%	74.1%	74.2%	75.8%	0.3%	-0.4%	1.1%
Cancer therapy team definitely tried to help patient deal with changes in energy levels (if patient had this symptom from cancer or drug therapy in the last 6 months)	52.4%	48.9%	49.5%	51.3%	-0.3%	-0.9%	0.3%
Cancer therapy team definitely tried to help patient deal with emotional problems (if patient had this symptom from cancer or drug therapy in the last 6 months)	44.2%	45.5%	45.9%	48.9%	1.5%*	0.2%	2.7%
Cancer therapy team definitely tried to help patient deal with nausea/vomiting (if patient had this symptom from cancer or drug therapy in the last 6 months)	80.4%	79.4%	77.9%	79.4%	-0.5%	-1.0%	0.1%

Measure	Adjusted Mean				Linear Time Trend Estimates		
	Baseline Wave	Int. Wave 1	Int. Wave 2	Int. Wave 3	Point Estimate	90% CLs	
	(Apr. 16–Sep. 16)	(Jul. 16–Dec. 16)	(Oct. 16–Mar. 17)	(Jan. 17–Jun. 17)		LCL	UCL
Cancer therapy team definitely tried to help patient deal with difficulty breathing (if patient had this symptom from cancer or drug therapy in the last 6 months)	58.2%	55.7%	59.0%	56.9%	-0.1%	-0.8%	0.6%
Cancer therapy team definitely tried to help patient deal with coughing (if patient had this symptom from cancer or drug therapy in the last 6 months)	48.5%	56.9%	53.6%	53.6%	1.3%	-0.2%	2.8%
Cancer therapy team definitely tried to help patient deal with constipation/diarrhea (if patient had this symptom from cancer or drug therapy in the last 6 months)	66.5%	63.7%	68.8%	68.8%	1.1%	-0.1%	2.3%
Cancer therapy team definitely tried to help patient deal with neuropathy (if patient had this symptom from cancer or drug therapy in the last 6 months)	49.1%	46.8%	47.6%	45.9%	-0.9%	-1.9%	0.1%
Individual Question: Talked about Other Services							
Cancer therapy team definitely talked with patient about additional services to manage care at home	22.0%	21.6%	22.2%	20.1%	-0.5%**	-0.9%	-0.1%
Cancer therapy team definitely talked with patient about things patient can do to maintain health during cancer treatment	47.1%	46.4%	47.5%	49.9%	0.9%**	0.2%	1.6%

Source: OCM patient survey.

Note: Int.: Intervention period

*p≤0.10, **p≤0.05, ***p≤0.01

Chemotherapy-Related Hospitalizations and Emergency Department Visits

Improved symptom management, expanded clinic hours, better communication with high-risk patients, and appropriate use of supportive medications, may together reduce ED visits and hospitalizations related to toxic side effects of chemotherapy. In the baseline period, 7.8 percent of OCM episodes had at least one chemotherapy-associated hospitalization and 11.6 percent had associated ED visits; these chemotherapy-related visits represent a small proportion of total hospitalization and ED visits (see Section 3.2.1). In comparison episodes, 7.3 percent had at least one chemotherapy-associated inpatient hospitalization and 11.6 percent had associated ED visits. The proportion of episodes with chemotherapy-associated hospitalizations and chemotherapy-associated ED visits decreased in both groups during PP1, and the estimated OCM impact was not statistically different (**Exhibit 29**).

Exhibit 29: Chemotherapy-Associated Hospitalizations and ED Visits

Measure	# of Episodes		OCM		COMP		Impact Estimates			
	OCM	COMP	Baseline Mean	Int. Mean	Baseline Mean	Int. Mean	DID	90% LCL	90% UCL	Percent Change
Episodes with chemotherapy-associated inpatient admission	489,710	579,678	7.8%	7.1%	7.3%	6.6%	0.1%	-0.2%	0.3%	0.9%
Episodes with chemotherapy-associated ED visit	489,710	579,678	11.6%	11.0%	11.4%	11.0%	-0.2%	-0.4%	0.1%	-1.5%

Source: Episode analytic file 2014–2017.

Notes: Some of the patients who had ED visits were admitted to the hospital, and are also recorded in the chemotherapy-associated inpatient visits. ED visits that do and do not result in an inpatient admission are presented separately in Appendix F.

OCM: OCM intervention group; COMP: Comparison group. Int.: Intervention period

Combining information above about supportive therapy from all of the analyses presented in this section, we see that in the first year, OCM practices were working to identify high-risk patients, improve access to urgent care, and improve supportive therapy, all with the goal of reducing ED visits and subsequent hospitalizations, especially those for chemotherapy toxicities. These improvements may require expanding space, hiring more staff, and other structural changes that are especially challenging for hospital-based practices, and where possible, may take more than one year to complete. Antiemetic therapy for patients undergoing emetogenic infused chemotherapy did not change in the OCM group relative to comparisons, and there was no OCM impact on chemotherapy-related ED visits or hospitalizations. We will continue to monitor changes in these key indicators of supportive therapy, as well as relative impact in patient-reported symptom management between OCM and comparison survey respondents.

3.6.4 Quality of End-of-Life (EOL) Care

OCM emphasizes advance care planning and incentivizes appropriate EOL care. This section explores issues related to the provision of end-of-life care for cancer patients.

When patients are terminally ill and further curative treatment is futile and may reduce quality of life, holistic care shifts to prioritizing pain management and symptom palliation. EOL care can be overseen by oncologists and often also involves other care providers such as palliative care specialists and hospice providers. The incorporation of palliative care for patients who may benefit, and the careful management of patients during transitions to hospice, are important elements of high quality EOL care.

OCM contains specific requirements and feedback to practices that are intended to improve advance care planning, care coordination, and EOL care. Eliminating ineffective, unnecessary, and often costly treatments at the end of life may improve quality of life and reduce TCOC for dying patients, while improving caregiver experiences with EOL care. This section of the report addresses advance care planning and palliative care, treatment at the end of life, hospice care, and caregiver ratings of EOL care.

Advance Care Planning and Palliative Care

OCM explicitly encourages advance care planning and it is one of the 13 Care Plan elements. Studies demonstrate that patients with documented advance directives (e.g., living wills) are less likely to receive health care interventions near to death.^{70, 71}

Practice leaders we interviewed during case studies generally embraced the idea of early discussions with patients for advance care planning. Most of the 12 practices mentioned efforts to improve their process for promoting early discussions and completing some form of advance care directive with their patients. Non-oncologist clinical staff, such as medical assistants, nurses, social workers, and advanced practice clinicians, may introduce the topic of advance care planning with patients; however, most practices rely on oncologists to hold detailed discussions about EOL planning.

Most oncologists we interviewed acknowledged that discussions about advance care planning can be difficult, especially when patients first enter treatment that they hope will be curative. Many emphasized that OCM provides an impetus to begin these discussions sooner, and some told us they use OCM as the justification to introduce advance care planning with their patients. Two practices we visited in the early months of OCM planned to offer more training to their oncologists about discussing advance directives and goals with patients. Some practices also use vetted tools and programs for advance care planning (e.g., Honoring Choices, Five Wishes, and Physician Order for Life-Sustaining Treatment [POLST] forms). Several oncologists at one practice that serves minority and immigrant communities told us they do not discuss palliative care or advance care planning until the patient or family asks, because in the past they felt that such discussions irreparably “broke the trust relationship” with patients from some cultures. At other practices we visited, the oncologists discuss advance directives with many of their patients at the start of treatment and revisit these plans as disease progresses. One physician who has practiced for more than 30 years explained that he no longer waits until a patient has advanced disease: he has learned that early and repeated conversations make this topic a routine part of giving and receiving cancer care, for which he credits OCM.

While most OCM practices encourage their patients to complete advance directives earlier in treatment, several noted the challenge of sharing these directives with patients’ other providers. Even if a copy of the advance directive is available in the practice’s EHR, it is not easily accessible to outside providers, such as emergency room physicians. Oncologists at several practices acknowledged that it is usually up to patients and their caregivers to bring a copy of the advance directive when seeking care at an ED.

⁷⁰ Teno, J. M., Gruneir, A., Schwartz, Z., et al. (2007). Association between advance directives and quality of end-of-life care: a national study. *J Am Geriatr Soc*, 55:189.

⁷¹ Brinkman-Stoppelenburg, A., Rietjens, J.A., & van der Heide, A. (2014). The effects of advance care planning on end-of-life care: a systematic review. *Palliat Med*, 28:1000.

All 12 practices we visited in Year One expressed keen interest in using more palliative care services. We observed differences in palliative care services offered at the practices owned by health systems versus those owned by independent practices, as summarized in **Exhibit 30**. At six independent practices, palliative care is provided by the oncologists (not by palliative care specialists), but two are exploring hiring palliative care specialists. The two other independent practices and the four health system-owned practices rely on palliative care specialists. Two practices added palliative care specialists specifically for OCM, two practices hope to add such services in the future, and two others are planning to expand existing palliative care services.

Exhibit 30: Palliative Care Services Offered

Strategy	Independent Practices	Health System-Owned Practices	Challenges	Planned Changes
Palliative care provided by oncologists at the practice	6			<ul style="list-style-type: none"> Two of these six practices plan to hire palliative care specialists
Palliative care provided by specialists on staff (or contracted) at the practice	2	2	<ul style="list-style-type: none"> Most palliative care specialists' salaries exceed what payers will reimburse for palliative care consultations; however, the service is still considered worthwhile from the practices' perspective as it improves oncologist productivity. 	
Patients have access to palliative care specialists at hospital (generally inpatient only)		2	<ul style="list-style-type: none"> Hospital palliative care specialists see mainly inpatients, and have limited time in their schedule for outpatient consultations. 	<ul style="list-style-type: none"> Expand palliative care services at the practice; offer symptom management earlier in treatment One practice hopes to provide space within the practice for the health system's palliative care specialist to see outpatients

Care at the End of Life

Multiple prior studies found that timely hospice referral, avoidance of medical interventions at the end of life, and death outside the hospital, reflect better quality of care and higher satisfaction as perceived by family members and caregivers.⁷² For example, previous research indicates that among Medicare patients with advanced-stage lung or colorectal cancer, receiving more than three days of hospice care, dying outside of the hospital, and having no ICU admission within 30 days of death, were associated with “excellent” family-reported ratings of EOL care. ICU admissions and greater use of medical care at the end of life were also associated with a lower rating of respectful and communicative care, and increased rates of depression among caregivers. Additionally, research finds that patients who died in a hospital or ICU experienced more physical and emotional distress at the end of life than did patients who died in a hospice. We measured several features of EOL care using claims, and validated these outcomes with proxy survey responses in Appendix F. Finally, while we assess all information available in Medicare claims regarding episodes for OCM and their comparators, it is important to keep in mind that chemotherapy triggers OCM-defined episodes. EOL care that discourages chemotherapy may keep episodes from being triggered, potentially altering the composition of the OCM group and DID results over time. The findings below are therefore likely a conservative estimate of the impact of OCM on care at the end of life. In the future, we will follow patients for additional months after their last OCM-defined episode ends, to include subsequent deaths in EOL analyses.

⁷² Ersek, M., Miller, S. C., Wagner, T. H., Thorpe, et al. (2017). Association between aggressive care and bereaved families’ evaluation of end of life care for veterans with non-small cell lung cancer who died in Veterans Affairs facilities. *Cancer*, 123(16), 3186–3194.

Kris, A. E., Cherlin, E. J., Prigerson, H., et al. (2006). Length of hospice enrollment and subsequent depression in family caregivers: 13-month follow-up study. *American Journal of Geriatric Psychiatry*, 14(3), 264–269.

Wright, A. A., Keating, N. L., Ayanian, J. Z., et al. (2016). Family perspectives on aggressive cancer care near the end of life. *Journal of the American Medical Association*, 315(3), 284–292.

Wright, A. A., Keating, N. L., Balboni, T. A., et al. (2010). Place of death: correlations with quality of life of patients with cancer and predictors of bereaved caregivers’ mental health. *Journal of Clinical Oncology*, 28(29), 4457–4464.

Wright, A. A., Zhang, B., Keating, N. L., et al. (2014). Associations between palliative chemotherapy and adult cancer patients’ end of life care and place of death: prospective cohort study. *BMJ*, 348, g1219.

Wright, A. A., Zhang, B., Ray, A., Mack, J. W., et al. (2008). Associations between end-of-life discussions, patient mental health, medical care near death, and caregiver bereavement adjustment. *Journal of the American Medical Association*, 300(14), 1665–1673.

Exhibit 31 shows that for patients who died during an OCM-defined episode, inpatient admissions and ICU use in the last 30 days of the patient’s life decreased among OCM episodes relative to comparable comparison episodes.

- The share of OCM episodes with any inpatient admission in the last 30 days of a patient’s life decreased while the share of comparison episodes with any inpatient admission in the last 30 days of a patient’s life increased ($p \leq 0.01$) resulting in a statistically significant relative decrease of 1.5 percentage points for OCM episodes relative to comparisons, a decline of 2.6 percent of the mean OCM inpatient admission rate in the baseline period.
- The share of OCM episodes for deceased patients that included at least one ICU stay in the last 30 days of the patient’s life increased slightly in the first PP, but comparison episodes increased more, ($p \leq 0.01$), resulting in a statistically significant relative decrease of 2.2 percentage points for OCM, an 8.1 percent decline relative to the mean OCM value in the baseline period.
- There was no statistically significant change in receipt of any chemotherapy during the last 14 days of life or ED use (two or more visits) in the last 30 days of life, during OCM episodes when the patient died, relative to comparison episodes.

We conclude that the OCM emphasis on advance care planning may be contributing to the estimated reductions in inpatient and ICU admissions for dying OCM patients, relative to the comparison group.

Caregiver Perceptions of EOL Care Quality

The vast majority of proxy (i.e., caregiver) survey respondents gave high ratings for the overall care their deceased loved one received in the last month of life. Proxy respondents overwhelmingly rated deceased patients’ overall experiences in the last month of life as “excellent,”⁷³ “very good,” or “good,” for both OCM patients and comparison patients (approximately 90 percent).⁷⁴ However, this was not equally true for individual questions about EOL care experiences. For example, while more than 70 percent of proxy survey respondents indicated that care providers always showed respect for what the dying patient had to say, only about half of proxy respondents reported that care providers always spent enough time with the dying patient.

⁷³ Forty-six percent of the proxies selected the highest rating (excellent) for the dying patient’s overall care experience in the last month of life, for both OCM patients and comparison patients.

⁷⁴ The proxy-reported overall rating varied considerably based on patients’ care preferences. Among proxies of patients who died in the baseline period, just before OCM began, 91.6 percent rated the overall experience as “excellent,” “very good,” or “good” if the dying patient preferred to relieve pain as much as possible, compared with 86.0 percent for dying patients who preferred to extend life as long as possible ($p \leq 0.01$). A smaller pre-OCM difference (91.5% vs. 87.6%; $p \leq 0.01$) was indicated by proxy respondents for deceased comparison patients.

Exhibit 31: Impact Estimates for Hospital-Based Care and Chemotherapy at the End of Life

Measure	Number of Episodes		OCM		COMP		Cumulative Impact Estimates			
	OCM	COMP	Baseline Mean	Int. Mean	Baseline Mean	Int. Mean	DID	90% LCL	90% UCL	Percent Change
Any chemotherapy during the last 14 days of life	51,243	57,394	13.0%	13.2%	12.2%	12.4%	0.003	-0.004	0.010	2.4%
Any inpatient admissions in the last 30 days of life	51,243	57,394	55.7%	55.4%	54.3%	55.4%	-0.015***	-0.026	-0.003	-2.6%
Any Intensive Care Unit (ICU) use in the last 30 days of life	51,243	57,376	26.6%	27.0%	22.6%	25.0%	-0.022***	-0.033	-0.010	-8.1%
Emergency Department (ED) use (2+ visits) in the last 30 days of life	51,243	57,394	15.3%	16.5%	15.4%	17.1%	-0.007	-0.015	0.001	-4.4%

Source: Episode analytic file, 2014–2017.

Note: OCM: OCM intervention group; COMP: Comparison group. Int.: Intervention period

*p≤0.10, **p≤0.05, ***p≤0.01

Exhibit 32 shows risk-adjusted EOL care experiences as reported by proxy survey respondents during the baseline period prior to OCM, separately for OCM patients and comparison patients. In the baseline survey, the majority of proxy respondents reported that OCM and comparison patients who died wished to relieve pain and discomfort as much as possible, rather than extending life as long as possible.⁷⁵ Proxies for deceased OCM patients were statistically less likely to report that providers followed the deceased patient’s wishes in the last month life “a great deal,” than were proxies for deceased comparison patients (80.4 percent OCM vs. 83.0 percent comparison; $p \leq 0.10$).⁷⁶ There was no statistically significant difference in any other proxy-reported care experience measures between the OCM and deceased comparison groups in the baseline survey.

Exhibit 32: Adjusted Measures on Proxy-reported EOL Care Experience, OCM Survey Baseline Wave (Apr.–Sep. 16)

Measure	Number of Respondents		Adjusted Mean		Difference in Adjusted Mean		
	OCM	COMP	OCM	COMP	Diff.	90% CLs	
						LCL	UCL
The patient’s overall experience in the last month of life was excellent/very good/good	2,121	1,709	90.4%	90.0%	0.3%	-1.4%	2.1%
Care providers always showed respect for what the patient had to say	2,096	1,681	72.8%	71.9%	0.9%	-1.8%	3.6%
Care providers always listened carefully to the patients	2,094	1,663	67.8%	67.0%	0.8%	-1.9%	3.6%
Care providers were always direct and straightforward when talking with the patient	2,070	1,650	61.0%	60.2%	0.8%	-2.1%	3.7%
Care providers always explained things in a way the patient could understand	2,066	1,646	61.8%	60.5%	1.3%	-1.3%	4.0%
Care providers always spent enough time with the patient	2,084	1,672	53.7%	52.8%	0.9%	-1.9%	3.7%
The patient never got conflicting information about care from different care providers	2,008	1,608	77.8%	77.5%	0.3%	-1.9%	2.5%
Care providers followed the patient’s wishes to a great extent	1,857	1,506	80.4%	83.0%	-2.6%*	-4.9%	-0.3%

Source: OCM patient survey.

Notes: OCM: OCM intervention group; COMP: Comparison group.

* $p \leq 0.10$, ** $p \leq 0.05$, *** $p \leq 0.01$

There was no statistically significant change in any proxy-reported EOL care experience from the baseline wave to the first three intervention waves for OCM patients.

⁷⁵ In the baseline survey wave, there was no statistical difference between OCM and comparison patients with regard to wishing to relieve pain and discomfort versus extending life as long as possible.

⁷⁶ This difference was most pronounced for deceased patients who were between 75 and 84 years old. In this age group, proxies for 78.8 percent of deceased OCM patients indicated that the patient’s wishes were followed by providers “a great deal,” compared with 84.9 percent among deceased comparison patients ($p \leq 0.01$).

Hospice Utilization and Caregiver Perceptions about Hospice Timing

Transition to hospice care at a clinically useful point in the patient's disease trajectory is an important goal of high quality EOL care. Cancer patients whose life is unlikely to last more than six months, may elect the Medicare hospice benefit. As noted, receiving more than three days of hospice care was perceived by caregivers as better EOL care than was very brief use of hospice prior to death.⁷⁷

Oncologists at all 12 practices we visited told us that they refer patients to hospice as needed, drawing on a short list of preferred hospice agencies, while acknowledging that patients choose which hospice to use. Four practices told us that they excelled in appropriate and timely use of hospice services prior to implementing OCM. Others were just starting to re-educate clinicians and improve relationships with hospice agencies; at the time of our visits, two practices had begun such education for their staff. Most oncologists at the independent practices we visited remain actively involved in their patients' care after hospice referral, serving as the "physician of record" and writing prescriptions for pain medication, oxygen, and other symptom management orders. In contrast, oncologists at the four health system-owned practices told us that they generally transfer responsibility to the hospice medical director and have no further contact with the patient.

Exhibit 33 shows that there was no statistically significant impact of OCM on any claims-based measures of hospital utilization or the timing of hospice entry/election. In both the baseline and intervention periods, OCM patients were slightly more likely to use hospice services than were comparison patients. However, OCM patients were also slightly more likely to enter a hospice only one or two days before death, which for many patients is too short to optimize comfort measures.

Since hospice entry typically requires documentation from a physician attesting that the patient is unlikely to live more than six months beyond referral, a discussion about hospice care is the first step toward hospice entry. The OCM patient survey asks proxy respondents for deceased patients whether providers discussed hospice care with the dying patient. If providers did discuss hospice care with the patient, the survey asks whether the deceased patient used hospice care and whether hospice care started at the right time (or started too early or too late). While responses from OCM and comparison proxy respondents were quite similar at baseline, hospice use varied considerably, depending on patients' preferences for care in the last month of life. Among deceased OCM patients in the baseline survey, 90.0 percent of those who preferred to relieve pain as much as possible received hospice care (according to their caregiver proxy respondents), compared with 78.7 percent of those who preferred to extend life as long as possible. A similar difference was reported by proxy respondents for deceased comparison patients (88.2% vs. 80.2% respectively). Among patients who received hospice care, most proxy survey respondents felt that it began at the right time, but this was slightly less true for OCM patients than for comparisons (80.1% OCM vs. 83.6% comparison; $p \leq 0.05$). Further, proxy respondents for deceased OCM patients were more likely to report that patients started hospice care too late than was true of proxies for deceased comparison patients (18.4% vs. 15.7%, $p \leq 0.10$). We conclude that despite adjustment for observable differences, the two groups differed before OCM began, at least as reported by proxy survey respondents, and there was more room to improve in timely hospice care for OCM patients.

⁷⁷ Kris, A. E., Cherlin, E. J., Prigerson, H., et al. (2006). Length of hospice enrollment and subsequent depression in family caregivers: 13-month follow-up study. *American Journal of Geriatric Psychiatry*, 14(3), 264–269.

Wright, A. A., Keating, N. L., Ayanian, J. Z., et al. (2016). Family perspectives on aggressive cancer care near the end of life. *Journal of the American Medical Association*, 315(3), 284–292.

Exhibit 33: Impact Estimates for Hospice Use Measures

Measure	Number of Episodes		OCM		COMP		Cumulative Impact Estimates			
	OCM	COMP	Baseline Mean	Int. Mean	Baseline Mean	Int. Mean	DID	90% LCL	90% UCL	Percent Change
Never admitted to hospice	51,243	57,394	32.8%	32.4%	35.0%	35.2%	-0.003	-0.015	0.008	-0.9%
Being on hospice 1–2 days before death	51,243	57,394	8.0%	8.7%	7.1%	7.4%	0.001	-0.005	0.008	1.8%
Hospice 3–180 days before death	51,243	57,394	57.8%	57.4%	56.3%	55.7%	0.001	-0.011	0.013	0.1%

Source: Episode analytic file, 2014–2017.

Note: OCM: OCM intervention group; COMP: Comparison group. Int.: Intervention period

The proportion of proxies who reported that providers discussed hospice increased over time among OCM patients who died (**Exhibit 34**), a statically significant trend ($p \leq 0.05$). Increased discussion about hospice care did not, however, translate into a greater use of hospice care, or earlier hospice entry, neither of which changed significantly for the OCM group over the early intervention survey waves.

Exhibit 34: Adjusted Measures on Proxy-reported Hospice Use, by OCM Patient Survey Wave (OCM Respondents Only)

Measure	Adjusted Mean				Linear Time Trend Estimates		
	Baseline Wave	Int. Wave 1	Int. Wave 2	Int. Wave 3	Point Estimate	90% CLs	
	(Apr. 16–Sep. 16)	(Jul. 16–Dec. 16)	(Oct. 16–Mar. 17)	(Jan. 17–Jun. 17)		LCL	UCL
Cancer therapy team discussed hospice care with the patient or family	82.4%	79.3%	83.2%	86.8%	1.6%**	0.4%	2.9%
The patient received hospice care	84.2%	82.1%	84.9%	84.9%	0.5%	-0.8%	1.8%
The patient started hospice at the right time	77.8%	80.1%	74.2%	75.7%	-1.2%	-3.0%	0.6%

Source: OCM patient survey.

Notes: Int.: Intervention period

* $p \leq 0.10$, ** $p \leq 0.05$, *** $p \leq 0.01$

Place of Death

The OCM survey asks proxy respondents about the deceased patients' actual and preferred place of death, and we use these two responses to determine whether a patient died where they wished to die. In the baseline survey, 81 percent of deceased OCM and comparison patients preferred to die at home or a relative's home, as opposed to institutional facilities such as hospitals, inpatient hospice facilities, or nursing facilities (**Exhibit 35**). In both groups, only about half of the deceased patients actually died at home or at a relative's home, and this was less true for OCM patients than for comparison patients (51.6% OCM vs. 54.8% comparison; $p \leq 0.10$).

Exhibit 35: Adjusted Measures on Proxy-reported Place of Death, OCM Patient Survey Baseline Wave (Apr.–Sep. 2016)

Measure	Number of Respondents		Adjusted Mean		Difference in Adjusted Mean		
	OCM	COMP	OCM	COMP	Diff.	90% CLs	
						LCL	UCL
The deceased patient died at his/her home or relative's home (as opposed to institutional facilities)	2,139	1,707	51.6%	54.8%	-3.3%*	-6.2%	-0.3%
The deceased patient's preferred place of death is his/her home or relative's home (as opposed to institutional facilities)	1,916	1,537	81.7%	81.3%	0.4%	-2.0%	2.7%
The patient died at his/her preferred place of death (i.e., patient's preferred place of death was the same as the place where patient actually died)	1,896	1,518	73.5%	76.4%	-2.9%*	-5.6%	-0.2%

Source: OCM patient survey.

Notes: OCM: OCM intervention group; COMP: Comparison group.

* $p \leq 0.10$, ** $p \leq 0.05$, *** $p \leq 0.01$

There was no statistically significant trend over time in the share of OCM patients who died at home or a relative's home, who preferred to die at home or at a relative's home, or who died at their preferred place of death, according to the proxies who responded to the survey. (**Exhibit 36**). The share of OCM patients who died in a hospital decreased from 22.0 percent in the baseline period to 20.7 percent in PP1. In contrast, the share of comparison patients who died in the hospital increased from 22.5 percent to 22.9 percent in the same period. The result is a statistically significant ($p \leq 0.05$) estimated change of 1.4 percentage points (or a 6.4% decrease relative to the mean OCM rate in the baseline).

Exhibit 36: Adjusted Measures on Proxy-reported Place of Death, by OCM Patient Survey Wave (OCM Respondents Only)

Measure	Adjusted Mean				Linear Time Trend Estimates		
	Baseline Wave	Int. Wave 1	Int. Wave 2	Int. Wave 3	Point Estimate	90% CLs	
	(Apr. 16–Sep. 16)	(Jul. 16–Dec. 16)	(Oct. 16–Mar. 17)	(Jan. 17–Jun. 17)		LCL	UCL
The patient died at his/her home or relative’s home (as opposed to institutional facilities)	48.7%	44.3%	45.6%	52.8%	1.3%	-0.2%	2.8%
The deceased patient’s preferred place of death is his/her home or relative’s home (as opposed to institutional facilities)	76.9%	79.5%	76.2%	81.3%	1.0%	-0.5%	2.5%
The patient died at his/her preferred place of death (i.e., patient’s preferred place of death was the same as the place where patient actually died)	75.0%	67.9%	71.8%	76.5%	0.8%	-0.6%	2.2%

Source: OCM patient survey.

Notes: Int.: Intervention period

Combining information from the results above provides a robust picture of EOL care and early impacts of OCM. First, based on analysis of Medicare claims, OCM appears to have reduced some hospital-based care at the end of life, relative to comparisons (i.e., inpatient admissions, ICU stays at the end of life), which reflects the more appropriate EOL care that OCM encourages. For both of these measures, the relative change was due to higher rates of hospital-based care over time in the comparison group, not lower rates over time in the OCM group.

Second, in the baseline survey, proxy respondents for deceased OCM patients were less likely to report that hospice care started “at the right time” than were proxy respondents for deceased comparison patients. There is some evidence that, over time, OCM practices are discussing hospice care with dying patients more, but this has not yet resulted in greater use of hospice care or improved timing of hospice entry.

In terms of place of death, our surveys indicate that most patients do not want to die in hospitals or other institutional settings, but there was no change over time in OCM patients dying where they prefer.

3.7 Secondary Outcomes: Other Payers' Experiences

Summary of Findings on Secondary Outcomes

Seventeen private payers partnered with CMS, and each signed a Memorandum of Understanding with CMS indicating intent to implement oncology models similar to OCM to decrease variation in oncology service requirements and financial incentives for practices participating in OCM.

- Private payers aligned more closely with the CMS approach for monthly payments to support enhanced oncology services than they did for calculation of PBPs, but there was considerable variation in both monthly payments and PBP calculations.
- Private payers expressed great interest in using OCM to implement or expand oncology value-based purchasing. While their models were similar, they deviated from OCM in many respects mainly due to administrative and technical challenges.

Other Payers Participating in OCM

CMS invited other payers to institute value-based payment models aligned with OCM for their covered populations served by OCM practices. CMS's goals in including other payers were to reduce burden on practices by having more payers use similar cost and quality models, and to increase leverage on practices to make changes consistent with such programs. This section describes the payment models used by other payers participating in OCM and the degree to which these align with OCM.

During the OCM PP1, 17 payers signed an OCM Memorandum of Understanding (MOU) with CMS and were developing oncology APMs aligned with OCM.⁷⁸ One withdrew soon after the Model began. We reviewed the applications and implementation updates from the remaining 16 payers and interviewed them in January and February 2017. Below we describe the models these payers implemented, or were in the process of developing, at that time.

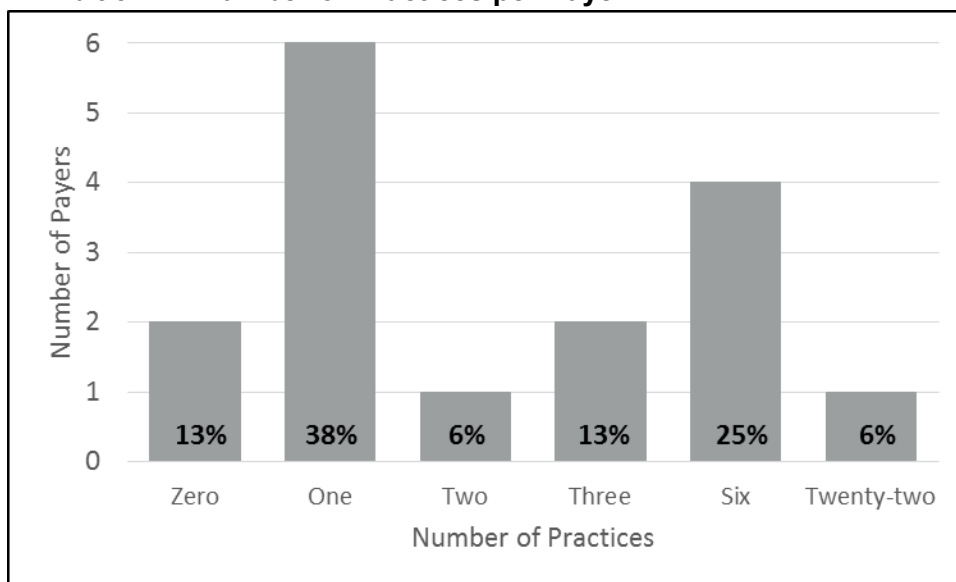
Payers and Practices

As of early 2017, two of the 16 payers had not yet enrolled any OCM practices to implement their models, at the time of our interview. Three payers owned by a single corporate entity intended to apply one consistent model, which was in development at the time of our interview. In the meantime, one of the three continued its previous oncology alternative payment model (APM). The other two payers did not plan to engage practices until the corporate model was complete.

Thirteen of the 16 payers had enrolled 1–6 OCM practices, as of February 2017; six had enrolled one OCM practice, and three had enrolled two or three practices (**Exhibit 37**). One payer had enrolled 22 practices.

⁷⁸ Oncology APM is defined here as a model developed by a payer in order to participate in OCM, which does not necessarily replicate all aspects of the OCM methodology. This section does not address any oncology models that payers implemented prior to OCM, or outside of their OCM agreement with CMS.

Exhibit 37: Number of Practices per Payer



Source: Interviewers with Other Payers, January–February 2017.

Fifty-one OCM practices were working with at least one of the 16 payers, as of February 2017. Forty of the 51 practices (78 percent) were each working with one OCM payer. Nine practices (18 percent) were working with two OCM payers, and two practices (4 percent) were working with three OCM payers.

Nine of the payers we interviewed were able to estimate the volume of patients seeking treatment at participating OCM practices. Eight of those nine payers expected to have 100 to 300 patients covered under their oncology APMs in any given month, while the ninth estimated 1,300 patients in its one OCM practice. The small size of the populations in OCM practices covered by each payer’s oncology APM raised numerous challenges for creating stable benchmarks and measuring changes in episode total costs of care (described below).

Lines of Business and Cancer Bundles in Oncology APMs

Eleven of the 16 payers (69 percent) included Medicare Advantage (MA) plans in their oncology APMs. One Medicaid managed care plan focused on MA beneficiaries eligible for both Medicare and Medicaid. Five payers (31 percent) implemented an oncology APM in their MA plans only, and three implemented an oncology APM in their commercial products only.

Each year the 16 payers are asked to complete Implementation Updates for CMS, specifying whether they include the following six cancers in their OCM-aligned oncology APMs: breast, colon, lung, pancreatic/liver, prostate, and lymphoma/ hematologic malignancies. We focused on the same six cancers in our interviews. Seven of the 16 payers (44 percent) told us they include all of the six cancers, while four payers (25 percent) include three or fewer of these cancers. Breast and lung cancer are each included by 13 of the 16 payers (81 percent), followed by colorectal and prostate cancer each included by 11 payers (69 percent). Nine payers (56 percent) include cancers other than the six CMS asked about; of these, two include all cancers that CMS includes in OCM, and one includes all cancers without exception.

Practice Requirements

Practices participating in OCM must offer enhanced oncology services and meet other requirements for the provision of oncology services to FFS Medicare beneficiaries. CMS asks payers participating in OCM to align their participation requirements with CMS's. Three payers told us they assume that if a practice is implementing a service or activity for Medicare, they are doing it for all patients. This assumption may be reasonable for technological changes, such as using a certified EHR technology, but not necessarily for services or activities that require changes in staffing (e.g., patient navigators) or workflow (e.g., development and documentation of Care Plans). Two payers had no prior experience using national oncology guidelines prior to OCM, and one of these implemented a clinical pathways tool specifically for its OCM-aligned oncology APM. Most payers also intend to require documentation of Care Plans and use of a certified EHR system. Nine payers (56 percent) told us they plan to require that practices provide patient navigation services, and 10 (63 percent) will require that patients have 24/7 access to providers who have access to patients' medical records. Two payers plan audits to ensure that practices meet all requirements.

Feedback to Support Practice Transformation

In order to guide and assess progress, practices need information about their performance. Many of the payers we interviewed provide feedback to practices in their oncology APMs about cost and utilization, and, in some cases, offer more granular data. Ten of the 16 payers (63 percent) offer monthly or quarterly feedback reports. Two payers (13 percent) do not give practices feedback reports about cost and utilization, but they do provide claims so practices can calculate their own metrics. The measures payers include in their feedback reports to practices range considerably, and the definitions used for a single measure also vary. For example, various payers report ED visits to practices as:

- Number of ED visits during a time period
- Cost of ED visits during a time period
- Rate of ED visits per patient during a time period
- Rate of ED visits per "cancer-month" (defined by the payer as a month in which a patient is receiving treatment for cancer)
- List of OCM patients with an ED visit in the previous month.

Payment Approaches

Payers align more closely with the CMS approach for monthly payments to support enhanced oncology services, than they do for calculation of PBPs.

All the payers we interviewed designed oncology APMs with different definitions of eligible patients and/or episodes. At least one described episode triggering and attribution as a single step: when a new cancer patient is identified, the responsible practice is also specified, and there is no retrospective attribution based on the plurality of E&M visits. Two payers (13 percent) use a claims-based approach for identifying eligible patient episodes, while 12 (75 percent) ask the practice to identify episodes for the patients they serve. Nine payers (56 percent) include receipt of hormonal therapy as an episode trigger, but the other seven do not.

The OCM methodology triggers a new episode if a patient continues to receive cancer treatment after a six-month episode ends, and episodes can run consecutively without limit. Two of the 11 payers with six-

month episodes allow a maximum of two consecutive episodes (i.e., they offer MEOS payments for a maximum of 12 months), and the others negotiated alternative arrangements to pay practices for care coordination and other enhanced services, including:

- Monthly payments at two levels with no maximum number of months
 - Higher payment in the first month to cover initial care coordination
 - Lower payment after the first month, for as long as the patient is receiving chemotherapy
- Monthly payments at three levels
 - Higher payment in the first month to cover initial care coordination
 - Lower payment after the first month, for as long as the patient is receiving chemotherapy
 - After the patient completes chemotherapy, payment for active monitoring in months during which the patient receives at least one in-person oncology service
- One-time payment for new chemotherapy patients and/or new palliative care patients, to cover up to 12 months of care management, with negotiated amounts varying across practices
- One-time payment for each new chemotherapy patient
- “Periodic and regular,” but not monthly, payment for each chemotherapy patient
- No MEOS payment—the payer provides “enhanced” generic chemotherapy payments rewarding the use of generics rather than brand name medications⁷⁹; the additional payments, which are available to all practices (not only OCM practices), average approximately the amount of the CMS MEOS payment
- Supplemental payment of \$10 per patient for an Advanced Directive discussion

MEOS payment amounts also vary widely among the 16 payers. Five payers (31 percent) offer \$160 MEOS payments; one of these also offers a higher first-month payment. One payer disclosed a MEOS amount that is less than \$160, and others consider their MEOS amounts to be proprietary.

Many payers were still developing their approach to PBPs at the time of our interview (Jan.–Feb. 2017), and payers described many challenges including small practice sample sizes, data systems that are difficult or expensive to change, overburdened or inexperienced payer analytic teams, and lack of timely data from practices. A few payers with full PBP methodologies described how they calculated total episode cost targets. This included:

- Paying practices for meeting utilization targets (decreasing inpatient hospitalizations and ED visits)
- Aggregating data from multiple practices to set a cost target
- Using data from the practice’s first year implementing OCM, rather than historic data, to set a cost target

Payers described a variety of comparators against which they measure a practice’s performance, including quality benchmarks, comparison with the payer’s other practices, and comparisons with historic patterns for both the practice and peer practices. Some payers had difficulty developing models that could adjust

⁷⁹ We did not ask the other payers whether they encourage the use of generics through payment mechanisms, but it is a common strategy in the industry.

for population risk, and described unstable estimates produced by small sample sizes (i.e., small practices).

Other Themes from Payer Interviews

Payers expressed great interest in and support for oncology value-based purchasing and enhanced oncology services, and were using the OCM to make important changes. Their models did not currently follow the OCM in many respects, mainly due to administrative and technical challenges, such as the following:

- Many practices have such low patient volume that payers cannot produce stable cost estimates over reasonable time periods.
- Small payers are challenged by the complexities of OCM. One small payer explained that “We don’t have dedicated FTEs to manage this, so wanted to keep it extremely simple in terms of administration [so we pay] a one-time care management fee.”
- Payers negotiate their oncology APM separately with each practice in their network, and many mentioned negotiations as a factor in program design or delay.
- Payers had a variety of pre-existing non-APM plans, some specific to oncology, which made it difficult to align with CMS’s OCM methodology. For example:
 - One payer excluded employer group (commercial) business to avoid renegotiating each individual client’s contract.
 - One payer had a wide variety of payment arrangements for pharmaceuticals—and a large self-insured population without pharmacy benefits—and decided that including oral chemotherapy and hormonal therapies was too complex.
 - One payer calculated medical and pharmaceutical costs separately to determine PBPs because many of its members do not have a pharmacy benefit.

Having an existing oncology medical home or other APM gave a payer valuable experience, and facilitated development of OCM-aligned models, but changing legacy systems and approaches can be challenging for payers and confusing for practices. For example, a payer that had reconciliation approaches in its existing APM kept the same approach because “Providers are used to it and . . . we had the infrastructure in place.” Another explained that “This is our first stab at a specialty value-based program so from the outset we tried to align it with our [other APM] in terms of our scoring logic.”

In 2018 and 2020 we will re-interview active OCM payers, to understand any changes in their models and impacts they’ve measured on patient outcomes and costs.

4. Conclusion

OCM and comparison practices were well matched in the baseline period, and trends in the two groups were consistent in the years prior to OCM. The two groups changed during PP1, reflecting changes in the national oncology field. Industry consolidation resulted in more OCM and comparison practices being affiliated with hospitals or health systems, and use of immunotherapies and oral (Part D) therapies increased in response to FDA approval of new drugs. These changes were similar in both groups and there was no evidence that OCM restricted adoption of important advances in cancer treatment.

The intervention and comparison groups were also well matched at baseline on most measures of patient-reported quality. There was no consistent pattern of change for the OCM group during Year One, and no indication that OCM either impaired or enhanced patient-reported care experiences.

During this early phase of OCM, all hospital utilization measures declined more for OCM practices than for comparison practices, and two declines, although small, were statistically significant: inpatient hospitalizations that included ICU stays, and ED visits. This consistent pattern may be an early signal of reduced use of costly hospital services in response to OCM financial incentives.

OCM most likely resulted in slightly lower TCOC (i.e., savings for Medicare, without including MEOS payments or PBPs), but there was no chance that these savings were sufficient to cover the maximum possible MEOS payments that OCM practices could have submitted. The Model includes PBPs to practices achieving savings relative to a benchmark and these costs will be factored into analyses when PBP payments are finalized.

In the first year of OCM, care process redesign focused on improving supportive care, patient education, and navigation services, with the goal of reducing ED visits and subsequent hospitalizations. Although all 12 OCM practices we visited in Year One described deliberate efforts to improve supportive care, there was not yet a measurable impact on ED visits or hospitalizations for complications from chemotherapy.

OCM requires—and provides financial support for—specific enhanced oncology services. OCM practices met some of these requirements before the Model began, especially offering 24/7 patient access to clinicians, and following evidence-based guidelines. Participating practices struggled to create Care Plans, including estimating beneficiary OOP costs, neither of which were well supported by their extant information technology systems.

In terms of quality, while there has been no overall impact on quality, there are some early indications of less hospital-based care at the end of life for beneficiaries served by OCM practices, including fewer inpatient admissions and ICU stays in the last month of life. There was no OCM impact on the rate of hospice use or timing of hospice entry.

We know that achieving meaningful practice transformation through mechanisms such as hiring new staff, upgrading EHRs, improving patient education, and leveraging new performance metrics and data for continuous quality improvement takes time. As OCM and its evaluation proceed in the coming years, we will continue to collect data directly from participants by conducting case studies with more OCM practices. We will also continue to survey patients and family members, and analyze claims data, to further investigate the early results described above, and explore additional relevant topics.

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Steve D'Amato
Maine
Jose R. Davila-Torres, MD
Puerto Rico
Marsha DeVita, NP, AOCN
New York
Stephen (Fred) Divers, MD
Arkansas
Chancellor Donald, MD
Louisiana
Erin Dunbar, MD
Georgia
David Eagle, MD
North Carolina
Nash Gabrail, MD
Ohio
Thomas Gallo
Virginia
Stuart Genschaw, MD
Michigan
Bruce Gould, MD
Georgia
Lucio Gordon, MD
Florida
Ed Graham
New York
Robert Green, MD
Florida
Dinesh Kapur, MD
Connecticut
Ed Licitra, MD
New Jersey
Joseph Lynch, MD
Oklahoma
Barbara L. McAneny, MD
New Mexico
Carol Murtaugh, RN, OCN
Nebraska
Mark Nelson, PharmD
Washington
Todd O'Connell
New York
Kashyap Patel, MD
South Carolina
Debra Patt, MD
Texas
Jeffrey Patton, MD
Tennessee
Marissa Rivera, MBA
California
Barry Russo
Texas
Mark Thompson, MD
Ohio

February 1, 2017

Physician-Focused Payment Model Technical Advisory Committee (PTAC)
c/o U.S. DHHS Asst. Secretary of Planning and Evaluation Office of Health Policy 200
Independence Avenue S.W., Washington, D.C. 20201

Submitted electronically via the PTAC Submission System

Letter of Intent – Community Oncology Alliance *Comprehensive Cancer Care Delivery*
Model

Dear Committee Members:

On behalf of the Community Oncology Alliance (COA), I am submitting this non-binding letter of intent (LOI) expressing our intent to submit a Physician-Focused Payment Model – *Comprehensive Cancer Care Delivery* – to the Physician-Focused Payment Model Technical Advisory Committee (PTAC) by March 31, 2017.

Model Overview

The *Comprehensive Cancer Care Delivery* model is built around the Oncology Care Model that COA has developed with input from patient, provider, and payer stakeholders. It is a patient-centered model of care built around 5 key domains of cancer care that are focused on enhancing the quality of care while achieving greater cost efficiencies. Unlike other models such as the Oncology Care Model, it does not start with a “chemotherapy event” but is a comprehensive model that starts with treatment, regardless of the modality of treatment, and follows through to survivorship and/or end-of-care.

Expected Participants

- Types of patients expected: Adult patients at risk for or diagnosed with cancer in the Medicare population that are treated in the outpatient, community setting.
- Estimated number and types of physicians: 1,400 oncologists. (Approximately 20% of the oncologists that treat cancer patients in the community setting)

Goals of the Payment Model

- Measured improvement in delivering comprehensive, quality, and efficient cancer care from screening to diagnosis and treatment, including end-of-life care.
- Reduction of cost through enhanced coordination of care, appropriately targeted treatments, reduction of unnecessary or redundant testing, minimizing unnecessary resources, and reducing hospital utilization, including emergency room, inpatient admissions, and inpatient readmissions.
- Improved patient outcomes from:

- Improved screening, diagnosis, and evidence-based treatment adherence
- Medication adherence
- Addressing social determinants and other barriers to care
- Appropriate and early access to palliative care, end-of-life care, and hospice
- Reducing hospital visits/care

Model Overview

- The model has two alternatives:
 - One-sided payment model with no financial risk to providers but with financial shared-savings incentives for clinical outcomes and positive quality metrics
 - Two-sided Payment model with shared financial risk and savings
- Payment structure is a risk-adjusted care management fee for each episode and with a shared-savings component around total cost of care.
- Model will also meet MACRA requirements as an advanced alternative payment model

Implementation Strategy

- The design for this model will be developed by COA, a non-profit (501.c.6) organization whose mission and focus is the preservation and fostering of quality, value, and patient-centered cancer care in communities across the country. COA represents approximately 60% of physicians, care teams, and patients that are involved in the community-based cancer care delivery model.
- COA will collaborate with other organizations and stakeholders throughout the design, implementation, management, and review of this model. Those include, but are not limited to:
 - The American College of Surgeon's Commission on Cancer
 - Association of Community Cancer Centers
 - National cancer patient advocacy organizations
 - National and regional insurance companies
 - National and regional employer health groups
- The implementation of this model will focus on effective reform through practical and meaningful criteria and measures while minimizing the complexity and administrative burden that are required by other models that are impediments to their adoption.

Timeline

- COA will commence communications and collaboration with key stakeholders for the initial design phase on May 30, 2017, or sooner if approved. We anticipate that this phase for a comprehensive review and discussions will last approximately 6 months.
- Recruitment and sign up for participation is targeted for late 2017 and the model will begin during the second quarter of 2018, if not sooner.

Sincerely,



Jeff Vacirca, MD
President



Roger A. Brito, D.O.
Senior Director Clinical Solutions
Sr. Medical Director/Oncology
CVS Health/Aetna Inc.
BritoR1@aetna.com

May 7th, 2019

Dear members of the PTAC,

I am writing to support the Community Oncology Alliance's OCM 2.0 proposal to build upon, enhance, and further the transformation and improvements in quality and value achieved in the Center for Medicare & Medicaid Innovation's Oncology Care Model (OCM).

Aetna represents approximately 20 million members per year. As a leader in payment reform for cancer care, along with a nationally recognized Oncology Medical Home Program, we can attest to the need for consistency, standards, transparency and improvements to correct deficiencies in the OCM.

Cancer care is complex and in a rapid and constant state of flux due to ever-increasing improvements in biotechnology and pharmaceutical breakthroughs. The price of these improvements remains high, creating "financial toxicity," which strains the patient community as well as the payer and employee sectors of health care delivery.

The OCM 2.0 has important components such as an emphasis on transparency and uniformity, an accreditation program to recognize and monitor exceptional cancer care, incentives to ensure value in cancer drug selection in an era of rapid clinical advances and increasing drug costs, and standards and flexibility for new performance-based payment methodologies. This comprehensive OCM 2.0 model aspires to lower the total cost of cancer care while simultaneously increasing quality.

COA emphasizes transparency, collaboration, efficiency, and broader stakeholder involvement so that early reform efforts will lead to standardization and expansion of reform initiatives. This includes care delivery that promotes quality and value as well as a payment model that recognizes these improvements.

As a recognized advocate for outstanding cancer care for all and a champion and crusader for universal reform in cancer care, COA is uniquely positioned to lead such a project, that I have no doubt will succeed.

Sincerely,

A handwritten signature in black ink that reads "Roger Brito".

Roger A. Brito, D.O.



May 10, 2019

Dear members of the PTAC,

I am writing to support the Community Oncology Alliance's OCM 2.0 proposal to build upon, enhance, and further the transformation and improvements in quality and value achieved in the Center for Medicare & Medicaid Innovation's Oncology Care Model (OCM).

We are a community oncology practice in Florida treating 35,000 patients a year. As a participating practice in the OCM, we can attest to the need for enhancements and improvements to correct deficiencies in the OCM.]

Cancer care is complex and in a rapid and constant state of flux due to ever-increasing improvements in biotechnology and pharmaceutical breakthroughs. The price of these improvements remains high, creating "financial toxicity," which strains the patient community as well as the payer and employee sectors of health care delivery.

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Sincerely,



Lucio N. Gordan, MD
PRESIDENT / MANAGING PARTNER
FCS

World Class Medicine. Hometown Care. www.flcancer.com



Infections Limited, P.S.

NWMS Hematology Oncology

April 30th, 2019

Dear members of the PTAC,

I am writing to support the Community Oncology Alliance's OCM 2.0 proposal to build upon, enhance, and further the transformation and improvements in quality and value achieved in the Center for Medicare & Medicaid Innovation's Oncology Care Model (OCM).

We are a community oncology practice in Washington treating 4500 new patients a year. As a participating practice in the OCM, we believe in the goals and value transformation that OCM has set out to achieve. However, to achieve these goals some corrections in the model are needed for success.

Cancer care is complex and new innovative treatments are becoming available each day. The price of these improvements remains high, creating "financial toxicity," which strains the patient community as well as the payer and employee sectors of health care delivery.

The OCM 2.0 has important components such as an emphasis on transparency and uniformity, an accreditation program to recognize and monitor exceptional cancer care, incentives to ensure value in cancer drug selection in an era of rapid clinical advances and increasing drug costs, and standards and flexibility for new performance-based payment methodologies. This comprehensive OCM 2.0 model aspires to lower the total cost of cancer care while simultaneously increasing quality.

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Sincerely,

Amy Ellis
Director, Quality and Value Based Care

Tacoma Office
1624 South I Street
Suite 305
Tacoma, Wa 98405
(253) 428-8700

Puyallup Office
2920 South Meridian
Suite 100
Puayllup, WA 98373
(253) 841-4296

Gig Harbor Office
11511 Canterwood Blvd.
Suite 45
Gig Harbor, WA 98332
(253) 858-4725

Federal Way Office
34509 9th Avenue South
Suite 102
Federal Way, WA 98003
(253) 952-8349

Bonney Lake Office
9230 Sky Island Drive
Suite 310
Bonney Lake, WA 98391
(253) 862-3434

Lakewood Office
11311 Bridgeport Way
Suite 304
Lakewood, WA 98499
(253) 983-1377



THE CENTER TX

THE CENTER FOR CANCER AND BLOOD DISORDERS

Medical Staff

Asm Ahmad, MD
 Revathi Angtapalli, MD
 Nicole Bartosh, DO
 Matthew Cavey, MD
 Kim Faight, FNP - C
 Gregory Fness, DO, FACP
 Prasanthi Ganesa, MD
 Heather Goddard, FNP
 Shandy Gusham, RN, FNP
 Chaney Grunow, PA - C
 Laurie Hill, PA - C
 Helena Iannaccone, RN, ANP, AOCNP
 Deepna Jaiswal, DO
 Il Lance Mandell, MD
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 A Seyi Ojo, MD
 Ray Page, DO, PhD, FACC
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 Vinaya Potluri, MD
 Alayna Powers, RN, FNP-C
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 Bibas Reddy, DO, MPH
 Morvard Rezaie, DO
 Michael Ross, MD
 Mary Ann Skiba, DO, FACC
 DeEtte Vasques, DO, FACC, FACC, FACC
 Nabila Waheed, DO
 Henry Xiong, MD, PhD
 Nicholas Yarrobino, PA-C
 Gary Young, MD
 Robyn Young, MD
 Haley Zimmerman, FNP-C

The Center @ Magnolia

800 W Magnolia Ave
 Fort Worth, TX 76104

Additional Locations

Southwest Fort Worth
 Burleson
 Weatherford
 MCA @ Arlington
 USMD @ Arlington
 Granbury
 Mineral Wells
 Stephenville

Phone for all locations

817-759-7000

May 9, 2019

Dear members of the PTAC,

I am writing to support the Community Oncology Alliance's OCM 2.0 proposal to build upon, enhance, and further the transformation and improvements in quality and value achieved in the Center for Medicare & Medicaid Innovation's Oncology Care Model (OCM).

We are a community oncology practice in Texas treating 14,000 patients a year. As a participating practice in the OCM, we can attest to the need for enhancements and improvements to correct deficiencies in the OCM.

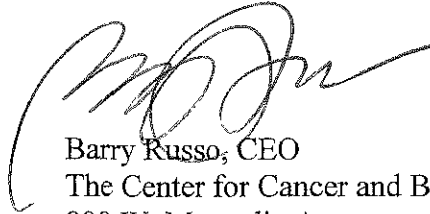
Cancer care is complex and in a rapid and constant state of flux due to ever-increasing improvements in biotechnology and pharmaceutical breakthroughs. The price of these improvements remains high, creating "financial toxicity," which strains the patient community as well as the payer and employee sectors of health care delivery.

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As a recognized advocate for outstanding cancer care for all and a champion and crusader for universal reform in cancer care, COA is uniquely positioned to lead such a project and I have no doubt will succeed.

Sincerely,

A handwritten signature in black ink, appearing to read 'Barry Russo', written in a cursive style.

Barry Russo, CEO
The Center for Cancer and Blood Disorders
800 W. Magnolia Ave.
Fort Worth, TX 76104

PTAC Submission Checklist

F. Submission

1. Letter of Intent Submission

LOIs should be uploaded to the PTAC submission system [website](#) in MS Word or PDF Format. A [guide](#) on how to upload to the system is available on the PTAC website. Submitters may contact PTAC@hhs.gov with any problems uploading their LOI. All LOIs will be posted on the PTAC’s website for availability to the public.

2. Proposal Submission

Complete proposals should be uploaded to the PTAC submission system [website](#). MS Word, MS Excel (appendices), or PDF formats are acceptable. A [guide](#) on how to upload to the system is available on the PTAC website. Submitters may contact PTAC@hhs.gov with any problems uploading their proposal. Once received, all proposals will be posted on the PTAC website for availability to the public.

3. Submission Checklist

The submission checklist is intended to aid submitters in reviewing their proposals for completeness and adherence to requirements. The submitter must complete and submit the checklist with the proposal. The completed checklist should be included in an appendix.

Requirement	Checkbox	Pages
Letter of intent submitted 30 days before the proposal	<input checked="" type="checkbox"/>	
Name and address of the submitter (individual or organization)	<input checked="" type="checkbox"/>	
Name, address, phone number, and e-mail address for the primary point of contact	<input checked="" type="checkbox"/>	
Title Page	<input checked="" type="checkbox"/>	
Table of Contents	<input checked="" type="checkbox"/>	
Abstract	<input checked="" type="checkbox"/>	
If the submitter is an organization, a letter of support from the governing board or responsible officer is included.	<input checked="" type="checkbox"/>	
Main body of the proposal is ordered by and includes the following sections:		
Model Description		
Background and Model Overview	<input checked="" type="checkbox"/>	
How the model would work from the patient’s perspective	<input checked="" type="checkbox"/>	
How the model would work from the perspective of participating eligible professionals, the patient’s	<input checked="" type="checkbox"/>	

primary care provider, and other providers (including hospitals, post-acute care providers, etc.) who would participate in or be affected by the model		
Response to Criteria		
Scope	<input checked="" type="checkbox"/>	
Quality and Cost	<input checked="" type="checkbox"/>	
Payment Methodology	<input checked="" type="checkbox"/>	
Value over Volume	<input checked="" type="checkbox"/>	
Flexibility	<input checked="" type="checkbox"/>	
Ability to be Evaluated	<input checked="" type="checkbox"/>	
Integration and Care Coordination	<input checked="" type="checkbox"/>	
Patient Choice	<input checked="" type="checkbox"/>	
Patient Safety	<input checked="" type="checkbox"/>	
Health Information Technology	<input checked="" type="checkbox"/>	
Main body of the proposal does not exceed 25 pages and formatting requirements are met.	<input checked="" type="checkbox"/>	

4. Withdrawal of a Submitted Payment Model

A submitter may withdraw a PFPM submitted to PTAC at any time prior to the PTAC’s deliberation on the proposal. The PTAC will not send any comments or a recommendation to the Secretary on any proposal that is withdrawn prior to PTAC’s deliberation. Once PTAC begins deliberating on a proposal, PTAC will complete its deliberation and transmit its comments and recommendation to the Secretary in accord with PTAC’s mandate from MACRA.

5. Resubmission of a Withdrawn Submission

After a proposal has been withdrawn, a party may resubmit the proposed PFPM to PTAC at any time. A new LOI is not required for the resubmission. To the extent that the schedules of PTAC members allow, a resubmitted proposal will be assigned to the same Preliminary Review Team (PRT) members who evaluated the initial proposal submission.