

**Bundled Payment for All Inclusive Outpatient Wound Care Services in Non Hospital Based
Setting
Environmental Scan
11/16/2018**

I. Overview

The purpose of this environmental scan is to provide members of the Physician-Focused Payment Model Technical Advisory Committee (PTAC) with background information on the context for the physician-focused payment model (PFPM), Bundled Payment for All-Inclusive Outpatient Wound Care Services in Non-Hospital-Based Settings, which was proposed by Dr. Ikram Farooqi of Seha Medical and Wound Care on October 15, 2018.

The scan focuses on the epidemiology of chronic wounds, issues in payment policy affecting chronic wound care, and problems in chronic wound care delivery, as well as results of proposed or similar models addressing chronic wound care. The Appendix includes the search terms and sources used to identify the research summarized below.

Epidemiology of Chronic Wounds

Definition of chronic wounds. Chronic wounds are those that fail to progress through the normal phases of wound healing, which include hemostasis, inflammation, granulation/proliferation, and remodeling/maturation (Mercandetti, 2017). The majority of chronic wounds are diabetic foot ulcers, venous leg ulcers, and pressure ulcers/injuries (Gupta et al., 2017). Chronic wounds are specified differently throughout the research literature and may or may not include nonhealing acute surgical, burn, or trauma wounds (Zakhary et al., 2017).

Population affected by chronic wounds and burden. Chronic wounds are common in older adults, and wound healing slows with age (Gould, et al, 2015). Therefore, patients with nonhealing wounds are likely to be older adults, nonambulatory or paralyzed, unable to provide self-care, and/or suffering from dementia (Nussbaum et al., 2018).

Chronic wounds are often accompanied by comorbidities such as venous insufficiency, peripheral arterial disease, and diabetes mellitus as well as other patient-centered factors that impede healing. Patient-centered factors include obesity, nicotine use, incontinence, pain, anemia, and psychosocial factors such as stress, anxiety, and depression (Gupta et al., 2017).

Underreporting, lack of a standard definition of “chronic wound,” and inaccurate diagnostic coding for wound care challenge the ability to estimate the burden of chronic wounds (Gould et al., 2015). Nussbaum et al.’s study of 2014 Medicare data (2018) found that nearly 15 percent of Medicare beneficiaries (8.2 million) had at least one type of wound or wound-related infection, with surgical wound infections, diabetic wound infections, and nonhealing surgical wounds the most common categories. Upper bound estimates of total Medicare fee-for service (FFS) spending on wound care was \$70.2 billion, with the highest cost related to hospital outpatient care (\$35.7 billion); hospital inpatient

costs were \$24.3 billion; Part B carriers and durable medical equipment were \$2.3 billion, by comparison. Nussbaum et al. found that chronic nonhealing wounds represent a large proportion of the Medicare budget and that the associated costs are largely in outpatient settings.

Types of providers involved in wound care. Wound care was historically provided in hospitals, but the implementation of the diagnosis-related group (DRG) payment system contributed to a shift toward other settings where there was no cap on the volume of wound care services. These include: long-term acute care hospitals (LTCHs), skilled nursing facilities (SNFs), provider-based outpatient wound care departments (PBDs), and home health agencies (HHAs). Hospital-based outpatient wound care departments (HOPDs) emerged with the introduction of setting-specific prospective payment system (PPS), but the rising number of malpractice claims, particularly those involving treatment of diabetic foot ulcers, have led to the referral of patients to wound care centers (WCCs) (Leon et al., 2016). WCCs are typically managed by qualified health care professionals (QHPs) with expert training in family medicine, podiatry, vascular surgery, physical medicine and rehabilitation, plastic surgery, or other specialties (Leon et al., 2016). The term “WCC” is used to refer to either a HOPD or a free-standing wound clinic office of a QHP (Leon et al., 2016).

Issues in Payment Policy

Medicare Guidelines. Per [CMS Billing and Coding Guidelines for Wound Care](#) (2017), “active wound care procedures are performed to remove devitalized and/or necrotic tissue to promote healing. Debridement is the removal of foreign material and/or devitalized or contaminated tissue from or adjacent to a traumatic or infected wound until surrounding healthy tissue is exposed. These services are billed when an extensive cleaning of a wound is needed prior to the application of primary dressings or skin substitutes placed over or onto a wound that is attached with secondary dressings.” Reimbursement is denied for performing deep debridement in a place of service other than inpatient hospital, outpatient hospital or ambulatory surgical center, or billing for debridement by an unqualified personal.

Variation in Medicare reimbursement by type of setting. Medicare payment for wound care varies by type of setting,¹ which has implications for physician payment for wound care services (Schaum, 2014; Nussbaum et al., 2018). For example, the Medicare Physician Fee Schedule (MPFS) pays the physician in QHP WCC more for some services, such as epidermal grafting, than the Hospital Outpatient Prospective Payment System (OPPS) pays the physician in HOPD WCC. The OPPS bundles the costs of labor and supplies into the facility fee with a separate professional fee for application at a reduced rate. Differences in payment across providers (by type and location) affect the options for wound dressing and topical wound therapy; these options may not be clinically warranted (Schaum, 2014).

Global Surgical Periods. In addition, QHP WCCs receive payment for the services, procedures, and/or applications of separately payable drugs and biologicals provided to the patient at each visit, as long as

¹ Inpatient settings are reimbursed under a DRG; HOPD WCCs are reimbursed under the OPPS; QHP WCCs are reimbursed under the MPFS; skilled nursing facilities are reimbursed under the Resource Utilization Group (RUG); and home health agencies are reimbursed under the Home Health Resource Group (HHRG).

these are not provided during a global surgical period (GSP)² (Schaum, 2014). Finally, unlike inpatient settings, which do not have restrictions on the immediate use of advanced strategies and dressings because all are reimbursed under a DRG, treatment provided by QHP WCCs and HOPD WCCs must take into account Medicare's requirement for the patient to fail 30 days of standard wound care (Leon et al., 2016).

Local Coverage Determination. The location of HOPD and QHP WCCs further determines Medicare reimbursement due to multiple Medicare Part A and Part B, home health agency, and durable medical equipment jurisdictions, each of which has its own Local Coverage Determination (LCD) policies. LCDs change frequently and are difficult to interpret, requiring QHPs to consult insurance specialists in order to implement them. These policies in turn determine the availability of dressing and advanced therapies at individual WCCs (Leon et al., 2016).

Problems in Wound Care Delivery

Evaluation and synthesis of wound care products and services. A number of studies focus on specific wound healing products or technologies, specific disease states, or certain aspects of care, such as patient/wound bed preparation.³ However, there is little synthesis of this research to provide evidence-based criteria to assist in the accurate diagnosis and appropriate management of chronic wounds (Gupta et al., 2017). Moreover, many products or groupings of products (e.g., alginates, foams, collagens, etc.) have not all been evaluated using real-world data to ensure that the most cost-effective and efficient regimen of dressings, etc. are stocked at WCCs (Leon et al., 2016).

Multidisciplinary approach. Challenges to wound care delivery include the appropriate and timely referral of patients to WCCs and patients' access to specialists. The consensus in the literature is that a multidisciplinary approach to wound care is the most important element to the success of treatment because no single health care provider is adequately equipped with the skills, knowledge, and experience to provide comprehensive care for all chronic wounds (Kim et al., 2013; Gould et al., 2015; Leon et al., 2016; Gupta et al., 2017). Members of a multidisciplinary wound care team should reflect the different pathologic processes involved in chronic wounds, including the following specialists: plastic surgeons, podiatric surgeons, vascular surgeons, general surgeons, orthopedic surgeons, and wound care nurse practitioners (Leon et al., 2016).

QHP WCCs may lack the capacity to effectively manage certain wounds due to the absence of key specialties within the care team. On the other hand, national chain HOPD WCCs employing multiple QHPs who work part time and use algorithms for care may limit the ability of a care team to develop a comprehensive and cohesive plan (Kim, 2013). As such, all WCCs have a responsibility to refer patients to specialists or clinics that can better address closure when patient wound care needs cannot be met (Leon et al., 2016).

² Medicare payment for a surgical procedure includes the preoperative, intra-operative, and post-operative services routinely performed by the surgeon or by members of the same group within the same specialty. There are three types of global surgical packages based on the number of post-operative days: 0-, 10-, or 90-day post-operative periods.

³ This scan did not focus on studies of individual products, technologies, disease states, or specific aspects of care.

Patient adherence. Patient adherence is a major determinant in the healing of chronic wounds and is especially critical to patient outcomes and cost of care. Inpatient adherence to treatment plans is much more likely than outpatient (Leon et al., 2016; Gupta et al., 2018).

Training. There is evidence that medical-school curricula are lacking adequate education about chronic wounds (Yim, 2014). Similarly, there are varying levels of wound care specialization among treatment providers and no standards for the level of wound care specialization among QHPs working in WCCs (Leon et al., 2016). Many payers have started requiring credentials, such as in hyperbaric medicine, in the hope of improving patient outcomes (Leon et al. 2016).

Quality Metrics and Patient Outcomes. Wound healing rate, or time to closure, is widely treated as the gold standard of wound outcomes in the research literature (Leon et al., 2016). Fife et al. (2018) found discrepancies in healing rates reported in the United States Wound Registry (USWR), a qualified clinical data registry, and those reported in randomized controlled trials (RCTs) and publicly reported wound outcomes. Specifically, RCTs and USWR data suggest that most patients do not heal their wounds within 12 weeks (55–70 percent); this compares with a mean publicly reported healing rate of 92 percent (Fife et al., 2018). Other measures, such as reduced amputation, reduced economic burden, improved function and ambulation, and improved quality of life, may be important complements to healing rates (Fife et al., 2018).

CMS' Quality Payment Program (QPP) requires that all wound care practitioners report at least one risk-adjusted, practice-relevant measure of wound outcomes. The Merit-Based Incentive Payment System (MIPS) recognizes wound care-relevant quality measures available through the USWR, which includes measures for diabetic foot ulcers and venous leg ulcers (Fife et al., 2018).

Results of Proposed or Similar Models

Background on the proposal submitter. The environmental scan identified no research published by the submitter. The proposer, Dr. Ikram Farooqi, is an independent physician working at Seha Wound Care in Wellesley, Massachusetts, a QHP WCC that includes Dr. Farooqi and two other employees (a Certified Medical Assistant and a certified Hyperbaric Oxygen Treatment technologist). Dr. Farooqi is board-certified in Internal Medicine and Geriatrics and is certified as a Wound Specialist Physician. He attended and graduated from Dow Medical College in 1990, completed his residency in Medicine at MedStar Georgetown University Hospital, an internship in Internal Medicine at Georgetown University Hospital in 1994, and a fellowship in Geriatric Medicine at Albany Medical College in 1998. He is affiliated with many hospitals, including Metrowest Medical Center and Newton-Wellesley Hospital. Treatments provided at Seha Wound Care include biopsies, manual lymphatic drainage, transcutaneous oximetry measurement, vacuum-assisted closure, and surgical debridement.ⁱ

Other payment models that address chronic wound care. This environmental scan did not identify existing or prior tests of payment models for chronic wound care provided by WCCs. Given the importance of hyperbaric oxygen therapy to wound care, CMS is testing the [Medicare Prior Authorization Model for Non-Emergent Hyperbaric Oxygen \(HBO\)](#), which is testing prior authorization for HBO to see if it reduces costs and maintains/improves quality of care.

II. Annotated Bibliography

Nussbaum, S. R., Carter, M. J., Fife, C. E., DaVanzo, J., Haught, R., Nusgar, M., & Cartwright, D. (2018). An economic evaluation of the impact, cost, and Medicare policy implications of chronic nonhealing wounds. *Value in Health, 21*, 27-32.

Subtopic(s): Epidemiology of the Disease; Issues in Medicare Payment Policy

Type of Source: Journal article

Objective: To determine the cost of chronic wound care for Medicare beneficiaries in aggregate, by wound type, and by setting.

Main Findings: Wounds impact nearly 15 percent of Medicare beneficiaries (8.2 million patients), and a conservative estimate of their annual cost is \$28 billion, with the majority of costs accruing in various outpatient settings. If wounds are included as a secondary diagnosis, the cost for wounds range from \$31.7 billion to \$96.8 billion. Any national estimate of wound care, which would include individuals not in the Medicare programs, would significantly exceed these Medicare expenditures.

Strengths/Limitations: The primary limitation was the challenge of relating charges specifically to the presence of a wound among patients with many comorbid diseases.

Generalizability to Medicare Population: Yes

Methods: Retrospective analysis of the Medicare 5% Limited Data Set (calendar year 2014) for beneficiaries who experienced wound-related episodes of care. Main outcomes were the prevalence of each wound type, Medicare expenditure for each wound type and aggregate, and expenditure by type of service.

Jones R. E., Foster D. S., & Longaker M. T. (2018). Management of chronic wounds—2018. *JAMA: Journal of the American Medical Association. 320*(14), 1481-1482.

Subtopic(s): Best Practices

Type of Source: Journal article

Objective: To review evidence for chronic wound management in the ambulatory setting.

Main Findings: Effective care for chronic wounds requires a multimodal approach, including wound bed optimization, management of chronic medical conditions, and consistent follow-up. Advanced wound therapies, such as negative-pressure wound therapy, can benefit some patients, but evidence to support the use of one specific advanced dressing type over another is limited. Cost-effectiveness is a key consideration given the expense of many advanced dressings. However, some of these products decrease dressing change frequency and may improve healing, which can lead to overall cost reductions. Dressings election can generally be based on wound assessment, physician and patient familiarity with the products, availability, and affordability.

Strengths/Limitations: N/A

Generalizability to Medicare Population: Yes

Methods: N/A

Fife, C. E., Eckert, K. A., & Carter, M. J. (2018). Publicly reported wound healing rates: The fantasy and the reality. *Advances in Wound Care*, 7(3), 77-94.

Subtopic(s): Issues in Medicare Payment Policy; Best Practices; Quality Metrics

Type of Source: Journal article

Objective: To develop criteria for honest reporting of wound outcomes, a requirement of the Quality Payment Program (QPP).

Main Findings: While wound care provider entities publicly report online a mean healing rate of 92%, it is likely that in the real world, among complicated patients, healing rates better than 40.0% are not achievable. Criteria are needed to report honest healing rates including standardized definitions of "healed wound" and "healing rate," defined wound care protocols, the inclusion of patient and wound demographics and the need to report whether any risk stratification was used, if any patients/wounds were not included in the wound healing rate denominator, at what point the healing rate is along the entire episode of care, and the total number of patients/wounds, disaggregated by provider and facility. Parameters are needed, which should be determined by consensus in the wound care community, to ensure that transparent and risk-stratified wound outcome data are reported.

Strengths/Limitations: See main findings.

Generalizability to Medicare Population: Yes

Methods: Compared healing rates from the U.S. Wound Registry (USWR) with randomized controlled trials found via PubMed searches and publicly reported data found via Google searches. USWR utilizes the Wound Healing Index, a validated risk-stratification method that can predict whether seven types of chronic wounds will heal.

[Billing and Coding Guidelines for Wound Care. Medicare Coverage Database. Centers for Medicare & Medicaid Services. \(2017\).](#)

Subtopic(s): Issues in Medicare Payment Policy

Type of Source: CMS-issued guidelines

Objective: To provide Medicare billing and coding guidelines for wound care.

Main Findings: This document provides billing and coding guidelines for the use of wound care-related CPT Codes 97597, 97598 and 11042-11047, as well as reasons for denial.

Strengths/Limitations: N/A

Generalizability to Medicare Population: N/A

Methods: N/A

[Augustin, M., Montero, E. C., Zander, N., Baade, K., Herberger, K., Debus, E. S., Diener, H., Neubert, T., & Blome, C. \(2017\). Validity and feasibility of the wound-QoL questionnaire on health-related quality of life in chronic wounds. *Wound Repair and Regeneration*, 25, 852-857.](#)

Subtopic(s): Best Practices; Quality Metrics

Type of Source: Journal article

Objective: To investigate the validity of the Wound-QoL questionnaire.

Main Findings: The Wound-QoL was found to be valid and responsive and is useful as a short questionnaire for assessing health-related quality of life from the patients' perspective.

Strengths/Limitations: A strength of the Wound-QoL questionnaire is that it was conceptualized on the basis of existing instruments. However, the current data were derived from specialized centers

and therefore there may be a selection of hard-to-heal wounds.

Generalizability to Medicare Population: No

Methods: Questionnaire administered to 227 patients from two large specialized wound centers and four community-based practices in Germany.

Mercandetti, M. and Cohen, A.J. (2017). Wound Healing and Repair: Overview, Types of Wound Healing, Categories of Wound Healing. *Medscape*.

Subtopic(s): Problems in Care Delivery

Type of Source: Clinical resource for healthcare professionals

Objective: To provide an overview of types of wound healing, categories of wound healing, overview of wound healing, and sequence of events in wound healing.

Main Findings: Wound healing is a complex and dynamic process of replacing devitalized and missing cellular structures and tissue layers. The human adult wound healing process can be divided into 3 or 4 distinct phases. Within these broad phases are a complex and coordinated series of events that includes chemotaxis, phagocytosis, neocollagenesis, collagen degradation, and collagen remodeling. The process of wound healing constitutes an array of interrelated and concomitant events. Understanding of these processes and effectors on these processes continues to expand.

Strengths/Limitations: N/A

Generalizability to Medicare Population: N/A

Methods: N/A

Zakhary, S. A., Davey, C., Bari, R., Bean, J., Reber, T., Gallagher, K., Couch, K., Hurlow, J., Laforet, K., Mclsaac, C., Napier, K., Vilar-Compte, D., Zakhary, E., Hermans, M., & Bolton, L. (2017). The development and content validation of a multidisciplinary, evidence-based wound infection prevention and treatment guideline. *Ostomy Wound Management*, 63(11), 18-29.

Subtopic(s): Epidemiology of the Disease; Best Practices; Quality Metrics

Type of Source: Systematic review

Objective: To describe derivation from published literature and content validation of a set of wound infection diagnosis, prevention, and treatment recommendations to serve multidisciplinary wound care teams as they manage patients with acute or chronic wounds across settings.

Main Findings: Produced a Wound Infection Checklist designed to harmonize interdisciplinary teams practicing across settings to improve the consistency and quality of care and outcomes for patients with or at risk of chronic or acute wound infection.

Strengths/Limitations: Does not include emergency wound infection management and needs best available evidence supporting the efficacy and safety of each recommendation before it becomes an evidence-based guideline.

Generalizability to Medicare Population: Yes

Methods: Review conducted by International Consolidated Wound Infection Guideline Task Force (ICWIGTF) composed of 19 multidisciplinary wound care professional members of the Association for the Advancement of Wound Care (AAWC, the host society), the Wound Healing Society, the Canadian Association for Enterostomal Therapy, and the Mexican Wound Healing Society (AMCICHAC).

Gupta, S., Andersen, C., Leon, J. de, Lantis, J. C., Snyder, R., Sumpio, B., Tettelback, W., Treadwell, T., Weir, D., & Silverman, R. P. (2017). Management of chronic wounds: diagnosis, preparation, treatment, and follow-up. *Wounds: A Compendium of Clinical Research and Practice*, September Supplement, 29(9), S19-S36.

Subtopic(s): Problems in Care Delivery; Best Practices; Quality Metrics

Type of Source: Expert panel report

Objective: To provide a summary of evidence-based wound management guidelines that can be used by wound care clinicians in all care settings to assist in the entire cycle of wound care (i.e., diagnosis, patient and wound bed preparation, treatment, and follow-up) for major chronic wound types.

Main Findings: Panel members identified major steps in managing chronic wounds, which often need to be repeated if a wound is not progressing. First, wound etiology must be accurately identified through a thorough assessment of both the patient and the wound. A multidisciplinary treatment team should be assembled to address patient-centered factors and underlying causes of the wound. Second, a treatment plan should be established with full agreement from the patient and caregiver(s). Third, the wound should be treated, beginning with wound bed preparation. Fourth, patient adherence to the care plan and wound healing progress should be monitored. Fifth, when the wound has healed, a follow-up plan should be established to help prevent recurrence.

Strengths/Limitations: Prior to the meeting, a literature search for peer-reviewed articles published through March 2016 was conducted by the sponsor, Acelyty Company (San Antonio, Texas), a manufacturer of wound healing products, utilizing PubMed, Ovid, and Science Direct. Eight of the most relevant articles containing treatment algorithms for different chronic wound types and infected wounds as well as guidelines for wound bed preparation were selected by the sponsor, which possibly presents some bias.

Generalizability to Medicare Population: Yes

Methods: Expert panel of 11 wound healing specialists experienced in various care settings convened from February 24–25, 2017, in Dallas, Texas, to discuss best practices and develop an overview of current guidelines for managing chronic wounds.

Leon, J. de, Bohm G. A., DiDomenico, L., Fearmonti, R., Gottlieb, H. D., Lincoln, K., Shah, J. B., Shaw, M., Taveau, H. S., Thibodeaux, K., Thomas, J. D., & Treadwell, T. A. (2016). Wound care centers: Critical thinking and treatment strategies for wounds. *Wounds: A Compendium of Clinical Research and Practice*, October Supplement, 28(10), S1-S23.

Subtopic(s): Problems in Care Delivery; Issues in Medicare Payment Policy; Best Practices; Quality Metrics

Type of Source: Expert panel report

Objective: To identify challenges in managing Wound Care Centers (WCCs) and to summarize literature- and experience-based recommendations from the panel meeting to inform clinical practice in the holistic management of patients and wounds in a WCC.

Main Findings: Recommendations provided in the following content areas: primary challenges for wound care centers, holistic preparation of patients and wounds for healing, control of patient factors affecting healing, considerations for special patient populations, wound bed preparation, critical thinking in developing treatment pathways, critical thinking for selection process, atypical wounds: special considerations for treatment, surgical wounds: special considerations for treatment, and complex chronic wounds: special considerations for treatment. In the first content

area, the primary recommendation was that moving patients appropriately through care centers should also be a quality indicator.

Strengths/Limitations: Panel members received a booklet of peer-reviewed studies selected by the sponsor (Acelyty, San Antonio, Texas) for review prior to the meeting, which possibly presents some bias.

Generalizability to Medicare Population: Yes

Methods: Expert panel of wound healing specialists experienced in the outpatient wound care setting convened March 17–18, 2016, in Dallas, Texas, to discuss best practices for treating patients in a WCC. The meeting was sponsored by Acelyty Company, a manufacturer of wound healing products, including devices and wound dressings.

Gould, L., Abadir, P., Brem, H., Carter, M., Conner-Kerr, T., Davidson, J., DiPietro, L., Falanga, V., Fife, C., Gardner, S., Grice, E., Harmon, J., Hazzard, W. R., High, K. P., Houghton, P., Jacobson, N., Kirsner, R. S., Kovacs, E. J., Margolish, D., Horne, F. M., Reed, M. J., Sullivan, D. H., Thom, S., Tomic-Canic, M., Walston, J., Whitney, J., Williams, J., Zieman, S., & Schmader, K. (2015). Chronic wound repair and healing in older adults: Current status and future research. *Wound Repair and Regeneration*, 23(1), 1-13.

Subtopic(s): Epidemiology of the Disease; Best Practices; Quality Metrics

Type of Source: Workshop Summary

Objective: To explore the current state of knowledge and research challenges, engage investigators across disciplines, and identify key research questions to guide future study of age-associated changes in chronic wound healing.

Main Findings: The basic biology underlying chronic wounds and the influence of age-associated changes on wound healing are poorly understood. Most studies have used in vitro approaches and various animal models, but observed changes translate poorly to human healing conditions. The impact of age and accompanying multimorbidity on the effectiveness of existing and emerging treatment approaches for chronic wounds is also unknown, and older adults tend to be excluded from randomized clinical trials. Poorly defined outcomes and variables, lack of standardization in data collection, and variations in the definition, measurement, and treatment of wounds also hamper clinical studies. A number of recommendations are made, including a list of research questions regarding wound healing in older adults for study in the following categories: epidemiology and quality of life; basic biology of wound healing, chronic wounds, and aging; molecular and cellular processes, inflammation; molecular and cellular processes, oxidative stress; molecular and cellular processes, microbial burden; clinical care, general; clinical care, novel therapeutic approaches; and clinical care, nutrition. Also provided in a list, potential outcomes for clinical studies of wound-healing in older adults are recommended, including: synergy between age and comorbidities, pathology of tissue left behind in the wound, costs of nonhealing wounds, goals for healing at the time of wound presentation, effects of standardized clinical decision support based on electronic medical records, quality of life, functional status, morbidity, pain, level of independence, sepsis, prevention of amputation and mortality, and palliative care versus healing.

Strengths/Limitations: N/A

Generalizability to Medicare Population: Yes

Methods: The Association of Specialty Professors, in conjunction with the National Institute on Aging and the Wound Healing Society convened a transdisciplinary group of experts in the fields of wound repair and regeneration, skin aging, geriatric conditions, and gerontology from across the United States and Canada, as well as program staff and scientists from the National Institute on Aging; the National Institute of Diabetes and Digestive and Kidney Diseases; the National Heart,

Lung, and Blood Institute; and the National Institute of Nursing Research. The workshop aimed primarily to review current knowledge in basic science and clinical topics; identify gaps in that knowledge; and develop a research agenda. This paper summarizes the proceedings from the workshop.

Yim, E., Sinha, V., Diaz, S. I., Kirsner, R. S. , Salgado, C. J. (2014). Wound healing in U.S. medical school curricula. *Wound Repair and Regeneration*, 22, 467-472.

Subtopic(s): Problems in Care Delivery

Type of Source: Journal article

Objective: To determine if the medical education offered by U.S. medical schools includes the basic principles of wound care and treatment options.

Main Findings: Researchers found that out of 55 schools, only 7 schools offered a formal wound healing elective. The University of Miami was the only school to include a surgical component. Students' response rate to the online survey was 39% (n=29). After completing the elective, 20 students (69%) felt confident in their knowledge of surgical and medical wound management. A majority of students (76%, n=22) felt that the elective was an important part of the medical school curriculum.

Strengths/Limitations: Small number of students sampled and low survey response rates from both the medical schools and students who took the course.

Generalizability to Medicare Population: N/A

Methods: Online survey sent to the highest-ranking dean with curriculum responsibilities at 134 U.S. allopathic medical schools with accredited or provisional status, as well as a different survey to 74 medical students who completed the wound healing elective at the University of Miami.

Schaum, K. D. (2014). Medicare payment: Surgical dressings and topical wound care products. *Advances in Wound Care*, 3(8), 553-560.

Subtopic(s): Problems in Care Delivery; Issues in Medicare Payment Policy

Type of Source: Journal article

Objective: To review patient's access to surgical dressing and topical wound care products in various settings in light of different Medicare payment systems that apply to each.

Main Findings: As patients move through care, their wound dressing and topical wound therapy options change due to the disparate Medicare payment systems, which is not always clinically warranted. For example, home health agencies are not qualified to perform surgical procedures of applying cellular and/or tissue-based products for wounds that failed standard care. Patients with these needs typically go to Hospital-Based Outpatient Wound Care Departments (HOPDs) or to their qualified health care professionals' (QHP) offices to have these products applied. However, home health agencies often change surgical dressing between patients' visits to the HOPC or QHP.

Strengths/Limitations: N/A

Generalizability to Medicare Population: Yes

Methods: N/A

Carter M. J. (2014). Economic evaluations of guideline-based or strategic interventions for the prevention or Treatment of Chronic Wounds. *Applied Health Economics and Health Policy*, 12(4), 373-389.

Subtopic(s): Problems in Care Delivery

Type of Source: Journal article/systematic review

Objective: To assess/compare the cost effectiveness of new interventions/systems designed to improve the prevention/treatment of chronic wounds in adult populations against current care and provide decision-makers with information on which to base future interventions for chronic wound management.

Main Findings: Few good economic studies exist quantifying the cost effectiveness of strategic or guideline-based interventions in regard to chronic wound management. The strongest evidence is for prevention and treatment of diabetic foot ulcers, prevention of pressure ulcers in long-term care settings, and treatment of patients with critical limb ischemia. Clinical practice guidelines are proliferating in the field of chronic wound care, but large gaps exist in demonstrating their cost effectiveness.

Strengths/Limitations: Strengths include that the systematic review included studies subject to rigorous quality review and that the review followed Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. Limitations include missed studies published in non-English languages or not cited in searched databases; judgment bias in assessing studies.

Generalizability to Medicare Population: N/A

Methods: Using PubMed, Scopus, HTA, and National Health Service Economic Evaluation Database (NHS EED), the author identified comparative health economic evaluations of interventions designed to prevent or treat adult chronic wounds that were guideline-based or strategic in nature and from which an incremental cost-effectiveness ratio or incremental net health benefit was reported or could be calculated. Quality assessment of studies was based on literature-reported methods. Studies were assigned strength of evidence ratings and recommendation level for decision makers. A total of 16 health economic evaluations were included.

Kim, P. J., Evans, K. K., Steinberg, J. S., and Pollard, M. E. (2013). Critical elements to building an effective wound care center. *Journal of Vascular Surgery*, 57(6), 1703-1709.

Subtopic(s): Epidemiology of the Disease; Problems in Care Delivery

Type of Source: Journal article

Objective: To review the critical elements to building and sustaining a successful multidisciplinary wound care center.

Main Findings: The multidisciplinary approach to wound care is the most important element to the success of a wound care center because no single health care provider is adequately equipped with the knowledge, skill, and experience to provide comprehensive care for complex wounds. A single physician needs to be the champion for the wound program. Specialists are then recruited into the core group as the wound center grows and often includes plastic surgeons, podiatric surgeons, vascular surgeons, general surgeons, orthopedic surgeons, and wound care nurse practitioners. Nonsurgical specialists in this core group can include internal medicine, dermatology, endocrinology, rheumatology, infectious disease, hematology, and/or emergency room physicians. A physician with surgical training brings an added dimension of offering both conservative and surgical treatment options. The physical space, EMRs, and financial support from the sponsoring institution are also important components.

Strengths/Limitations: Recommendations based on author's experience over 15 years in building a tertiary care academic-based wound center focused on limb salvage.

Generalizability to Medicare Population: N/A

Methods: N/A

Horn S. D., Fife C. E., Smout R. J., Barrett R. S., Thomson B. Development of a wound healing index for patients with chronic wounds. *Wound Repair & Regeneration*. 2013;21(6):823-832.

Subtopic(s): Problems in Care Delivery

Type of Source: Journal article

Objective: To develop a comprehensive stratification system for patients with wounds that predicts healing likelihood.

Main Findings: The authors developed a comprehensive stratification system for patients with wounds that predicts healing likelihood, the Wound Healing Index (WHI). Certain patient and wound factors affect the likelihood of healing in a predictable way. Some variables predicted significantly in nearly all logistic regression models: wound size, wound age, number of wounds, evidence of bioburden, tissue type exposed (Wagner grade or stage), being nonambulatory, and requiring hospitalization during the course of care. Variables significant in some models included renal failure, renal transplant, malnutrition, autoimmune disease, and cardiovascular disease. The prevalence of significant comorbid conditions (e.g., diabetes among patients with nondiabetic ulcers, malnutrition, renal transplant) confirms previous observations that the majority of patients typically seen in outpatient wound centers would have been excluded from virtually all randomized controlled trials thus far performed in the field of wound healing. The WHI can validly predict likelihood of wound healing among real-world patients and can facilitate comparative effectiveness research to identify patients needing advanced therapeutics.

Strengths/Limitations: Strengths include that this study is among the largest wound-healing studies ever performed and represents a significant advance both in terms of the volume of data analyzed and the completeness of the dataset. Limitations include that data is affected by the quality and consistency of clinical documentation; the ICD-9-CM coding system cannot specifically identify many wound or ulcer types; and the WHI was validated with a particular wound-care specific EHR, but the variables can be translated to other platforms.

Generalizability to Medicare Population: N/A

Methods: Using medical record data from the United States Wound Registry (USWR), the authors created and validated a comprehensive stratification system for patients with wounds that predicts healing likelihood, the WHI. Complete medical record data on 50,967 wounds from the U.S. Wound Registry were assigned a clear outcome (healed, amputated, etc.). Factors known to be associated with healing were evaluated using logistic regression models. Significant variables ($p < 0.05$) were determined and subsequently tested on a holdout sample of data. A different model predicted healing for each wound type.

III. Appendix: Research Questions, Data Sources, Key Word, and Search Term Table

The environmental scan includes a review of information from existing peer-reviewed and non-peer-reviewed publications. We conducted a formal search of major medical, health services research, and general academic databases. We also conducted targeted searches of content available in the grey literature. We reviewed the websites of professional associations/societies and CMS for relevant evaluation reports and program documentation. The table below lists the research questions motivating this environmental scan as well as the sources and search terms used, which included combinations of medical subject headings (MeSH) terms and key words that are listed in table below.

Table 1. Search Strategy

Research Questions	Search Terms	Sources
Epidemiology of Wound Care		
Clearly define the issue/population by addressing the following: 1. What is the definition of chronic wound? 2. What types of chronic wounds/chronic non-healing wounds affect Medicare beneficiaries? 3. What is the population (e.g., comorbidities, sociodemographic) affected by chronic wounds/chronic nonhealing wounds? 4. What are the trends in wound care centers/clinics with respect to organizational structure (e.g., hospital-based vs. free-standing/independent providers and types of providers involved in wound treatment)?	Chronic wounds Nonhealing wounds Wound care centers/clinics Independent wound care provider Hospital-based wound care center Wound care professionals Comorbidities Cost chronic wound care	PubMed; Google Scholar; Sources cited in proposal; American Professional Wound Care Association; Association for the Advancement of Wound Care
Issues in Payment Policy		
5. What are Medicare guidelines for wound care reimbursement? How does reimbursement vary between services provided in hospital-based facilities and independent/freestanding clinics? 6. How do global period restrictions and local coverage determinations apply to hospital-based vs. independent/freestanding clinics? What is the evidence that these prevent non-hospital-based providers to be reimbursed for the same services provided in a facility?	+wound care Medicare	MedPAC; Medicare coverage database; PubMed; Google Scholar; Association for the Advancement of Wound Care
Problems in Care Delivery		
7. What is current practice/standard of care/evidence-based guidelines with respect to treatment of chronic wounds/chronic nonhealing wounds? a. What services compose wound care treatment? (What is included/not included in Seha’s proposed bundle?)	Best practices Patient outcomes of chronic wound care Complications in wound care treatment, untreated wounds Quality measures chronic wound care	Cochrane; NCQA; CMS Measures Inventory Tool; American Professional Wound Care Association;

Research Questions		Search Terms	Sources
b. What types of providers and settings are most commonly used for treatment of chronic wounds/chronic nonhealing wounds? c. Is there evidence that current practices are problematic, especially for providers in independent practices? (Note: the proposal makes the distinction between algorithm-based treatment vs. individual patient need.) d. Is there evidence that current practices in wound treatment pose quality or patient safety concerns (including any concerns relating to care coordination)? e. Is there evidence for treating different types of patients/wounds in different settings? For example, are certain types of patients with chronic wounds inappropriate candidates for treatment in a private physician office? 8. What quality metrics and patient outcomes are associated with wound care?	Patient experience chronic wound care	Association for the Advancement of Wound Care; PubMed	
Results of Proposed or Similar Models			
9. Is there literature available on the proposal submitter?	Seha Medical and Wound Care Wellesley Wound Care Ikram Farooqi Wound care conference	Google	
10. What, if any, other payment models exist to address chronic wound care? Have these been implemented and/or evaluated?	Wound care payment model Chronic wounds ACOs + wound care Managed care + wound care Bundled payment + wound care	CMMI; Public comments on Benchmark Rehab proposal; Association for the Advancement of Wound Care; PubMed	

Two NORC staff members between 10/31/18 and 11/12/18 conducted more than 53 searches of major medical and academic databases, including PubMed and the University of Chicago Library; government websites including MedPac, CMS, and CMMI; and the websites of relevant professional associations, including American Professional Wound Care Association and the Association for the Advancement of Wound Care. Human filtering was conducted on search results based on whether the title and abstract of the materials found matched inclusion criteria.

Some of our searches yielded a high number of results, including results that did not meet all of our inclusion criteria, despite the use of search engine filters when possible. For example, when searching PubMed the following search engine filters were applied: published in past 10 years, human populations, and English language. Despite these search engine filters, a PubMed search using “quality

of life” and “chronic wounds” as MeSH terms produced 1,021 hits. Also, research conducted with non-U.S. populations were obtained via PubMed searches despite the use of these search engine filters. Other search engines possessed even fewer filter options, such as Google Scholar.

Therefore, the creative combination of MeSH terms/keywords were necessary to narrow down the number of results to enable human filtering. For example, a Google Scholar search using “bundled payment models” and “chronic wounds” as keywords yielded 853 results, whereas a search using “bundled payment models” and “chronic nonhealing wounds” as keywords produced 58 results. More targeted search engines, such as the American Professional Wound Care Association or Association for the Advancement of Wound Care, were also utilized to narrow results but did not always produce enough results. For example, a search of the American Professional Wound Care Association engine using “wound care bundled payment” as keywords did not produce any results. Likewise, a search of the Association for the Advancement of Wound Care search engine using “hospital based wound care” as keywords did not produce any results. These professional association websites also returned results including nonrelevant web pages, such as sites on membership requirements, requiring human filtering.

Human filtering was also necessary because the largest category of the potentially relevant materials found was research on specific wound healing products or technologies, specific disease states, or a certain aspect of care such as patient/wound bed preparation. We decided not to include these materials because of the specific nature of these findings and the thinking that more relevant to the purposes of this environmental scan are overviews of these findings to provide evidence-base criteria to assist in the accurate diagnosis and appropriate management of chronic wounds. Finally, another tactic for finding relevant materials was that once key materials were identified, a Google Scholar search was conducted on the names of these materials put in quotes in order to produce the “cited by” link underneath the citation provide by Google Scholar.

ⁱ Seha Wound Care & Hyperbarics. “Welcome to Seha Wound Care.” <http://wellesleywoundcare.com/>

**Bundled Payment for All Inclusive Outpatient Wound Care Services in Non Hospital Based
Setting: Supplemental Information for the PRT
12/17/2018**

1. Local Coverage Determinations and Global Periods in Wound Care

SEHA issues regarding global period restrictions and local coverage determinations:

“A significant portion of the cost of chronic wound care is due to hospital facility charges. On the other hand various Medicare guidelines, global period restrictions and LCDs prevent non-hospital based providers to get reimbursed for all the same services provided during a patient visit.” (p. 2)

“Additionally based on various Medicare guidelines, global period restrictions and LCDs (33631, 33614 etc.) non-hospital based providers cannot get reimbursed for all the services provided in a single visit. This means billing either for evaluation and management or one item/procedure at a time due to conflict with medicare assigned global periods. For example when a debridement is done an unna boot (compression bandage) cannot be charged at the same time though it is a necessary component of the healing process in many cases. It is necessary for controlling edema which prevents the wounds from healing in venous leg ulcers (in hospital based wound clinics they are done and reimbursed at the same time through part 'A' billing). This raises the cost of doing care in private setting. This means either the physician has to absorb the cost of supplies and application of unna boot done when a debridement is needed or simply send the patient to a hospital based clinic.” (p. 5)

“nonsensical global periods and LCDs” (p. 7)

“Current system of payment puts a lot of burden on documentation to justify not only the actual visit but each and every aspect of care and counseling provided yet reimbursement is limited due to various conflicting rules and global periods. The current system also makes it difficult to provide all the necessary care in the most efficient way which may require multiple procedures at the same visit due to various LCD restrictions.” (p. 9)

“For certain very small wounds an autologous pinch graft is a better option but the 90 day global periods becomes a strong deterrent to utilize this option.” (p. 9)

Local Coverage Determinations

Local coverage determinations (LCDs) are made by Medicare Administrative Contractors (MACs) ruling whether a particular item or service is covered on an intermediary or carrier-wide basis. LCDs are specific to each setting and state. They can change frequently and are difficult to interpret, requiring qualified health care professionals to consult insurance specialists to implement them. These policies in turn create variation in the availability of dressings and advanced therapies across settings (Leon et al., 2016). Some wound care providers, practitioners, and manufacturers have reported that navigating the LCD system is complex and they have not had the opportunity to be involved in the process of obtaining coverage for services, procedures, and products they believe should be covered (Schaum, 2018). The LCDs can change what is used to treat wounds depending on the type of setting and in which state the patient is getting treatment.

Of note, yet not specific to wound care, the Centers for Medicare & Medicaid Services (CMS) has recently updated the LCD process in response to the statutory requirements in the 21st Century Cures Act and stakeholder feedback received in the proposed 2018 Physician Fee Schedule (PFS) Rule (82 FR 33950) and through meetings and correspondence (Medicare Learning Network, October 2018). Stakeholder concerns included:

- lack of local coverage process transparency, including notifying stakeholders of proposed revisions to, and drafting of, new LCDs
- ineffective MAC processes for soliciting from, and providing to, stakeholders feedback on information provided during open public meetings
- lack of non-physician representation on Contractor Advisory Committees (CACs)
- CAC meetings are not open to the public (Medicare Learning Network, October 2018).

The new process allows interested parties within a MAC's jurisdiction to request a new LCD, as well as to respond to proposed LCDs (Schaum, 2018). In addition, the new process requires MACs to use clinical guidelines, consensus documents, and consultation when developing an LCD; public notice and comment periods; and open CAC meetings (Schaum, 2018). According to the CMS Manual, Pub 100-08 Medicare Program Integrity, these changes take effect on January 8, 2019.

These changes have the potential to enable wound management professionals to have an easier time navigating the LCD process and to avoid many reimbursement issues. With the opportunity to request new LCDs and respond to proposed LCDs, wound management professionals and providers could take a more active role in gaining Medicare coverage for services, procedures, and products backed by published clinical evidence (Schaum, December 2018).

Global Periods

Global periods apply to many common wound care services: for example, HCPCS 97597 (removal of devitalized tissue), 11042 (debridement of subcutaneous tissue), 11043 (debridement of muscle or fascia), and 11044 (debridement of bone) (Section 2, Table 3). Skin autografts have a 90-day global period. Global periods are a bundled payment that includes all the necessary services normally furnished by a provider before, during, and after a procedure. Medicare payment for a surgical procedure includes the preoperative, intra-operative, and post-operative services routinely performed by the provider or by members of the same group with the same specialty. Physicians in the same group practice who are in the same specialty must bill and be paid as though they were a single physician. Additional services performed during the global period that are related to the site of service and performed by the same physician group are not separately payable.

In the hospital outpatient department, physicians are reimbursed at the facility price, and the hospital receives the Ambulatory Payment Classification (APC) payment amount for the service that reflects facility costs. In physician offices, the physician receives the non-facility rate, which includes direct and indirect practice expense components. Table 3 compares the payment rates for common wound care treatments in physician offices and hospital outpatient departments. Some MACs will only reimburse for bone debridement in facilities—for example, the GSURG-051 Wound Care Billing and Coding Guidelines (LCD Database ID Number L28572) explicitly limits 11044 and related code 11047 (for additional debridement area) to inpatient hospitals, outpatient hospitals, and ambulatory surgical centers.

For services with a zero-day global period, all services occur on the same day with no pre- or post-operative periods, and the visit on the day of surgery is not separately payable. The global payment also includes intraoperative services that are normally a usual and necessary part of a surgical procedure; all additional medical or surgical services required of the surgeon during the postoperative period of the surgery because of complications that do not require additional trips to the operating room (OR); postsurgical pain management; supplies, except for those identified as exclusions; miscellaneous services such as dressing changes, local incisional care, removal of operative pack, and removal of cutaneous sutures, staples, lines, wires, tubes, drains, casts, and splints. Physicians should not bill an evaluation and management (E&M) service on the same day as when a minor surgery is performed. This rule applies to the many wound care procedures assigned zero-day global surgical periods that are performed in the physician/qualified health professional (QHP) office or in the HOPD. Splints and casting supplies provided in a physician's/other QHP's office are payable separately under the reasonable charge payment methodology. Table 1 includes the supply and labor cost inputs (excluding physician work) for Healthcare Common Procedure Coding System (HCPCS) 97597, 11042, 11043, and 11044 used to determine the global payment rate for these services.

At least some MACs include skin substitutes as part of the dressings for wound care (see [LCD L28572](#), for example) and bundle with the global payment. The cost of these skin substitutes can vary greatly (Table 2). In the hospital outpatient department, low-cost skin substitutes are bundled with the APC payment, but high-cost skin substitutes are separately payable. There are also CPT codes for the application of skin substitutes that can only be billed under the Outpatient Prospective Payment System, or OPPOS (C5271-C5278). Therefore, physicians in freestanding physician offices must absorb the cost of these high-cost skin substitutes if used in treatment, whereas physicians performing the service in the HOPD would be able to receive separate payment. In addition to skin substitutes, a number of advanced dressings are available that could aid in wound healing (for example, hydrocolloid, hydrogel, collagen, foams, alginates, hypafix, kerlix, or profore dressings). The evidence for these dressings in improving wound outcomes is limited (AHRQ, 2014; NICE, 2016), and the cost of using these treatments may not be fully reflected in the zero-day global payment rates that are based on Kling bandages, Telfa dressing, Fabco gauze, and Micropore surgical tape.

Unna Boots and Other Therapies

Unna Boots (HCPCS 29580) are the application of a paste boot. The non-facility 2018 national payment amount for Unna Boot application is \$63, and the non-facility fee schedule amount is \$29.88. The APC payment rate in facilities is \$168.95 in 2018, for a combined payment of \$198.83. The physician applies an Unna boot to the leg of a patient. An Unna boot is typically used to treat or prevent venostasis dermatitis or ulcers of the lower leg. It is also used to control postoperative edema like that resulting from an amputation. The physician prepares this semirigid dressing by first making a paste of zinc oxide, gelatin, and glycerin. This is applied to the skin of the leg. A spiral or figure eight bandage is wrapped evenly over the leg. Paste is then reapplied, and further bandages are applied in the same fashion until the desired rigidity is obtained. Elastic bandages are often added to the dressings for reinforcement.

Negative Pressure Wound Therapy (HCPCS 97605, 97608) is applied to the wound bed through a foam or gauze contact medium using an electrically, battery, or mechanically powered pump; this involves achieving an airtight vacuum seal. The treatment is thought to assist healing by providing a moist environment and removing interstitial fluid and exudate and enhancing granulation tissue formation,

angiogenesis and tissue perfusion (Grothier, 2012). The 2018 non-facility national payment amount of this therapy is \$45.00 for an area less than 50 centimeters; the facility fee schedule reimbursement is \$26.64, plus an OPPS payment of \$168.95. This therapy does not have a global period, but it is subject to multiple procedure payment reductions.

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Table 1. Supply Inputs of Selected Wound Care Zero-Day Global Periods

from 2019 Medicare Physician Fee Schedule Final Rule Direct PE Inputs

97597 : Removal of devitalized tissue up to 20 cm

Category	Description	Price	Quantity
Kit, Pack, Tray	pack, cleaning, surgical instruments	7.1568	1
Kit, Pack, Tray	pack, minimum multi-specialty visit	2.1122	1
Gown, Drape	drape, sterile barrier 16in x 29in	0.498	1
Gown, Drape	drape, sterile, fenestrated 16in x 29in	0.5753	1
Gown, Drape	drape, sterile, for Mayo stand	1.5335	1
Gown, Drape	gown, staff, impervious	1.186	1
Gown, Drape	towel, non-sterile	0.4057	2
Gown, Drape	underpad 2ft x 3ft (Chux)	0.2525	1
Hypodermic, IV	syringe 50-60ml	0.9432	1
Cutters, Closures, Cautery	blade, surgical (Bard-Parker)	0.5713	2
Wound Care, Dressings	bandage, Kling, non-sterile 3in	0.4645	1
Wound Care, Dressings	dressings, 3in x 4in (Telfa, Release)	0.1205	2
Wound Care, Dressings	gauze, self-adherent roll 0.5in to 2in (Fabco, Gauztex)	0.0222	72
Wound Care, Dressings	gauze, sterile 4in x 4in (10 pack uou)	0.899	2
Wound Care, Dressings	tape, surgical paper 1in (Micropore)	0.004	12
Pharmacy, Rx	sodium chloride 0.9% irrigation (500-1000ml uou)	2.3905	1
Pharmacy, NonRx	basin, irrigation	1.6565	1
Pharmacy, NonRx	hydrogen peroxide	0.0123	10
Pharmacy, NonRx	silver nitrate applicator	0.1	1

11042: Debridement of subcutaneous tissue 20 sq cm

Kit, Pack, Tray	pack, cleaning, surgical instruments	7.1568	1
Kit, Pack, Tray	pack, minimum multi-specialty visit	2.1122	1
Gown, Drape	drape, sterile barrier 16in x 29in	0.498	1
Gown, Drape	drape, sterile, fenestrated 16in x 29in	0.5753	1
Gown, Drape	drape, sterile, for Mayo stand	1.5335	1
Gown, Drape	gloves, sterile	0.8575	1
Gown, Drape	gown, staff, impervious	1.186	2
Gown, Drape	towel, non-sterile	0.4057	2
Gown, Drape	underpad 2ft x 3ft (Chux)	0.2525	1
Hypodermic, IV	syringe 50-60ml	0.9432	1
Cutters, Closures, Cautery	blade, surgical (Bard-Parker)	0.5713	2
Wound Care, Dressings	bandage, Kling, non-sterile 3in	0.4645	1
Wound Care, Dressings	dressings, 3in x 4in (Telfa, Release)	0.1205	2
Wound Care, Dressings	gauze, self-adherent roll 0.5in to 2in (Fabco, Gauztex)	0.0222	72
Wound Care, Dressings	gauze, sterile 4in x 4in (10 pack uou)	0.899	2
Wound Care, Dressings	tape, surgical paper 1in (Micropore)	0.004	10
Pharmacy, Rx	sodium chloride 0.9% irrigation (500-1000ml uou)	2.3905	1
Pharmacy, NonRx	basin, irrigation	1.6565	1
Lab	culture swab system (Culturette)	0.8887	1

11043: Debridement of muscle/fascia up to 20 sq cm

Kit, Pack, Tray	pack, cleaning, surgical instruments	7.1568	1
Kit, Pack, Tray	pack, minimum multi-specialty visit	2.1122	1
Gown, Drape	drape, sterile barrier 16in x 29in	0.498	1
Gown, Drape	drape, sterile, fenestrated 16in x 29in	0.5753	1
Gown, Drape	drape, sterile, for Mayo stand	1.5335	1
Gown, Drape	gloves, sterile	0.8575	2
Gown, Drape	gown, staff, impervious	1.186	2
Gown, Drape	towel, non-sterile	0.4057	2
Gown, Drape	underpad 2ft x 3ft (Chux)	0.2525	1
Hypodermic, IV	needle, 18-27g	0.0767	2
Hypodermic, IV	syringe 10-12ml	0.1905	1
Hypodermic, IV	syringe 50-60ml	0.9432	1
Cutters, Closures, Cautery	blade, surgical (Bard-Parker)	0.5713	3
Wound Care, Dressings	bandage, Kerlix, sterile 4.5in	1.469	2
Wound Care, Dressings	dressings, 3in x 4in (Telfa, Release)	0.1205	2
Wound Care, Dressings	gauze, sterile 4in x 4in (10 pack uou)	0.899	2
Wound Care, Dressings	tape, surgical paper 1in (Micropore)	0.004	12
Pharmacy, Rx	lidocaine 1%-2% inj (Xylocaine)	0.0413	6
Pharmacy, Rx	sodium chloride 0.9% irrigation (500-1000ml uou)	2.3905	1
Pharmacy, NonRx	basin, irrigation	1.6565	1
Pharmacy, NonRx	hydrogen peroxide	0.0123	20
Pharmacy, NonRx	silver nitrate applicator	0.1	2
Pharmacy, NonRx	swab-pad, alcohol	0.0198	2
Lab	culture swab system (Culturette)	0.8887	1

11044: Debridement of bone up to 20 sq cm

Kit, Pack, Tray	pack, cleaning, surgical instruments	7.1568	1
Kit, Pack, Tray	pack, minimum multi-specialty visit	2.1122	1
Gown, Drape	drape, sterile barrier 16in x 29in	0.498	1
Gown, Drape	drape, sterile, fenestrated 16in x 29in	0.5753	1
Gown, Drape	drape, sterile, for Mayo stand	1.5335	1
Gown, Drape	gloves, sterile	0.8575	2
Gown, Drape	gown, staff, impervious	1.186	2
Gown, Drape	towel, non-sterile	0.4057	2
Gown, Drape	underpad 2ft x 3ft (Chux)	0.2525	1
Hypodermic, IV	needle, 18-27g	0.0767	2
Hypodermic, IV	syringe 10-12ml	0.1905	1
Hypodermic, IV	syringe 50-60ml	0.9432	1
Cutters, Closures, Cautery	blade, surgical (Bard-Parker)	0.5713	3
Wound Care, Dressings	bandage, Kerlix, sterile 4.5in	1.469	2
Wound Care, Dressings	dressings, 3in x 4in (Telfa, Release)	0.1205	2
Wound Care, Dressings	gauze, sterile 4in x 4in (10 pack uou)	0.899	1
Wound Care, Dressings	tape, surgical paper 1in (Micropore)	0.004	12
Pharmacy, Rx	lidocaine 1%-2% inj (Xylocaine)	0.0413	6
Pharmacy, Rx	sodium chloride 0.9% irrigation (500-1000ml uou)	2.3905	1
Pharmacy, NonRx	basin, irrigation	1.6565	1
Pharmacy, NonRx	hydrogen peroxide	0.0123	20
Pharmacy, NonRx	silver nitrate applicator	0.1	2
Pharmacy, NonRx	swab-pad, alcohol	0.0198	2
Lab	culture swab system (Culturette)	0.8887	1

Table 2. Medicare Payment Allowance Limits for Selected Part B Skin Substitutes that Are Bundled Dressings by an Illustrative MAC

HCPCS Code	Short Description	HCPCS Code Dosage	Payment Limit	High-/Low-Cost Skin Substitute
Q4104	Integra bmwd	--	--	High
Q4105	Integra drt or omnigraft	--	--	High
Q4107	Graftjacket	1 SQ CM	87.494	High
Q4108	Integra matrix	--	--	High
Q4110	Primatrix	--	--	High
Q4111	Gammagraft	1 SQ CM	7.26	Low
Q4112	Cymetra injectable	1 CC	754.72	<i>not listed</i>
Q4113	Graftjacket xpress	1 CC	754.72	<i>not listed</i>
Q4115	Alloskin	1 SQ CM	11.207	Low
Q4116	Alloderm	--	--	High
Q4117	Hyalomatrix	--	--	Low
Q4121	Theraskin	1 SQ CM	45.834	High

Source: L28572 and Medicare Part B Drugs October 2018 Pricing File

2. Payment for Wound Care in Different Settings

Table 3. Reimbursement for Wound Care in Physician Offices versus Hospital Outpatient Departments

HCPCS CODE	SHORT DESCRIPTION	2018 Medicare Physician Fee Schedule ¹				2018 Hospital Outpatient Prospective Payment System ²		Total HOPD (APC + Facility PFS)	Total PFS Payment in a Freestanding Office Setting
		Procedure Status	Global	Non- Facility Price	Facility Price	APC Status Indicator	APC Payment		
97597	Rmvl devital tis 20 cm/<	A	000	\$85.32	\$24.48	T	\$168.95	\$193.43	\$85.32
97598	Rmvl devital tis addl 20cm/<	A	ZZZ	\$28.44	\$11.52	N	--	\$11.52	\$28.44
97602	Wound(s) care non-selective	B	XXX	<i>(not currently priced by PFS)</i>		Q1	\$168.95	\$168.95	--
97605	Neg press wound tx </=50 cm	A	XXX	\$45.00	\$26.64	Q1	\$168.95	\$195.59	\$45.00
97606	Neg press wound tx >50 cm	A	XXX	\$53.28	\$28.80	Q1	\$310.80	\$339.60	\$53.28
97607	Neg press wnd tx	C	XXX	<i>(contractor priced under PFS)</i>		T	\$310.80	\$310.80	<i>(varies)</i>
97608	Neg press wound tx >50 cm	C	XXX	<i>(contractor priced under PFS)</i>		T	\$310.80	\$310.80	<i>(varies)</i>
97610	Low frequency non-thermal us	A	XXX	\$136.44	\$17.28	Q1	\$168.95	\$186.23	\$136.44
11042	Deb subq tissue 20 sq cm/<	A	000	\$120.60	\$64.08	T	\$310.80	\$374.88	\$120.60
11043	Deb musc/fascia 20 sq cm/<	A	000	\$235.08	\$160.92	T	\$488.20	\$649.12	\$235.08
11044	Deb bone 20 sq cm/<	A	000	\$321.84	\$238.68	J1	\$1,348.03	\$1,586.71	\$321.84
11045	Deb subq tissue add-on	A	ZZZ	\$42.48	\$27.36	N	--	\$27.36	\$42.48
11046	Deb musc/fascia add-on	A	ZZZ	\$75.24	\$58.32	N	--	\$58.32	\$75.24
11047	Deb bone add-on	A	ZZZ	\$127.44	\$102.96	N	--	\$102.96	\$127.44

Sources: ¹ Medicare Physician Fee Schedule (PFS) Database (data updated 5/2018); ² Hospital OPPS Addendum B, January 2018

PFS procedures status codes: A = Active Code. These codes are paid separately under the PFS, if covered. There will be RVUs and payment amounts for codes with this status. B = Payment for covered services are always bundled into payment for other services not specified. There will be no RVUs or payment amounts for these codes, and no separate payment is ever made. When these services are covered, payment for them is subsumed by the payment for the services to which they are incident (an example is a telephone call from a hospital nurse regarding care of a patient). C = Carriers/MACs priced code. Carriers/MACs will establish RVUs and payment amounts for these services, generally on an individual case-by-case basis following review of documentation, such as an operative report.

Global period codes: 000 = zero-day global period; XXX = global concept does not apply; ZZZ = add-on code that is related to another service (primary procedure) and is always included in the global period of the other service.

APC status indicators: J1 = Hospital Part B services paid through a comprehensive APC; N = No additional payment, payment included in line items with APCs for incidental service; Q1 = Packaged services subject to separate payment based on criteria—a procedure with status indicator Q1 is packaged if there are any procedures on the same day with status indicators: S, T, U, or X; T = Significant procedure subject to multiple procedure discounting.

As shown in Table 3, the unadjusted base Medicare payment rates for common wound care services are higher in HOPDs than in private free-standing physician offices. In HOPDs, the payment includes reimbursement for physician services at the facility Medicare PFS rate as well as an APC payment to the hospital for facility costs. In physician offices, the reimbursement includes the non-facility Medicare PFS rate only. For debridement of subcutaneous tissue (CPT 11042), the reimbursement in a physician office is \$120.60, whereas it is \$374.88 in an HOPD.

HOPDs and physician offices are the most common sites of wound care. However, some wound care services do occur in alternative locations. Reimbursement rates for wound care services in Ambulatory Surgical Centers (ASCs) are slightly lower than in HOPDs. ASCs are paid through APCs within the OPPS (with a few differences), but the conversion factor for ASCs is lower. For example, the reimbursement for a debridement CPT 11042 in an ASC is \$226 (a \$161.92 APC payment plus the \$64.08 facility MFPS rate), compared with \$374.88 in HOPDs. Both HOPDs and ASCs have higher payment rates for CPT 11042 than physician offices, where the reimbursement is \$120.60.

Medicare beneficiaries in skilled nursing facilities (SNFs) may have chronic wounds that require treatment. SNF reimbursement is based on a predetermined daily rate based on patient characteristics and expected utilization use. The rate covers all operating and capital costs that efficient facilities would be expected to incur in furnishing most SNF services. Certain high-cost, low-probability ancillary services are paid separately and are not included in the consolidated billing, but wound care is not explicitly listed among these services. The professional component of physician services furnished to SNF patients is separately reimbursed, but the technical component is subject to consolidated billing and must be reimbursed by the SNF. Therapy services (physical, occupational, and speech/language) are all considered part of the consolidated bundle (CMS 2018).

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3. International Standards for Wound Care: Wound Care in the United Kingdom

The National Health Service (NHS) sets national health policies, standards, and some payments but leaves much of the health care determination process to localities. There are 195 Clinical Commissioning Groups (CCGs) that oversee two-thirds of the NHS budget and set local contracts with primary and social care providers, among other duties (NHS Clinical Commissioners, n.d.). Except for wound dressing prices, which are listed in the national drug tariff, wound care systems and compensation rates vary across the United Kingdom.

The National Institute for Health and Care Excellence (NICE) used meta-analysis to provide cost- and clinical-effectiveness reports for wound dressings. In its report, NICE cites a lack of quality evidence on the effects of using advanced dressings for treatment, as well as questioning their cost-effectiveness (NICE, 2016). NICE finds that silver dressings are not cost-effective in most situations and may delay wound healing (Carter et al., 2010) and should only be used when there are signs of infection. Otherwise, the recommendations are limited. They advise that dressing selection and frequency of change should be carefully determined after assessment of a patient's wounds and needs (NICE, 2016). If there is no evidence for one dressing over another, they recommend using the least-costly option. Additionally, they suggest prescribing primary care dressings on a short-term basis for most patients, which can reduce waste and ensure clinical review at appropriate times (National Prescribing Centre, 2012).

NICE also has assessed the effectiveness of new wound treatments and therapies. They determined that, in the community setting, the Debrisoft monofilament debridement pad showed evidence of quicker debridement and fewer nurse visits, which could lead to cost savings compared to hydrogel, gauze, and larvae products (NICE, 2014). NICE determined there is sufficient evidence to support the use of negative pressure wound therapy (NPWT) for managing open abdominal wounds in certain cases if providers follow its guidelines (NICE, 2013). In the case of NPWT, as with dressings, they advise further research.

NICE and the NHS also provide recommendations for CCGs about wound care prevention and treatment strategies based on expert advice and case studies. NICE recommends establishing a formulary for dressings and educating providers on the use of relevant products to improve continuity of care (National Prescribing Centre, 2012). Additionally, they advise communities to establish routine wound screenings such that all people over 75 or with a clinical concern are screened during primary care visits, inpatients are checked weekly and on admission and discharge, and those receiving nursing care are checked at least every four weeks. NHS has funded multiple local programs aimed at preventing waste, which have found that communities can decrease dressing waste and save money through removing individual prescriptions and instead establishing a centralized process at either the institution or community level (NHS Business Services Authority, 2017 & 2018).

Overall, NICE cites a lack of data to sufficiently advise treatment strategies for wound care and recommends further research into the efficacy of wound dressings and treatments. Since wound dressings are classified as medical devices, the quality of evidence required for approval is lower than for medicines, leading to lower-quality randomized controlled trials (RCTs). The high costs and increasing prevalence of wound care needs have caused increasing discussion of further research into treatment effectiveness and strategies to reduce costs (Guest et al., 2017). The NHS has created financial incentives that run through the end of the current payment system in April for reporting wound

assessments, with the goal of increasing assessments for wounds that haven't healed within four weeks (Fletcher & Barrett, 2018). At present, NICE advises providers to prescribe the wound dressing they deem best suited for the patient's wound and care needs, with a preference for the least costly option should there be insufficient reason for any specific dressing, and to maintain consistent screening of wounds.

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