

# Physician-Focused Payment Model Technical Advisory Committee

## Preliminary Review Team Report to the Physician-Focused Payment Model Technical Advisory Committee (PTAC)

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In accordance with the Physician-Focused Payment Model Technical Advisory Committee's (PTAC's) proposal review process, proposals for Physician-Focused Payment Models (PFPMs) that contain the information requested by PTAC's *Proposal Submission Instructions* will be assigned to a Preliminary Review Team (PRT). The PRT will draft a report containing findings regarding the proposal for discussion by the full PTAC. This PRT report is preparatory work for the full PTAC and is not binding on PTAC. This report is provided by the PRT to the full Committee for the proposal identified below.

### A. Proposal Information

- 1. Proposal Name:** LUGPA Advanced Payment Model for Initial Therapy of Newly Diagnosed Patients with Organ-Confined Prostate Cancer
- 2. Submitting Organization or Individual:** Large Urology Group Practice Association (LUGPA)
- 3. Submitter's Abstract:**

"The LUGPA Alternative Payment Model (APM) will create episode-based payments for newly diagnosed prostate cancer patients with localized disease. Data suggests that a subgroup of this population can safely defer active intervention (AI) thus avoiding overutilization of services while reducing morbidity and cost. We have designed an episode-based payment that aligns incentives with clinical best practices and recently issued guidelines for physicians to recommend active surveillance (AS) in clinically appropriate patients with low-risk localized prostate cancer, allowing these patients to avoid unnecessary interventions. The APM will incentivize patient-physician shared decision making, compensating physicians for the management time required to responsibly continue these patients on AS. Benchmarks would be defined based on a practice's historical clinical decision making, considering prior use of AS vs. immediate intervention. Practices would be eligible for a performance-based payment if they met certain quality thresholds and for enhancing performance year utilization of AS relative to a historical period.

We believe that this model will meet Quality Payment Program (QPP) requirements for an advanced alternative payment model, as we require use of certified electronic health record technology (CEHRT), tie payments to quality measures, and require that participating practices bear sufficient financial risk. Participation by smaller practices will be facilitated by variations within the APM with lessened levels of financial risk.”

## B. Summary of the PRT Review

The proposal was received on July 5, 2017. The PRT met between August 7, 2017 and November 3, 2017. A summary of the PRT’s findings are provided in the table below.

### PRT Rating of Proposal by Secretarial Criteria

Criteria Specified by the Secretary (at 42 CFR§414.1465)	PRT Rating	Unanimous or Majority Conclusion
1. Scope (High Priority)	Does Not Meet	Majority
2. Quality and Cost (High Priority)	Meets	Unanimous
3. Payment Methodology (High Priority)	Meets	Majority
4. Value over Volume	Meets	Unanimous
5. Flexibility	Meets	Unanimous
6. Ability to be Evaluated	Meets	Unanimous
7. Integration and Care Coordination	Does Not Meet	Unanimous
8. Patient Choice	Meets	Unanimous
9. Patient Safety	Meets	Unanimous
10. Health Information Technology	Does Not Meet	Unanimous

## C. Information Reviewed by the PRT

### 1. Proposal Summary

The PRT reviewed the LUGPA proposal as well as additional information provided by the submitter in written responses to questions from the PRT. The submitter also participated in a phone call with the PRT. The proposal, questions and answers, and call transcript are available on the PTAC [website](#).

This proposal focuses on treatment for Medicare patients diagnosed with organ-confined prostate cancer, with the intention of incentivizing providers away from active intervention (AI) toward active surveillance (AS). The submitters argue this supports the triple aim of improving beneficiary care and experience, improving health, and reducing expenditures. The submitters acknowledge in their proposal that recent guidelines from the American Urological Association, the American Society for Radiation Oncology, and the Society of Urologic Oncology support the recommendation of AS as “the best available care option for very low-risk localized prostate cancer patients and “the preferable care option for most low-risk localized

prostate cancer patients.” In addition, the submitters highlight that the National Comprehensive Cancer Network (NCCN) guidelines suggest a preference for AS for men with very low-risk prostate cancer and life expectancy below 21 years and certain men with Gleason scores of 7. The submitter estimates that about 63,000 Medicare FFS beneficiaries are diagnosed with localized prostate cancer annually; 77% receive AI such as radiation therapy, prostatectomy, and/or hormonal therapy. The average cost of AI is \$32,788, and treatments can result in diminished sexual function, urinary incontinence, bowel dysfunction, and urinary irritation for patients.

This model aims to align provider incentives for increased use of AS for appropriate patients with a two-part payment model: a \$75 monthly care management fee during AS episodes and a performance-based payment reflecting provider performance on quality measures and total costs of care during the AS episode compared to a historical benchmark. The model focuses on urologists as eligible professionals; PAs/NPs at participating practices as well as other medical specialists are not excluded from participating. Medicare patients who are diagnosed with localized prostate cancer after a biopsy constitute the population eligible for initial episodes and could continue subsequent 12-month episodes on AS.

The monthly care management fee is relatively straightforward and is structured to support the enhanced services not currently reimbursed by FFS Medicare, such as tracking AS beneficiaries to ensure compliance, tracking lab results longitudinally in a consistent format, educating beneficiaries about disease progression, social services, and reviewing the care plan. Providers would receive a \$75 monthly payment during each initial or subsequent 12-month clinical episode (\$900 total annually); payments could be split among providers based on their role in managing active surveillance. The submitter clarified that the payment is not intended to support comprehensive care management for all of a patient’s comorbidities.

The performance-based payments would retrospectively compare actual initial episode expenditures on total cost of Part A and B services against a target amount, calculated using a complex formula. The model divides patients diagnosed with localized prostate cancer after biopsy into 12 sub-categories, three AS sub-categories, and nine AI subcategories reflecting treatments delivered (e.g., prostatectomy only, hormone and radiation therapy, etc.). Ultimately, each APM Entity would receive a single composite benchmark price based on practice-specific and regional historical utilization of AS and practice-specific performance year composition of episodes within AS and AI episode categories. The regional (Census Division) benchmark is derived from three regional provider strata: academic medical centers, hospital-based providers, and office-based providers. The model creates case-mix weighted practice and regional historical episode expenditures that are blended to create the benchmark price, giving greater weight to the regional historical expenditures over time (25% regional in years 1 and 2, 50% regional in year 3, 75% regional in years 4 and 5). The benchmark would be 100% regionally-based for practices with fewer than 36 historical

initial episodes. A benchmark price would be set for each of the 12 subcategories, but the APM Entity would receive performance-based payments based on a combined benchmark price based on all of the practice’s performance year episodes. The composite benchmark is created by first summing AS and AI composite benchmark prices and then weighting by the proportion of AS and AI episodes at the practice and regionally using the following formula, with the regional component weighted at 25% as an example:

$$\begin{aligned}
 bench_{comp} &= \left( 0.75 \times AS_{wt_{pr}} + 0.25 \times AS_{wt_{reg}} \right) \times bench_{AS} \\
 &+ \left( 0.75 \times AI_{wt_{pr}} + 0.25 \times AI_{wt_{reg}} \right) \times bench_{AI}
 \end{aligned}$$

The target price would be 98% of the composite benchmark price. APM Entities that reduce actual expenditures below the geographically adjusted target amount would be eligible for a performance-based payment of up to 100% of the difference between target and actual expenditures, depending on performance on quality measures (per Table 4 in the proposal), subject to a 20% stop-gain limit. APM Entities that do not reduce expenditures would pay back up to 125% of the difference, up to a 20% stop-loss limit.

## 2. Additional Information Reviewed by the PRT

### a) Data Analyses

The PRT did not seek additional data analyses for this proposal.

### b) Literature Review and Environmental Scan

ASPE, through its contractor, conducted an abbreviated environmental scan that included a review of peer-reviewed literature as well as a search for relevant gray literature, such as research reports, white papers, conference proceedings, and government documents. The abbreviated environmental scan is available on the [PTAC website](#).

Documents comprising the environmental scan were primarily identified using Google and PubMed search engines. Key words guiding the environmental scan and literature review were directly identified from the letter of intent (LOI). The key word and combination of key words were utilized to identify documents and material regarding the submitting organization, the proposed model in the LOI, features of the proposed model in the LOI, or subject matter identified in the LOI.

Key terms used included “Large Urology Group Practice Association (LUGPA),” “LUGPA APM,” “Prostate Cancer,” “Quality Payment Program (QPP),” “Value-based Care Reimbursement,” “Medicare,” “MACRA Episode-Based Cost Measure.”

These documents are not intended to be comprehensive and are limited to documents that meet predetermined research parameters, including a five-year look back period, a primary focus on U.S.-based literature and documents, and relevancy to the LOI.

As part of this environmental scan, the PRT reviewed the Centers for Medicare and Medicaid Services' (CMS') Oncology Care Model.

To address the PRT's request for additional information, the contractor conducted a review of the literature to understand the evidence of enrollment rates of active surveillance (AS) and active intervention (AI). The literature search strategy included 28 peer-reviewed articles relevant to "low-risk, clinically localized prostate cancer" using PubMed and Google Scholar. Since the number of relevant literature dated within the five-year publication period was few, there are articles cited in this literature review that are dated beyond the five-year period. Publications included in this review are dated from 2002 to the present. The keywords utilized in this literature review are listed below and were used in combination or independently of each other:

- active intervention
- active surveillance
- anxiety
- criteria
- clinically localized
- curative treatment
- definitive therapy
- delayed intervention
- disease progression
- eligibility
- enrollment
- initial management
- immediate treatment
- incidence
- initial treatment
- long-term
- low-risk
- mortality rates
- newly diagnosed
- overtreatment
- percentage
- prostate cancer
- prostate-specific antigen
- quality of life
- side effects
- symptoms
- strategies
- therapy
- underutilization

### **c) Public Comments**

The PRT reviewed five public comment letters on the proposal. The public comment letters are available on the PTAC [website](#).

### **d) Other Information**

The PRT spoke with a urologist at the University of Pennsylvania, on treatment of prostate cancer. The PRT also obtained information from the CMS Center for Medicare and Medicaid Innovation (CMMI) regarding the proposal. The PRT submitted questions to the applicant organization, which it answered in writing, and then had a follow-up phone call with the applicant to clarify various aspects of the proposal.

## D. Evaluation of Proposal Against Criteria

**Criterion 1. Scope (High Priority Criterion).** Aim to either directly address an issue in payment policy that broadens and expands the CMS APM portfolio or include APM Entities whose opportunities to participate in APMs have been limited.

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**PRT Qualitative Rating: Does Not Meet Criterion**

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Strengths:

- Urologists are currently not significant participants in the Oncology Care Model (OCM) or other APMs.
- Patients targeted by the LUGPA proposal — low to medium risk with organ-contained prostate cancer — are not generally eligible for OCM, which has an episode trigger based on receipt of chemotherapy.

Weaknesses:

- Although it expands some opportunities for participation, the overall potential scope of the LUGPA proposal in terms of providers, patients, and reduced costs is relatively small — only 6,000 urologists, 19,000 newly diagnosed patients per year, and \$28 million in estimated savings per year.
- The proposal is unclear about non-urologists' participation in care management of these patients and thus potential participation in the APM.
- The trend toward increased use of AS for localized prostate cancer is already occurring even without revisions to Medicare payment policy.
- The submitter has highlighted an important flaw in the current Medicare reimbursement system, namely that in a pure FFS payment setting, items and services related to AI in prostate cancer yield greater revenues than items and services related to AS. At the same time, a real shift in the field is occurring with evidence supporting greater use of active surveillance. What is not clear for the majority of the PRT is whether recent changes in the physician fee schedule might allow for opportunities for increased instances of active surveillance:
  - use of Medicare's Chronic Care Management Fee or Complex Chronic Care Management Fee, which offer reimbursement outside of professional E&M visits that could approach and/or exceed the submitter's proposed monthly coordination fees;
  - CPT codes established for additional services that are not covered in E&M visits, for example:
    - CPT 99487 (for 60 minutes): Increases reimbursement for complex CCM.

- CPT 99489 (each additional 30 minutes; CPT 99489 can only be reported in conjunction with CPT 99487): Increases reimbursement for complex CCM.
  - Add-on code G0506: A one-time code to reimburse providers (average \$65.34) for extra time that wouldn't have been part of the typical visit, but is required to initiate CCM services and create a comprehensive care plan for the patient.
- The PRT debated how much opportunity would be created under the proposed APM to ensure that more patients were engaged in appropriate AS services. It is not clear whether a PFPM is appropriate for an intervention which might have other existing opportunities to adhere to nationally recognized guidelines.

Summary of Rating:

Though the LUGPA proposal does create new opportunities to participate in an APM for a limited number of providers and patients, the majority of the PRT felt it does not meet the criteria for several reasons. First, the current reimbursement system does provide support through the Chronic Care Management fee that could apply to patients with organ-confined prostate cancer. Second, recent guidelines from relevant medical societies support AS as the best available care option for patients with low-risk localized prostate cancer, and urology practices are changing behaviors and increasingly using AS for appropriate patients even without revisions to Medicare payment policy. Though this model might accelerate adoption of AS by making it more attractive financially, it may not be necessary or the wisest way to achieve it.

**Criterion 2. Quality and Cost (High Priority Criterion). Are anticipated to improve health care quality at no additional cost, maintain health care quality while decreasing cost, or both improve health care quality and decrease cost.**

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**PRT Qualitative Rating: Meets Criterion**

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Strengths:

- AS appears to be appropriate for many more patients than currently receive it or watchful waiting. Patient satisfaction and quality of care would likely improve with increased patient education, more robust process for shared decision-making and reduced complications associated with AI.
- Costs would likely fall with reduced utilization of AI because each AI episode costs about 2.5 times more than an AS episode. The model would incentivize clinicians to choose AS, whereas current reimbursements incentivize AI.

Weaknesses:

- The standard of care is moving toward AS already, particularly in academic settings where financial incentives and institutional resources may support AS to a greater degree. It is difficult to estimate how long the transition to AS for appropriate patients would take under the current payment system, as the shift requires changing behavioral patterns within a specialty.
- One of the proposed quality measures is time on AS. While this technically may be appropriate if AS is currently underutilized, it sets up a self-referral feedback loop and sets a low bar for performance.
- The proposed actions for CMS, including an audit of additional clinical details to monitor quality, could be burdensome for both CMS and providers.

Summary of Rating:

The PRT unanimously agreed the LUGPA proposal meets this criterion. The evidence suggests that a significant share of patients with localized prostate cancer could be enrolled initially in AS, avoiding or delaying the costs of AI until medically appropriate without compromising patients' health. Patients would also delay or avoid the potential complications of AI, which would improve patient satisfaction and quality of life. The proposed model would likely accelerate adoption of AS in the short term, but the PRT notes that care delivery is already trending toward AS, and at some point in the future the ideal rates of AS will be achieved and the model will no longer be necessary.

**Criterion 3. Payment Methodology (High Priority Criterion). Pay APM Entities with a payment methodology designed to achieve the goals of the PFPM criteria. Addresses in detail through this methodology how Medicare and other payers, if applicable, pay APM Entities, how the payment methodology differs from current payment methodologies, and why the Physician-Focused Payment Model cannot be tested under current payment methodologies.**

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**PRT Qualitative Rating: Meets Criterion**

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Strengths:

- The LUGPA proposal includes a care management fee to support upfront costs to incentivize treatment changes in the currently desired direction, as well as a performance-based incentive to reduce costs below historical practice and regional norms.



Weaknesses:

- This model, in particular the inclusion of a performance-based payment, seems like a very complex way to incentivize AS versus AI.
- Though the performance-based payments reflect total cost of care during the episode, the model does not address integration with other providers who may be important components of care management for patients with comorbidities.
- The model is not affected by the evolving standard of care toward AS among proper control groups. In effect, a participating provider would “earn” savings if the provider beat historical personal and historical regional norms.
- The heavy weights on a specific practice-based component make savings very easy to obtain. Thus, while the model is designed to encourage adoption of the current standard of care in proportion and type of patients who are given AS, the standards for success are so low that almost anyone who was overusing AI before could gain financially from doing what is currently recommended by guidelines to be the best available care option.
- All history-based benchmarks lose their power to incentivize over time as practice patterns trend toward the optimal clinical level.

Summary of Rating:

The majority of the PRT members concluded that the LUGPA proposal meets this criterion because the payment methodology technically will incentivize the desired change in treatment modalities. The PRT is mindful that there may be alternatives that could achieve this objective in a better or more simple manner, such as to recalibrate the fee schedule amounts for AS versus AI or to use control groups and the current standard of care rather than practice historical expenditures to develop contemporaneous spending targets, requiring ex post financial reconciliation, as in the downside risk ACO models. The PRT also questioned why the model emphasized total cost of care when it provides no clear mechanism or incentives to address *total* care costs, only those costs associated with care for prostate cancer.

**Criterion 4. Value over Volume. Provide incentives to practitioners to deliver high-quality health care.**

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**PRT Qualitative Rating: Meets Criterion**

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Strengths:

- Current reimbursement policies incentivize urologists to deliver a high volume of services to patients with localized prostate cancer, such as prostatectomy, hormone and radiation therapy, and other services. This model shifts incentives away from high volume.

Weaknesses:

- Standard care is already shifting toward AS for localized prostate cancer, reducing the net value of the financial incentives in this model.

Summary of rating:

The PRT unanimously agreed that the proposed model meets this criterion because it does incentivize providers to shift treatments away from intensive interventions toward AS.

**Criterion 5. Flexibility. Provide the flexibility needed for practitioners to deliver high-quality health care.**

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**PRT Qualitative Rating: Meets Criterion**

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Strengths:

- Through the care management fee, the model provides financial support to deliver enhanced services for active surveillance. It also provides flexibility for APM Entities to design their AS activities, tailoring them to fit patient populations, practice structure and culture, and local resources.

Weaknesses: None noted.

Summary of Rating:

The PRT unanimously agreed the LUGPA proposal offers financial support and flexibility for providers to undertake a range of activities to deliver high-quality health care.

**Criterion 6. Ability to be Evaluated. Have evaluable goals for quality of care, cost, and any other goals of the PFPM.**

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**PRT Qualitative Rating: Meets Criterion**

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Strengths:

- The details of the model and required calculations are clearly described in the proposal.
- The quality measures and performance targets are clearly specified to facilitate evaluation and most are based on validated, accepted measures of quality.

Weaknesses:

- With the shift toward increased use of AS for localized prostate cancer, finding control groups using appropriate standards of care would require some work but is feasible. This is not required for the model implementation as written, but it would be required for a proper evaluation to be done.
- The time on active surveillance metric is a new measure developed for this PFPM and does not have the same validation as other proposed quality measures.

Summary of Rating:

The PRT unanimously agreed the proposal meets this criterion. Though finding an appropriate control group may prove challenging in a rigorous evaluation, the goals of the model are clearly specified and measurable.

**Criterion 7. Integration and Care Coordination. Encourage greater integration and care coordination among practitioners and across settings where multiple practitioners or settings are relevant to delivering care to the population treated under the PFPM.**

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**PRT Qualitative Rating: Does Not Meet Criterion**

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Strengths:

- The care management fee will support coordinated urological care for patients with localized prostate cancer during the AS episode. The submitter clarified this fee could be split with multiple providers based on their role in the AS treatment.

Weaknesses:

- The shared savings component of the model focuses on total cost of care, but the model does not address integration with other primary care providers and specialists to manage comprehensive care for the patients. Many patients are likely to have comorbidities (e.g., high blood pressure, diabetes, coronary artery disease, depression, etc.) that impact the total cost of care as well as the patients' state of mind during AS.
- The model does not require care coordination or integration with other specialties or provide a plan for allocating the care management fee or gains or losses from total cost of care.

#### Summary of Rating:

The PRT unanimously agreed the proposal does not meet this criterion. The proposal would not harm care coordination or care integration, but it also does not encourage greater integration across settings. The model uses the total cost of care to calculate shared savings or losses, but the model is agnostic to the potential contribution of other health conditions and providers to a patient's total cost of care. The PRT was disappointed the model did not explicitly address how participating APM Entities would coordinate with other providers to manage total cost of care during the AS episode.

#### **Criterion 8. Patient Choice. Encourage greater attention to the health of the population served while also supporting the unique needs and preferences of individual patients.**

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##### **PRT Qualitative Rating: Meets Criterion**

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#### Strengths:

- The shared decision making measure would encourage providers to educate patients about treatment options for localized prostate cancer and would likely increase patient comfort with AS versus AI. The model would support the needs and preferences of individual patients and facilitate patient choice in their treatment.

Weaknesses: None noted.

#### Summary of Rating:

The PRT unanimously agreed the proposal meets this criterion. Current reimbursements may limit patient choice by encouraging providers to pursue AI, even if the patient may prefer AS or watchful waiting. This model seeks to balance the financial incentives for providers so that patient preferences can play a greater role in treatment decisions.

#### **Criterion 9. Patient Safety. Aim to maintain or improve standards of patient safety.**

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##### **PRT Qualitative Rating: Meets Criterion**

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#### Strengths:

- For patients with localized prostate cancer, AS rather than AI could improve patient safety by avoiding unnecessary surgery, radiation or hormone therapies that could produce unpleasant side effects that compromise patient safety.

Weaknesses:

- The model proposes that CMS could devise a set of corrective actions for outlier practices that have an increase in AS beyond an acceptable limit or inappropriately surveil beneficiaries based on data submitted by providers. This places a large reporting burden on providers and a large enforcement burden on CMS.
- The model also proposes that patients contact CMS for help if they feel they were inappropriately assigned to AS. This puts a large burden on the patient to ensure safety.
- Corrective action/contact CMS for help in the event of fear/belief about inappropriate assignment to AS puts a large burden on the patient and CMS to ensure patient safety.

Summary of Rating:

Overall, the PRT agreed this proposal meets the criterion of patient safety because the model incentivizes a shift away from treatments that have undesired side effects for patients.

**Criterion 10. Health Information Technology. Encourage use of health information technology to inform care.**

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**PRT Qualitative Rating: Does Not Meet Criterion**

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Strengths:

- The tracking of lab results and other AS activities during the episode would implicitly require health information technology (HIT).

Weaknesses:

- The model does not encourage new efforts to improve information flow to inform care and instead relies on the existing state of the world of HIT.
- The model does not explicitly address how providers might use HIT to achieve quality and performance goals.

Summary of Rating:

The PRT unanimously agreed the model does not meet this criterion. It does not actively encourage new uses of HIT to inform care for patients with localized prostate cancer. Providers could rely on existing HIT infrastructure and current HIT usage patterns to track patients during the episode.

## **F. PRT Comments**

This proposal is an example of a very hard case, which Mr. Justice Holmes warned us in the legal context, can lead to very bad case law and confounding precedents. The majority of the PRT thought the proposal technically satisfied many of the high priority payment model criteria. The PRT members all do believe this proposal would align incentives more in the direction of the evolving standard of care, but we also unanimously felt the net effect of this proposal is wholly unsatisfactory in the signal its favorable recommendation would send to other applicants and specialties. The PTAC process is unlikely to serve the Secretary, the Medicare program, or the country well if it comes to be seen as a device to be paid more for providing guideline-recommended care for patients. Therefore we recommend rejection, but if it is to be considered by CMS/CMMI, the PRT would strongly urge the payment model to be changed from historical practice performance based and into a more rigorous reference pricing model using control groups implementing current standard of care (i.e., higher AS usage rates) to develop spending targets or benchmarks against which total cost of care performance will be judged.