LUGPA Advanced Payment Model for Initial Therapy of Newly Diagnosed Patients with Organ-Confined Prostate Cancer

A Proposal to the Physician-Focused Payment Model Technical Advisory Committee
July 5, 2017

Submitted by:

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Physician – Focused Payment Model Technical Advisory Committee
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LUGPA APM for Initial Therapy of Newly Diagnosed Patients with Organ-Confined Prostate Cancer ("LUGPA APM")

Dear Committee Members,

On behalf of LUGPA, we are pleased to submit the LUGPA APM for Initial Therapy of Newly Diagnosed Patients with Organ-Confined Prostate Cancer ("LUGPA APM") for the Committee's review.

The LUGPA APM model creates episode-based payments for newly diagnosed prostate cancer patients with localized disease that aligns incentives for physicians to recommend active surveillance in clinically appropriate patients, allowing these patients to avoid unnecessary interventions.

We believe that the LUGPA APM meets the criteria established for an advanced APM in that it encourages value based care, emphasizes shared decision making, produces real savings for the Medicare program and appropriately balances practice financial incentives and risk. If adopted, we believe that this APM model will optimize outcomes, increase beneficiary satisfaction, reduce utilization of unnecessary services while decreasing healthcare spending relative to the current payment system, thereby optimizing both the value and quality of care for newly diagnosed localized prostate cancer patients.

We believe that this proposal exemplifies the type of innovative thinking that MACRA intended to foster and thank the Committee for its time and consideration.

Respectfully submitted,

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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.

I. Background and Model Overview

In 2015, an estimated 79,000 Medicare FFS beneficiaries were newly diagnosed with prostate cancer, 79% of which (approximately 63,000 cases) were localized to the prostate.[1] 77% of men diagnosed with localized prostate cancer received active intervention (AI); for some men this decision which could diminish their quality of life while adding to healthcare costs.[2] We propose the LUGPA Alternative Payment Model (APM) for Initial Therapy of Newly Diagnosed Patients with Organ-Confined Prostate Cancer (LUGPA APM) as a physician-focused payment model (PFPM) to align quality and financial incentives for physicians and other eligible professionals (EPs) to efficiently manage and coordinate care for men diagnosed with prostate cancer. The LUGPA APM supports the triple aim of improving beneficiary care and experience, improving health, and reducing expenditures.

While the pace of scientific advances, clinical best practices and standards of care have accelerated, the current Medicare FFS payment systems have not evolved synchronously. This has created a misalignment of incentives which results in decision making that promotes AI for men with localized prostate cancer – data suggests that some of these patients are appropriate candidates for active surveillance (AS). Specifically, analysis suggests that an "average" AI episode costs Medicare over 2.5 times that of an AS episode for appropriate patients, which translates to a difference of more than $20,000 per episode[3]. Common active interventions for newly diagnosed patients with organ-confined prostate cancer include radiation therapy, prostatectomy, hormonal therapy, and combinations thereof, and may be associated with the risk of adverse clinical events including diminished sexual function, urinary incontinence, bowel dysfunction, and urinary irritation[4,5,6,7,8]. Moreover, when AS is selected there are no current payment methodologies for services required to effectively surveil men with localized prostate cancer – this lack of resources may contribute to the high drop-out rate for patients who initially choose AS. Evidence suggests that patient education and engagement can help maintain appropriate patients on AS over time and mitigate long-term regret associated with making certain AI choices when AS was an appropriate option[9,10]. We propose a model that introduces a care management fee structure for AS of beneficiaries diagnosed with localized prostate cancer by constructing LUGPA APM episodes attributed to urology practices:

- Initial 12-month episodes of care, beginning with prostate biopsy and a diagnosis of prostate cancer, for both beneficiaries receiving AS and those receiving AI.

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[1] See Appendix 3 for the analysis methodology.

[2] See Appendix 3 for the analysis methodology.

[3] The reduction is calculated from the amounts shown in Table 2 as $32,788 in average active intervention episode spending less $12,658 in average active surveillance episode spending.

[4] Chien et. al., Health-related quality of life outcomes from a contemporary prostate cancer registry in a large diverse population, BJUI, doi: 10.1111/bju.13843

[5] Jang, et. al., Long-term quality of life after treatment for prostate cancer: patient-reported outcomes in the second posttreatment decade, Cancer Medicine, doi: 10.1002/cam4.1103

[6] Banerji et. al., A prospective study of health-related quality-of-life outcomes for patients with low-risk prostate cancer managed by active surveillance or radiation therapy, Urologic Oncology 2016.12.015

[7] Barocas, et. al., Association Between Radiation Therapy Surgery or Observation for Localized Prostate Cancer and Patient Reported Outcomes After 3 Years, JAMA, 2017:317(11):1126-1140

[8] Chen, et. al., Association Between Choice of Radical Prostatectomy, External Beam Radiotherapy, Brachytherapy, or Active Surveillance and Patient Reported Quality of Life Among Men With Localized Prostate Cancer, JAMA, 2017:317(11):1141-1150

[9] Lang, et. al., The influence of Psychosocial Constructs on the Adherence to Active Surveillance for Localized Prostate Cancer in a Prospective, Population-based Cohort, Urology, 103: 172-178

[10] Hoffman, et. al., Treatment Decision Regret Among Long-Term Survivors of Localized Prostate Cancer: Results From the Prostate Cancer Outcomes Study, JCO May 11, 2017

- Subsequent 12-month episodes of care for beneficiaries who remain on AS at the end of an initial 12-month AS episode.

We believe that aligning incentives to support AS will promote the goals of the triple aim, especially if the national volume of prostate biopsies increases in response to evolving screening recommendations by various task force and association guidelines[11,12].

The LUGPA APM would incorporate quality measures across several domains, including efficiency and cost reduction, communication and coordination of care, outcomes, and patient-reported outcomes. This includes two new proposed quality measures. The first measures time on AS. The second is a patient survey about shared decision making (SDM) modified from National Quality Forum (NQF) 2962. Performance on all quality measures would be linked to a practice's performance-based payment.

The LUGPA APM would include a two-part payment model: [13]

- A $75 monthly care management fee for initial and subsequent AS episodes (up to $900 per episode).
- A performance-based payment for enhancing performance year utilization of AS relative to a historical period.

The care management fee would pay for enhanced services required to appropriately surveil beneficiaries. The performance-based payment would retrospectively reconcile initial episode spending (total cost of care) against a risk-adjusted target amount that is calculated from historical practice-specific and regional episodes, including utilization of AS, and using the composition of performance year episodes.

Through the proposed quality measures and payment model, we believe that the LUGPA APM will transform urology practice throughout the United States by improving quality of care while also reducing expenditures. Estimates from Medicare claims data suggest that the LUGPA APM could reduce expenditures by $138 million in five performance years, with Medicare saving approximately $51 million, which is approximately a 37% reduction in expenditures, (see Appendix 3 for analysis of a single performance year).

II. Scope of Proposed PFPM (High Priority Criterion)

1. Related to physician or other eligible professionals' practices:

a. What types of eligible professionals and practices would participate in this payment model?

Eligible professionals (EPs), including urologists, at large and small urology and multispecialty practices would be the target APM entities. The LUGPA APM provides a direct path to PFPM participation for EPs treating patients newly diagnosed with organ-confined prostate cancer. To date few urology practices have participated in other APMs; the Centers for Medicare and Medicaid Services (CMS) estimates that only 88 urologists would be qualified participants in advanced APMs in 2017.[14]

b. How many practices or numbers of physicians or other eligible professionals have expressed interest and willingness to participate in the model if it is approved?

43 LUGPA practices (more than 1,400 eligible professionals) are actively engaged in developing urology APMs, including the LUGPA APM (LUGPA member letters of support are shown in Appendix 2). We anticipate substantial interest from other urologists, as the LUGPA APM would appeal to all urology practices treating prostate cancer (small or large, independent or hospital-owned, and with or without integration of ancillary services).

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[11] Clinically Localized Prostate Cancer: AUA/ASTRO/SUO Guideline. 2017. http://www.auanet.org/Documents/education/clinical-guidance/Clinically-Localized-Prostate-Cancer.pdf

[12] National Comprehensive Cancer Network Prostate Cancer Guidelines version 2.2016.

[13] Similar to the CMS Oncology Care Model.

[14] Quality Payment Program Final Rule Table 58 (81 FR 214 77520).

c. How many physicians or other eligible professionals and patients could participate if the model was expanded to scale?

In 2014, more than 6,000 physicians, predominantly urologists, billed Medicare FFS for prostate biopsy, almost all of whom could participate in the LUGPA APM.[15] Also, because 63% of urologists have a primary medical team that includes at least one PA/NP, several thousand non-physician EPs could participate if the model expanded to scale.[16] EPs in other specialties at practices with integrated services would also be able to participate, and practices with non-integrated services may develop care teams that include EPs from other specialties.

d. How would the payment model work for employed or independent EPs, and what changes in compensation might be necessary for EPs, if applicable?

The practice would be identified by Tax Identification Numbers (TINs), and the entity associated with the TIN would bear financial risk. Similar to OCM, it may be necessary to pool TINs together when a practice uses multiple TINs or when EPs work with multiple practices. All episodes would be attributed to the TIN that bills the professional claim for the prostate biopsy. The participating entity or pool of TINs would maintain agreements with EPs to adjust financial incentives, subject to certain parameters. This could involve compensation for increased utilization of AS or individual EP performance on quality measures. These arrangements would support the development of care teams described above. We believe it would be necessary for the Office of the Inspector General (OIG) to create a Stark law waiver to facilitate such arrangements.

e. Has the model been implemented by other payers, and if so, what was the experience?

To our knowledge, the model has not been implemented by other payers. However, recent guidelines from the American Urological Association (AUA), American Society for Radiation Oncology (ASTRO), and the Society of Urologic Oncology (SUO) 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."[17] Likewise, 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 score of 7.[18] Recent research suggests that approximately 43% of new prostate cancer cases have a Gleason score below 7, that 36% of new cases had a Gleason score of 7, and that 79% of all new cases were stage I/II.[19] Research suggests that the percentage of newly diagnosed patients receiving AI has recently been increasing.[20] Analysis of initial prostate cancer diagnoses in Medicare FFS shows that 23% of new cases utilize AS (see Table 2 below), with substantial variation across U.S. Census

[15] CMS Physician and Other Supplier Data CY 2014 available at: http://www.cms.gov/apps/ama/license.asp?file=http://download.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/Downloads/Medicare_National_HCPCS_Aggregate_CY2014.zip

[16] https://www.auanet.org/common/pdf/research/census/AUA-Census-2015-State-of-the-Urology-Workforce-and-Practice-in-the-United-States.pdf

[17] Clinically Localized Prostate Cancer: AUA/ASTRO/SUO Guideline. 2017. http://www.auanet.org/Documents/education/clinical-guidance/Clinically-Localized-Prostate-Cancer.pdf

[18] National Comprehensive Cancer Network Prostate Cancer Guidelines version 2.2016.

[19] KA Herget, DP Patel, HA Hanson, et al. Recent Decline in Prostate Cancer Incidence in the United States, by age, stage, and Gleason score. Cancer Med.; 5(1) 136-141.

[20] T Borza SR Kaufman, VB Shahinian, P Yan, et al. Sharp Decline in Prostate Cancer Treatment among Men in the General Population, but not among Diagnosed Men. Health Affairs 2017; 36(1) 108-115.

Divisions.[21] Thus we believe that there is substantial room to increase AS among men with localized prostate cancer, possibly to 33% – 35%.

2. Related to patient population(s):

a. What is the size of the population anticipated to benefit from the model in its initial stages and if the model were expanded to scale?

Analysis shows that there were approximately 63,000 Medicare FFS beneficiaries newly diagnosed with localized prostate cancer in 2015.[22] This is the basis for annual initial episode volume. Men who complete 12 months on AS would be eligible to begin a subsequent surveillance episode. Beneficiaries would complete another SDM survey at the beginning of a subsequent episode (Appendix 1 includes the proposed survey).

Based on LUGPA member engagement and anticipated broad interest from other urologists, we believe that from the outset of the PFPM, participating practices could furnish services to approximately 19,000 (~30%) Medicare FFS beneficiaries diagnosed with localized prostate cancer each year. Future decreases in prostate cancer incidence would lower this figure.

Though national episode volume was estimated using the 2015 5% Medicare Limited Data Set (LDS) claims files and SEER data, different criteria were used to identify episodes following *initial* prostate cancer diagnosis when analyzing the distribution of initial episodes across treatment modality, including AS, and episode expenditures.

Specifically the analysis is based on the 2011 – 2015 5% Medicare LDS claims files, limited to beneficiaries who had Medicare Part A and B, who were not enrolled in Medicare Advantage, and who were non-ESRD. Beneficiaries who had a prostate biopsy in 2013 – 2014 with continuous enrollment 24 months before and 12 months after the biopsy date were identified. Beneficiaries with either a prior biopsy or AI (either with a prostate cancer diagnosis code) in the 24 months before the 2013 or 2014 biopsy were excluded. Beneficiaries with metastatic cancer in the 12 months after the 2013 or 2014 biopsy were also excluded. Lastly, for inclusion it was required that beneficiaries either began AI within 12 months of biopsy or had a prostate cancer diagnosis on qualifying claims.

Appendix 3 contains a full description of the methodology. One limitation is that this analysis does not include Medicare Part D, but we do not believe this greatly affects the results because the only Part D drugs specific to the prostate are used to treat metastatic prostate cancer that has spread beyond nearby lymph nodes. Stringent criteria were imposed to identify only initial prostate cancer diagnoses, which limited the sample of patients. Less stringent criteria would be more feasible if the LUGPA APM were recommended for implementation. For example, CMS could create a non-payable G code that APM entities could bill to attest to a new diagnosis of prostate cancer for men with fewer than 24 months of continuous Medicare FFS enrollment.

In the analysis, 23% of men nationally were on AS for at least 12 months after their initial diagnosis, with substantial variation across U.S. census divisions.[23] Increasing that figure to 33% in the LUGPA APM would move approximately 1,900 men from AI to AS annually in the PFPM. The corresponding figure at scale (including all providers nationally) is approximately 6,260.

b. How are patients expected to benefit and how would they be protected against unintended consequences?

[21] Analysis of the 2013 – 2015 5% Medicare Limited Data Set claims shows that historical utilization of active surveillance ranges from 20% in the Middle Atlantic, East South Central, and West South Central U.S. Census Divisions to 29% in New England.

[22] See Appendix 3 for the analysis methodology.

[23] https://www2.census.gov/geo/pdfs/maps-data/maps/reference/us_regdiv.pdf. See footnote 11 for the range of historical utilization of active surveillance across U.S. Census Divisions.

Patients would benefit from delaying, when appropriate, the untoward side effects that can be associated with AI, and receiving enhanced services while on AS. We believe that this would improve beneficiary quality of life as well as decrease out-of-pocket expenditures, without increasing the risk of negative clinical outcomes. Below in section III we propose strategies to monitor for unintended consequences of the PFPM and mechanisms to ensure APM entity accountability should unintended consequences arise.

APM entities would be required to submit certain information to CMS via registry or another mechanism for each beneficiary starting an initial episode. This information includes histopathological grade and stage, prostate-specific antigen (PSA) results, molecular/genetic biomarkers if applicable, and an attestation that the beneficiary's age and health status made the beneficiary a candidate for either AS or AI. This attestation would occur through a non-payable G code that CMS would create for the LUGPA APM. This would ensure that beneficiaries are candidates for inclusion in the LUGPA APM.

3. What are the overall anticipated impacts on Medicare spending?

Estimates show that Medicare expenditures could decrease by almost $28 million per year with 19,000 annual episodes – with Medicare receiving more than $10 million from the 2% discount and APM entities receiving more than $17 million in net performance-based payments. Additional information is in Appendix 3. If the model scaled nationally to 100% participation, those figures would increase to almost $91 million in aggregate expenditure reductions split between Medicare (more than $33 million) and APM entities (more than $57 million).

4. What are the expected spillover effects on Medicaid, CHIP, TRICARE/VA, or private health spending, or on those beneficiaries/enrollees, if any?

We do not anticipate direct spillover effects onto other payers, but we are actively engaged with other payers with the goal of implementing the LUGPA APM in non-Medicare populations.

III. Quality and Cost (High Priority Criterion)

1. How is care delivery expected to improve in order to achieve savings or improve quality, including:

a. Where and by how much will health care services or costs be reduced

In contrast to the existing FFS mechanisms that reimburse providers more for actively treating prostate cancer, the proposed PFPM will align financial incentives and compensate participating EPs when they place beneficiaries on AS. This will incent appropriate utilization of AS and reduce utilization of active interventions like prostatectomy or radiation. Analysis suggests that each additional initial episode that receives AS rather than AI will reduce Medicare spending on average by 59%, or more than $19,000, after accounting for the proposed care management fee.[24] This difference drives the estimated expenditure reductions above in section II.3.

b. If quality will be improved beyond a baseline, how and by how much will quality be improved? If quality will not be improved, how will quality be maintained?

We anticipate that the PFPM will improve quality beyond the historical experience. In addition to increasing AS when clinically appropriate, the proposed quality measures will likely increase follow up rates after biopsy and decrease utilization of unnecessary bone scans. We also anticipate that the proposed time on AS quality measure will increase AS duration, when clinically appropriate, for beneficiaries that opt for AS. Likewise, we believe that the SDM quality measure will improve beneficiary experience as beneficiaries become more engaged in choosing the course of treatment that is most likely to suit them.

[24] The reduction is calculated from the amounts shown in Table 2 as $32,788 in average active intervention episode spending less $12,658 in average active surveillance episode spending and $900 in care management fees.

2. What are the nature and magnitude of barriers and risks to the model's success and how will they be overcome?

We believe the major barriers are changing practice patterns and assuring physicians that the LUGPA APM is financially viable. This is true especially in practices with integrated ancillary services. Additionally, AS is not clinically appropriate for all men diagnosed with prostate cancer. Below in section III.7, we propose strategies to monitor that physicians utilize AS when clinically appropriate and that physicians do not delay appropriate interventions until the end of an initial 12-month AS episode.

To the extent that AS is not always clinically appropriate, the potential increase in AS will be limited. Practices that already utilize AS for most or all of their low-risk patients may find that they cannot increase the proportion of their beneficiaries on AS.

Lastly, enhanced services beyond reimbursement for biopsy and office visits are required to manage AS after completion of the initial 12-month episode. For this reason, we propose that the care management fee also apply to beneficiaries who begin subsequent AS episodes and that these beneficiaries be included in the PFPM.

3. What metrics will be used to assess performance under the model including the impact of the model on total cost of care?

Table 1. ***Proposed LUGPA APM Quality Measures and Performance Targets***

Category	Measure Name	Notes	Performance Target
Efficiency and Cost Reduction	Avoidance of overuse of bone scan for staging low risk prostate cancer	PQRS 102; NQF 0389; Registry/EHR	85% target (at least 85% don't receive bone scan)
Communication and Care Coordination	Biopsy follow-up	PQRS 265; Registry	80% target
Outcomes	Time on active surveillance	Develop for PFPM; Calculated from administrative claims	Improvement relative to historical baseline
Patient-Reported Outcome	Prostate cancer shared decision making process	Modified from NQF 2962 to apply to all beneficiaries in initial episodes; Beneficiary survey	Pay for reporting in year 1; then improvement relative to previously submitted data
Cost of Care	All Medicare Part A and B payments in initial episodes	NA	Performance-based payment calculation

Notes: PQRS is Physician Quality Reporting System. Performance targets for PQRS 102 and 265 are based on improvement relative to the 2015 means at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/Downloads/PY2016-Prior-Year-Benchmarks.pdf

4. What approach will be used to develop any innovative metrics proposed for inclusion in the model?

a. Time on Active Surveillance

We propose to calculate the measure of AS survival using administrative claims data, so that CMS can easily calculate the measure for all beneficiaries nationally that meet criteria for inclusion in the LUGPA APM.

Patients will be all beneficiaries who start an initial episode on AS. We propose creating three non-payable G-Codes to document why a beneficiary left AS, including beneficiary choice, lack of compliance, and disease progression. AS would be the lack of any AI, which allows for calculation from claims data, both in LUGPA APM performance years and historically. Time will be measured in months from the start of a beneficiary's initial episode under the LUGPA APM until death or AI. The numerator would be the sum of months on AS across all beneficiaries who start an initial AS episode. The denominator would be the number of beneficiaries in initial or subsequent episodes. The measure could be risk adjusted by weighting the distribution of beneficiaries across the low, medium, and high risk AS categories. The measure will be a useful marker of how successful a practice is at encouraging and maintaining AS when clinically appropriate. The measure can be calculated for all AS beneficiaries, even outside of the LUGPA APM and that it could be used in MIPS track of QPP.

b. Shared Decision Making

We also propose a patient-reported outcome measure based on the decision aide that underlies NQF 2962.[25] For that measure, beneficiaries in initial or subsequent episodes would answer four questions about interactions with EPs when deciding to go on AS or to have an AI:

- EPs describing the options for intervention or AS.
- EPs discussing the reasons for active interventions.
- EPs discussing the reasons for AS.
- EPs asked for patient input in the decision.

Beneficiary responses to each question would receive a score of 0 or 1. The numerator would be the sum of the value of all beneficiary responses and the denominator would be the number of beneficiaries who answered the questions. We include a proposed survey instrument in Appendix 1. If surveying beneficiaries is not feasible, it would be possible for EPs to document in the EHR the beneficiaries with which the EPs discussed the above four elements of SDM when deciding on AS or AI. Under this alternative, the numerator would be the number of beneficiaries with which the EPs discussed the above four elements and the denominator would be the number of episodes. While this would not capture patient-reported outcomes, it would be easier to collect. We believe that either of these measures would ensure that practices seek patient input when deciding on an intervention or surveillance and that treatment was both clinically appropriate and aligned with beneficiaries' treatment goals.

5. What approach will be used to incorporate data from multiple sources to support total cost of care, resource utilization, or clinical quality metrics?

Our proposed measures include information from practice EHRs or data registries (PQRS 102, 265), Medicare claims (time on AS), and beneficiary surveys (proposed SDM measure). Information on time on AS and SDM surveys could be collected for participating and non-participating practices. Total cost of care would be measured from standardized Medicare allowed amounts. Practice performance on all quality measures would also be tied to the performance-based payment calculation, as described below in section IV.1.a.

6. What approach to electronic reporting of and timely feedback on performance measures will be used? How will the approach take into account capturing and sharing data from the EHRs of all clinicians who provide relevant care for the attributed patient population, aggregation and calculation of measures, and provision of timely feedback to support performance improvement?

[25] http://www.qualityforum.org/QPS/2962.

Participating practices' EHRs would need to be able to generate output relating to PQRS measures 102 and 265 for transmission to CMS to calculate quality performance, likely on a quarterly or semiannual frequency. We do not believe that the LUGPA APM would require interoperability between APM entities' EHRs and other EHRs because the proposed measures would be captured by the APM entities' EHR, beneficiary survey, or claims data.

7. What level of monitoring or auditing will be required?

We propose that the LUGPA APM incorporate monitoring and auditing in a few ways. First, to limit incentives to select healthier patients, we propose that the risk adjustment for initial episodes incorporate the CMS-Hierarchical Condition Category (HCC) scores of beneficiaries in initial AS episodes as well as the type of AI for beneficiaries receiving AI.[26] Thus, target prices will be reflective of the underlying population attributed to each LUGPA APM entity.

Second, we propose that practices be required to submit information for each initial episode, including histopathological grade and stage, PSA results, molecular/genetic biomarkers if applicable, and an attestation regarding beneficiary health status. This information will demonstrate the appropriateness of AS or intervention.

We also propose additional monitoring regarding the timing of AI. We propose comparing the proportion of performance year beneficiaries receiving AI shortly after an initial episode against the analogous proportion from the historical period and at other LUGPA APM entities. CMS could devise a set of corrective actions for outlier practices that have an increase beyond an acceptable limit or that actively surveil inappropriate beneficiaries, including corrective action plans or financial penalties.

8. Are there any prior or planned statistical analyses to estimate the impact of the model on spending and quality of care?

Appendix 3 describes claims analysis and financial modeling about the impact of the model on spending. The analysis does not estimate the impact on quality of care, but for reasons described above in this section, we believe that the LUGPA APM will improve quality of care.

IV. Payment Methodology (High Priority Criterion)

1. Payment methodology:

a. How would entities be paid under the proposed model, including the amount of new payments, and what is the methodology for calculating such payments?

1. Overview

The PFPM includes initial and subsequent 12-month episodes for Medicare FFS beneficiaries that are diagnosed with prostate cancer. There is a two-part payment model[27] that incorporates:

- A monthly care management fee of $75 per beneficiary for initial and subsequent 12-month AS episodes (up to $900 per episode).
- A performance-based payment for enhancing performance year utilization of AS relative to a historical period.

2. Care Management Fee

The care management fee would pay for the management and care coordination necessary to surveil beneficiaries. While Medicare currently pays FFS for some services, like office visits or performing a biopsy, it does not pay for the enhanced services EPs would furnish in the PFPM, including tracking AS beneficiaries to ensure compliance, tracking lab results longitudinally in a consistent format to reduce overutilization of PSA testing, educating beneficiaries about disease progression, social services, and reviewing/revising the care plan. The payment would apply to initial and subsequent AS episodes. $900 is roughly 7% of average initial AS episode spending of $12,658. While the care management payment would be billable for beneficiaries in an initial

[26] https://www.cms.gov/medicare/health-plans/medicareadvtgspecratestats/risk-adjustors.html.
[27] Similar to OCM.

or subsequent episode, subsequent episode expenditures would not be included in the performance-based payment calculations. However, these beneficiaries would still be part of the LUGPA APM. Participating practices would report all quality measures for subsequent episodes, which would be included when evaluating practices' quality performance and its tie to payment and repayment.

We propose that CMS would create a new G-code for LUGPA APM EPs to bill the monthly care management fee. Participating practices would provide CMS with a list of NPIs that could bill the care management fee, to be updated on a periodic basis.

3. Performance-Based Payment

The performance-based payment would retrospectively compare actual initial episode spending against a target amount.[28] Beneficiaries who are diagnosed with localized prostate cancer after biopsy would begin 12-month initial total cost of care episodes, including all part A and B services starting with the prostate biopsy. The episode would be classified into one of proposed 12 subcategories shown in Table 2. Additional discussion of how beneficiaries will be assigned to a subcategory is in subsection e below. Though each category will have a component benchmark price for the performance year, each APM entity would ultimately receive a single composite benchmark price calculated based on:

1. Practice-specific and regional historical utilization of AS; and
2. Practice-specific performance year composition of episodes in subcategories within AS and AI episode categories

This would align financial incentives to utilize clinically appropriate AS, even for higher-risk beneficiaries, as measured by HCC score, and would ensure that practices not be penalized for utilizing appropriate active interventions.

Table 2. ***Estimated Episode Volume and Average Allowed Cost, by Episode Subcategory***

Proposed Episode Categories and Subcategories	Distribution of Episodes	Annual Episodes	Average Episode Cost
Active Surveillance	**22.8%**	**14,283**	**$12,658**
Active Surveillance – L	7.3%	4,573	$7,340
Active Surveillance – M	7.9%	4,949	$11,721
Active Surveillance – H	7.6%	4,761	$18,740
Active Intervention	**77.2%**	**48,356**	**$32,788**
Prostatectomy only	13.5%	8,456	$21,680
Radiation therapy only	21.9%	13,718	$35,669
Hormone and radiation therapy	23.6%	14,783	$42,808
Hormone therapy only	8.4%	5,262	$18,675
Prostatectomy and radiation therapy	1.0%	626	$43,370
Cryoablation only	2.1%	1,315	$21,949
Prostatectomy, hormone, radiation therapy	1.0%	626	$47,089
Prostatectomy and hormone therapy	1.0%	626	$23,538
Other	4.7%	2,944	$27,701
Total	**100.0%**	**62,640**	**$28,199**

Notes: See Appendix 3 for the analysis methodology.

[28] We propose to utilize the CMS payment standardization methodology when calculating performance year and historical episode expenditures. http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1228772057350

We propose that the subcategory benchmark prices be calculated based on three years of historical episodes trended forward to the applicable performance year to account for changes in CMS fee schedules. Additionally, we propose that the three year historical period be updated for performance years 4 – 5 to account for more recent prevalence of AS.

(1) Historical Episode Periods

We propose that performance year 1 – 3 benchmark prices would be calculated from initial 12-month episodes that began in 2013 – 2015 (ending in 2014 – 2016) and that performance year 4 – 5 benchmark prices would be calculated from episodes beginning in 2016 – 2018. We propose to include performance-based payments/repayments for initial episodes in 2018 when updating prices for performance years 4 – 5.

Historical episodes would be identified and attributed to practices using performance year algorithms and would be categorized into one of the above subcategories. Additional details on the categorization/risk adjustment are below in subsection e. Historical episode allowed amounts would be trended to the performance year using the methodology described in this subsection before blending with regional historical episode expenditures.

(2) Regional Historical Episodes

To account for the regional variation in the utilization of AS and because many practices may not have sufficient historical volume, we propose to blend practice-specific and regional historical experience. We propose to define region in LUGPA APM as the U.S. Census Division of the practice, similar to the Comprehensive Care for Joint Replacement model (CJR) and the Episode Payment models (EPMs); moreover, we propose that the regional experience be stratified into three categories – academic hospital-based, other hospital-based, and physician office, so that regional component more closely aligns to the setting in which APM entities deliver care. Regional historical episode allowed amounts would also be trended forward to the performance year using the methodology described prior to blending with a practice's experience. The regional weight would increase from 25% in the first two performance years to 50% in the third, and to 75% in the fourth and fifth. Practices with fewer than 36 historical initial episodes would receive a 100% regional weight in all performance years, similar to CJR/EPMs. When updating the regional historical period to 2016-2018, we propose to exclude LUGPA APM entities when calculating the regional averages.

Table 3. ***Proposed Historical Periods and Regional Weights for each Performance Year***

Performance Year	Calendar Year	Historical Period (Episodes Initiate)	Practice/Regional Blend
1 - 2	2018, 2019	2013 - 2015	75% practice; 25% regional
3	2020	2013 - 2015	50% practice; 50% regional
4 - 5	2021, 2022	2016 - 2018	25% practice; 75% regional

We believe that coupling an updated the historical period with a gradually increasing regional weight will allow practices to succeed in the PFPM and CMS to set accurate prices that account for regional utilization of AS in later years of the LUGPA APM.

(3) Trending Methodology

We propose that the trending methodology account for changes in Medicare payment systems that occur from the end of the applicable historical period through each performance year, similar to the methodology in CJR/EPMs.[29] In general, this would be accomplished by calculating unit cost trend factors from each year of the historical baseline period to the performance year for the following categories of expenditures:

[29] A general discussion of this approach is available at 82 CFR 314 https://www.gpo.gov/fdsys/pkg/FR-2017-01-03/pdf/2016-30746.pdf.

- Radiation therapy
- Drugs and administration
- Radiology
- Cryoablation
- Prostatectomy professional
- Inpatient Prospective Payment System (including IRF)
- Outpatient Prospective Payment System (other than above)
- Physician fee schedule (other than above)
- Home Health
- Skilled Nursing Facility PPS
- Other services

However, unlike in CJR/EPMs, we propose that each separately billable service (e.g. claim, claim line, or revenue center) would be assigned one of the above service categories and trended using the trend factor for the applicable category and the year in which the service occurred. To the extent necessary, the unit cost trends could be updated within a performance year as more information becomes available or CMS revises payment rates.

Alternatively, CMS could run every claim through the most recent version of its Payment Standardization Methodology so that it always calculates historical episode expenditures in performance year dollars.

Either approach would provide a degree of certainty in episode subcategory target prices to both CMS and participating practices, which is a key advantage relative to trend factors that are calculated retrospectively, such as in OCM. Also, either approach obviates the need to calculate practice-specific or regional update factor weights, as in CJR/EPMs.

(4) Blending Practice-Specific and Regional Historical Episode Expenditures

Because certain episode subcategories have low volume, we propose to pool episode spending across episode subcategories when blending practice and regional historical episode expenditures, similar to CJR/EPMs.

i. National Severity Factors

The first step is to calculate national severity factors for each episode subcategory. We propose setting the severity factor for the Hormone and Radiation Therapy episode subcategory (the most common historical subcategory) equal to one. Severity factors for each other subcategory would be calculated from national trended historical episode expenditures as:

$$\frac{Natl.avg.episode\ expenditures\ in\ Subcategory\ X\ episodes}{Natl.avg.episode\ expenditures\ in\ Hormone\ and\ Radiation\ Therapy\ episodes}$$

This would occur for each subcategory, and the severity factor would represent how much more or less expensive each episode subcategory is relative to the Hormone and Radiation therapy episode subcategory.

ii. Practice and Regional Case-Mix Weights

After calculating each severity factor, practice-specific case-mix weights would be calculated based on each practice's (APM entity's) historical episodes as:

$$\frac{Total\ hist.episode\ count}{\sum_{i\ in\ All\ subcats}\left((subcat_i\ hist\ episode\ count) * (subcat_i\ severity\ factor)\right)}$$

Episodes in subcategories that are more expensive than Hormone and Radiation Therapy would count as more than one episode, and vice versa. The practice case-mix weight would then be multiplied by the practice's average trended historical episode expenditures to account for the practice's distribution of episodes across episode subcategories. These steps would be performed for each practice and each regional strata (academic hospital-based, hospital-based, physician office).

iii. Blending Practice and Regional Historical Episode Expenditures to Calculate Subcategory Benchmark Prices

After calculating case-mix weighted practice and regional historical episode expenditures, we propose to calculate a blended average of the two amounts using the applicable practice-specific and regional blending weights described above. The result would be the practice's benchmark price for Hormone and Radiation Therapy episodes because we proposed to set the severity factor to 1 for that episode subcategory. Benchmark prices for other episode subcategories would be calculated as the product of the Hormone and Radiation Therapy benchmark price and the national severity factor for each episode subcategory. We believe that this would maintain price differentials across episode subcategories, so that practices would not be penalized for utilizing active interventions appropriately. CMS would be able to calculate subcategory benchmark prices prospectively, subject to payment system updates that occur during a performance year.

While performance year episodes would be assigned a single subcategory with a known subcategory benchmark price, the subcategory benchmark prices would be combined into a composite benchmark price applicable to all of the practice's performance year episodes.

(5) Calculating the Composite Benchmark and Target Prices

After setting the subcategory benchmark prices, we propose to combine the subcategory prices into a composite benchmark price, as described below.

i. Performance Year Active Surveillance and Active Intervention Benchmark Prices

In the first step, we propose to create AS and AI benchmark prices based on a combination of the subcategory benchmark prices and the performance year distribution of a practice's episode subcategories within the AS and AI categories. The AS benchmark price would be calculated as:

$$bench_{AS} = \frac{\sum_{i\ in\ AS\ subcats.}\left((subcat_i\ PY\ episode\ count) * (subcat_i\ benchmark\ price)\right)}{Total\ AS\ PY\ episode\ count}$$

The AI benchmark price would be calculated analogously.

ii. Historical Proportion of Active Surveillance Episodes

After calculating AS and AI benchmark prices, we propose to calculate the composite benchmark price using weights calculated from the historical proportion of AS episodes at the practice and in the region. The practice's historical proportion of AS episodes would be calculated as

$$AS_{wgt_{pr}} = \frac{Active\ Surv.hist.episode\ count}{hist.episode\ count}$$

The practice's historical proportion of AI episodes would be calculated as

$$AI_{wgt_{pr}} = 1 - AS_{wgt_{pr}}$$

The regional historical proportions would be calculated analogously. The composite benchmark price is then calculated as a weighted average of the AS and AI benchmark prices:

$$bench_{composite} = \left(X * AS_{wgt_{pr}} + (1-X) * AS_{wgt_{reg}}\right) * bench_{AS} + \left(X * AI_{wgt_{pr}} + (1-X) * AI_{wgt_{reg}}\right) * bench_{AI}$$

In the calculation, X is the practice-specific weight for the applicable performance year, as shown above in Table 3 (e.g. X is 75% in performance years 1 – 2). The composite benchmark price would apply to all of the practice's performance year episodes for the performance-based payment calculations. The composite benchmark price incorporates the distribution of a practice's performance year episodes across subcategories and the historical proportion of AS episodes. These two aspects of the price adjust the composite benchmark price to a practice's performance year episodes and align financial incentives to utilize AS in the performance year, when clinically appropriate, without penalizing appropriate active interventions. While practices would prospectively know the subcategory benchmark price for an episode, they will not know

the composite benchmark price until reconciliation. However, we believe that practices would be able to estimate the composite benchmark price throughout the performance year based on the treatment decisions for their episodes. For example, a beneficiary who received only a prostatectomy would be classified into the Prostatectomy only subcategory.

CMS would calculate the composite target price as 98% of the composite benchmark price.

(6) Calculating the Performance-Based Payment

APM entities and other providers who furnish services to beneficiaries during initial episodes would continue to be paid FFS throughout a performance year. After a performance year, CMS would compare actual initial episode spending, including the care management fees for initial episodes, against the APM entity's target amount (calculated as the product of the number of initial episodes and the composite target price) for the performance year. Additionally, we propose that CMS adjust for geographic variation in Medicare prices because all calculations up to this point would utilize the CMS Payment Standardization Methodology, which does not adjust for geographic variation. The geographic adjustment factor for a practice would be based on the CMS Geographic Practice Cost Index (GPCI) and the CMS Hospital Wage Index specific to the area in which a practice is located. It would depend on the mix of professional services, facility services, and drugs administered by the practice (with drug expenditures not being adjusted because the GPCI and hospital wage index are not applicable to drug expenditures), similar to OCM.

APM entities that reduce actual expenditures below the target amount would be eligible for a performance-based payment of up to 100% of the difference depending on the APM entities' performance on quality metrics, subject to the 20% stop-gain limit.[30] APM entities that do not reduce expenditures would pay back up to 125% the difference, up to the 20% stop-loss limit. CMS would retain a 2% discount of the benchmark amount, any reduction to a performance-based payment due to quality performance, any increase to a repayment due to quality performance, and expenditure reductions beyond the stop-gain limit of 20%.

We propose to link performance-based payments and repayments directly to the proposed quality measures by applying the multipliers in Table 4 to the difference between the target amount and actual spending.

Table 4. ***Proposed Performance-Based Payment and Repayment Multipliers***

Quality Performance Targets Achieved/Exceeded	Performance-Based Payment Multiplier	Repayment Multiplier
0	0%	125%
1	0%	100%
2	50%	100%
3	75%	100%
4	100%	75%

This link incents improved quality performance, even if expenditures exceed the target amount. We believe that this is a sufficient tie to quality to meet criteria for being an advanced APM.

APM entities would be able to enter into gainsharing arrangements with participating and non-participating EPs to align incentives for all providers who furnish services during episodes.

b. Will the proposed model include other payers in addition to Medicare, and if so, is a different payment methodology needed for those payers?

We are actively working with other payers to gauge interest in implementing the LUGPA APM in non-Medicare populations because more than 40% of men who receive prostate cancer diagnoses are less than 65 and thus likely to have commercial insurance. Substantial changes to the payment methodology would not be required to implement with other payers.

[30] The stop-gain and stop-loss limit would be calculated at +/- 20% of the practice's target amount.

c. How will the model enable entities to sustain the expected changes in care delivery over time?

The LUGPA APM will enable APM entities to sustain changes in care delivery by aligning incentives to provide clinically appropriate care to men with prostate cancer. If the model is successful, it would scalable, and it could be possible to create a single prospective Medicare payment for the expected cost of care in the 12 months after initial prostate diagnosis.

d. How are the targets for success defined, and what are the penalties for failure?

APM entities must reduce expenditures below the target amount to be eligible for a performance-based payment. APM entities that do not reduce expenditures will be required to repay Medicare for up to 125% of the amount by which expenditures exceed the target amount. APM entities that do reduce expenditures below the target amount will also need to achieve or exceed quality targets for each of the quality metrics described in section III.3.

e. What methodology will be used for risk adjustment (if relevant)?

We believe that adjusting target prices on the basis of historical prevalence of AS and intervention, on the basis of performance year composition of episodes across the 12 proposed episode subcategories, and stratifying the regional average by academic hospital-based, hospital-based, and physician office setting will adequately account for variation in episode spending.

Actively surveilled beneficiaries will be categorized into one of three risk groups – low, medium, or high based on the beneficiary's HCC risk score for the calendar year in which he is diagnosed with prostate cancer and receive a corresponding subcategory target price. The risk groups will be based on national tertiles of HCC risk scores for beneficiaries receiving AS in the historical period. The distribution of AS across these groups would be used as weights when calculating the performance year AS benchmark price. We propose that HCC scores for performance year episodes and historical period are calculated using the same version of the HCC risk adjustment methodology. This will ensure that differences in risk scores are attributable to differences in underlying health rather than periodic updates to the HCC risk adjustment methodology. All of the historical modeling was based on the 2014 HCC risk adjustment methodology.

Beneficiaries receiving AI will be categorized into one of nine AI episode subcategories based on the specific modality of treatment or combination thereof, which the historical analysis shows to be strongly correlated with episode spending. The distribution of AI episodes across these subcategories would be used as weights when calculating the performance year AI benchmark price.

The AS and AI benchmark prices would then be combined into a single per-episode performance year composite benchmark price with weights calculated from the historical proportion of AS and intervention episodes, incenting increased performance year utilization of AS when clinically appropriate.

2. How does the payment methodology differ from current Medicare payment methodologies/Center for Medicare and Medicaid Innovation (CMMI) models for physicians or other eligible professionals and why cannot it be tested under current payment methodologies/CMMI models?

While aspects of the proposed payment methodology are based other CMS initiatives, we believe that we make several improvements relative to existing methodologies. First, our proposed trending methodology will be more accurate than existing trending methodologies because it separately trends historical expenditures in each service category to the performance year rather applying a composite update factor that applies to each APM entity or region. We believe that our approach is conceptually simpler and easier to explain to APM entities. Second, we account for variation in practice type when blending a practice's experience with the regional experience. Third, we incorporate HCC risk adjustment for beneficiaries on AS and account for the

composition of performance year active interventions. We believe this is appropriate in the context of this model because the episodes capture the total cost of care over a year rather than related services over a shorter time frame. Fourth, we combine subcategory prices into a single composite benchmark price per episode that incents AS without strongly penalizing AI when appropriate.

Though OCM and the SDM Model for ACOs include prostate cancer, we believe the LUGPA APM is substantively different enough to warrant testing in its own right.

OCM is the only current CMS APM specific to cancer, but only beneficiaries receiving chemotherapy trigger an OCM episode. To-date few urology practices have enrolled in OCM, and to our knowledge, CMS is not accepting additional applications for OCM. Moreover, the vast majority of beneficiaries receiving androgen deprivation therapy or chemotherapy have prostate cancer that has spread beyond the prostate (M0/M1 disease) and would not be eligible to initiate episodes in our proposed PFPM. The LUGPA APM incents urology practices to manage beneficiary care efficiently and effectively, and we believe that the LUGPA APM would greatly benefit all beneficiaries diagnosed with organ confined prostate cancer, regardless of the treatment decision. In the rare event that there is overlap between a LUGPA APM episode and an OCM episode, we propose that LUGPA APM episodes would take precedence over OCM episodes because LUGPA APM entities will bear risk for 12-months of spending after diagnosis for prostate cancer, which is greater than the 6-month OCM episodes. Moreover, LUGPA APM episodes would be attributed prospectively to the TIN that performed the initial biopsy, whereas OCM episodes are retrospectively attributed well after the end of a performance year. This follows similar logic to CMS in its decision to exclude from EPMs and CJR episodes those beneficiaries who are prospectively aligned to ACOs that bear substantial downside risk, including MSSP Track 3 and Next Generation ACOs.[31]

CMS also announced a SDM model that will be embedded within 50 Medicare Shared Savings and Next Generation ACOs, with another 50 serving as a comparison group. Under the SDM model, ACOs are paid $50 per SDM service, but the SDM model does not fundamentally alter the financial risk that an ACO bears. Nor is the SDM model an advanced APM. Prostate cancer localized to the prostate gland is one of the conditions included in the SDM.

Though the LUGPA APM incents clinically appropriate AS and includes a SDM quality measure, we believe the LUGPA APM is truly a physician-focused model, unlike CMS's ACO models. The LUGPA APM creates clearer incentives for urology practices than the SDM model and could be scaled for implementation in almost all urology practices in the country, including those that do not have arrangements with ACOs. The proposed PFPM will also allow for a rigorous evaluation of its incentives that can be compared against the experience of ACO-aligned beneficiaries who receive SDM services in the SDM model. If necessary, it could be possible to exclude from the proposed PFPM any beneficiaries prospectively-aligned to one of the ACOs in the SDM model or its comparison group.

3. What degree of financial risk will the entity and its physicians or other eligible professionals bear as a consequence of this proposed model?

We propose to cap individual episode spending at a regional outlier cap, set as two standard deviations above average regional episode spending within each episode category and stratified by practice type. This will protect practices against individual episodes with extreme outliers spending. We propose that this cap would apply both in the performance years and historical episodes used to set target prices.

[31] 42 CFR Parts 510 and 512, based on 82 FR 180 – 651, available at: https://www.gpo.gov/fdsys/pkg/FR-2017-01-03/pdf/2016-30746.pdf.

Additionally, practices would generally bear 75% - 125% marginal risk for 12-month total cost of care for initial episodes relative to the composite target price, depending on quality performance, up to +/- 20% stop-gain/stop-loss limit. The 20% stop-loss limit exceeds the nominal financial risk standard for the advanced APM. We propose to allow practices with less than 36 historical episodes apply to have stop-loss/stop-gain limits set at +/- 5% throughout the model.

4. Where relevant, how will the model address:

a. Establishing the accuracy and consistency of identification/coding of diagnoses/conditions?

We believe that the model will encourage accurate and consistent coding of a diagnosis of prostate cancer. There are set HCPCS codes for performing prostate biopsies that will be used to identify initial prostate cancer episodes, as shown in Appendix 3.

b. Clinical appropriateness of the payment unit?

We believe that the proposed payment methodology directly incents utilization of AS, when clinically appropriate, without penalizing the use of clinically appropriate but more expensive active interventions. Additionally, the proposed quality metrics, especially the SDM and time on AS measures would support clinical appropriateness when choosing between AS and active interventions. All of the quality measures have a direct tie to the performance-based payment component of the model.

Additionally, we propose monitoring strategy in section III.7, under which CMS could develop corrective actions for practices found to be delaying AI.

c. Accurately assigning claims for payment to particular episodes of care?

We do not envision issues assigning claims to episodes of care. After a beneficiary's initial episode is attributed to a practice, any claim that Medicare pays in the subsequent 12 months would be assigned to that episode.

5. Barriers that make a new payment methodology necessary:

a. Are there any barriers in the current payment system that prevent or discourage the change in care delivery?

Currently practices have strong financial incentives to actively intervene after diagnosing prostate cancer, and the enhanced services required to manage beneficiaries on AS are not paid under Medicare FFS. We believe that this model significantly alters the financial incentives so that practices can work with beneficiaries to choose the most clinically appropriate course of treatment after prostate cancer diagnosis, including AS.

b. Are you aware of any barriers that exist in state or federal laws or regulations?

CMS does not currently reimburse the enhanced services required to actively surveil beneficiaries, rather than actively intervening, are not adequately. Additionally, we believe that it will be necessary to waive parts of certain fraud and abuse laws to allow gainsharing with EPs.

c. Will the proposed model have an impact if regulatory barriers (if present) are not addressed?

The LUGPA APM would not sufficiently alter financial incentives for EPs without waiving parts of certain fraud and abuse laws to allow gainsharing.

V. Value over Volume

1. What financial incentives will be provided to encourage physicians and other eligible professionals to deliver high-value health care?

a. How will these incentives influence physician or other eligible professionals' behavior?

Through the care management fee and by setting target prices for initial 12-month episodes, we expect that the proposed PFPM will align financial incentives for participating EPs to engage beneficiaries in SDM and to utilize AS, when clinically appropriate, after initial diagnosis of prostate cancer. We believe that this will decrease utilization of active interventions like

prostatectomy, radiation therapy, and hormone therapy for beneficiaries with prostate cancer, without diminishing beneficiary outcomes or quality of life.

b. Has the submitter had prior experience with the use of these incentives?

LUGPA has not had prior experience with these specific incentives.

2. Will non-financial incentives be used to promote physicians and other eligible professionals' delivery of high-value health care?

a. How will these incentives influence practitioner behavior? Please be clear about how you expect changing incentives to be manifested throughout the delivery system.

Quality metrics around time on AS and SDM would lead the EPs to think more explicitly about beneficiary outcomes and quality of life and to include beneficiaries in the decision-making process. We expect that this too would increase utilization of AS and decrease utilization of active interventions.

b. Has the submitter had prior experience with the use of these incentives?

LUGPA has not had prior experience with these specific incentives.

VI. Flexibility

1. Can the proposed model be adapted to accommodate the breadth and depth of differences in clinical settings and patient subgroups?

The LUGPA APM is designed to be applicable to most, if not all, men diagnosed with localized prostate cancer. The payment methodology accounts for a range of practice settings, adjusts for different beneficiary risks and active interventions, and can calculate composite target prices regardless of practice size. While small or rural practices with low episode volume might expect more variation in episode expenditures, such practices can mitigate their financial risk by applying for an alternative risk track with lower stop-loss/stop-gain limits. Thus we believe that the model would be feasible for urology or multispecialty practices (both independent and hospital-owned) across the spectrum of size, and locations.

2. How can the proposed model be adapted to account for changing technology, including new drug therapies or devices?

We propose that new technologies, therapies, and devices will be incorporated into the performance year episode spending. If necessary, the trending mechanism could be adjusted to ensure it accounts also for new technologies to the extent they are anticipated to be utilized in the performance year. Alternatively, CMS could explore a novel therapies adjustment similar to OCM to ensure the model does not create an explicit disincentive for practices to adopt novel therapies that are particularly effective but also expenses.

3. To what extent will practitioners have to adapt to operational burdens and reporting requirements that result from the proposed payment model?

We believe that the LUGPA APM would not require much additional infrastructure for successful participation. Also, the LUGPA APM reporting burden would not be more onerous than the MIPS reporting burden a practice would face absent participation in the LUGPA APM.

4. How will model participants prepare and build the infrastructure to implement the proposed model?

We believe the LUGPA APM will lead to comprehensive practice transformation as EPs rethink the practice of urology under new incentives to utilize AS and compensation for performing enhanced services while surveilling beneficiaries. EPs will need to be educated about these aspects of LUGPA APM to increase the likelihood of success. Additionally, practices will need to work to field the SDM beneficiary surveys, bill the new G codes appropriately, and submit several pieces of information that are key to determining whether a beneficiary is a good candidate for AS (i.e., histopathological grade and stage, PSA results, attestation to beneficiary health, and molecular or genetic biomarker testing results, when available).

VII. Ability to be Evaluated

1. **Is the impact of the PFPM on metrics that are included as part of the proposed model able to be evaluated? If so please describe how.**

Yes. We propose that CMS attribute all episodes in the country, regardless of if the physician who performs the prostate biopsy participates in the LUGPA APM or not. It would then be possible to utilize matching techniques to identify a comparison group of non-participating practices that closely matched APM entities' observable characteristics. While this would not be as rigorous as a randomized control trial, we believe that this is a robust methodology for evaluating a voluntary PFPM and is similar to CMS's evaluation approach in other voluntary initiatives. We also believe that identifying APM entities as a TIN or pool of TINs, rather than as individual physicians within a practice, will facilitate identification of a comparison group.

2. **What are the evaluable goals at various levels (e.g., for a population, for a provider entity, for individual physicians, etc.)?**

The evaluable goals would be for the population of beneficiaries attributed to participating practices and possibly for different types of participating practices. Evaluable outcomes include the prevalence of AS, utilization of different active interventions, total cost of care, time on AS, mortality, complications, utilization of other services, beneficiary outcomes as measured in claims and surveys, and disease progression.

3. **Are there any evaluations of the proposed model under development, underway or that have been conducted?**

To our knowledge there are no evaluations under development, underway, nor that have been conducted.

4. **Are there other questions beyond the impact on core metrics which the evaluation should focus on, including through the use of qualitative methods?**

The evaluation should focus on how many beneficiaries are in compliance with clinical guidelines for care after diagnosis with prostate cancer. We believe that the proposed quality measures will measure adherence to a category 1 pathway and that it would be possible to link adherence to improved quality and lower expenditures.

VIII. Integration and Care Coordination

1. **What types of physicians, non-physicians, and other eligible professionals would likely be included in the implementation of this model in order to achieve desired outcomes?**

The LUGPA APM primarily involves urologists and other EPs that work directly with urologists; however, because the LUGPA APM entities would be at risk for beneficiaries' total cost of care for a 12-month period, LUGPA APM entities would need to collaborate with EPs across the continuum of care, including primary care physicians/non-physicians, other specialists, therapists, and facility-based providers. APM entities would be able to enter into gainsharing arrangements with non-participating EPs.

2. **How would the model lead to greater integration and care coordination among practitioners and across settings?**

The enhanced services furnished to surveilled beneficiaries would increase integration of care and care coordinators – for example, by tracking PSA results longitudinally in a standardized format, participating EPs would be able to reduce overutilization of PSA screening.

3. **To what extent would the proposed model result in changes in workforce requirements compared to more traditional arrangements?**

As described above in section IV.4, the LUGPA APM would re-frame urology practice for participants. It will require education to secure buy-in from physicians and other EPs. Additionally, different skills, relative to current practice, may be required to comprehensively furnish enhanced services to beneficiaries on AS.

4. How will the model address coordination with care team members that are not financially accountable?

Because participating practices would collaborate with non-participating EPs who are not financially at risk for the total cost of care in initial episodes, we propose that participating EPs would be able to enter into gainsharing arrangements with non-participating EPs that play a large role in coordinating care and generating improved outcomes while reducing expenditures.

IX. Patient Choice

1. How is patient choice preserved under the model by accommodating individual differences in patient characteristics (including social needs, etc.), conditions, and health-related preferences while furthering population health outcomes?

The LUGPA APM preserves beneficiary freedom to receive services from any EP who accepts Medicare FFS. Thus, each beneficiary will be able to receive services tailored to his specific circumstances and preferences from any EP that accepts Medicare payment.

2. How would the payment model affect disparities among Medicare beneficiaries by race, ethnicity, gender, disability, and geography?

The LUGPA APM will address disparities among beneficiaries by compensating EPs for furnishing enhanced services necessary to actively surveil beneficiaries, the need for which is likely more acute among beneficiaries in traditionally underserved populations and who live in rural areas and may have less access to care.[32,33]

3. How would the payment model expand the demographic, clinical, or geographic diversity of participation in alternative payment models beyond existing CMS models (e.g., would the proposed payment model address populations which are not currently addressed in current CMMI models)?

We believe that the population of men with localized prostate cancer is not well represented in most CMS APMs, which have had relatively low participation from urology practices to-date. Thus the LUGPA APM would expand the clinical diversity of participation in CMS APMs.

X. Patient Safety

1. How would the proposed model ensure that patients are not harmed by efforts to achieve savings or to improve specific aspects of quality/outcomes?

This would be achieved through several mechanisms. First we propose to measure performance on quality measures related to time on AS. Second the proposed payment methodology adjusts prices based on performance year episode-subcategories, resulting in a higher price if a practice is attributed more episodes for beneficiaries who are higher-risk or require AI. Third, we propose monitoring strategies that would allow CMS to create corrective actions and possible financial penalties for practices that delay necessary treatment to reduce expenditures. LUGPA APM Beneficiaries and non-participating providers would also be able to contact CMS if they believed that a participating practice was engaging in behavior that was harming beneficiaries.

2. What measures would be used to ensure the provision of necessary care and monitor for any potential stinting of care?

This is described above in this section and section III.7.

3. To what degree will the proposed model ensure the integrity of its intended benefits and what embedded monitoring and potential adjustments are under consideration, should unintended or other incongruent behaviors occur?

This is described above in this section and section III.7.

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[32] R Kraus, L Ji, R Jennelle, et al. Active Surveillance: Do Low-Income Patients Adhere to Protocol. J Clin Oncol. 2017; suppl 62, abstract 53.

[33] A Jemal, E Ward, X Wu, et al. Geographic Patterns of Prostate Cancer Mortality and Variations in Access to Medical Care in the United States. Cancer Epidemiol Biomarkers Prev; 14(3): 590-595.

XI. Health Information Technology

1. How would patients' privacy be protected if new providers or caregivers will have access to personal health information (PHI)?

APM entities that receive beneficiary PHI or need to request any necessary PHI from CMS would attest to following CMS's guidelines for usage, storage, and destruction of beneficiary PHI in order to be able to receive beneficiary PHI from CMS.

2. How would the model facilitate or encourage transparency related to cost and quality of care to patients and other stakeholders?

We propose that each LUGPA APM practice would receive, on a monthly basis, claims-level data and more aggregated summary data related to LUGPA APM episodes attributed to the practice and historical episodes that would have met criteria for inclusion in LUGPA APM, similar to other CMS APMs. Additionally, we propose to disseminate aggregated regional and national data on historical and performance year episodes, both at participating practices and non-participating practices so that practices are able to place their own episode utilization and spending in a broader regional and national context as points of comparison.

3. Will interoperability of electronic health records be needed to guide better decision-making?

While interoperability of EHRs is a laudable goal and would aid in decision making, we do not believe that it will be necessary to guide better decision making in the LUGPA APM.

4. Will any information technology innovations be used to support improved outcomes, improve the consumer experience, or enhance the efficiency of the care delivery process?

We propose that each APM entity utilize Certified Electronic Health Record Technology (CEHRT) so that the LUGPA APM meets necessary criteria for being an advanced APM.

5. How will any health IT requirements included in the model ensure that clinicians have the flexibility to choose from a variety of solutions to meet their needs and leverage existing technology assets where possible?

While participating practices would be required to utilize CEHRT, we believe that the reporting requirements would not limit flexibility to choose from a range of EHRs to best meet each practice's needs.

XII. Supplemental Information

The following appendices provide additional information on the LUGPA APM, including a detailed description of the analysis of Medicare claims for beneficiaries undergoing prostate biopsy in 2013-2014.

XIII. Appendices

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Appendix 1. Proposed Survey Instrument for Prostate Cancer Shared Decision Making Quality Measure Modified from NQF 2962

Survey Instrument

Please answer these questions about what happened when you talked with health care providers including doctors, nurses and other health care professionals about the different choices available for treating prostate cancer.

1. Did any of your health care providers talk with you about prostate cancer treatment options such as surgery (radical prostatectomy) or radiation therapy, or about not actively treating your prostate cancer (active surveillance or watchful waiting)?
   □ Yes

   □ No

2. How much did you and your health care providers talk with you about the reasons for prostate cancer treatments like prostatectomy or radiation therapy?
   □ A lot

   □ Some

   □ A little

   □ Not at all

3. How much did you and your health care providers talk with you about the reasons for not actively treating your prostate cancer (active surveillance)?
   □ A lot
   □ Some
   □ A little
   □ Not at all

4. Did any of your health care providers ask you what treatment you wanted to treat your prostate cancer or if you would rather wait to treat your prostate cancer?
   □ Yes

   □ No

Answers of Yes, A Lot, or Some will receive 1 point, other answers receive 0 points. The total possible points per survey is 4. The responses will be averaged across all beneficiaries attributed to each practice.

Adapted from:
Section 3 of: http://www.massgeneral.org/decisionsciences/assets/pdfs/PCA_DQI_SV.pdf
Sepucha KR. Decision Quality Worksheet: For Treating Prostate Cancer v.1.0. ©Massachusetts General Hospital, 2010, last reviewed 2013. Downloaded from: http://www.massgeneral.org/decisionsciences/research/DQ_Instrument_List.aspx.

June 30, 2017

Physician-Focused Payment Model Technical Advisory Committee (PTAC)
c/o Angela Tejeda
Assistant Secretary for Planning and Evaluation
200 Independence Ave. SW
Washington, DC 20201

Dear PTAC committee members and Ms. Tejada:

The undersigned physician group practices, comprising over 1400 providers in 43 groups across 27 states write to you supporting the LUGPA APM for Initial Therapy of Newly Diagnosed Patients with Organ-Confined Prostate Cancer ("LUGPA APM"). According to data published in the 2015 Medicare Provider Utilization and Payment Data: Physician and Other Supplier Public Use Files, the undersigned groups collectively perform approximately 15% of all Medicare urology services in the United States.

The LUGPA APM addresses a major clinical need by realigning financial incentives with best clinical practices. We are committed to developing and adhering to standardized clinical pathways that are consistent with evidence-based literature; however, our ability to successfully manage patients in accordance with these pathways can be hampered by lack of resources. The misalignment between historical payment models and best clinical practices is exemplified in the management of prostate cancer.

Prostate cancer remains the most commonly diagnosed solid tumor in men within the US, and in 2017, it is estimated to be the third leading cause of cancer death in men. [1] Research suggests that a substantial subset of patients with newly diagnosed prostate cancer may safely defer active intervention (AI) at the time of diagnosis and instead be closely monitored via active surveillance (AS). Unfortunately, many of these patients drop out of AS protocols for non-clinical reasons; [2] the LUGPA APM not only provides practices with the resources to monitor and counsel patients on AS but also to better integrate shared decision making in the initial and ongoing phases of therapy – these resources will likely improve adoption and adherence rates for AS.

[1] Cancer Facts & Figures 2017. Accessed at https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2017/cancer-facts-and-figures-2017.pdf

[2] R Kraus, L Ji, R Jennelle, et al. Active Surveillance: Do Low-Income Patients Adhere to Protocol. J Clin Oncol. 2017; suppl 62, abstract 53.

Our practices are committed to providing integrated, comprehensive services to patients with genitourinary disease. As such, we are highly supportive of initiatives that help us deliver patient-centered, value based care that incorporate the principles of shared decision making and best clinical practices. At present, our ability to incorporate these goals is constrained by the lack of models that allow for urologists to fully participate in alternative payment models – in the final MACRA rule, CMS estimated that a mere 88 urologists (0.8% of the nation's practicing urologists) will qualify as APM participants in 2017.[3] The LUGPA APM will fill a much needed void for the majority of urologists in the United States.

In summary, the LUGPA APM encourages value based care, emphasizes shared decision making while producing real savings for the Medicare program. In addition, the LUGPA APM is timely in that it addresses the immediate clinical concern of overtreatment and overutilization of services; we believe that this proposal exemplifies the type of innovative thinking that MACRA intended to foster. We urge the PTAC to recommend this payment model for adoption by the Secretary as a high priority.

Respectfully submitted (alphabetically by State)

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[3] CMS-5517-FC, 81 Fed. Reg. 77008 (Nov. 4, 2016).

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LUGPA APM Financial Feasibility Analysis

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June 7, 2017

Background

Integra Connect engaged Milliman to analyze Medicare claims data for the development of the LUGPA Alternative Payment Model for Initial Therapy of Newly Diagnosed Patients with Organ-Confined Prostate Cancer (LUGPA APM). The LUGPA APM would align incentives to support the utilization of clinically appropriate active surveillance for Medicare beneficiaries newly diagnosed with localized prostate cancer by creating 12-month episodes of care that begin with prostate cancer diagnosis.

LUGPA is proposing the LUGPA APM to the Physician-Focused Payment Model Technical Advisory Committee (PTAC). The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) created incentives for providers to participate in physician-focused payment models (PFPMs), as well as mechanisms for proposing new models through the PTAC. The PTAC has 11 members who review proposals and make recommendations to the Secretary of the Department of Health and Human Services (HHS).[1]

The PTAC members will review and deliberate on the LUGPA APM proposal. Based on the review and deliberations, PTAC members will make one of four recommendations on the proposal to the Secretary of HHS:

- Do not recommend the proposed payment model to the Secretary
- Recommend the proposed model for limited-scale testing
- Recommend the proposed model for implementation
- Recommend the proposed model for implementation as a high priority

Based on the PTAC recommendation, the Secretary of HHS will work with the Centers for Medicare and Medicaid Services (CMS) to determine whether or not to implement the proposed model and at what scale. In the event that a model is implemented by CMS, groups of providers that participate in the alternative payment model (APM) will be known as APM entities. These APM entities can receive incentive payments or other benefits (such as reductions in quality reporting requirements) based on their APM participation.

[1] More information on the PTAC, the specific criteria for PTAC review of PFPM proposals, and what constitutes a PFPM is available at: https://aspe.hhs.gov/ptac-physician-focused-payment-model-technical-advisory-committee. Accessed April 18, 2017.

For this work, the authors worked closely with John Verniero, who manages the Integra Connect urology portfolio, and representatives from three urology practices – Dr. Deepak Kapoor, Chairman and CEO of Integrated Medical Professionals and LUGPA Chairman of Health Policy and Government Relations, Dr. Kathy Latino, Medical Director of Integrated Medical Professionals, Dr. Todd Cohen, Carolina Urology Partners, and Dr. Jonathan Henderson, Regional Urology and LUGPA secretary. Dr. Neal Shore, LUGPA President, and Dr. Gary Kirsh, LUGPA Past President, also provided valuable input. This memo describes our analysis of the LUGPA APM.

Purpose and Findings

This analysis is a high-level financial feasibility analysis of the LUGPA APM in a Medicare population, and it is intended to provide supporting detail for LUGPA's PTAC proposal. Using the assumptions and methods stated below, we found that the LUGPA APM could increase the utilization of clinically appropriate active surveillance for Medicare FFS beneficiaries diagnosed with localized prostate cancer and could decrease Medicare allowed costs for those beneficiaries relative to current FFS payment methods.

LUGPA believes that the LUGPA APM would be classified as an advanced APM that operates as a bundled payment for 12-month initial episodes of care. LUGPA APM entities would be independent physician group practices (PGPs) or hospital-based PGPs. Under the proposed payment methodology, CMS would continue to pay for services on a fee-for-service (FFS) basis and APM entities would be able to bill a monthly $75 care management fee that pays for the enhanced services required to actively surveil beneficiaries. A performance-based payment calculation would compare aggregate CMS allowed costs for initial 12-month episodes against a discounted target price.

Episodes would include all Part A and B services, but not Part D prescription drugs. This is because the only Part D drugs specific to prostate cancer are used to treat metastatic prostate cancer that has spread beyond the prostate rather than organ-confined prostate cancer. The target price would be calculated from historical practice-specific and regional episodes, including utilization of active surveillance, and would be risk adjusted using the composition of performance year episodes. Specifically, the target price would be risk adjusted to account for the distribution of Hierarchical Condition Category (HCC) risk scores among beneficiaries on active surveillance and to account for the types of active interventions that beneficiaries receive.[2]

The proposed discount is 2%, which would accrue to CMS and represent savings to the Medicare trust fund. Participating APM entities would receive up to 100% of gains and repay up to 125% of losses compared with the discounted target price, subject to proposed stop-loss/gain limits of -/+ 20%. Additionally, LUGPA APM entities would be able to bill the care management fee for subsequent 12-month episodes for beneficiaries who remain on active surveillance after

[2] For our modeling, we used the 2014 HCC methodology. More information on the HCC risk adjustment methodology is at: https://www.cms.gov/medicare/health-plans/medicareadvtgspecratestats/risk-adjustors.html. Accessed May 2, 2017.

an initial 12-month episode. Spending in these subsequent episodes would not be reconciled against a discounted target price. The LUGPA APM PTAC proposal contains a more complete description of the proposed payment methodology.

Caveats and Limitations

The LUGPA APM would require changes to Medicare payment policy, and we do not consider the likelihood of such changes in our analysis. Our analysis is high-level and does not represent a complete financial projection of the LUGPA APM, and any organization wanting to assess feasibility would need to perform a significant amount of initial analysis. An important limitation of this work is that it is a "snapshot" analysis that does not account for start-up expenses or gradual growth of patient volumes. In addition, this model is framed for 2013-2015 and does not account for future known or unknown changes in Medicare reimbursement. The results are based on analysis of the 5% Medicare Limited Data Set (LDS) claims files for 2011-2015 and the Surveillance, Epidemiology, and End Results (SEER) program data on the incidence of prostate cancer through 2014. In Medicare claims, it is not possible to directly identify active surveillance of prostate cancer. As described below, we impose stringent criteria to identify men with claim-based evidence of a diagnosis of prostate cancer who do not receive active intervention and to classify those men as being actively surveilled. However, there are scenarios in which a beneficiary without prostate cancer could be classified based on our criteria as a prostate cancer patient on active surveillance, due to circumstances such as misuse of prostate cancer diagnosis codes or repeated prostate biopsies intended to test for prostate cancer but with a negative result. Any analysis using different data sets, assumptions, time periods, or methodology will produce different results.

The authors of this memo are employed by Milliman, Inc., and the findings represent the authors' conclusions. Integra Connect funded this work to support the LUGPA APM PTAC application; this material may not be suitable for other purposes. For this work we relied on information from LUGPA regarding the number of LUGPA practices actively supporting the development of APMs and the types of active intervention that would most likely decrease when active surveillance increases. Jonah Broulette is a Member of the American Academy of Actuaries and meets its qualification standards for this work.

Methodology

Our analysis consisted of the following steps:

1. Identifying a national cohort of historical episodes ("historical cohort") initiated in 2013-2014 which are similar to those episodes that would be eligible for the LUGPA APM and classifying historical episodes into active surveillance and active intervention episode categories.
2. Determining the Medicare national average 12-month episode allowed costs for the historical episodes identified in step 1.

3. Estimating the number of 2015 historical episodes using 2015 Medicare nationwide demographic data and SEER data on the incidence of prostate cancer by age and combining this overall estimate of prostate cancer incidence with the treatment distribution and episode allowed costs from the historical cohort. Because we apply stringent criteria that reduces the size of the historical cohort in step 1 (for example, requiring 24 months of continuous enrollment in Medicare Parts A and B prior to the prostate biopsy in 2013 or 2014), in step 3, we combine estimates of allowed costs and the treatment distribution from the historical cohort with an overall estimate of 2015 prostate cancer incidence in the Medicare FFS population.
4. Estimating the possible increase in active surveillance that could occur in the LUGPA APM based on historical utilization and published research on the incidence of low-risk localized prostate cancer.
5. Estimating the potential reduction in Medicare FFS allowed costs under the LUGPA APM and comparing the allowed costs against a discounted target price calculated according to the proposed payment methodology.

HISTORICAL COHORT IDENTIFICATION

We used the 5% Medicare Limited Data Set (LDS) claims files for 2011-2015 to identify the historical cohort of beneficiaries who were initially diagnosed with prostate cancer in 2013 or 2014. Cohort inclusion and exclusion criteria were based on practical considerations and designed to capture beneficiaries newly diagnosed with prostate cancer. Beneficiaries were required to meet the following eligibility criteria to be included in the historical cohort:

- Enrolled in fee-for-service (FFS) Medicare (not Medicare Advantage)
- Continuously enrolled in both Part A and Part B
- Medicare entitlement not based on end-stage renal disease (ESRD)

For patients meeting these eligibility criteria, we identified all beneficiaries who received a prostate biopsy in 2013 or 2014 and then applied the following claims-based inclusion criteria:

- Beneficiaries were required to have 24 months prior to the initiating biopsy and 12 months after (or until death, whichever was less) of continuous enrollment
- Beneficiaries were excluded if they had a prior biopsy (with a corresponding prostate cancer diagnosis in any position) or prior active intervention (with a corresponding prostate cancer diagnosis in any position) within the 24 months prior to the initiating biopsy
- Beneficiaries were excluded if they had a claim coded with a metastatic cancer diagnosis code within the 12 months following the initiating biopsy
- Patients were required to meet a qualified claims criteria, described below, or have evidence of active intervention (with a corresponding prostate cancer diagnosis code in any position) within the 12 months following biopsy

- The qualifying claims criteria followed similar logic to the Healthcare Effectiveness Data and Information Set (HEDIS) criteria and included:[3]
  - At least one acute inpatient claim or observation with a prostate diagnosis code in any position on the claim; or
  - At least two outpatient, emergency department (ED) or nonacute inpatient claims on different dates of service, with a prostate diagnosis code in any position on the claim

Historical episodes were considered to begin on the date of the initiating biopsy and end 12 months thereafter. After constructing historical episodes, we classified episodes into the following categories:

- Active Intervention – identified by receipt of an active intervention within the 12 months following initial biopsy[4]
  - Active intervention episodes were further classified into 9 subcategories based on the types of active intervention received:
    - Prostatectomy only
    - Radiation therapy only
    - Hormone and radiation therapy
    - Hormone therapy only
    - Prostatectomy and radiation therapy
    - Cryoablation only
    - Prostatectomy, hormone, radiation therapy
    - Prostatectomy and hormone therapy
    - Other – active intervention initiated 6 to 12 months following the initial biopsy or combinations of active interventions that began within 6 months following the initial biopsy with low national episode volume
    - Episodes containing chemotherapy (non-hormonal) were excluded from the model
  - For subcategories involving multiple active intervention types, only one was required to begin within 6 months following the initiating biopsy
- Active Surveillance – identified by no active intervention within the 12 months following the initiating biopsy
  - Active surveillance episodes were further classified into 3 subcategories based on national tertiles of HCC risk scores
  - It is possible that some men who do not have prostate cancer could be identified as being on active surveillance for a few reasons. First, it is possible that providers misuse prostate cancer diagnosis codes when treating a beneficiary for other prostate conditions like benign prostatic hyperplasia (BPH) after an initial prostate biopsy. Second, it is possible that a

[3] http://www.ncqa.org/hedis-quality-measurement. Accessed May 2, 2017.
[4] All episodes with active intervention beginning after 6 months following initiating biopsy were grouped into the "other" category.

beneficiary could receive additional biopsies to test for prostate cancer within a year after an initial biopsy that is negative for prostate cancer.

DEVELOPMENT OF HISTORICAL EPISODE MEDICARE COSTS

After identifying the historical cohort, we constructed historical episode allowed costs for the cohort using the 5% Medicare LDS claims files for 2013-2015.[5] We tabulated the Medicare allowed amount for all Part A and B claims that occurred during a historical episode, beginning with the initiating prostate biopsy and ending 12 months thereafter, aligning with the proposed LUGPA APM episode definition. When modeling the hypothetical practice scenarios and the overall reduction in expenditures, we capped historical episode expenditures at two standard deviations above national average spending within each episode subcategory to simulate the effect of the cap LUGPA proposes, which is set at two standard deviations above average regional episode spending in each episode category, stratified by practice type. It was not practical to model the cap at the regional level due to sample size constraints in the 5% Medicare LDS claims.

ESTIMATING 2015 HISTORICAL EPISODES AND COMBINING WITH HISTORICAL COHORT TREATMENT DISTRIBUTION AND ALLOWED COSTS

To estimate the number of 2015 historical episodes, we combined the age distribution of male Medicare FFS beneficiaries in the 2015 5% Medicare LDS claims data with SEER data on the prostate cancer incidence by age and the percentage of newly diagnosed prostate cancer cases that were localized to the prostate.[6]

Table 1 below shows our estimates of 2015 national episode volume for newly diagnosed localized prostate cancer. Column B shows the estimated number of non-ESRD male Medicare FFS beneficiaries in the 2015 grouped by the age ranges for which SEER calculates prostate cancer incidence rates. These estimates are based on the 2015 5% Medicare LDS membership files multiplied by a factor of 20. Column C shows the SEER age-specific prostate cancer incidence rates, which we applied to each Medicare beneficiary age group to estimate new prostate cancer cases in 2015 by age group (column D). SEER data also shows that 79% of new cases are localized to the prostate,[7] and we multiplied the results in column D by 79% to estimate the number of new localized prostate cancer cases in 2015 (column E). Lastly, we summed the results across age groups, yielding an estimate of 62,640 newly diagnosed localized prostate cancer cases in 2015 in the Medicare FFS population.

After estimating the number of new Medicare localized prostate cancer cases in 2015, we combined that estimate with historical cohort estimates of the distribution of episodes across subcategories and the average allowed costs for each episode subcategory. Table 2 shows

[5] Additional details are in the Data Sources and Reliance section.

[6] SEER Incidence and US Death Rates, Age-Adjusted and Age-Specific Rates by Race, SEER 5-Year Relative and Period Survival (Percent) by Race, Diagnosis Year, Stage and Age. Available at: https://seer.cancer.gov/csr/1975_2014/results_merged/sect_23_prostate.pdf. Accessed May 2, 2017.

[7] SEER 5-Year Relative and Period Survival (Percent) by Race, Diagnosis Year, Stage and Age. Available at: https://seer.cancer.gov/csr/1975_2014/results_merged/sect_23_prostate.pdf. Accessed May 2, 2017.

these estimates. We estimate that in 2015, there were almost 14,300 active surveillance episodes (~23%), evenly split (by construction) across tertiles of HCC risk scores. Average allowed costs for active surveillance episodes was $12,658, ranging from $7,340 for episodes in the lowest risk tertile to $18,740 in the highest risk tertile. We estimate that there were more than 48,350 active intervention episodes in 2015, with average allowed costs of $32,788. Within active intervention subcategories, average allowed costs ranged from $21,680 for beneficiaries who only received a prostatectomy only to $47,089 for beneficiaries who received a combination of prostatectomy, radiation therapy, and hormone therapy during a 12-month episode. Across all 62,640 active surveillance and active intervention episodes, the average allowed cost was $28,199, with a total estimated allowed cost of almost $1.8 billion.

ESTIMATING THE POTENTIAL INCREASE IN ACTIVE SURVEILLANCE IN THE LUGPA APM

As shown on Table 2, only around 23% of Medicare FFS beneficiaries diagnosed with localized prostate cancer are placed on active surveillance, with the remaining 77% receiving costly active intervention that may have side effects that diminish their quality of life. National Comprehensive Cancer Network (NCCN) guidelines support the utilization of active surveillance for men with very low-risk prostate cancer and life expectancy of 20 years or less.[8] Additionally, recent guidelines from the American Urological Association (AUA), American Society for Radiation Oncology (ASTRO), and the Society of Urologic Oncology (SUO) support the recommendation of active surveillance 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.[9] Also, recent research suggests that 43% of new prostate cancer cases have Gleason score ≤6 and 36% of new cases have a Gleason score of 7.[10] Most men with Gleason score of 6 and some with Gleason score of 7 would likely be candidates for active surveillance. Thus, we estimate that national utilization of active surveillance could increase substantially, possibly to around 33-35%.

ESTIMATING THE POTENTIAL REDUCTION IN MEDICARE FFS ALLOWED COSTS UNDER THE LUGPA APM

Before estimating the total potential reduction in Medicare allowed costs, we modeled two hypothetical practice scenarios according to the payment methodology in the LUGPA APM proposal, with a few caveats because we relied on the 5% Medicare LDS claims files. First, we used the national average of episode allowed costs in each subcategory for both the hypothetical practice and the regional component of the target price. Second, we capped individual episode expenditures at two standard deviations above the national average allowed costs in each episode subcategory, rather than two standard deviations above the regional

[8] National Comprehensive Cancer Network Prostate Cancer Guidelines version 2.2016.
[9] Clinically Localized Prostate Cancer: AUA/ASTRO/SUO Guideline. 2017. http://www.auanet.org/Documents/education/clinical-guidance/Clinically-Localized-Prostate-Cancer.pdf..
[10] KA Herget, DP Patel, HA Hanson, et al. Recent Decline in Prostate Cancer Incidence in the United States, by age, stage, and Gleason score. Cancer Med.; 5(1) 136-141.

average allowed. Third, we did not stratify based on practice type (i.e. independent, academic hospital-based, or other hospital-based). Fourth, we did not incorporate practice performance on the LUGPA APM's proposed quality measures. Nonetheless, the modeling demonstrates the different financial outcomes for a hypothetical practice that increases use of active surveillance and for a hypothetical practice that does not increase use of active surveillance.

Table 3 presents a scenario in which a hypothetical practice with 200 performance year episodes successfully increases active surveillance from 23% in a three-year baseline period to 33% in the performance year by reducing prostatectomy and radiation therapy, each by 5 percentage points.[11,12] In this scenario, the total benchmark allowed costs, before application of the 2% CMS discount, would be $5,337,800. CMS would retain a 2% discount of $106,800, leaving target allowed costs of $5,231,000. Based on the practice's increased utilization of active surveillance, we estimate that its actual allowed costs would be $4,984,500, inclusive of care management fees for beneficiaries on active surveillance ($900 per episode). If the practice achieved all of the performance targets for the LUGPA APM quality measures, it would earn a performance-based payment of $246,500. That amount would be reduced if the practice achieved fewer performance targets.

Table 4 presents a different scenario in which a hypothetical practice with 190 performance year episodes is only able to increase active surveillance from 23% in the baseline period to 25% in the performance year, with a corresponding 1 percentage point reduction to both prostatectomy and radiation therapy.[13] Because there are relatively more performance year prostatectomy episodes, total benchmark allowed costs are only $5,274,800 in this scenario. The CMS discount would be $105,500, and total target allowed costs would be $5,169,300. Because the practice did not increase active surveillance in the performance year, its actual allowed costs, inclusive of care management fees, would be $5,238,900, which exceeds the target by $69,600. If the practice achieved all of the quality measure performance targets, it would only be required to pay back 75% of that amount. However, if the practice achieved fewer quality measure performance targets, it would have to pay back up to 125% of that amount.

To date, 44 LUGPA practices, representing more than 1,500 urologists, are actively engaged in developing APMs for urology. Additionally, LUGPA anticipates substantial interest from other urologists, who have had limited APM engagement to date.[14,15] Based on this, we estimate that approximately 30% of the annual national episode volume, around 19,000 episodes annually, could occur in the LUGPA APM. Table 5 shows an annual snapshot of reduced expenditures in the LUGPA APM under the following assumptions:

[11] The increase to 33% is based on the above estimate that active surveillance could increase nationally to 33-35%.
[12] LUGPA identified prostatectomy and radiation as the two types of active intervention that would most likely decrease if active surveillance increased.
[13] LUGPA identified prostatectomy and radiation as the two types of active intervention that would most likely decrease if active surveillance increased.
[14] CMS estimates that 11,600 urologists bill Medicare FFS each year. QPP Final Rule Table 58 (81 FR 214 77520).
[15] More than 6,000 physicians bill Medicare FFS for prostate biopsy annually. CMS Physician and Other Supplier Data CY 2014 available at: http://www.cms.gov/apps/ama/license.asp?file=http://download.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/Downloads/Medicare_National_HCPCS_Aggregate_CY2014.zip. Accessed May 3, 2017.

- 95 practices participate in the LUGPA APM with an average of 190 episodes per year
- 80% (76) of the practices perform similarly to the hypothetical practice in Table 3 and increase active surveillance from 23% to 33% and achieve all quality performance targets, earning 100% of performance-based payments
- 20% (19) of the practices perform similarly to the hypothetical practice in Table 4 and increase active surveillance from 23% to 25% and achieve 2 or 3 quality performance targets, requiring 100% repayment of losses

Under those assumptions, active surveillance would increase from 23% in the baseline period to 31% in the performance year. Prostatectomy would decrease from 15% to 11%, and radiation therapy would decrease from 20% to 16%. Total benchmark allowed costs would be $505.9 million, and CMS would retain $10.1 million as a 2% discount. Total target allowed costs would be $495.8 million compared to actual allowed costs of $478.4 million – generating aggregate performance-based payments of $17.4 million. Practices achieving a 10% increase in active surveillance, as measured by the APM, would receive performance-based payments in excess of $17.4 million, while practices only achieving a 2% increase in active surveillance would repay CMS for losses. Additionally, the CMS discount of $10.1 million exceeds the cost of care management fees for subsequent episodes that occur after completion of initial active surveillance episodes. If all beneficiaries who completed an initial active surveillance episode in the performance year were to complete a 12-month subsequent episode in the following year, care management fees for the subsequent episodes would total $5.3 million, around half of the estimated CMS discount for the previous performance year.[16] In actuality, not all beneficiaries would complete a subsequent episode, so $5.3 million is an upper bound of the estimated additional cost of subsequent episodes.

Table 6 shows an alternative scenario where 60% of practices performed similarly to the hypothetical practice in Table 3 and 40% of practices performed similarly to the hypothetical practice in Table 4. Under those assumptions, active surveillance would only increase from 23% in the baseline period to 30% in the performance year. CMS would still retain $10.1 million as a 2% discount, but net performance-based payments would decrease to $11.4 million.

Data Sources and Reliance

5% MEDICARE LIMITED DATA SET CLAIMS FILES

The historical cohort was constructed using the 5% Medicare LDS claims files for 2011-2015. The 5% Medicare LDS claims files contain all Medicare paid FFS claims generated for a 5% random sample of Medicare beneficiaries in the U.S. The 5% Medicare LDS claims files include diagnosis codes, procedure codes, and Medicare severity diagnosis related group (MS-DRG) codes, along with site of service information including provider IDs. The data also provides monthly eligibility data for each beneficiary including demographics, eligibility status and an indicator for HMO enrollment.

[16] This is calculated as the product of 31% active surveillance episodes, 19,000 total episodes, and $900 in care management fees per subsequent episode.

SURVEILLANCE, EPIDEMIOLOGY, AND END RESULTS PROGRAM PROSTATE CANCER DATA

SEER compiles data from several tumor registries (areas) in the United States, and the prostate cancer incidence rates by age group and stage distributions are compiled from the SEER 18 areas – Alaska Native Registry, Atlanta, California excluding San Francisco/San Jose-Monterey/Los Angeles, Connecticut, Detroit, Georgia excluding Atlanta/Rural Georgia, Hawaii, Iowa, Kentucky, Los Angeles, Louisiana, New Jersey, New Mexico, Rural Georgia, San Francisco, San Jose-Monterey, Seattle, and Utah.[17,18]

SEER calculated prostate cancer incidence rates using 2010-2014 registry data and age-adjusted the rates to the 2000 US Census age groups. SEER calculated the stage distribution using 2007-2013 registry data and classified stage using SEER Summary Stage 2000.[19] The SEER incidence are not payer-specific, and we assumed that the incidence would not vary for the Medicare FFS population.

[17] https://seer.cancer.gov/registries/terms.html. Accessed May 4, 2017.
[18] https://seer.cancer.gov/csr/1975_2014/results_merged/sect_23_prostate.pdf. Accessed May 2, 2017.
[19] https://seer.cancer.gov/tools/ssm/SSSM2000-122012.pdf. Accessed May 4, 2017.

Tables

TABLE 1. ESTIMATES OF 2015 NATIONAL HISTORICAL EPISODE VOLUME

AGE GROUP	ESTIMATED MALE MEDICARE FFS BENEFICIARIES	SEER INCIDENCE RATES PER 100,000	PROJECTED PROSTATE CANCER CASES (B)*(C)/100,000	PROJECTED LOCALIZED CANCER CASES (D)*0.79
(A)	(B)	(C)	(D)	(E)
0-35	350,900	0.00	0	0
35-39	182,500	0.80	0	0
40-44	220,300	8.80	20	20
45-49	308,700	38.80	120	90
50-54	470,700	123.40	580	460
55-59	631,500	265.30	1,680	1,330
60-64	704,300	450.00	3,170	2,500
65-69	3,710,200	693.40	25,730	20,330
70-74	3,001,800	718.40	21,560	17,030
75-79	2,168,100	632.10	13,700	10,820
80-84	1,494,500	468.80	7,010	5,540
85-89	938,800	396.40	3,720	2,940
90-94	401,300	396.40	1,590	1,260
95 AND OLDER	101,600	396.40	400	320
TOTAL – 100% ESTIMATE	**14,685,200**		**79,280**	**62,640**

Notes: Estimated Male Medicare FFS beneficiaries includes beneficiaries enrolled in Parts A and B and excludes beneficiaries whose entitlement for Medicare is based on ESRD. The figures are calculated from the 5% Medicare LDS files for 2015 inflated by a factor of 20. SEER data shows that 79% of incident prostate cancer cases are localized to the prostate.
Sources: 2015 5% Medicare LDS claims files; SEER Incidence and US Death Rates, Age-Adjusted and Age-Specific Rates by Race; SEER 5-Year Relative and Period Survival (Percent) by Race, Diagnosis Year, Stage and Age.

TABLE 2. ESTIMATES OF 2015 NATIONAL HISTORICAL EPISODE VOLUME, AVERAGE EPISODE ALLOWED COST, AND TOTAL ALLOWED COSTS, BY EPISODE SUBCATEGORY

PROPOSED EPISODE CATEGORIES AND SUBCATEGORIES	ESTIMATED DISTRIBUTION OF EPISODES IN 5% SAMPLE	ESTIMATED ANNUAL EPISODES (B)*62,640	AVERAGE EPISODE COST	TOTAL COST OF ALL EPISODES (C)*(D)
(A)	(B)	(C)	(D)	(E)
ACTIVE SURVEILLANCE	22.8%	14,283	$12,658	$180,794,000
ACTIVE SURVEILLANCE - LOW HCC	7.3%	4,573	$7,340	$33,567,000
ACTIVE SURVEILLANCE – MEDIUM HCC	7.9%	4,949	$11,721	$58,007,000
ACTIVE SURVEILLANCE – HIGH HCC	7.6%	4,761	$18,740	$89,220,000
ACTIVE INTERVENTION	77.2%	48,356	$32,788	$1,585,509,000
PROSTATECTOMY ONLY	13.5%	8,456	$21,680	$183,330,000
RADIATION THERAPY ONLY	21.9%	13,718	$35,669	$489,304,000
HORMONE AND RADIATION THERAPY	23.6%	14,783	$42,808	$632,831,000
HORMONE THERAPY ONLY	8.4%	5,262	$18,675	$98,268,000
PROSTATECTOMY AND RADIATION THERAPY	1.0%	626	$43,370	$27,150,000
CRYOABLATION ONLY	2.1%	1,315	$21,949	$28,863,000
PROSTATECTOMY, HORMONE THERAPY, RADIATION THERAPY	1.0%	626	$47,089	$29,477,000
PROSTATECTOMY AND HORMONE THERAPY	1.0%	626	$23,538	$14,735,000
OTHER	4.7%	2,944	$27,701	$81,551,000
TOTAL	**100.0%**	**62,640**	**$28,199**	**$1,766,303,000**

Notes: The sum of estimated annual episodes in each subcategory does equal the total because subcategory episodes are rounded to the nearest integer. All Total Episode Costs are rounded to the nearest thousand dollars. It is possible that some beneficiaries without prostate cancer could be categorized as active surveillance due to circumstances such as miscoding or repeat prostate biopsies. Based on the distribution of risk scores for beneficiaries classified as active surveillance in the 5% Medicare LDS claims files, active surveillance beneficiaries with HCC risk scores ≤ 0.473 were categorized as low HCC; active surveillance beneficiaries with HCC risk scores between 0.473 and 0.885 were categorized as medium HCC; and active surveillance beneficiaries with HCC risk scores > 0.885 were categorized as high HCC.

Sources: 2013-2015 5% Medicare LDS claims files; SEER Incidence and US Death Rates, Age-Adjusted and Age-Specific Rates by Race; SEER 5-Year Relative and Period Survival (Percent) by Race, Diagnosis Year, Stage and Age.

TABLE 3. FINANCIAL MODEL FOR HYPOTHETICAL PRACTICE THAT INCREASES ACTIVE SURVEILLANCE FROM 23% TO 33%

Table 3 shows the performance-based payment for a hypothetical practice that increases active surveillance from 23% in the 3-year baseline period to 33% in the performance year by reducing prostatectomy from 15% to 10% and radiation therapy from 20% to 15%.[20] The underlying episode costs are capped at two standard deviations above the mean for each subcategory to simulate the proposed LUGPA APM payment methodology. Total benchmark allowed costs are calculated based on the historical prevalence of active surveillance versus active intervention and the performance year composition of active interventions.

	3-YEAR BASELINE PERIOD		PERFORMANCE YEAR	
(A)	(B)	(C)	(D)	(E)
	EPISODES (N AND DISTRIBUTION)	CAPPED AVERAGE EPISODE COST	EPISODES (N AND DISTRIBUTION)	CAPPED AVERAGE EPISODE COST
NUMBER OF EPISODES	600		200	
EPISODE CATEGORY DISTRIBUTION				
ACTIVE SURVEILLANCE	23%	$10,800	33%	$11,700
ACTIVE INTERVENTION	77%	$30,938	67%	$31,435
PROSTATECTOMY ONLY	15%		10%	
RADIATION THERAPY ONLY	20%		15%	
ALL OTHER ACTIVE INTERVENTION	42%		42%	
				TOTALS
BENCHMARK ALLOWED COSTS				$5,337,800
CMS DISCOUNT (2%)				**$106,800**
TARGET ALLOWED COSTS				$5,231,000
ACTUAL ALLOWED COSTS				$4,984,500
PERFORMANCE-BASED PAYMENT/LOSS				**$246,500**

Sources: 2013-2015 5% Medicare LDS claims files; SEER Incidence and US Death Rates, Age-Adjusted and Age-Specific Rates by Race; SEER 5-Year Relative and Period Survival (Percent) by Race, Diagnosis Year, Stage and Age.

[20] LUGPA identified prostatectomy and radiation as the two types of active intervention that would most likely decrease if active surveillance increased.

TABLE 4. FINANCIAL MODEL FOR HYPOTHETICAL PRACTICE THAT INCREASES ACTIVE SURVEILLANCE FROM 23% TO 25%

Table 4 shows the performance-based loss for a hypothetical practice that increases active surveillance from 23% in the 3-year baseline period to 25% in the performance year by reducing prostatectomy from 15% to 14% and radiation therapy from 20% to 19%.[21] The underlying episode costs are capped at two standard deviations above the mean for each subcategory to simulate the proposed LUGPA APM payment methodology. Total benchmark allowed costs are calculated based on the historical prevalence of active surveillance and the performance year composition of active interventions.

	3-YEAR BASELINE PERIOD		PERFORMANCE YEAR	
(A)	(B)	(C)	(D)	(E)
	EPISODES (N AND DISTRIBUTION)	CAPPED AVERAGE EPISODE COST	EPISODES (N AND DISTRIBUTION)	CAPPED AVERAGE EPISODE COST
NUMBER OF EPISODES	600		200	
EPISODE CATEGORY DISTRIBUTION				
ACTIVE SURVEILLANCE	23%	$10,800	25%	$11,700
ACTIVE INTERVENTION	77%	$30,938	75%	$31,026
PROSTATECTOMY ONLY	15%		14%	
RADIATION THERAPY ONLY	20%		19%	
ALL OTHER ACTIVE INTERVENTION	42%		42%	
				TOTALS
BENCHMARK ALLOWED COSTS				**$5,274,800**
CMS DISCOUNT (2%)				$105,500
TARGET ALLOWED COSTS				$5,169,300
ACTUAL ALLOWED COSTS				$5,238,900
PERFORMANCE-BASED PAYMENT/LOSS				**-$69,600**

Sources: 2013-2015 5% Medicare LDS claims files; SEER Incidence and US Death Rates, Age-Adjusted and Age-Specific Rates by Race; SEER 5-Year Relative and Period Survival (Percent) by Race, Diagnosis Year, Stage and Age.

[21] LUGPA identified prostatectomy and radiation as the two types of active intervention that would most likely decrease if active surveillance increased.

TABLE 5. AGGREGATE FINANCIAL MODEL FOR LUGPA APM, ASSUMING 100 PARTICIPATING PRACTICES

Table 5 shows the net performance-based payments in a scenario where 80 hypothetical practices perform similarly to the hypothetical practice shown in Table 3 and 20 hypothetical practices perform similarly to the hypothetical practice shown in Table 4. The underlying episode costs are capped at two standard deviations above the mean for each subcategory to simulate the proposed LUGPA APM payment methodology. Total benchmark allowed costs are calculated based on the historical prevalence of active surveillance and the performance year composition of active interventions.

	3-YEAR BASELINE PERIOD		PERFORMANCE YEAR	
(A)	(B)	(C)	(D)	(E)
	EPISODES (N AND DISTRIBUTION)	CAPPED AVERAGE EPISODE COST	EPISODES (N AND DISTRIBUTION)	CAPPED AVERAGE EPISODE COST
NUMBER OF EPISODES	57,000		19,000	
EPISODE CATEGORY DISTRIBUTION				
ACTIVE SURVEILLANCE	23%	$10,800	31%	$11,700
ACTIVE INTERVENTION	77%	$30,938	69%	$31,353
PROSTATECTOMY ONLY	15%		11%	
RADIATION THERAPY ONLY	20%		16%	
ALL OTHER ACTIVE INTERVENTION	42%		42%	
				TOTALS
BENCHMARK ALLOWED COSTS				505,894,000
CMS DISCOUNT (2%)				**10,121,300**
TARGET ALLOWED COSTS				495,772,700
ACTUAL ALLOWED COSTS				478,361,100
PERFORMANCE-BASED PAYMENT/LOSS				**$17,411,600**

Sources: 2013-2015 5% Medicare LDS claims files; SEER Incidence and US Death Rates, Age-Adjusted and Age-Specific Rates by Race; SEER 5-Year Relative and Period Survival (Percent) by Race, Diagnosis Year, Stage and Age.

TABLE 6. ALTERNATIVE AGGREGATE FINANCIAL MODEL FOR LUGPA APM, ASSUMING 100 PARTICIPATING PRACTICES

Table 6 shows the net performance-based payments in a scenario where 60 hypothetical practices perform similarly to the hypothetical practice shown in Table 3 and 40 hypothetical practices perform similarly to the hypothetical practice shown in Table 4. The underlying episode costs are capped at two standard deviations above the mean for each subcategory to simulate the proposed LUGPA APM payment methodology. Total benchmark allowed costs are calculated based on the historical prevalence of active surveillance and the performance year composition of active interventions.

	3-YEAR BASELINE PERIOD		PERFORMANCE YEAR	
(A)	(B)	(C)	(D)	(E)
	EPISODES (N AND DISTRIBUTION)	CAPPED AVERAGE EPISODE COST	EPISODES (N AND DISTRIBUTION)	CAPPED AVERAGE EPISODE COST
NUMBER OF EPISODES	57,000		19,000	
EPISODE CATEGORY DISTRIBUTION				
ACTIVE SURVEILLANCE	23%	$10,800	30%	$11,700
ACTIVE INTERVENTION	77%	$30,938	70%	$31,271
PROSTATECTOMY ONLY	15%		12%	
RADIATION THERAPY ONLY	20%		17%	
ALL OTHER ACTIVE INTERVENTION	42%		42%	
				TOTALS
BENCHMARK ALLOWED COSTS				504,697,000
CMS DISCOUNT (2%)				**10,096,600**
TARGET ALLOWED COSTS				494,600,400
ACTUAL ALLOWED COSTS				483,194,700
PERFORMANCE-BASED PAYMENT/LOSS				**$11,405,700**

Sources: 2013-2015 5% Medicare LDS claims files; SEER Incidence and US Death Rates, Age-Adjusted and Age-Specific Rates by Race; SEER 5-Year Relative and Period Survival (Percent) by Race, Diagnosis Year, Stage and Age.

Appendices

APPENDIX TABLE 1. CANCER INTERNATIONAL CLASSIFICATION OF DISEASE VERSION 9 AND 10 (ICD-9 AND ICD-10) DIAGNOSIS CODES USED IN ANALYSIS

CANCER TYPE	CODE SYSTEM (ICD-9, HCPCS, ETC.)	CODE
PROSTATE CANCER	ICD-9	185
PROSTATE CANCER	ICD-10	C61
SECONDARY AND UNSPECIFIED MALIGNANT NEOPLASM OF LYMPH NODES	ICD-9	196.X
SECONDARY MALIGNANT NEOPLASM OF RESPIRATORY AND DIGESTIVE SYSTEMS	ICD-9	197.X
SECONDARY MALIGNANT NEOPLASM OF OTHER SPECIFIED SITES	ICD-9	198.X
SECONDARY AND UNSPECIFIED MALIGNANT NEOPLASM OF LYMPH NODES	ICD-10	C77.X
SECONDARY MALIGNANT NEOPLASM OF RESPIRATORY AND DIGESTIVE ORGANS	ICD-10	C78.X
SECONDARY MALIGNANT NEOPLASM OF OTHER AND UNSPECIFIED SITES	ICD-10	C79.X

APPENDIX TABLE 2. PROSTATE BIOPSY HCPCS AND CPT CODES USED IN ANALYSIS

CODE SYSTEM (ICD-9, HCPCS, ETC.)	CODE	CODE DEFINITION
HCPCS	G0416	SAT BIOPSY 10-20
HCPCS	G0417	SAT BIOPSY PROSTATE 21-40
HCPCS	G0418	SAT BIOPSY PROSTATE 41-60
HCPCS	G0419	SAT BIOPSY PROSTATE >60
CPT	55700	BIOPSY OF PROSTATE
CPT	55705	BIOPSY OF PROSTATE

APPENDIX TABLE 3. PROSTATE CANCER ACTIVE INTERVENTION TREATMENT CODES USED IN ANALYSIS

TREATMENT TYPE	CODE SYSTEM (ICD9, HCPCS, ETC.)	CODE	CODE DEFINITION
CASTRATION	CPT	54520	REMOVAL OF TESTIS
CHEMO/IMMUNOTHERAPY	HCPCS	A9600	SR89 STRONTIUM
CHEMO/IMMUNOTHERAPY	HCPCS	A9604	SM 153 LEXIDRONAM
CHEMO/IMMUNOTHERAPY	HCPCS	A9606	RADIUM RA223 DICHLORIDE THER
CHEMO/IMMUNOTHERAPY	HCPCS	J9043	CABAZITAXEL INJECTION
CHEMO/IMMUNOTHERAPY	HCPCS	J9045	CARBOPLATIN INJECTION
CHEMO/IMMUNOTHERAPY	HCPCS	J9060	CISPLATIN 10 MG INJECTION
CHEMO/IMMUNOTHERAPY	HCPCS	J9171	DOCETAXEL INJECTION
CHEMO/IMMUNOTHERAPY	HCPCS	J9181	ETOPOSIDE INJECTION
CHEMO/IMMUNOTHERAPY	HCPCS	J9293	MITOXANTRONE HYDROCHL / 5 MG
CHEMO/IMMUNOTHERAPY	HCPCS	Q2043	SIPULEUCEL-T AUTO CD54+ 96401
CRYOABLATION	CPT	55873	CRYOABLATE PROSTATE
HORMONE THERAPY	HCPCS	J3315	TRIPTORELIN
HORMONE THERAPY	HCPCS	J9155	DEGARELIX
HORMONE THERAPY	HCPCS	J9202	GOSERELIN
HORMONE THERAPY	HCPCS	J9217	LEUPROLIDE
HORMONE THERAPY	HCPCS	J9225	VANTAS
HORMONE THERAPY	HCPCS	S0175	FLUTAMIDE
PROSTATECTOMY	CPT	55810	EXTENSIVE PROSTATE SURGERY
PROSTATECTOMY	CPT	55812	EXTENSIVE PROSTATE SURGERY
PROSTATECTOMY	CPT	55815	EXTENSIVE PROSTATE SURGERY
PROSTATECTOMY	CPT	55840	EXTENSIVE PROSTATE SURGERY
PROSTATECTOMY	CPT	55842	EXTENSIVE PROSTATE SURGERY
PROSTATECTOMY	CPT	55845	EXTENSIVE PROSTATE SURGERY
PROSTATECTOMY	CPT	55866	LAPARO RADICAL PROSTATECTOMY
PROSTATECTOMY	MS-DRG	665	PROSTATECTOMY W MCC
PROSTATECTOMY	MS-DRG	666	PROSTATECTOMY W CC
PROSTATECTOMY	MS-DRG	667	PROSTATECTOMY W/O CC/MCC
PROSTATECTOMY	ICD-9 P	60.3	SUPRAPUBIC PROSTATECTOMY
PROSTATECTOMY	ICD-9 P	60.4	RETROPUBIC PROSTATECTOMY
PROSTATECTOMY	ICD-9 P	60.5	RADICAL PROSTATECTOMY
RADIATION THERAPY	CPT	77261	RADIATION THERAPY PLANNING
RADIATION THERAPY	CPT	77262	RADIATION THERAPY PLANNING
RADIATION THERAPY	CPT	77263	RADIATION THERAPY PLANNING
RADIATION THERAPY	CPT	77280	SET RADIATION THERAPY FIELD
RADIATION THERAPY	CPT	77285	SET RADIATION THERAPY FIELD
RADIATION THERAPY	CPT	77290	SET RADIATION THERAPY FIELD
RADIATION THERAPY	CPT	77293	RESPIRATOR MOTION MGMT SIMUL
RADIATION THERAPY	CPT	77295	3-D RADIOTHERAPY PLAN

RADIATION THERAPY	CPT	77299	RADIATION THERAPY PLANNING
RADIATION THERAPY	CPT	77300	RADIATION THERAPY DOSE PLAN
RADIATION THERAPY	CPT	77301	RADIOTHERAPY DOSE PLAN IMRT
RADIATION THERAPY	CPT	77305	TELETX ISODOSE PLAN SIMPLE
RADIATION THERAPY	CPT	77306	TELETHX ISODOSE PLAN SIMPLE
RADIATION THERAPY	CPT	77307	TELETHX ISODOSE PLAN CPLX
RADIATION THERAPY	CPT	77310	TELETX ISODOSE PLAN INTERMED
RADIATION THERAPY	CPT	77315	TELETX ISODOSE PLAN COMPLEX
RADIATION THERAPY	CPT	77316	BRACHYTX ISODOSE PLAN SIMPLE
RADIATION THERAPY	CPT	77317	BRACHYTX ISODOSE INTERMED
RADIATION THERAPY	CPT	77318	BRACHYTX ISODOSE COMPLEX
RADIATION THERAPY	CPT	77321	SPECIAL TELETX PORT PLAN
RADIATION THERAPY	CPT	77326	BRACHYTX ISODOSE CALC SIMP
RADIATION THERAPY	CPT	77327	BRACHYTX ISODOSE CALC INTERM
RADIATION THERAPY	CPT	77328	BRACHYTX ISODOSE PLAN COMPL
RADIATION THERAPY	CPT	77331	SPECIAL RADIATION DOSIMETRY
RADIATION THERAPY	CPT	77332	RADIATION TREATMENT AID(S)
RADIATION THERAPY	CPT	77333	RADIATION TREATMENT AID(S)
RADIATION THERAPY	CPT	77334	RADIATION TREATMENT AID(S)
RADIATION THERAPY	CPT	77336	RADIATION PHYSICS CONSULT
RADIATION THERAPY	CPT	77338	DESIGN MLC DEVICE FOR IMRT
RADIATION THERAPY	CPT	77370	RADIATION PHYSICS CONSULT
RADIATION THERAPY	CPT	77371	SRS MULTISOURCE
RADIATION THERAPY	CPT	77372	SRS LINEAR BASED
RADIATION THERAPY	CPT	77373	SBRT DELIVERY
RADIATION THERAPY	CPT	77385	NTSTY MODUL RAD TX DLVR SMPL
RADIATION THERAPY	CPT	77386	NTSTY MODUL RAD TX DLVR CPLX
RADIATION THERAPY	CPT	77387	GUIDANCE FOR RADIAJ TX DLVR
RADIATION THERAPY	CPT	77399	EXTERNAL RADIATION DOSIMETRY
RADIATION THERAPY	CPT	77401	RADIATION TREATMENT DELIVERY
RADIATION THERAPY	CPT	77402	RADIATION TREATMENT DELIVERY
RADIATION THERAPY	CPT	77403	RADIATION TREATMENT DELIVERY
RADIATION THERAPY	CPT	77404	RADIATION TREATMENT DELIVERY
RADIATION THERAPY	CPT	77406	RADIATION TREATMENT DELIVERY
RADIATION THERAPY	CPT	77407	RADIATION TREATMENT DELIVERY
RADIATION THERAPY	CPT	77408	RADIATION TREATMENT DELIVERY
RADIATION THERAPY	CPT	77409	RADIATION TREATMENT DELIVERY
RADIATION THERAPY	CPT	77411	RADIATION TREATMENT DELIVERY
RADIATION THERAPY	CPT	77412	RADIATION TREATMENT DELIVERY
RADIATION THERAPY	CPT	77413	RADIATION TREATMENT DELIVERY
RADIATION THERAPY	CPT	77414	RADIATION TREATMENT DELIVERY
RADIATION THERAPY	CPT	77416	RADIATION TREATMENT DELIVERY
RADIATION THERAPY	CPT	77417	RADIOLOGY PORT FILM(S)

RADIATION THERAPY	CPT	77418	RADIATION TX DELIVERY IMRT
RADIATION THERAPY	CPT	77421	STEREOSCOPIC X-RAY GUIDANCE
RADIATION THERAPY	CPT	77422	NEUTRON BEAM TX SIMPLE
RADIATION THERAPY	CPT	77423	NEUTRON BEAM TX COMPLEX
RADIATION THERAPY	CPT	77424	IO RAD TX DELIVERY BY X-RAY
RADIATION THERAPY	CPT	77425	IO RAD TX DELIVER BY ELCTRNS
RADIATION THERAPY	CPT	77427	RADIATION TX MANAGEMENT X5
RADIATION THERAPY	CPT	77431	RADIATION THERAPY MANAGEMENT
RADIATION THERAPY	CPT	77432	STEREOTACTIC RADIATION TRMT
RADIATION THERAPY	CPT	77435	SBRT MANAGEMENT
RADIATION THERAPY	CPT	77469	IO RADIATION TX MANAGEMENT
RADIATION THERAPY	CPT	77470	SPECIAL RADIATION TREATMENT
RADIATION THERAPY	CPT	77499	RADIATION THERAPY MANAGEMENT
RADIATION THERAPY	CPT	77520	PROTON TRMT SIMPLE W/O COMP
RADIATION THERAPY	CPT	77522	PROTON TRMT SIMPLE W/COMP
RADIATION THERAPY	CPT	77523	PROTON TRMT INTERMEDIATE
RADIATION THERAPY	CPT	77525	PROTON TREATMENT COMPLEX
RADIATION THERAPY	CPT	77600	HYPERTHERMIA TREATMENT
RADIATION THERAPY	CPT	77605	HYPERTHERMIA TREATMENT
RADIATION THERAPY	CPT	77610	HYPERTHERMIA TREATMENT
RADIATION THERAPY	CPT	77615	HYPERTHERMIA TREATMENT
RADIATION THERAPY	CPT	77620	HYPERTHERMIA TREATMENT
RADIATION THERAPY	CPT	77750	INFUSE RADIOACTIVE MATERIALS
RADIATION THERAPY	CPT	77761	APPLY INTRCAV RADIAT SIMPLE
RADIATION THERAPY	CPT	77762	APPLY INTRCAV RADIAT INTERM
RADIATION THERAPY	CPT	77763	APPLY INTRCAV RADIAT COMPL
RADIATION THERAPY	CPT	77767	HIGH INTENSITY BRACHYTHERAPY 1 CHANNEL
RADIATION THERAPY	CPT	77768	HIGH INTENSITY BRACHYTHERAPY 2/> CHANNEL
RADIATION THERAPY	CPT	77770	HDR BRACHYTX 1 CHANNEL
RADIATION THERAPY	CPT	77771	HDR BRACHYTX 2-12 CHANNEL
RADIATION THERAPY	CPT	77772	HDR BRACHYTX OVER 12 CHAN
RADIATION THERAPY	CPT	77776	APPLY INTERSTIT RADIAT SIMPL
RADIATION THERAPY	CPT	77777	APPLY INTERSTIT RADIAT INTER
RADIATION THERAPY	CPT	77778	APPLY INTERSTIT RADIAT COMPL
RADIATION THERAPY	CPT	77785	HDR BRACHYTX 1 CHANNEL
RADIATION THERAPY	CPT	77786	HDR BRACHYTX 2-12 CHANNEL
RADIATION THERAPY	CPT	77787	HDR BRACHYTX OVER 12 CHAN
RADIATION THERAPY	CPT	77789	APPLY SURFACE RADIATION
RADIATION THERAPY	CPT	77790	RADIATION HANDLING
RADIATION THERAPY	CPT	77799	RADIUM/RADIOISOTOPE THERAPY
RADIATION THERAPY	CPT	55860	EXPOSURE OF PROSTATE FOR INSERTION OF RADIOACTIVE SUBSTANCE
RADIATION THERAPY	CPT	55862	EXPOSURE OF PROSTATE FOR INSERTION OF RADIOACTIVE SUBSTANCE, WITH LYMPH NODE BIOPSY

RADIATION THERAPY	CPT	55865	EXPOSURE OF PROSTATE FOR INSERTION OF RADIOACTIVE SUBSTANCE, WITH BILATERAL PELVIC LYMPHADENECTOMY
RADIATION THERAPY	HCPCS	G6001	ECHO GUIDANCE RADIOTHERAPY
RADIATION THERAPY	HCPCS	G6002	STEREOSCOPIC X-RAY GUIDANCE
RADIATION THERAPY	HCPCS	G6003	RADIATION TREATMENT DELIVERY
RADIATION THERAPY	HCPCS	G6004	RADIATION TREATMENT DELIVERY
RADIATION THERAPY	HCPCS	G6005	RADIATION TREATMENT DELIVERY
RADIATION THERAPY	HCPCS	G6006	RADIATION TREATMENT DELIVERY
RADIATION THERAPY	HCPCS	G6007	RADIATION TREATMENT DELIVERY
RADIATION THERAPY	HCPCS	G6008	RADIATION TREATMENT DELIVERY
RADIATION THERAPY	HCPCS	G6009	RADIATION TREATMENT DELIVERY
RADIATION THERAPY	HCPCS	G6010	RADIATION TREATMENT DELIVERY
RADIATION THERAPY	HCPCS	G6011	RADIATION TREATMENT DELIVERY
RADIATION THERAPY	HCPCS	G6012	RADIATION TREATMENT DELIVERY
RADIATION THERAPY	HCPCS	G6013	RADIATION TREATMENT DELIVERY
RADIATION THERAPY	HCPCS	G6014	RADIATION TREATMENT DELIVERY
RADIATION THERAPY	HCPCS	G6015	RADIATION TX DELIVERY IMRT
RADIATION THERAPY	HCPCS	G6016	DELIVERY COMP IMRT
RADIATION THERAPY	HCPCS	G6017	INTRAFRACTION TRACK MOTION
RADIATION THERAPY	HCPCS	0073T	DELIVERY COMP IMRT
RADIATION THERAPY	HCPCS	0197T	INTRAFRACTION TRACK MOTION

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