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August 31, 2017

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LUGPA Responses to the PTAC Preliminary Review Team's Questions on
LUGPA APM for Initial Therapy of Newly Diagnosed Patients with Organ-
Confined Prostate Cancer ("LUGPA APM") Submitted by LUGPA

Dear ASPE/PTAC Staff,

On behalf of LUGPA, we thank the PTAC for the thoughtful review of the
LUGPA APM. Below please find responses to the questions posed in the e-mail of
August 17, 2017.

1. *The PRT would like to better understand how care delivery and payment under the LUGPA APM would differ from the Oncology Care Model as well as fee-for-service Medicare. A table (with the LUGPA APM, OCM, and FFS as the three column headings) highlighting key areas of difference would be helpful.*

Response: Below is a table comparing key parameters of the LUGPA APM with OCM and Medicare fee-for-service (FFS). While both OCM and the LUGPA APM are designed to reduce expenditures and improve the quality of care for beneficiaries with prostate cancer (and, in the case of OCM, other types of cancer), we do not anticipate substantial overlap in the beneficiaries enrolled in the LUGPA APM and OCM. This is because the LUGPA APM will enroll beneficiaries with organ-confined prostate cancer while many OCM beneficiaries with prostate cancer are receiving androgen deprivation therapy or other lines of approved chemotherapy for metastatic disease:



Category	LUGPA APM	OCM	Medicare FFS
Patient Population	Beneficiaries diagnosed with low-risk organ-confined prostate cancer	Beneficiaries diagnosed with cancer, including prostate cancer, receiving chemotherapy	All Medicare FFS beneficiaries
Overarching incentive	Provide high-value care by encouraging appropriate use of active surveillance (AS) and shared decision making, reducing total cost of care and improving quality	Provide high-value care by reducing total cost of care and improving quality	FFS, which only compensates physicians for use of active intervention (AI) to treat prostate cancer
Episode Initiation	Prostate biopsy and diagnosis of prostate cancer	Initiation of chemotherapy and cancer diagnosis	NA
Episode duration	12 months	6 months	NA
Allows multiple episodes	Initial episode after initial diagnosis followed by subsequent episode. Only initial episodes included in performance-based payment calculation	Yes. All episodes for certain reconciliation eligible cancer types are included in performance-based payment calculations	NA
Services included in episode	All services, including care management payment	All services, including payment for enhanced oncology services	NA
Payment Model	\$75 monthly care management fee for enhanced surveillance services in AS episodes and retrospective performance-based payment for all initial episodes	\$160 monthly payment for enhanced oncology services and retrospective performance based payment for reconciliation eligible episodes	No payment for enhanced services or shared savings payments
Tie to Quality	Shared savings or losses tied to quality performance	Performance-based payment linked to quality performance	NA

Table 1: Comparison of LUGPA APM with OCM and Medicare FFS

2. Please provide an example of how you expect the model to be experienced by (a) a patient and (b) a urologist.

Response: We expect that patients enrolled in the model will still be able to access the physicians they choose and will still receive regular Medicare fee-for-service bills. They will additionally have access to enhanced opportunities for shared decision making via the novel

tools proposed in the APM. Beneficiaries will be notified of their enrollment in the LUGPA APM, similar to other CMS initiatives. Beneficiary cost sharing burden will not change, and there will be no cost sharing for the \$75 monthly care management fee, similar to OCM. The LUGPA APM will also improve the quality of care that beneficiaries receive and the inclusion of a modified version of NQF 2962 as a quality measure will engage beneficiaries through increased emphasis on shared decision making regarding the choice of AS or AI.

The practitioner will gain access to resources which will support monitoring the patients on a longitudinal basis to ensure that the proper patients are able to remain on AS. The practitioner will also be provided with new incentives to manage total cost and quality of care for beneficiaries in the model - these incentives will result in lower costs and improved quality of care for men diagnosed with prostate cancer.

3. *Provide a description of the type of shared decision making that might be incentivized in the model versus under current practice, with particular attention to patients that may want to “get the cancer out.”*

Response: Patients newly diagnosed with serious illness have emotional distress associated with their treatment; data shows that this is particularly true with prostate cancer.¹ This anxiety dovetails with the incentives associated with the fee-for-service model, which preferentially compensates physicians not only for surgical removal (“get the cancer out”) but other forms of intervention as well. The counseling that is necessary to have patients understand the natural history of disease and assure that patients are engaged in the decision making process is precisely what this APM is designed to foster. By including a modified version of NQF 2962 as a quality measure, beneficiaries will be engaged by providers in shared decision making, and beneficiary responses to the four questions about the shared decision making process (shown below) will be linked to the performance-based payment calculations in the LUGPA APM:

- a. 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)?
 - b. How much did you and your health care providers talk with you about the reasons for prostate cancer treatments like prostatectomy or radiation therapy?
 - c. How much did you and your health care providers talk with you about the reasons for not actively treating your prostate cancer (active surveillance)?
 - d. 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?
4. *Were any unintended consequences to this model considered (e.g., increasing the number of unnecessary biopsies), and how would they be addressed?*

Response: We have proposed safeguards against practitioners “gaming” the APM by ensuring that appropriate patients on AS remain on AS. Given the recent release by the United States Preventative Services Task Force (USPSTF) of its draft updated recommendation regarding prostate cancer screening (issuing a grade “C” recommendation for prostate cancer screening for

¹ Orom H, Nelson CJ, Underwood W, et al. Factors associated with emotional distress in newly diagnosed prostate cancer patients. *Psycho-Oncology*. 2015 Nov 1;24(11):1416-22.

men aged 50-69),² we can anticipate that the number of necessary biopsies will increase; implementation of this APM is thus timely and addresses issues of clinical necessity. Moreover the decision of who to biopsy is fairly well prescribed.³

We also considered whether the model would create incentives to actively surveil inappropriate beneficiaries or to continue surveillance past the point of clinical appropriateness. The model addresses these potential adverse incentives in several ways. First, the risk adjustment inherent to the target price methodology is based on HCC scores of AS beneficiaries and the types of AI used in the performance period so that the target price is reflective of each APM entity's underlying patient population. The risk adjustment also guards against irregular treatment patterns such as placing a beneficiary on androgen deprivation therapy for a period of time before actively intervening with surgery or radiation at a later time period. Second, the requirement to submit information on histopathological grade and stage, PSA results, molecular/genetic biomarkers if applicable, and an attestation regarding beneficiary health status will ensure the appropriateness of beneficiaries being actively surveilled. Third, we propose monitoring the frequency of AI immediately following an initial 12-month episode. APM entities that are outliers on the monitoring measure will run the risk of corrective actions that CMS can impose.

5. *Medicare beneficiaries often have multiple comorbidities. The proposal indicates that interoperability of EHRs is not necessary under the model. How do you anticipate information sharing between urologists and primary care physicians will take place? Is the model expected to change current practice? If so, how and in what ways?*

Response: As urologists are the principle caregivers for those with organ-confined prostate cancer, there often is overlap in the provision of primary care services in these patients. We anticipate that the care coordination fee will facilitate and thus increase communication between urologists and primary care physicians. Resources provided by the care management fee can be used to develop plans to improve communication and develop stronger relationships with primary care physicians and to track progress even in the absence of interoperable EHRs. Additionally, by including PQRS 265 as a quality measure that is tied to the performance-based payment calculations, participating urologists will be directly measured on communicating biopsy results with primary care physicians. We have deliberately set a relatively high performance target of 80% for the measure, 10 percentage points above the 2015 national rate of 70%.⁴ rough enhanced care coordination and the other parameters of the LUGPA APM, we anticipate that the proportion of patients receiving AS will increase from historical baselines, and those patients who opt for AS will be able to remain on AS for a longer period of time.

² USPSTF 2017 draft proposal regarding prostate cancer screening. Accessed at: <https://www.uspreventiveservicestaskforce.org/Page/Document/draft-recommendation-statement/prostate-cancer-screening>

³ See, for example, National Comprehensive Cancer Network (NCCN) or the American Urological Association guidelines for diagnosis of prostate cancer. Available at: https://www.nccn.org/professionals/physician_gls/PDF/prostate.pdf and <http://www.auanet.org/documents/education/clinical-guidance/Prostate-Cancer-Detection.pdf>, respectively; Accessed 8/29/2017.

⁴ Table 2 at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/Downloads/PY2016-Prior-Year-Benchmarks.pdf>. Accessed 8/22/2017.

6. *Further describe the enhanced services that the \$75 monthly care management fee would support. Would biopsies and office visits be covered by the fee or would they continue to be paid on a fee-for-service basis?*

Response: Biopsies and office visits would continue to be paid FFS. However, because this is a total cost of care model, for the initial 12 month period, total expenditures will be reconciled against historical benchmarks as described in the proposal. Subsequently, the care management fee would be for just that; any services beyond care management would be compensated on a fee for service basis. As stated in the proposal, we believe that this fee will cover a range of services that are not currently reimbursed, including:

- Tracking AS beneficiaries to ensure compliance throughout episodes
- Tracking lab results longitudinally in a consistent format to reduce overutilization of PSA testing, which is important in light of the aforementioned USPSTF recommendation
- Continually educating beneficiaries about disease progression
- Social services and coordinating care across practitioners
- Reviewing/revising the care plan

7. *Is there a limit on the number of AS episodes for a given patient?*

Response: No. It is hoped that patients on AS could be managed with AS indefinitely; the resources required to track these patients do not decrease with time – if anything, care management becomes more important the longer a patient is from the initial diagnosis in order to effectively monitor the patient’s clinical status and manage their expectations. We also proposed that beneficiaries would be required to complete an additional shared decision making survey (modified NQF 2962) at the initiation of each subsequent AS episode as a mechanism to ensure that the beneficiary and participating physician have aligned treatment goals.

8. *What would happen under the model if the patient sought a second opinion outside of the practice participating in the model?*

Response: Patients are entitled to be counseled by whichever clinician they desire in the process of making their best decision prior to therapy and ultimately choose care by the provider and site of service of their choosing. The APM does not restrict this ability. Even if a beneficiary ultimately receives an active intervention from another urology practice, the APM entity that performed the initial biopsy would be responsible for the beneficiary’s total cost of care and quality of care in the initial episode. We believe that this prospective attribution methodology, while not without drawbacks, will afford APM entities the certainty of knowing their attributed beneficiary population. This is in contrast to other CMS initiatives, like OCM, which uses a retrospective attribution methodology, under which practices do not know which episodes accrue to them until several months after the end of a performance period. In addition, we believe that this attribution methodology will serve as a safeguard against “cherry-picking” patients with the highest potential for incentive payments.

9. *The episode begins when a beneficiary is diagnosed with localized prostate cancer after biopsy. Did the submitters consider addressing upstream problems (i.e., inappropriate PSA testing)?*

Response: As with prostate biopsy, there are well prescribed guidelines for performing PSA testing, and we expect that PSA testing will increase in light of the USPSTF's recent recommendation. The model has safeguards to ensure the appropriateness of beneficiaries enrolled in the model, namely the submission of information on histopathological grade and stage, PSA results, molecular/genetic biomarkers if applicable, and an attestation regarding beneficiary health status will ensure the appropriateness of beneficiaries being actively surveilled.

10. *Participants in the model are responsible for total cost of care. For the patient population targeted in this model, do you have a sense of what proportion of non-urology spending leads to total cost? Describe how urologists would manage this spending?*

Response: We find approximately 10% of spending in Active Surveillance episodes to be urology-related and approximately 71% of spending in Active Intervention episodes to be urology-related. We define urology related as claims that include one of the following:

- A prostate cancer ICD-9 or ICD-10 diagnosis code (ICD-9: 185, ICD-10: C61)
- A provider specialty code of 34, corresponding to urology
- A prostate cancer-specific active intervention⁵

We anticipate that the managing urologist will be able to influence non-urology related spending by coordinating with primary care physicians and other specialists, which is part of the purpose of the monthly care management fee.

11. *The proposal indicates that to date few urology practices have participated in APMs. From your perspective, what are the key impediments to urologists participating in existing APMs?*

Response: There are simply not enough clinically applicable APMs to allow for participation by the general urology community. With limited urological spending in ACOs, it is not always financially worthwhile for urologists to participate in ACOs, even in Next Generation ACOs that are likely to achieve qualified participant status.⁶ Practices interested in participation often have difficulty engaging with and remaining in ACOs. These factors contribute to CMS's estimate that only 88 urologists, out of more than 11,000 urologists who bill Medicare FFS, would be qualified participants in Advanced APMs in 2017.⁷

Urologist participation is also low in OCM, likely because of the requirements for OCM episodes. As noted above, beneficiaries do not initiate OCM episodes until the initiation of chemotherapy. Most beneficiaries with prostate cancer in OCM are likely to be receiving

⁵ Prostate cancer active intervention codes can be found on page 49 of the PTAC proposal: <https://aspe.hhs.gov/system/files/pdf/255906/LUGPAAPM.pdf>

⁶ Overall, Medicare Part B payments to urologists represented \$1.7 billion out of a total of \$104 billion in Medicare Part B physician/supplier payments in 2016. <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareFeeforSvcPartsAB/Downloads/Specialty2016.pdf>. Accessed 8/23/2017.

⁷ Quality Payment Program Final Rule Table 58 (81 FR 214 77520).

androgen deprivation therapy (ADT) to treat metastatic disease. Data suggests that these patients typically make up a small portion of a urologist's patients.⁸ As such, the burden of participation in OCM was likely not enough to offset the potential gains from participation for most urology practices.

12. The proposal indicates that participation by smaller practices will be facilitated by variations within the APM with lessened levels of financial risk. Do you have a sense of the proportion of urologists that are in small or rural practices vs. larger practices?

Response: Yes, the American Urological Association (AUA) publishes figures in its annual census. In 2016, 90% of urologists practiced in metropolitan areas (population greater than or equal to 50,000), 7.8% practiced in micropolitan areas (population between 10,000 and 49,999), 1.8% practiced in small towns (population 2,500 – 9,999), and 0.5% practiced in rural areas (population below 2,500).⁹

The annual census also contains information on the size of urology practices. In 2016, 15.9% of urologists practiced as solo practitioners, 26.3% in practices with 2-4 urologists, 23.7% in practices with 5-9 urologists, 16.4% in practices with 10-15 urologists, and 17.8 in practices with more than 15 urologists.¹⁰

13. The PRT is interested in knowing where the proposed quality measures are in terms of development, testing, and endorsement.

Response: These measures have been developed in theory and require formal testing by CMS in the APM. The APM (and by extension, the measures within) have been accepted by the three largest urology organizations in the United States (AUA, AACU, and LUGPA). With regards to specific measures, the shared decision making measure is a modification of NQF 2962, which has already been endorsed. The shared decision making measure will be applied to a broader patient population, but the core content remains intact and will be tested in the APM. The time

⁸ The Physician and Other Supplier Data CY 2015 suggests that the average urologist in the United States treats approximately 11 unique Medicare beneficiaries with ADT. This is calculated by identifying unique beneficiary counts by urologist in the United States for all men who received Part B drugs associated with CPT codes J3315 (Injection, triptorelin pamoate, 3.75 mg), J9155 (Injection, degarelix, 1 mg), J9202 (Goserelin acetate implant, per 3.6 mg), J9217 (Leuprolide acetate (for depot suspension), 7.5 mg), J9225 (Histrelin implant (vantas), 50 mg) in 2015 and dividing this by all urologists who provided services to Medicare beneficiaries that year. It should be noted that part D drugs used to treat advanced prostate cancer (ezalutamide and abiraterone) are used to treat castrate resistant prostate cancer – these agents are only indicated subsequent to and in conjunction with the Part B medications used for ADT captured above. However, calculations utilizing the Medicare PUF data has the following caveats: 1) beneficiary counts for each HCPCS code and physician are suppressed in the PUF if the count is below 11. This may artificially lower the average number of patients treated with ADT per urologists; conversely 2) any beneficiary who receives more than one of the Part B ADTs in a year (which could occur if a patient switches from one medication to another) would be double counted, which would raise the average ADT beneficiary count/urologist assuming that the treating physician's beneficiary counts were not suppressed. Medicare 2015 PUF data accessed at: <https://data.cms.gov/Medicare-Physician-Supplier/Medicare-Physician-and-Other-Supplier-National-Pro/p3uv-6dv4/data>.

⁹ Table 1-5 of *2016 State of the Urology Workforce and Practice in the United States*. Available at: <http://www.auanet.org/Documents/research/census/AUA-Census-2016-State-of-the-Urology-Workforce-and-Practice-in-the-United-States.pdf>. Accessed 8/22/2017.

¹⁰ Table 4-1 of *2016 State of the Urology Workforce and Practice in the United States*. Available at: <http://www.auanet.org/Documents/research/census/AUA-Census-2016-State-of-the-Urology-Workforce-and-Practice-in-the-United-States.pdf>. Accessed 8/22/2017.

on AS measure was developed for the LUGPA APM, and we anticipate that it would be tested in the model prior to receiving endorsement from an entity such as NQF.

14. The PRT is also interested in better understanding the time on AS as a quality measure. More information on the measures (e.g., specifications) would help the PRT better understand the rationale for the measure and the incentives it creates.

Response: we have not drafted formal specifications for the measure. The proposal provides details on the non-payable G-Codes that would be created for the measure and how it would be calculated. Specifically, there would be three non-payable G-Codes used to describe reasons beneficiaries left AS:

- Beneficiary choice
- Lack of compliance with AS protocol
- Disease progression

The calculation of the measure would be straightforward:

- Denominator – number of beneficiaries in initial or subsequent AS episodes
- Numerator – sum of number of months beneficiaries in the denominator were on AS. The number of months would be measured from the beginning of an initial episode to the time of death or AI
- Risk adjustment – if necessary, the measure could be risk adjusted to account for beneficiaries in the low, medium, and high risk AS subcategories. This would be accomplished by calculating the time on AS measure for each subcategory and then calculating a weighted average of the three subcategories using the number of patients in each subcategory as weights.

There is not a current mechanism to track the duration of AS, and we believe that this measure fills that void. We believe that this measure will allow APM entities to better track beneficiaries on AS and that there would be an incentive to extend the duration of AS when clinically appropriate. Moreover, non-participating urologists could use the G-Codes, allowing CMS to track the duration of AS nationally.

15. The proposal states, “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.” Please describe the rationale for stratification by these three settings.

Response: Practitioners in each of these settings are likely to experience very different patient mixes and historical patterns of AS and types of AI. Additionally, these settings are associated with different rates of expenditures, tied to both CMS payment rates and the types of AI used in cases, as well as different financial structures for the physicians. Thus, our proposal to stratify by these three settings is designed to ensure that target prices are set as accurately as possible to ensure a proper comparison of actual expenditures against the targets in the performance-based payment calculations.

Once again, we thank the PTAC for considering the LUGPA APM. We look forward to continuing to work together to develop value-based payment models that align physician incentives with clinical best practices that incorporate shared decision making. Please do not hesitate to contact us with any additional questions in advance of the public meeting regarding this proposal.

Respectfully submitted,



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Deepak A. Kapoor, M.D.
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November 8, 2017

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Re: Follow-up to LUGPA-PRT Discussion of 10/27/2017

Dear ASPE/PTAC Staff,

We thank the Preliminary Review Team for taking the time to further review with us details of the LUGPA APM for Initial Therapy of Newly Diagnosed Patients with Organ-Confined Prostate Cancer (“LUGPA APM”). Below please find a brief summary of some of the questions discussed during the conversation of October 27, 2017.

1. *Will any of the monthly care management fee be shared with PCPs? If so, how?*

It is not the intention of the model to proscribe how the care management fee is to be divided amongst participants of the care team. As further delineated in (4) below, it is anticipated that there will be costs associated with the services necessary to continue surveillance; the care management fee will be used to offset these costs. That said, the care management fee is intended to cover costs specifically associated with active surveillance and care coordination related to prostate cancer; it is not intended to function as a substitute for the CCM program to manage patient co-morbidities.

2. *The PRT is interested in hearing LUGPA’s perspective on why rates of AS vs. AI are significantly higher in academic vs. community practices and potential reasons for this difference.*

The development of AS protocols at academic institutions has largely been under protocol. These protocols are typically supervised and monitored by either dedicated personnel (i.e. clinical research coordinators) or by clinicians who are allotted time by their institutions to conduct research. These resources typically do not exist in a community practice; as such, it is to be expected that not only the adoption of AS but the adherence to AS protocols is more challenging for community physicians. For example, a review of 16 practices participating in the Michigan Urological Surgery Improvement Collaborative (MUSIC) found that compliance with NCCN recommendations varied from approximately 10% to more than 60% by practice, with median compliance rates only 26.5%.¹ Enabling

¹ Luckenbaugh AN, Aufferberg GB, Hawken SR, et al. Variation in Guideline Concordant Active Surveillance Followup in Diverse Urology Practices. J Urol. 2017 Mar;197(3 Pt 1):621-626.



practices to have the resources to adequately monitor and coordinate care for their AS patients is precisely the intent of the care management fee; we anticipate that this would substantially lessen variability of adoptions of AS based on site of service.

3. *The proposed model places responsibility on the urologist total cost of care in this model, which is significantly different than their current role. How do they see this working?*

The determination to use a total cost of care model was based on an analysis of the treatment-specific costs relative to overall costs for patients newly diagnosed with prostate cancer. To determine costs, we identified patients who received either AS or AI in Medicare 5% beneficiary sample data in 2011-2015 using the methodology described in the LUGPA APM submission. We then mapped all service utilization within these episodes to various cost categories. Claims were allocated to a service line based on ICD-9 procedure codes, CPT codes, HCPCs codes, revenue codes, place of service codes and DRGs. Services were flagged as "urology-related" if coded in any position with a '185' or 'C61' diagnosis code, coded with specialty code 34 (urology), or service code was for a prostate-cancer-specific procedure, regardless of specialty. Below is a summary of the analysis:

Modality	Episodes	Treatment Cost (\$)	Total Cost (\$)	% Treatment Related
AS	1,022	1,253	12,658	9.9%
AI	3,460	23,169	32,788	70.7%

Table 1: Treat and Total Costs by Treatment Modality

The national distribution of the modalities of therapy at baseline revealed that 23% of patients received AS while 77% of patients received AI. A weighted average of treatment costs vs. total cost of care reveals that 56.7% ($0.23 \times 9.9\% + 0.77 \times 70.7\%$) of the patient's total cost of care at baseline is directly referable to treatment of prostate cancer. As such, since the majority of costs were referable to costs in the purview of the prostate cancer care management team, the total cost of care model is appropriate.

4. *The PRT is interested in further details on AS-related costs that necessitate the \$75 monthly PMPM payment.*

We estimated the annual cost to provide enhanced services to surveil appropriate beneficiaries with low-risk prostate cancer by identifying professionals who could perform these enhanced services. Estimates are displayed for three scenarios that vary by the number of hours that each professional would spend on a specific activity. The cost is determined by multiplying the hourly wage (including fringe benefits) of the professional performing the activity by the estimated number of hours it would take to perform that activity under low, medium and high number of hours. The salary range and fringe benefits data was obtained from the Bureau of Labor Statistics Occupational Employment Statistics of May 2016² and the Employer Costs for Employee Compensation report of June 2017.³ Compensation for urologists was determined from the Medscape Physician Compensation report of 2017.⁴ For the purpose of this analysis urologist compensation was taken to include costs of fringe benefits.⁵ Results are summarized in the table below:

² Bureau of Labor Statistics Occupational Employment Statistics of May 2016. Accessed at: <https://www.bls.gov/oes/special.requests/oesml6nat.zip>.

³ Bureau of Labor Statistics Employer Costs for Employee Compensation report of June 2017. Accessed at: <https://www.bls.gov/news.release/pdf/ecec.pdf>

⁴ Medscape Physician Compensation Report 2017. Accessed at: <https://www.medscape.com/slideshow/compensation-2017-overview-6008547#4>

⁵ Compensation data for physicians in community practice typically does not include fringe benefits. As most urologists are self-employed or part of pass-through professional entities (whether professional corporations or limited liability ventures) costs of items such as health insurance and retirement are typically at individual discretion and borne by the practitioner.

Activity	Professional	Pre-Load Hourly Wage	Fringe Benefit and Other Loads	Post-Load Hourly Wage	Annual Hours Estimate			Annual Total Cost Estimate		
					Low	Medium	High	Low	Medium	High
Tracking AS beneficiaries to ensure compliance throughout episodes	Registered Nurse	\$34.70	46.40%	\$50.81	1	1.5	2	\$50.81	\$76.22	\$101.62
Tracking lab results longitudinally in a consistent format to reduce overutilization of PSA testing, which is important in light of the aforementioned HSPSTF recommendation	Nurse Practitioner	\$50.30	46.40%	\$73.65	1	1.5	2	\$73.65	\$110.48	\$147.30
Continually educating beneficiaries about disease progression	Urologist	\$192.31	-	\$192.31	1	2	3	\$192.31	\$384.62	\$576.93
Care coordination with other providers and social services	Care Navigator	\$26.69	46.40%	\$39.08	2	4	6	\$78.16	\$156.32	\$234.48
Reviewing / revising the care plan	Urologist	\$192.31	-	\$192.31	0.5	1	2	\$96.16	\$192.31	\$384.62
Total					5.5	10	15	\$491.09	\$919.94	\$1,444.95

Table 2: Cost Determinants for Monthly Care Management Fee

For the purpose of the LUGPA APM model, the monthly management fee was based on the annual medium estimate divided by 12 and rounded to the nearest \$5.

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5. *How does the model handle the variability in current protocols for AS that currently exist, such as the definition of very low risk, low risk, etc., and when AS is no longer warranted?*

It is not the intent of the model to dictate clinical decision making. That said, we are aware that there is a distinct lack of consensus regarding what constitutes the most appropriate methodology to surveil appropriate patients; in part, this clinical uncertainty likely accounts for the variability seen nationally in surveillance rates that is reported in the LUGPA APM model and by others.^{6,7} Also concerning is that this variability is strongly influenced by socio-economic status; not only is AS more common in whites and in patients with higher socio-economic status,⁸ but adherence to AS has been shown to be lower in poorer communities.⁹ In addition to the direct patient benefits and cost savings, a secondary purpose of the APM is to create a methodology by which patients on AS can be more precisely identified and tracked; no such mechanism exists today. Indeed, merely determining which patients are on AS is at present laborious process of exclusion. We anticipate that if approved, this APM will by its very nature lead to greater consensus in best practices for surveillance pathways as practices seek to enhance clinical outcomes with optimal resource use.

Once again, we thank the PTAC for considering the LUGPA APM. We look forward to continuing to work together to develop value-based payment models that align physician incentives with clinical best practices that incorporate shared decision making. We look forward to being on the agenda for a public hearing as soon as the preliminary review team completes its evaluation. Please do not hesitate to contact us with any additional questions as you continue your review.

Respectfully submitted,



Neal D. Shore, M.D.
President



Deepak A. Kapoor, M.D.
Chairman, Health Policy

⁶ Hoffman KE, Niu J, Shen Y, et al. Physician variation in management of low-risk prostate cancer: a population-based cohort study. *JAMA Intern Med.* 2014 Sep;174(9):1450-9.

⁷ Cher ML, Dhir A, Auffenberg GB, et al. Appropriateness Criteria for Active Surveillance of Prostate Cancer. *J Urol.* 2017 Jan;197(1):67-74.

⁸ Filson CP, Schroeck FR, Ye Z, et al. Variation in use of active surveillance among men undergoing expectant treatment for early stage prostate cancer. *J Urol.* 2014 Jul;192(1):75-80.

⁹ 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.



LUGPA

Integrated Practices
Comprehensive Care

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

**Comments to PTAC
Regarding PRT Recommendations**

December 8, 2017

Submitted by:

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December 8, 2017

Physician – Focused Payment Model Technical Advisory Committee
c/o US DHHS Asst. Secretary for Planning and Evaluation Office of Health Policy
200 Independence Ave SW
Washington, DC 20201
PTAC@hhs.gov

Re: LUGPA Response to PRT Recommendation

Dear PTAC Committee Members,

We thank the Physician-Focused Payment Model Technical Advisory Committee (PTAC) and the Preliminary Review Team (PRT) for their review of the LUGPA APM. However, we disagree in the strongest possible terms with the PRT's rationale and recommendation. In this document we respond to several aspects of the PRT Report with which we disagree or take issue.

I. Overview

In the background section of the LUGPA APM submission, we wrote:

“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.”¹

During our October 27th teleconference with the PRT, a PRT member commented that this statement, was the single best sentence he had seen included in any submission up to that point, and a statement he could not agree with more. Despite this sentiment, and acknowledging that the LUGPA APM it aligns incentives with scientific advances, standards of care, and clinical best practice PRT is recommending rejection of this proposal.

In the concluding comments of the PRT report on the LUGPA APM, the PRT writes: “The PRT members all do believe this proposal would align incentives more in the direction of the evolving standard of care, but we also unanimously felt the net effect of this proposal is wholly unsatisfactory in the signal its favorable recommendation would send to other applicants and specialties. The PTAC process is unlikely to serve the Secretary, the Medicare program, or the country well if it comes to be seen as a device to be paid more for providing guideline-recommended care for patients. Therefore we recommend rejection, but if it is to be considered by CMS/CMMI, the PRT would strongly urge the payment model to be changed from historical practice performance based and into a more rigorous reference pricing model using control groups implementing current standard of

¹ LUGPA APM Proposal available at: <https://aspe.hhs.gov/system/files/pdf/255906/LUGPAAPM.pdf>.



care, (i.e., higher active surveillance usage rates) to develop spending targets or benchmarks against which total cost of care performance will be judged.”²

This comment contains three thoughts, which are counter to value-based care and the entirety of the MACRA legislation goals.

- First, while acknowledging that the LUGPA APM as designed will align incentives to increase the likelihood of appropriate active surveillance, the PRT throughout their review minimizes the value of the LUGPA APM by referring to the evolving standard of care and increases of active surveillance (AS) over time. By recommending rejection of the LUGPA APM, the PRT is hoping AS rates will increase rather than recommending a clear approach to support the transition to appropriate AS occurring sooner rather than later or perhaps ever – this is in spite of their acknowledgement that the rate of increase cannot be estimated under the current payment system. This is neither valid nor reasonable: while surveillance rates may gradually increase, there are potentially tens of thousands of men whose lives can be immediately improved while simultaneously saving hundreds of millions of program dollars by accelerating that process. The fact that at some point this APM will have fulfilled its purpose and can be phased out is not a reason not to adopt it; in fact, we look forward to that reality.
- Second, the PRT states that the Secretary of the Department of Health and Human Services, Medicare, and the country will not be served if the PTAC approves models that align financial incentives to furnish care in accordance with nationally recognized guidelines. We strenuously disagree with this notion. We believe that furnishing care in accordance with nationally recognized guidelines is a crucial component to delivering high-quality, patient-centered care and that aligning provider incentives with that goal is foundational to accomplishing it. Indeed, then Secretary of HHS Sylvia Burwell articulated in the *New England Journal of Medicine* that HHS would focus on three strategies to drive progress. Of these, Ms. Burwell states, “The first is incentives: a major thrust of our efforts is to create an environment in which hospitals, physicians, and other providers are rewarded for delivering high quality health care and have the resources and flexibility they need to do so.”³ Existing CMS APMs like the Oncology Care Model (OCM) follow through on that promise, creating incentives to promote support furnishing care in accordance with nationally recognized clinical guidelines. By aligning financial incentives with clinical best practices and providing resources to encourage provider and patient compliance, the LUGPA APM mirrors not only existing CMS programs, but the agencies stated goals.
- Third, the PRT comments that if CMS/CMMI considers the LUGPA APM, it urges the payment model be changed from a historical practice performance based model to a reference price based on practices who have high AS rates currently. We believe that this is counter to the payment models in existing CMS APMs, which often make explicit adjustments for each participant’s experience, even when prices are partially based on data from non-participants. We have proposed to calculate spending targets by blending historical practice performance with historical regional performance to balance incentives. Moreover, we proposed to increase the regional weight over time and to update the historical period used to set spending targets in later model years.

Below, we respond to specific aspects of the PRT report. We wish to thank Dr. Matthew Cooperberg, and Dr. David Penson, for providing letters articulating the current state of active surveillance for prostate cancer and an expert response to the PRT report, respectively. These physicians are undisputed thought leaders in the field of prostate cancer, active surveillance, and health policy and provide an independent perspective on the need for the LUGPA APM to be approved. We also thank the American Urological Association for their continued input and ongoing support for this proposal.

² LUGPA APM Preliminary Review Team Report to the Physician-Focused Payment Model Technical Advisory Committee available at: <https://aspe.hhs.gov/system/files/pdf/255906/LUGPAPreliminaryReviewTeamPRTReport.pdf>

³ Burwell SM. Setting value-based payment goals--HHS efforts to improve U.S. health care. *N Engl J Med*. 2015 Mar 5;372(10):897-9.

II. Number of Providers, Patients, and Costs (Criterion: Scope)

The PRT indicates that the LUGPA APM does not meet the criterion for Scope, a high priority criterion, and that the number of providers, patients and costs is relatively small. However, based on available data, at present, only 88 urologists nationwide will be qualified participants in APMs in 2017.⁴ Conversely, the LUGPA APM could expand participation in APMs to approximately 75% of the nation's urologists, or practically all of the 6,000 urologists who bill Medicare for prostate biopsies annually.⁵ Urologists have had limited opportunity for participation in APMs to date, and we believe that specialty-focused APMs urgently need to be implemented to provide specialists, including urologists, with viable opportunities for participation.

While the PRT cites estimates that 19,000 patients could be enrolled in the model annually, with savings of approximately \$28 million, this refers specifically to the data shown in Table 5 of the Financial Appendix of the LUGPA APM proposal which estimates \$28 million in reduced spending per year. This table incorporates both the change in spending for episodes and also the target price mechanism. The table also assumes that there are 19,000 episodes spread across participating practices, with 80% of practices increasing AS from 23% to 33% (good performance) and 20% of practices increasing AS only from 23 to 25% (bad performance). This results in an overall increase in AS from 23% to 31%, rather than 23% to 33%. Additionally, the decrease in AI accrues solely to reductions in beneficiaries receiving prostatectomy only (average cost per episode of \$20,805 after capping high episode expenditures) and radiation only (average cost per episode of \$34,410 after capping high episode expenditures). Lastly, the estimate also incorporates the \$900 care management fee for initial AS episodes, which equates to more than \$5 million.

There is also a \$91 million total saving within the LUGPA APM proposal in Table 6 of the Financial Appendix which may be misconstrued as the maximal possible savings possible in the APM. This is not so, rather this number represents a scenario where all 62,640 national annual episodes occur in the LUGPA APM, but the national level of AS only increases by 8%. Specifically this number is calculated by increasing the \$28 million spending reduction figure from Table 5 of the Financial Appendix (actually \$27.5 million) by the ratio of 62,640 national episodes to 19,000 episodes shown on Table 5. This equals \$90.7 million. Again, this understates the potential scope of the project, which is illustrated in the table below:

Intervention	Baseline			Potential		
	% Use	Average Episode Cost	Annual Cost (millions of dollars)	% Use	Average Episode Cost	Annual Cost (millions of dollars)
AS	22.8%	\$ 12,658	\$ 180.8	43.0%	\$ 12,658	\$ 340.9
AI	77.2%	\$ 32,788	\$ 1,585.6	57.0%	\$ 32,788	\$ 1,170.7
Total			\$ 1,766.3			\$ 1,511.6

Table 1: Potential Cost Reductions with Full Implementation of LUGPA APM

Under the baseline scenario, the total annual cost is \$1.766 billion, while total annual cost under the full potential scope of the project is only \$1.512 billion. As such, the full potential scope of the project is to reduce expenditures referable to the management of prostate cancer by over *\$254 million*, or an overall reduction of 14.4% in cost of care.⁶ Clearly, this savings is meaningful to both the Medicare program, as well as to beneficiaries, who would save over \$50 million annually in co-insurance costs.

⁴ Quality Payment Program Final Rule Table 58 (81 FR 214 77520).

⁵ 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

⁶The potential scope of the project is derived based on calculating the difference in total spending between the baseline scenario when 22.8% of the 62,640 national episodes use AS and the potential scenario where 43.0% of the 62,640 national episodes use AS. We assume that average episode cost remains constant in each category, and we have not incorporated the LUGPA APM 2% CMS discount or other aspects of the LUGPA APM payment methodology, such as capping expenditures in high cost episodes.

III. Care Coordination and Health IT (Criteria: Scope, Integration and Care Coordination, Health Information Technology)

We strenuously disagree with the PRT’s assertion that this proposal does not encourage care coordination and is unclear about non-urologists’ participation. We articulated to the PRT both in writing and during a teleconference that we deliberately did not proscribe how the LUGPA APM care management fee was to be distributed amongst the care management team because of the multiple models of care that exist nationally. We anticipate that these models of care vary based on geography, practice size, patient demographics and hospital affiliation. The following two tables illustrate the wide variation in practice patterns for urology nationwide:⁷

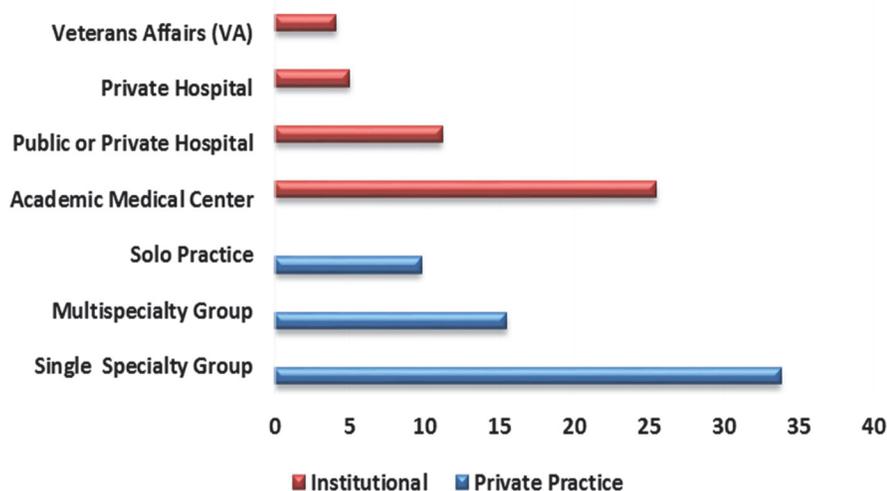
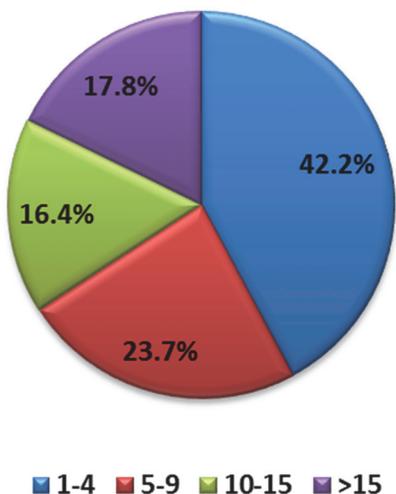


Figure 1: Urologists by Practice Size

Figure 2: Urology by Practice Type, % Total Urologists

As we can see, 42% of Urologists are in groups of 4 or less, and 16% are in multispecialty groups. So, for example, smaller practices could form care teams consisting of urologists, primary care providers, radiation oncologists and/or others involved in providing resources to optimize the care of the patients. These providers could develop novel gain share arrangements as part of a comprehensive care team approach which they would not likely be able to manage internally within the small practice, perhaps even forming virtual groups as permitted by CMS in 2018. Multispecialty groups could organize the care team across specialties and disciplines within the broader group, allocating resources and responsibilities in accordance with each group’s individual makeup. In these private practice scenarios, practices would also be able to incorporate aligned institutional partners for both resources and downstream gain share arrangements. Within institutional settings, providers in different departments would be able to create workflow strategies to enhance shared-decision making, again, drawing resources from and distributing revenues to those that were contributing to the process.

Each care team will need to individually allocate the care management fee based on actual work performed, and we believe that the LUGPA APM aligns incentives for care coordination and integration, with flexibility left to providers to determine the best care coordination model that will optimize patient care in the context of relevant patient characteristics, geographical and environmental aspects, and practice dynamics.

⁷ The State of the Urology Workforce and Practice in the United States 2016. Accessed at: <http://www.auanet.org/Documents/research/census/AUA-Census-2016-State-of-the-Urology-Workforce-and-Practice-in-the-United-States.pdf>

The PRT also suggests that the chronic care management (CCM) HCPCS codes could be used in lieu of the LUGPA APM care management fee. This would not be an appropriate mechanism to compensate for the needed enhanced AS services or to foster care coordination for several reasons.

First, as previously articulated to the PRT, the CCM may only be used once per month by a single provider, and there are specific eligibility requirements for CCM.⁸ CMS states that, “[P]atients with multiple (two or more) chronic conditions expected to last at least 12 months or until the death of the patient, and that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline are eligible for CCM services.” Many beneficiaries with organ-confined prostate cancer would not meet this criteria and thus not qualify for CCM payments.

Moreover, as outlined in our response to the PRT on their request for a budget build-up for the enhanced services needed for a successful AS program for appropriate patients, we believe that the CCM payments will not fully compensate for enhanced services that support the critically important goals of advancing surveillance utilization as well as achieving its compliance and adherence for quality care outcomes which are provided by the care management team. This team may be comprised of Registered Nurses, Nurse Practitioners, Urologists, Other Providers and Care Navigators. Moreover, the independent literature review provided to the PRT supports the position that there is a high level of patient anxiety after a diagnosis of prostate cancer⁹ as well as patient fatigue associated with compliance with surveillance protocols.¹⁰ At present, there is no mechanism to provide compensation for the unique resources needed to manage these issues, perhaps contributing to the high variability in guidelines adherence even amongst practices engaged in AS protocols.¹¹ As we articulated in our proposal and to the PRT, the LUGPA APM care management fee will support services necessary to maintain patients on surveillance protocols, including

- Tracking AS beneficiaries to ensure compliance throughout episodes
- Tracking lab results longitudinally in a consistent format to reduce overutilization of PSA testing
- Continually educating beneficiaries about disease progression
- Social services and coordinating care across practitioners
- Reviewing/revising the care plan

As there is a specific set of resources specifically needed to manage patients on AS protocols, the use of the CCM (even if possible) would preclude its use for any other disease state management. This could compromise the ability for primary care physicians to receive compensation for managing non-prostate cancer conditions including cardiovascular disease, chronic obstructive pulmonary disease, depression, diabetes or hypertension, to name but a few.

Finally, the CCM fee is not an appropriate mechanism to support care coordination with healthcare professionals outside an individual practice in that sharing this fee may well be illegal. In addition to Federal law, at least 33 states have unique regulations that govern payments between providers;¹² as primary care physicians may be the source of the initial referral to the specialist, sharing CCM fees could clearly constitute a violation of the letter if not the spirit of fee-splitting or anti-kickback statutes. The substantial penalties associated with even technical violations of these laws, would have a chilling effect on practices seeking to use this vehicle to coordinate services for patients on AS protocols.

⁸ CMS Chronic Care Management Services Fact Sheet, accessed at: <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/ChronicCareManagement.pdf>

⁹ Watts, S., Leydon, G.M., Arden-Close, E, et al. Managing distress in prostate cancer: a feasibility study into the design and evaluation of a novel psychological support intervention for managing distress in prostate cancer *Journal of Alternative and Complementary Medicine*, 2015 20(5), A61.

¹⁰ Choyke, PL., Loeb, S. Active surveillance of prostate cancer. *Oncology*, 2017 31(1), 67

¹¹ Luckenbaugh AN, Auffenberg GB, Hawken SR, et al. Variation in Guideline Concordant Active Surveillance Followup in Diverse Urology Practices. *J Urol*. 2017 Mar;197(3 Pt 1):621-626.

¹² Ustin M, Brass C. Examining Fee Splitting Statutes in the Context of Value-Based Healthcare. Accessed at: <https://www.manatt.com/Insights/Newsletters/Health-Update/Examining-Fee-Splitting-Statutes-in-the-Context-of>

Relating to Health Information Technology, the PRT concluded that the LUGPA APM does not encourage new uses of health information technology to inform care. This is not correct. While true that the LUGPA APM does not require uniquely proprietary technology to operationalize the APM nor to manage patients (a fact which we view as a strength by not creating an additional hurdle or cost to implementation), it does require that existing technologies, namely electronic health records (EHR) and care management tools be used more robustly. For example, as included in the LUGPA APM proposal, APM entities would be required to submit certain information to CMS via a qualified clinical data registry (QCDR) 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. Legacy EHR systems were not designed or programmed to capture such data discretely and instead are often included, if at all, in free text fields. In order to transform an existing EHR system into a clinical operating and decision support tool, and to convert data into formats required for QCDRs, practices may need to work with EHR vendors to enhance their systems and by so doing encourage novel uses of existing, albeit enhanced technology.

IV. Trends in Active Surveillance (Criteria: Scope, Cost and Quality, Payment Methodology, Value over Volume)

Throughout the PRT report, the PRT comments that the trend towards AS is already occurring. It also notes that "The standard of care is moving toward AS already, particularly in academic settings where financial incentives and institutional resources may support AS to a greater degree. It is difficult to estimate how long the transition to AS for appropriate patients would take under the current payment system, as the shift requires changing behavioral patterns within a specialty." In fact, we believe that behavior patterns must change not only within urology, but across all providers, including facilities, who care for patients with prostate cancer, along with modifying expectations of patients themselves. We believe that absent intervention, it will take many years for AS rates to increase to appropriate levels and that the LUGPA APM will greatly hasten the transition. The independent review provided to PRT finds that "the proposed APM addresses the ongoing need to promote AS to both eligible professionals and patients by remunerating providers for implementing AS via a management fee and performance-based payments."¹³

The review also cites a recent paper that documents a "secular trend of increasing use of AS from 11.6 percent in 2010 to 27.3 percent in 2013."¹⁴ However, the cited paper does not represent the full scope of patients who could benefit from AS. The data for the paper are derived from the National Cancer Database (NCDB), which is a "national hospital-based oncology database," and thus "may limit evaluation of patients receiving care at outpatient community centers that are not accredited by the ACS/CoC [American College of Surgeons/Commission on Cancer]". Further, the analysis only includes men with very-low risk prostate cancer – of the 448,773 men diagnosed with prostate cancer from 2010 – 2013 in the NCDB, only 40,839, or 9%, meet the inclusion criteria. The paper does not provide any statistics on the prevalence of AS in the remaining 91% of the population, many of whom would be likely candidates for AS. The paper shows that AS has increased for a small subset of men in the NCDB who have very-low risk prostate cancer and who met all inclusion criteria for the paper, but it does not provide information on the prevalence of AS for men with low-risk prostate cancer or for any men who are not in the NCDB. In particular, overall use of AS could be lower if outpatient community centers that are not accredited by the ACS/CoC use AS less frequently than cancer centers that are accredited by the ACS/CoC. Those who argue that AS is at high levels already often cite analyses of the CaPSURE registry. However, practices within this registry are self-selected and may not be representative of urology practices across the nation. This point is clearly articulated by the lead author of those papers – Dr. Matthew Cooperberg – in his letter to the PTAC. A more appropriate representation of non-selected practices may be the AUA AQUA registry – an analysis of

¹³ LUGPA APM Preliminary Review Team Report to the Physician-Focused Payment Model Technical Advisory Committee available at: <https://aspe.hhs.gov/system/files/pdf/255906/LUGPAPreliminaryReviewTeamPRTReport.pdf>

¹⁴ Parikh, RR., Kim, S., Stein, M.N., Haffty, B. G., Kim, I.Y., Goyal, S. (2017). Trends in active surveillance for very low risk prostate cancer: do guidelines influence modern practice? *Cancer Med*, Oct: 6(10): 2410-2418.

this data showed that since 2014, two-thirds of men eligible for AS actually received immediate intervention.

We are also deeply concerned regarding the disparity in patient selection with respect to AS. Evidence demonstrates that most men who are placed on surveillance protocols are white and of higher socio-economic status¹⁵ and that even when offered surveillance, African-American men are followed less stringently than Caucasians.¹⁶ Furthermore, compliance with follow-up is lower in both African-American men and men of lower socio-economic status^{17,18} Furthermore, there is literature suggesting that selection criteria and follow-up regimens may need to be different in African-American men¹⁹ but broad consensus is lacking given the relative paucity of data in this arena. By providing resources to practices the disparity in surveillance rates between races and socio-economic status should be greatly reduced. Furthermore, by creating a standardized reporting method for both stage and grade at time of diagnosis along with ongoing monitoring metrics, the natural history of AS in different populations will be much better understood. This should enable optimization of AS pathways as time goes forward.

The PRT comment suggests that the establishment of a clinical guideline constitutes acceptance or broad implementation of that guideline; in fact, literature suggests that modifying physician behavior is much more complex and is best achieved by specific strategies that encourage adherence.²⁰ Studies that report high rates of adherence to AS pathways typically include limited, relatively homogenous data sets in their analysis; non-selected population analyses support the notion that the majority of men eligible to receive active surveillance do not, in fact, do so. At least eight barriers to adoption of AS are clearly articulated in the analysis presented to the PRT; there is no reason to believe that these will spontaneously resolve. Adoption of the LUGPA APM will not only accelerate overall adoption of AS but also facilitate reduction of the disparity in AS utilization based on race and socio-economic status.

V. Benchmark Methodology (Criterion: Payment Methodology)

Though the PRT found that the LUGPA APM proposal met the Payment Methodology criterion, we disagree that setting spending targets based on current standard of care in contemporaneous control groups would be preferable to spending targets based on regional and practice-specific historical experience. There are important regional aspects of AS rates. As noted in our proposal, average use of AS for men with localized prostate cancer varies from 20% in the Middle Atlantic, East South Central, and West South Central U.S. Census Divisions to 29% in New England.²¹ Variations in AS vs. AI rates are multi-factorial in nature and cherry picking “high performing” practices is not a prudent or valid benchmark. The PRT also notes that contemporaneous spending targets are used in downside risk ACO models. However, ACO models incorporate a broader beneficiary population rather than the focused population of men with organ-confined prostate cancer. ACO benchmarking methodologies also include an adjustment for the underlying risk of the population attributed to a specific ACO, which adjusts the spending targets to better reflect the experience of each ACO. Another downside to using contemporaneous control groups to set spending targets is that the targets would be largely unknown until after a performance year completes, as only then could CMS determine the use of AS in the contemporaneous control groups. This would create additional uncertainty for participants in the model.

¹⁵ Filson CP, Schroeck FR, Ye Z, et al. Variation in use of active surveillance among men undergoing expectant treatment for early stage prostate cancer. *J Urol*. 2014 Jul;192(1):75-80.

¹⁶ Krishna S, Fan Y, Jarosek S, et al. Racial Disparities in Active Surveillance for Prostate Cancer. *J Urol*. 2017 Feb;197(2):342-349.

¹⁷ Kraus R, Ji L, Jennelle R, et al. Active Surveillance: Do Low-Income Patients Adhere to Protocol. *J Clin Oncol*. 2017; suppl 62, abstract 53.

¹⁸ Abern MR, Bassett MR, Tsivian M, et al. Race is associated with discontinuation of active surveillance of low-risk prostate cancer: Results from the Duke Prostate Center. *Prostate Cancer and Prostatic Diseases* (2013) 16, 85–90.

¹⁹ Odom BD, Mir MC, Hughes S, et al. Active surveillance for low-risk prostate cancer in African American men: a multi-institutional experience. *Urology*. 2014 Feb;83(2):364-8.

²⁰ Curry SJ. Organizational interventions to encourage guideline implementation. *Chest*. 2000 Aug;118(2 Suppl):40S-46S.

²¹ LUGPA APM Proposal available at: <https://aspe.hhs.gov/system/files/pdf/255906/LUGPAAPM.pdf>.

Using high-performing practices as an initial benchmark is also counter to the design of APMs such as CJR or OCM. Benchmarking performance on a practice's historical performance, plus an increasingly weighted regional benchmark is more clinically and practically relevant. Additionally, basing benchmarks in a voluntary model on high-performing practices will likely result in spending targets that are only attractive to practices that are already high performers. Practices who currently use AS less frequently may find such high benchmarks unattainable and, thus, not participate in the model nor alter behavior to more closely align with best practices.

VI. Total Cost of Care (Criteria: Payment Methodology, Care Coordination and Integration)

The PRT repeatedly questions whether urologists will accept a total cost of care model. We remind the PTAC that the total cost of care applies only to the first year after prostate cancer diagnosis, and that for that first year, management of prostate cancer accounts for an aggregate of approximately 57% of total care costs for beneficiaries on AS and AI. Furthermore, because virtually all practicing urologists are excluded from participation in APMs, they are already subject to total cost of care calculations through the resource component of MIPS. There are no episodes of care referable to urology in MIPS; therefore, patients are attributed to urologists based on the plurality of E&M visits. Under this methodology, the cost for any service the beneficiary receives, regardless of who furnishes the service, is attributed to the provider who furnishes the plurality of E&M visits. We believe that physicians would much rather be responsible for costs that they can at least partially control than be surprised by retrospective attribution of patient costs in the MIPS methodology. This is demonstrated by the over 1,400 individual urologists who expressed their written support for this proposal. Moreover, the proposal has the strong support of both the American Urological Association and the American Association of Clinical Urologists.

VII. Time on Active Surveillance Quality Measure (Criterion: Cost and Quality)

The PRT notes that the proposed quality measure for time on AS would create a self-referral feedback loop and create a low bar for performance. We disagree with both assertions. It is not clear how the time on AS would create a self-referral feedback loop. As we note in the proposal, the LUGPA APM will preserve beneficiary freedom of choice to receive care from any eligible professional who accepts Medicare, regardless of whether the professional participates in the LUGPA APM. With regards to the low bar for performance – there is currently no bar for performance and no mechanism to measure time on AS in a standardized/consistent manner. Moreover, practices who put beneficiaries on AS do not have an incentive to ensure beneficiaries are compliant with AS protocols, and in fact are incentivized via the current fee-for-service model to advance patients to AI. We believe it prudent to collect data on this measure before setting benchmarks for improvement. If the LUGPA APM is implemented, CMS may decide to create more stringent quality benchmarks than a practice's improvement relative to its own history; however, we believe that our proposal is an appropriate starting point for collecting this information and linking the quality measures with the performance-based payment.

VIII. Auditing and Monitoring (Criteria: Cost and Quality, Patient Safety)

We disagree with PRT's assertion that the proposed auditing and monitoring activities could be burdensome for both CMS and providers. We took great effort to ensure that information participants would be required to submit to CMS could be captured with a reasonable effort using technology that most practices would already have, albeit recognized that existing technology may need to be enhanced and/or used differently as discussed above. For example, it is not clear to us that it will be burdensome to report information like 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. All pieces of information except for the attestation are likely already being captured in a participant's electronic health record and reported via a qualified clinical data registry. Further, we proposed that CMS create a new non-payable G code that participants can submit on a claim to perform the attestation. With regards to CMS, we do not believe that the proposed monitoring and auditing activities for inappropriate use of AS would be more burdensome than similar

activities in existing APMs. Most monitoring could be performed in an automated fashion using electronic information from participants. CMS could then perform audits or impose corrective actions for participants that were outliers on CMS's automated monitoring. We also note the inconsistencies in the PRT concerns on the one hand about burdens being placed on Providers (which are in fact not present due to the use of technology), while also concluding (incorrectly) that the LUGPA APM does not encourage new uses of Health Information Technology.

Additionally, the LUGPA APM will preserve beneficiary freedom of choice to seek care from any eligible professional who accepts Medicare. Thus, beneficiaries who are hesitant to be placed on AS are able to seek opinions regarding potential treatment options from any eligible professional, regardless of participation in the LUGPA APM.

IX. Opportunities to Adhere to Guidelines (Criterion: Scope)

The PRT notes that it is not clear whether a PFPM is appropriate for an intervention which might have other existing opportunities to adhere to nationally recognized guidelines. We are not aware of other existing opportunities and believe that the LUGPA APM will create strong incentives to provide care in line with nationally recognized guidelines. As stated above, we vigorously disagree with the notion that the Secretary of the Department of Health and Human Services, Medicare, and the country will not be served if the PTAC approves models that align financial incentives to furnish care in accordance with nationally recognized guidelines.

We agree with the independent review provided to PRT which found that the proposed APM would promote AS to professionals and patients. The PRT goes on to conclude that this proposal meets many of the high priority criteria for approval and agrees that this will align incentives to provide better care, yet recommends rejection. We believe that it is short sighted to recommend rejection of the LUGPA APM under the assumption that AS rates will passively increase in spite of obstacles recognized by the PRT – the LUGPA APM represents a new mechanism for active engagement to support the transition to appropriate use of AS.

X. Conclusion

We disagree in the strongest possible terms with the PRT's rationale and recommendation. We do not believe that use of AS will increase quickly without explicit intervention, and we believe that the LUGPA APM will align incentives to support appropriate use of AS, care coordination between urologists and non-urologists, and provision of care in accordance with nationally recognized guidelines. This proposal, if adopted, will improve the lives of thousands of men, save hundreds of millions of program dollars, align incentives for providers with clinical best practices, and provide an avenue for specialty physicians previously excluded to participate in APMs. This proposal precisely meets the goals articulated by Congress in MACRA, and echoed by HHS in public commentary. We believe that there is clear and abundant justification for the PTAC to recommend this to the Secretary for implementation as a high priority.

Respectfully submitted,



Neal D. Shore, M.D.
President



Deepak A. Kapoor, M.D.
Chairman, Health Policy



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December 8, 2017

Physician-Focused Payment Model Technical Advisory Committee
c/o Angela Tejada, ASPE
200 Independence Avenue, SW
Washington, DC 20201

Re: PTAC Preliminary Review Team Report on for LUGPA Advanced
Payment Model for Initial Therapy of Newly Diagnosed Patients with
Organ-Confined Prostate Cancer

Dear Committee Members:

The American Urological Association (AUA), representing more than 15,000 urologists in the United States, would like to express our continued strong support for the LUGPA Advanced Payment Model for Initial Therapy of Newly Diagnosed Patients with Organ-Confined Prostate Cancer (“LUGPA APM”).

The AUA remains committed to providing value based care to patients with urologic needs and in April 2016 formed an Alternative Payment Model (APM) workgroup devoted to developing and reviewing new APMs. The AUA APM workgroup is made of up diverse AUA member urologists from a variety of geographic locations and practices types. The workgroup worked closely with the Brandeis and American College of Surgeons teams that submitted the Episode Based Grouper APM to PTAC and the Secretary of Health and Human Services.

The AUA APM workgroup also reviewed carefully the LUGPA APM prior to initial submission to PTAC and provided a letter of support, dated August 8, 2017. In particular, we reviewed and provided feedback to LUGPA about the value of broad participation in the LUGPA APM, the financial modeling, and clinical appropriateness of the proposed model.

Headquarters

Michael T. Sheppard, CPA, CAE
Chief Executive Officer

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We have reviewed the Preliminary Review Team's report and would like to provide the following comments.

- The Preliminary Review Team expressed concern about the number of urologists who would volunteer to be responsible for the total cost of care of patients after prostate biopsy. Our perspective is that there already urologists, particularly in large or multispecialty groups, interested in the broad responsibility for patient care. We expect that urologists will be interested in this model since a majority of care in the first year after prostate cancer diagnosis is related to the prostate cancer.
- The Preliminary Review Team expressed concern about the number of urologists for whom the LUGPA APM could apply. However, since CMS published data reports that fewer than 1% of urologists are in APMs and urologists have limited participation in the Oncology Care Model, we believe it important to have the LUGPA APM available to urologists and urology patients.
- The Preliminary Review Team expressed concern that the model would be rewarding physicians for following clinical guidelines. Although there is growing recognition that active intervention may be deferred in a subset of patients, the use of active surveillance represents a paradigm shift in care. As such, numerous barriers still exist to modify physician and patient behavior. Consequently, adoption of surveillance is highly variable. These barriers are exacerbated by lack of resources to ensure compliance with surveillance protocols and misaligned payment incentives which encourage active intervention. Therefore, the LUGPA APM realigns payments with clinical best practices as well as provides resources to manage the surveillance process, which will accelerate the use of surveillance.

In summary, the AUA believes this APM will be broadly adopted by urologists in all types of practice and will be of value to urologic patients nationwide. The AUA supports adoption of this APM by the entire specialty, and we appreciate the opportunity to provide this additional feedback.

Thank you in advance for your consideration.

Sincerely,

A handwritten signature in blue ink, appearing to read 'Christopher Gonzalez', with a stylized flourish at the end.

Christopher Gonzalez, M.D.
Chair, AUA Public Policy Council



*David F. Penson, MD, MPH
Professor and Chair, Department of Urologic Surgery
Hamilton and Howd Chair in Urologic Oncology
Director, Center for Surgical Quality and Outcomes Research*

December 3, 2017

Physician – Focused Payment Model Technical Advisory Committee
c/o US DHHS Asst. Secretary for Planning and Evaluation Office of Health Policy
200 Independence Ave SW
Washington, DC 20201
PTAC@hhs.gov

Re: LUGPA APM for Initial Therapy of Newly Diagnosed Patients with Organ-Confined Prostate Cancer (“LUGPA APM”).

Dear PTAC Members

As a board-certified urologic oncologist who focuses on urological malignancies, it is my pleasure to write to you regarding the LUGPA APM under review by the full PTAC on December 19, 2017. In addition to my clinical responsibilities, I am a federally funded researcher with a focus on patient-reported outcomes, survivorship and comparative effectiveness in prostate cancer. I have previously served as the American Urological Association's representative to the nation's Commission on Cancer and as Chair of the National Institute of Health's Health Services Organization and Delivery (HSOD) study section. HSOD is the panel which primarily reviews policy-relevant grant applications to the NIH. While I respect and admire the PRT for their work in reviewing the LUGPA APM, I must respectfully disagree with their recommendation regarding this proposal.

At present, there are limited opportunities for urologists to participate in alternative payment models outside of the ACO environment and only a handful of urology practices are participating in the Oncology Care Model (OCM). There are no urology specific APMs in existence, nor to my knowledge are any under development by CMS. Furthermore, while CMS has exempted over 60% of the nation's providers from MIPS reporting requirements, these exemptions are not even across specialties – the vast majority of the nation's urologists did not receive MIPS exemptions, and so must be subject to MIPS scoring. As such, the LUGPA APM fills a void that will enable urologists to productively engage in value based models while simultaneously addressing a clear clinical deficit, that of highly variable adoption of active surveillance (AS) in clinically appropriate patients newly diagnosed with prostate cancer.

There is broad consensus that a substantial subset of patients may safely defer immediate active intervention (AI). This understanding as led to consensus guidelines (including AUA and NCCN) recommending AS for certain very low- and low- risk patients newly diagnosed with cancer. However, AS for prostate cancer is unique in that although it is recommended as appropriate therapy, there is still lack of consensus on precisely which patients should be surveilled, how that surveillance should be performed, and what constitutes criteria for patients to be shifted to AI. Complicating data collection is that determining AS rates from claims data is a diagnosis of exclusion; there is no diagnostic code specifically referable to AS. Since some patients with prostate cancer may defer AI for a variety of

reasons, determining actual AS rates can be very challenging. That said, there is agreement in the literature that adoption of AS varies greatly by geography, practice type, and patient demographic. The reason for variable adoption of AS is likely multifactorial; the data provided to the PRT by their independent review cites an excellent article by Loeb et al. articulating at least 7 non-economic factors that adversely impact AS adoption. When these factors are combined with a fundamental misalignment in payment incentives, it becomes easier to understand the challenges faced by physicians, particularly those in community practices that may lack the resources available to institutionally-based providers, in adopting and adhering to surveillance protocols.

I have reviewed the economic underpinnings of the proposal and come to a different conclusion than the PRT regarding the scope of this project. The PRT excerpts estimates from the proposal that 19,000 patients could be enrolled in the model annually, with savings of approximately \$28 million. However, the PRT did not include in their report that this cost savings reflects participation by only 30% of eligible urologists and that use of active surveillance increases from 23% of episodes (the baseline national utilization rate identified by the submitters) to 31% of episodes. This disregards the potential upside for the proposal, if there is more widespread uptake of the APM by urologists (which is likely given the dearth of urology-specific models). Consider the following- Of the approximately 63,000 Medicare beneficiaries newly diagnosed with prostate cancer each year, approximately 43% would be candidates for AS; as 23% of patients actually receive AS, that suggests that when broadly adopted, over 12,500 men annually would be spared unnecessary intervention with a costs savings averaging \$20 thousand per patient. As such, the potential Medicare program savings are actually over \$250 million annually, and would include over 75% of urologists – this certainly qualifies as a project of significant scope.

I must respectfully disagree with the expert interviewed by the PRT certain issues. First is the notion that urologists would not accept a total cost of care model. The total cost of care proposed in the LUGPA APM is confined to the first year of the program and is used for calculation of the performance bonus. During this first year after diagnosis, the majority of costs incurred directly relate to the management of the patient's newly diagnosed prostate cancer. As such, it is reasonable to assume that providers would be willing to assuming risks based on costs that they themselves have the ability to control and therefore modify. Furthermore, the total cost of care is measured against a risk-adjusted cohort; in the example cited in the interview, the while the total cost of care of a patient with 6 comorbidities with prostate cancer would be charged to the care group managing the APM, that cost would be compared to an approximately equal risk-adjusted patient without prostate cancer. In addition, as urologists are disproportionately required to report for MIPS, they are already subject to total cost of care as part of the resource use requirement; in 2018 this will account for 10% of the MIPS score but by 2019 this, by statute, increases to 30% of the MIPS score. Unlike this APM, where the majority of costs attributed relate to a specific disease state under control of the care group, attribution under the MIPS is retrospective and based, for a specialist, on the plurality of patient's E&M visits for the year. Consequently, specialists will be attributed patients they may have seldom seen and be attributed costs they had no control over. Success in the resource use component of MIPS for specialists is nothing more than luck of the draw in patient attribution – it is unfathomable why a physician would choose this rather than costs they can control.

Both the PRT and expert interviewed suggest that this APM is a mechanism for groups with ancillary services to recoup revenue lost from radiation, and that ownership of ancillary services is responsible for

low adoption rates of AS. I believe that the former represents a misunderstanding of the economics of care for prostate cancer and the latter, as described above, is opinion not supported by facts. Simply put, a reduction in use of radiation services for prostate cannot be replaced by other professional or technical services and to imply that an APM around AS would allow urologists to recoup this lost revenue is simply unrealistic. Regardless, this APM aligns payment incentives with clinical best practices that will impact every provider who cares for prostate cancer at every site of service, and benefits all patients stricken with this disease.

The PRT expert suggests that patients on surveillance protocols independently comply with follow-up. This has not been my experience and is directly contrary with published literature on the subject. It is important to recognize that AS follow-up data look beyond institutions with specifically designed surveillance protocols who have dedicated resources to track patients and ensure compliance; these resources are not available to most practitioners and as such, AS adherence rates in these sites cannot be taken as representative of care available to most patients. Data suggests that compliance with AS protocols is highly variable, and patients experience both anxiety and fatigue the longer that they are surveilled. This results in patients that may be either lost to follow-up or choose AI for non-clinical reasons. Providing dedicated resources to practices specifically for the purpose of implementing AS protocols should elevate compliance standards across the US, benefitting many thousands of Medicare beneficiaries.

With further regard to resources required to implement AS, the PRT also suggests that the CCM is an appropriate mechanism to compensate for services necessary to perform AS appropriately. I disagree on two counts. The first is that the CCM is designed to cover all aspects of chronic care management, and does not uniquely address the services needed to properly track and counsel patients on AS for prostate cancer. The proposal submitters do an excellent job of providing a detailed overview of services that may be required to perform AS with a reasonable and appropriate budget. These services are not dissimilar to those provided in the OCM. Unlike the OCM, however, the PMPM fee associated with the LUGPA APM is for a single disease state and not management of co-morbidities, which accounts for why it is lower than that associated with OCM. Second is that the CCM may be billed by one provider each month. Under present anti-kickback statute, these fees may not be shared between providers in separate billing entities as this would constitute illegal fee splitting. The only way such fees could be split is under the auspices of a risk model such as the LUGPA APM; by using the CCM as a justification to reject the LUGPA APM the PRT has effectively created a proverbial "Catch-22," in that you must use the CCM in lieu of the APM but you cannot legally do this without an APM construct. Furthermore, as the LUGPA APM PMPM provides reimbursement unique to services for managing patients on AS, using the CCM for this even within the constructs of an APM could deprive providers from resources needed to manage multiple co-morbidities. The PMPM in the proposal and the CCM should be considered as compensation for distinct services, in those patients where both are needed the programs would be complementary, not exclusionary.

The PRT suggests that if Medicare were to adopt this program, it should apply a unique set of criteria to any potential shared savings that accrue, suggesting that practices be benchmarked against those already performing AS to high degree. This is inconsistent with shared savings models previously introduced by CMS and is fundamentally illogical; indexing practices who are willing to take two-sided risk against performance targets they are unlikely to meet will not encourage enrollment. Furthermore,

December 3, 2017

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this does not recognize that variations in adoption of AS may be associated with the existing lack of resources practices currently face; the LUGPA APM already corrects for this creating a baseline which is a composite of both practice and regional historical use patterns. The APM ensures that we continue to “move the needle” by shifting the emphasis more towards the regional data as time progresses. The model suggested by the PRT would discourage provider participation and hence further impede adoption of AS.

In summary, the PRT acknowledges that the proposal is technically sound and would align payment incentives with clinical best practices. The LUGPA APM would accelerate adoption of an evolving clinical best practice, prevent tens of thousands of Medicare beneficiaries from being subject to the morbidities of unnecessary procedures, potentially save hundreds of millions of program dollars and introduce an entire specialty to value based care. It strikes me that this is 100% in keeping with the spirit of MACRA and something that CMS would encourage.

I urge the PTAC committee to recommend this proposal to the Secretary for implementation as a high priority.

Respectfully Submitted

Sincerely,

A handwritten signature in black ink, appearing to read "David F. Penson". The signature is fluid and cursive, with the first name "David" being the most prominent.

David F. Penson, MD, MPH
Hamilton and Howd Chair in Urologic Oncology
Chair, Department of Urologic Surgery
Professor, Departments of Urologic Surgery, Health Policy and Medicine
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December 8, 2017

To whom it may concern:

I am writing in reference to the prostate cancer APM proposed by LUGPA, in order to provide some additional information about prostate cancer management trends. I am Associate Professor of Urology and Epidemiology & Biostatistics at the UCSF Helen Diller Family Comprehensive Center. I have over 15 years experience in health services research focused primarily on prostate cancer. Among the over 280 papers I've published are multiple studies of practice patterns for active surveillance and localized prostate cancer (including the JAMA 2015; 314:80 study cited in one of the responses to the proposed APM). As a long-standing advocate for active surveillance for low-risk prostate cancer (Cooperberg et al, JCO 2004; 22:2141), I served on the panel that published the only major U.S. guideline on active surveillance (Chen et al, JCO; 34:2182), and also serve as Senior Physician Advisor for the American Urological Association's national AQUA Registry, launched in 2014, which achieved Qualified Clinical Data Registry (QCDR) status in 2016 and now includes over 3 million patients from over 100 urology practices nationwide (see Cooperberg et al, Urol Pract 2017; 4:30) based on automated data extraction from EHR systems.

Active surveillance has historically been under-used for men with low-risk disease, with rates through 2010 consistently under ~10% of eligible patients – see JAMA 2015; 314:80. This paper is based on the CaPSURE registry, which has tracked practice patterns across 45 mostly community-based urology practices since the 1990s. CaPSURE practices are larger than most urology practices and have been exposed to their own data for many years, and thus are not strictly representative of wider U.S. practices. Likewise, studies from MUSIC which showed surveillance rates up to 50% (Auffenberg et al., JAMA Surg 2017 epub) likewise reflect the fact that practices in this Michigan-based registry have actively been working to increase their use of surveillance. As such, these groups may not represent a representative cross-section of practice patterns nationwide. Even within these groups, both the CaPSURE and MUSIC papers both showed extensive variation in surveillance use across region and individual urology practice (Cooperberg et al. JCO 2010; 28:1117).

It is important to understand that the shift towards active surveillance indicates not an incremental change but rather a true paradigm shift in

the management of low-risk prostate cancer. This likely explains why other studies have shown much lower rates of surveillance (e.g., Maurice et al, JAMA Intern Med 2015; 175:1569). Data from the AQUA registry (presented by me at the 2017 AUA Annual Meeting), representing over 40,000 men in 91 practices newly diagnosed with prostate cancer since 2014, indicate that overall 33% of men with low-risk prostate cancer are managed with active surveillance. However, there is a very broad degree of variation seen across practices and; 3 practices had AS rates in excess of 60% while approximately a quarter of practices did not use AS at all.

Thus, while tremendous progress has been made in recent years, we still have a very long way to go in optimizing use of surveillance; for men with low-risk prostate cancer, the rate of active surveillance really should be closer to 80%, as has been achieved in countries like Sweden (Loeb et al, JAMA Oncol 2017; 3:1393). Multiple factors still work against broader uptake of surveillance, including variability in risk assessment, physician and patient beliefs and preferences, and financial incentives that favor treatment over surveillance (Ganz et al. Ann Intern Med 2012; 156:591). The consistency and quality of followup for men on surveillance is also highly variable (Luckenbaugh et al, J Urol 2017; 197:621), and may be a particular problem for African American men (Ahern, Prostate Cancer Prostatic Dis 2013; 16:85).

Thus not only is there still a great need to improve use and quality of active surveillance, but the APM proposal comes at the perfect time. Use of surveillance has been endorsed by guidelines only in the past two years, and great variation still exists in its implementation. Furthermore, health information technology is improving rapidly, and the AQUA Registry offers a ready platform on which urologists can rely for data collection and reporting, and which will serve as the basis for a new generation of health services research. Participation in the APM, meanwhile, may draw more urologists to participate in AQUA.

For these reasons, I am excited about the possibilities the APM proposal offers, and very much hope CMS will consider approving it.

Sincerely,



Matthew R. Cooperberg
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