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August 8, 2017

Physician Focused Payment Model Technical Advisory Committee
c/o Angela Tejeda
Office of the Assistant Secretary for Planning and Evaluation
US Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Submitted electronically: PTAC@hhs.gov

Dear PTAC Members,

The American Society for Radiation Oncology (ASTRO) is pleased to submit comments on the *LUGPA Advanced Payment Model for Initial Therapy for Newly Diagnosed Patients with Organ-Confined Prostate Cancer*. We appreciate this opportunity to comment and look forward to further engagement should this model be considered for implementation.

ASTRO members are medical professionals, practicing at community hospitals, academic medical centers, and freestanding cancer treatment centers in the United States and around the globe, and who make up the radiation therapy treatment teams that are critical in the fight against cancer. These teams often include radiation oncologists, medical physicists, medical dosimetrists, radiation therapists, oncology nurses, nutritionists and social workers, and treat more than one million cancer patients each year. We believe this multi-disciplinary membership makes us uniquely qualified to provide input on the inherently complex issues related to Medicare payment policy.

ASTRO's comments focus on the efforts of the *LUGPA Advanced Payment Model for Initial Therapy for Newly Diagnosed Patients with Organ-Confined Prostate Cancer,* which seeks to implement a guideline issued by ASTRO in collaboration with the American Urological Association and the Society of Urologic Oncology (SUO) that supports the use of Active Surveillance (AS) as an appropriate care option for low-risk, localized prostate cancer patients. Reductions in the use of Active Intervention (AI), when appropriate, can avoid possible side effects of definitive therapy that may be unnecessary, improve quality of life, and reduce the risk of treating small indolent cancers, thus ensuring better patient value.

However, the model is limited to a very small segment of the prostate cancer population. According to the application, only approximately 1,900 men would move from AI to AS based on LUGPA's estimates. Furthermore, it appears to be addressing a problem that has been increasingly well addressed through patient and physician education efforts that have led to substantial increases in the percent of patients with low risk cancer being managed

appropriately with active surveillance. Also, there is an apparent methodological shortcoming in the LUGPA analysis.

Regarding the impact of education on AS utilization, an analysis of the Cancer of the Prostate Strategic Urologic Research Endeavor (CapSURE) database revealed that between 2010 and 2013, already 40.4 percent of low-risk tumors were managed by AS, a substantial increase from prior years[1]. The rate is even higher in men aged 75 years or more, at 76.2 percent. Interestingly, a qualitative study on decision-making by prostate cancer physicians revealed that financial incentive did not appear to play a major role in recommending AS among physicians interviewed. It was noted by authors of the study that there is a lack of emphasis on AS during urology training, with greater emphasis placed on procedural skills, and that there is a need to make AS a core part of urology training and continuing medical education.[2]

Regarding the methodology used in the LUGPA proposal, the estimates of the recent use of AS based on the 5 percent Medicare Limited Data Set do not break down the rate based on cancer risk categories (low-, intermediate-, and high-risk based on NCCN or other accepted criteria). Instead, HCC categories are used, but these by themselves do not necessarily inform the choice to recommend AS. A more informative source of data helpful to understand the stage-based patterns of care for prostate cancer would be the SEER-Medicare database, which the analysis references for other data but not for this important baseline metric.

In summary, while this model seems like a well-intentioned effort to promote AS for low risk prostate cancer patients, the amount of time and effort necessary to develop a model around this type of program for a small number of patients may not justify the possible savings to Medicare. Additionally, with broad and growing acceptance of AS as a reasonable clinical approach to low risk prostate cancer, the problem for which this model was designed to address, may not actually exist. Finally, we question the accuracy of some key baseline parameter estimates of AS in low risk prostate cancer based on the lack of detail on clinical stage available in the source used.

We propose that the management of prostate cancer represents a good example of an instance in which a broader PFPM would encompass a larger patient population, yielding more savings and greater efficiencies. There are well established guidelines available to inform providers and patients about standard approaches for low-, intermediate-, and high-risk patients diagnosed with prostate cancer treatment. ASTRO recommends that consideration be given to a broader

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[1] Cooperberg, M. R. & Carroll, P. R. Trends in management for patients with localized prostate cancer, 1990–2013. JAMA 314, 80–82 (2015)

[2]Loeb S, Curnyn C, Fagerlin A, Braithwaite RS, Schwartz MD, Lepor H, Carter HB, Sedlander E. Qualitative study on decision-making by prostate cancer physicians during active surveillance. BJU international. 2017 Jul 1;120(1):32-9.

model that focuses on establishing a modality agnostic approach to care, regardless of disease stage, with incentivization to comply with well-vetted treatment guidelines, which we believe will improve quality and provide cost-savings opportunities. The appropriate recommendation of AS for low risk patients could be a part of such a model, serving as a potential quality indicator alongside other metrics applicable to the clinical scenarios wherein active intervention is more appropriate.

Thank you for the opportunity to provide written comments. If you have any questions, please contact Anne Hubbard, Director of Health Policy, at 703-839-7394 or Anne.Hubbard@ASTRO.org.

Sincerely,

Laura I. Thevenot
Chief Executive Officer

American Urological Association

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August 8, 2017

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

Re: Support 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 strong support for the LUGPA Advanced Payment Model for Initial Therapy of Newly Diagnosed Patients with Organ-Confined Prostate Cancer ("LUGPA APM").

Prostate cancer remains the most commonly diagnosed solid tumor in men within the US. In 2017, prostate cancer is estimated to be the third leading cause of cancer death in men.[1] Research has found that a substantial subset of patients with newly diagnosed prostate cancer may safely defer active intervention at the time of diagnosis and instead be closely monitored via active surveillance. Recent analysis of newly diagnosed prostate cancer cases show more than 40 percent had a Gleason score ≤ 6, which suggest that a large number of patients would be likely candidates for active surveillance.[2]

CMS has acknowledged that less than one percent of urologists participate in APMs and only a few urology practices participate in the Oncology Care Model (OCM) APM. The lack of participation in APMs represents a clear need for urology physician-focused payment models (PFPMs). We believe that this model qualifies as an Advanced APM because of its proposed use of certified electronic health record technology, linkage of quality measures to payment, and more than nominal risk incurred by participating practices. We expect the LUGPA APM will appeal to diverse urologists who have limited engagement in APMs to date.

Recent estimates of Medicare claims data indicate that the LUGPA APM could reduce expenditures for prostate cancer treatment by $138 million in five performance years, saving the Medicare program approximately $51 million.

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In addition to reduced program spending, the LUGPA APM will improve quality for patients, better align financial incentives with current clinical best practice standards, provide practices with the resources to monitor and counsel patients on active surveillance, and better integrate shared decision making in the initial and ongoing phases of therapy. The LUGPA APM creates a model to further support the appropriate use of active surveillance, helping those men avoid or defer active intervention. The LUGPA APM will also be a strong compliment to future APMs that will further engage urologists in payment system reforms.

The AUA fully supports the potential clinical and financial benefits of the LUGPA APM and urges the Committee to recommend the payment model for adoption by the Secretary of Health and Human Services as a high priority. We hope that the Committee also will be mindful of the need for more PFPMs for specialists, as it proceeds with its review and evaluation of the LUGPA APM. Thank you in advance for your consideration. If you have any questions, please contact Lisa Miller-Jones at (202) 403-8501 or lmiller@auanet.org.

Sincerely,

Chris M. Gonzalez, MD, MBA
Chair, Public Policy Council

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

[2] KA Herget, DP Patel, HA Hanson, et al. Recent Decline in Prostate Cancer Incidence in the United States, by age, stage, and Gleason score. Cancer Med. 2016; 5(1) 136-141.

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August 8, 2017

Jeffrey Bailet, MD
Chairperson, PTAC
Attn: Designated Federal Official for PTAC
200 Independence Ave SW
Washington, DC 20201

Submitted electronically via PTAC@hhs.gov

Re: Public Comment on LUGPA Advanced Payment Model for Initial Therapy of Newly Diagnosed Patients with Organ-Confined Prostate Cancer

Dear Committee Members,

The American Association of Clinical Urologists (AACU) respectfully submits these comments on the LUGPA Advanced Payment Model for Initial Therapy of Newly Diagnosed Patients with Organ-Confined Prostate Cancer (hereinafter "LUGPA APM") to the Physician-Focused Payment Model Technical Advisory Committee for its consideration.

Founded in 1968 by urologists concerned by the government's increasing role in the practice of medicine, the AACU is a professional organization representing the interests of more than 3,000 urologists across the United States, as well as urologic societies engaged as advocacy affiliates. We are dedicated to developing and advancing heath policy education as it affects urologic practice in order to preserve and promote the professional autonomy of our members and support the highest quality of care for patients. Our members care for hundreds of thousands of prostate cancer patients each year, with a variety of disease management strategies.

While urologists are nationally committed to the successful implementation of MACRA, urology participation in APMs is limited. In fact, CMS currently reports that less than 1% of urologists nationwide participate in APMs, and only five urology practices across the nation participate in the OCM. As such, the AACU recognizes that there is clearly a need for a urology-specific PFPM and applauds LUGPA in taking the initiative to develop a payment model that aims to increase urologists' participation in APMs.

The AACU is also pleased that the LUGPA APM has been designed to allow for participation from virtually all urology practices treating prostate cancer—whether large or small, independent or hospital-based, and with or without ownership of ancillary services—making it accessible to the vast majority of urologists treating patients newly diagnosed with organ-confined prostate cancer.

Prostate cancer is the second most common cancer and the third leading cause of cancer-related death in American men, killing more than 26,000 men annually.[1] In 2015, an estimated 79,000 Medicare Fee for Service beneficiaries were newly diagnosed with prostate cancer, 79% of which (approximately 63,000 cases) were localized to the prostate.[2] Of those men diagnosed with localized prostate cancer, 77% received active intervention (AI), a decision that in some cases has proven ineffective and costly.

Based on research suggesting that a subgroup of this population can safely defer AI and instead be closely monitored via active surveillance (AS), the LUGPA APM seeks to align incentives with clinical best practices and recently issued guidelines for physicians to recommend AS in clinically appropriate patients with low-risk localized prostate cancer. As such, this APM will not only provide urologists with the resources to monitor and counsel patients on AS, but it will also allow them to better integrate shared decision making in the initial and ongoing phases of therapy.

Furthermore, the AACU believes that the LUGPA APM will align financial incentives by compensating participating urologists for placing beneficiaries on AS, unlike the existing FFS mechanisms that reimburse physicians more for actively treating prostate cancer. As such, this will incentivize the appropriate utilization of AS and reduce utilization of active interventions like prostatectomy or radiation. Analysis suggests that each additional initial episode that receives AS rather than AI will reduce Medicare spending on average by 59%. And even further, based on Medicare claims data, estimates suggest that the LUGPA APM could reduce expenditures by $138 million in five performance years, saving Medicare approximately $51 million.

The AACU strongly believes that by incentivizing AS and providing physicians with the resources to pursue this course of action when appropriate, the LUGPA APM will help avoid overutilization of services while reducing morbidity and cost, thereby accomplishing the triple aim of improving beneficiary care and experience, improving health outcomes, and reducing healthcare costs.

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

[2] Estimated from 2015 CMS 5% sample data, SEER Incidence and US Death Rates, Age-Adjusted and Age-Specific Rates by Race, and SEER 5-Year Relative and Period Survival (Percent) by Race, Diagnosis Year, Stage and Age. Available at https://seer.cancer.gov/csr/1975_2014/results_merged/sect_23_prostate.pdf.

The AACU again wishes to thank you for the opportunity to comment on this proposed payment model. In all, we strongly believe that the LUGPA APM prioritizes value-based care in accordance with the core principles of MACRA and if implemented, will greatly improve the quality of care for prostate cancer patients at a lower cost. We therefore respectfully urge the PTAC to support the LUGPA APM and recommend it for adoption by the Secretary as quickly as possible.

Sincerely,

Charles A. McWilliams, MD
President, AACU

Jeffrey M. Frankel, MD
Chair, UROPAC

PHEN

Prostate Health Education Network, Inc.

August 8, 2017

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

Dear Committee Members,

On behalf of the Prostate Health Education Network, I am pleased to write this letter of support for the APM for Initial Therapy of Newly Diagnosed Patients with Organ-Confined Prostate Cancer, submitted by LUGPA ("LUGPA APM").

PHEN's mission is to eliminate the African American prostate cancer disparity. Black men in the United States have the nation's highest prostate cancer incidence and mortality rates. PHEN's mission also includes advocacy efforts to increase the overall support and resources to wage a war on prostate cancer that will eventually lead to a cure for the disease for the benefit of all men. PHEN's Rally Against Prostate Cancer (RAP Cancer) is a set of national initiatives towards achieving the organization's overall mission. A key PHEN tenet is that "knowledge is the best defense against prostate cancer" which is the foundation for these RAP Cancer initiatives:

- The PHEN Survivor Network established in to mobilize Black prostate cancer survivors to work collectively towards eliminating the racial disparity.
- Monthly Support Group Meetings which brings survivors and their families together to learn about new prostate cancer developments, treatments and clinical trials.
- The "Annual African American Prostate Cancer Disparity Summit" convening survivors and leaders within medicine, research, government and industry to address policy and medical issues necessary to eliminate the prostate cancer racial disparity.
- PHEN Online Television is an educational resource with a library of enduring video programs across a broad spectrum of subjects and topics. These videos are available to be used for special educational programs hosted by PHEN and PHEN partners.
- The "Annual Father's Day Rally" in partnership with churches nationwide who hold a special recognition and prayer for prostate cancer survivors and loved ones impacted by the disease during their Father's Day services.
- PHEN's Educational Symposiums brings medical specialists, community leaders and the public together for in-depth educational presentations on specific topics.
- Monthly Treatments and Clinical Trials E-Newsletter that educates about evolving treatments and clinical trials to help keep Black America current and knowledgeable in these areas which are critical to eliminating the disparity.

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Website: www.ProstateHealthEd.org Email: thomas@ProstateHealthEd.org

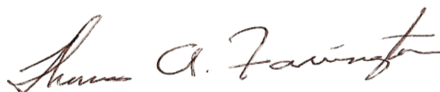
- PHEN's Virtual Walk to Raise Prostate Cancer Awareness was launched to raise the visibility and knowledge about prostate cancer issues and generate public support.

Racial disparity continues to be an issue in access to novel treatments for prostate cancer. This issue is particularly complex with active surveillance (AS) for prostate cancer. Although data suggests that deferring immediate intervention for prostate cancer is an option for many men newly diagnosed with prostate cancer, the situation for African-American men is much different. African-Americans are much more likely to leave surveillance protocols for non-clinical reasons.[1] A significant issue with surveillance protocols is that currently, physicians are compensated for therapeutic interventions – there are essentially no resources that are devoted to counseling patients about their options regarding surveillance, nor is there any mechanism in place to monitor and encourage compliance with surveillance should it be selected. By supplying practitioners with resources to track and support patients on surveillance, adoption and adherence rates for AS are certain to increase – this is particularly critical in African-American communities where access to care can be a major issue.

An additional benefit of this APM is the ability to track outcomes for AS patients longitudinally. Literature suggests that on existing surveillance protocols, the risk of switching to active intervention is much greater for African-American men than Caucasians; [2] however, the reasons for this are unclear. By creating reporting mechanisms that track patient satisfaction and inclusiveness in decision making, important questions on access can be addressed – a critical first step in reducing the existing disparity in prostate cancer therapy.

In summary, the LUGPA APM is a cost-effective vehicle that moves prostate cancer treatment substantively towards value based care with real monitoring of shared decision making. In addition, the LUGPA APM can address questions regarding access and outcomes for African-American men on AS, which can help us understand and resolve racial disparities in this arena. PHEN strongly supports this proposal and urges the PTAC to recommend it to the Secretary for adoption as a high priority.

Sincerely,



Thomas A. Farrington
President

[1] 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.

[2] Sundi D, Faisal FA, Trock BJ, et al. Reclassification rates are higher among African American men than Caucasians on active surveillance. Urology. 2015 Jan;85(1):155-60.

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August 18, 2017

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

Dear PTAC committee members and Ms. Tejada:

On behalf of Urology of Indiana, the largest urologic practice in Indiana with a dedicated focus on providing premier urological care, I am pleased to write this support letter for the LUGPA APM for Initial Therapy of Newly Diagnosed Patients with Organ-Confined Prostate Cancer ("LUGPA APM").

Urology of Indiana is a fully integrated, breakthrough urological care facility. Our patients are able to visit their neighborhood physician and also obtain streamlined access to our state-of-the-art pathology laboratory, radiation and imaging services. By having these services readily available, we can more effectively manage our patient's health care as a whole, while insuring they receive the highest standard of quality. Our board-certified physicians and medical staff are experts on the latest advances in urological care and are leaders in bringing new technology and treatment options to our community.

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

Our practice is committed to providing integrated, comprehensive services to patients with genitourinary disease. We believe that the LUGPA APM encourages value based care, emphasizes shared decision making while producing real savings for the Medicare program. We urge the PTAC to recommend this payment model for adoption by the Secretary as a high priority.

Respectfully submitted

Britt McDermott, CEO
Urology of Indiana
679 E County Line Road
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