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1000 Corporate Boulevard  
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U.S. Toll Free: 1-866-RING-AUA  
(1-866-746-4282)

Phone: 410-689-3700

Fax: 410-689-3800

Email: [AUA@AUAnet.org](mailto:AUA@AUAnet.org)

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September 24, 2018

*Electronically Submitted*

Seema Verma, Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attn: CMS-1695-P  
Mail Stop C4-26-05  
7500 Security Boulevard  
Baltimore, MD 21244-1850

Re: Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Requests for Information on Promoting Interoperability and Electronic Health Care Information, Price Transparency, and Leveraging Authority for the Competitive Acquisition Program for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model (RIN: 0938-AT30)

Dear Administrator Verma:

The American Urological Association (AUA) is a globally-engaged organization with more than 22,000 members practicing in more than 100 countries. Our members represent the world's largest collection of expertise and insight into the treatment of urologic disease. Of the total AUA membership, more than 15,000 are based in the United States and provide invaluable support to the urologic community by fostering the highest standards of urologic care through education, research and the formulation of health policy.

The AUA appreciates the opportunity to provide comment to the Centers for Medicare and Medicaid Services (CMS) on the proposed rule that provides updates to the Hospital Outpatient Prospective Payment System (OPPS), the Ambulatory Surgical Center (ASC) Payment System, and associated quality reporting programs for calendar year (CY) 2019. Our comments are limited to the sections of the proposed rule that are most applicable to AUA members.

### Complexity Adjustment for Blue Light Cystoscopy with Cysview®

CMS proposes to continue to apply a "complexity adjustment" to pay for the Blue Light Cystoscopy with Cysview® procedure when performed in the hospital outpatient setting. Although we are pleased that CMS has recognized that Blue Light Cystoscopy with Cysview® procedures require extra resources beyond traditional "white light" cystoscopy, and therefore, should

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be assigned additional payment to minimize the harmful effects that the “packaged payment” policy has imposed on utilization of the procedure, CMS’ proposal is incomplete.

The proposed 2019 complexity adjustment increases hospital payment for only 2 of the 7 applicable cystoscopy CPT codes in which Blue Light Cystoscopy with Cysview® is used (52204 and 52224). This means that only a fraction of Blue Light Cystoscopy with Cysview® procedures will be eligible for additional payment through the complexity adjustment. This is because CMS continues to apply technical volume and cost eligibility criteria to its application of complexity adjustments, which in the case of certain Blue Light Cystoscopy with Cysview® procedures, cannot be met because utilization of the procedure has been constrained as a direct result of CMS’ “packaged payment” policy. For the benefit of bladder cancer patients who need this treatment, which is now included in the Guideline for Diagnosis and Treatment of Non-Muscle Invasive Bladder Cancer jointly published by the AUA and the Society of Urologic Oncology (SUO), we urge CMS to apply the complexity adjustment to all Blue Light Cystoscopy with Cysview® procedures (CPT codes 52000, 52204, 52214, 52224, 52234, 52235, and 52240).

We further encourage CMS to improve access to Blue Light Cystoscopy with Cysview® in the ASC setting, particularly given that the procedure is now FDA approved for administration with a flexible scope for surveillance cystoscopy of Non Muscle Invasive Bladder Cancer. CMS should either apply the complexity adjustment to all Blue Light Cystoscopy with Cysview® procedures when performed in the ASC setting, or CMS should unpackage Cysview® from the procedure payment when administered in the ASC—similar to what CMS is proposing for non-opioid pain management drugs in 2019. CMS should encourage, and not disincentivize, medically necessary utilization of Blue Light Cystoscopy with Cysview® for the benefit of bladder cancer patients and the Medicare program.

As noted above, treatment of bladder cancer patients with Blue Light Cystoscopy with Cysview® is supported by the AUA/SUO Guideline. CMS’ reimbursement policies should facilitate access to this critical drug. However, current policies, which package Cysview® with procedure payments and fail to adequately reimburse facilities for the extra costs and resources required to provide this treatment, instead create barriers to recommended care for patients with bladder cancer. CMS should modify its Medicare Hospital Outpatient Proposed Rule to ensure that all Blue Light Cystoscopy with Cysview® procedures are subject to the complexity adjustment or, in the alternative, that Cysview® is unpackaged from the Blue Light Cystoscopy procedure payment.

### New Device Pass-Through Applications

CMS received new device pass-through applications for the AquaBeam System and the SpaceOAR System. Neither of these applications was approved for device pass-through payment during the quarterly review process. The AUA recommends that

CMS reconsider these determinations and provides additional comment for each system below.

***AquaBeam System:*** The AquaBeam System is intended for the resection and removal of prostate tissue in males suffering from lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia (BPH). CMS invites public comment on whether the technology meets criteria for device pass-through payment, including criteria for establishing a new device category.

The AUA believes that AquaBeam System meets all the criteria for a transitional pass-through payment, including the newness criteria, the device eligibility requirements, and the category, cost, and substantial clinical improvement requirements for establishing a new device category, and we highlight CMS' agreement on several criteria (e.g. cost and existing payment category). Cleared by the FDA in December 2017, the AquaBeam System offers a safe and effective alternative treatment to the gold standard, transurethral resection of the prostate (TURP), as well as to non-resective treatments and open simple prostatectomy across all prostate sizes.

To begin, the AUA believes that the AquaBeam System meets the device eligibility requirements. The AquaBeam System handpiece is integral to the service provided, is a single use item, comes into contact with human tissue, and is surgically inserted. Additionally, it is not equipment or other apparatus for which depreciation and financing expenses are recovered, or a material or supply furnished incident to a service. And unlike a scalpel or other commonly-used operating room instrument, its primary function is not to create an incision or other surgical path. Rather, it is surgically inserted into the patient bladder via the urethra for resecting prostatic tissue.

Further, we believe there is sufficient evidence to demonstrate the substantial clinical improvement Aquablation therapy offers compared to those existing therapies. AquaBeam relies on a combination of real-time, multi-dimensional imaging, the accuracy of an autonomous robot and a heat-free, submerged waterjet. These contribute to improved patient safety and outcomes, as supported by the WATER<sup>1</sup> and WATER II studies<sup>2</sup>, and the body of literature in the BPH treatment space overall. We also believe that the AquaBeam System offers men, irrespective of prostate size, the opportunity to undergo a minimally invasive procedure in an outpatient setting. Patients and physicians should be empowered to choose higher quality care in a lower intensity setting, aligned with CMS' desire to move treatment from higher acuity settings to lower acuity settings, where clinically appropriate.

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<sup>1</sup> Gilling, P. *et al.* WATER – A Double-Blind Randomized Controlled Trial of Aquablation vs. Transurethral Resection of the Prostate in Benign Prostatic Hyperplasia, *The Journal of Urology* 2018

<sup>2</sup> Desai, M. *et al.* WATER II (80–150 mL) procedural outcomes. *BJUI* 2018

Given all of the above, the AUA urges CMS to approve the AquaBeam System transitional pass-through payment application.

***SpaceOAR® System:*** The SpaceOAR® System is a polyethylene glycol hydrogel spacer that temporarily positions the anterior rectal wall away from the prostate to reduce the radiation delivered to the anterior rectum during prostate cancer radiotherapy treatment. CMS' disapproval of this system for transitional pass-through status focuses on the question of whether the technology meets the substantial clinical improvement criterion; otherwise, CMS does not raise concerns about other criteria for approving transitional pass-through status.

The AUA believes that the SpaceOAR technology does meet substantial clinical improvement criteria. SpaceOAR System is the only prostate-rectum spacer that is FDA-cleared for context of prostate radiotherapy because it is the only device of its kind to undergo a prospective randomized trial and therefore is the only product legally marketed in the U.S. for this indication. While there are some examples in the literature of other materials used in this indication (hyaluronic acid, absorbable balloon), none of them are FDA cleared as prostate rectum spacers. Furthermore, the SpaceOAR System is the only biodegradable biomaterial currently utilized for spacing in the context of prostate radiotherapy.

The FDA was heavily involved in the SpaceOAR System phase III trial design, with the primary focus being safety. A low and intermediate risk prostate cancer population was specifically selected as one with low comorbidities, better allowing for spacer safety determination. Additionally, when the study was designed, it was believed that a toxicity reduction primary endpoint was not possible, as sample size determination suggested an excessively large number of patients would be required. Therefore, a rectum dose reduction primary endpoint was accepted as a surrogate for toxicity reduction.

Since the SpaceOAR System is the first absorbable spacer for use in prostate radiotherapy, there are limited comparable products. The closest comparable product is the endorectal balloon (ERB), which is used to reduce rectum radiation by stabilizing the prostate during radiotherapy. ERBs are placed inside the rectum and inflated with air each time the patient lays down on the table to receive radiotherapy. These balloons prevent gas from distending the rectum while radiotherapy is being delivered, thus improving prostate stability. However, very much unlike the SpaceOAR, the distended rectum created by the ERB pushes the anterior rectum closer to the prostate and therefore farther into the high radiation dose zone.

Based on the phase III trial and additional evidence, we believe the criterion for substantial clinical improvement over similar treatments has been met, particularly when comparing SpaceOAR System to endorectal balloon (ERBs). Further, we believe that the SpaceOAR system meets all the other criteria for approval of

transitional pass-through payment. As such, we recommend CMS grant the SpaceOar System transitional pass-through status beginning January 1, 2019.

### APC Assignment for New Code 538X3 (Transurethral destruction of prostate tissues; by radiofrequency generated water vapor thermotherapy)

CPT code 538X3 will replace HCPCS code C9748 (Transurethral destruction of prostate tissue; by radiofrequency water vapor (steam) thermal therapy to treat BPH) effective January 1, 2019. We believe that the most appropriate APC assignment for CPT code 538X3 is APC 5375 (Level 5 Urology and Related Services).

Since January 1, 2018, the Rezum treatment procedure has been described by code C9748. This C code was assigned to APC 5373 (Level 3 Urology and Related Services) for 2018. The AUA believes the assignment of C9748 to APC 5373 is incorrect because APC 5373 does not contain procedures that are either clinically-similar or resource (cost)-similar to C9748.

The procedures that are the most similar 538X3 are as follows:

- **53852** (*Transurethral destruction of prostate tissue; by radiofrequency thermotherapy*)
- **53850** (*Transurethral destruction of prostate tissue; by microwave thermotherapy*)

Each of these codes shares the same code descriptor (up to the semicolon) with the Rezum code 538X3:

- **538X3** (*Transurethral destruction of prostate tissue; by radiofrequency generated water vapor thermotherapy*)

The primary difference between each of these codes is the energy source used to destroy or shrink prostate tissue: 53852 uses radiofrequency energy, 538X3 (Rezum) uses radiofrequency generated water vapor thermotherapy, while 53850 uses microwave energy. Otherwise, the procedures and resources used in these procedures are all very similar, as discussed further below.

Table 1 below shows the proposed APC assignments, payment rates, the geometric mean costs for these three clinically similar procedures.

**Table 1**

<b>CPT Code</b>	<b>2019 Proposed APC</b>	<b>Proposed Payment</b>	<b>Geo Mean Cost</b>
538X3 (Rezumi)	5373 Level 3	\$1,731.32	–
53852 (Radio Freq)	5375 Level 5	\$3,776.12	\$2,972.69
53850 (Microwave)	5374 Level 4	\$2,755.49	\$3,290.77

As depicted in Table 1, 538X3 (Rezumi's) proposed APC assignment is to an APC with a significantly lower payment rate than the two other similar BPH treatment codes.

Additional evidence of clinical and resource similarity of 538X3 to both 53852 and 53850 is provided by the 2019 proposed Physician Fee Schedule (PFS) RVUs and Payment amounts for these three codes. CPT codes 53852 and 53850 were reevaluated by the RUC along with new CPT code 538X3 because the codes capture very similar procedures that are all in the same clinical family within the CPT book.

Table 2 shows the proposed RVUs for these three codes.

**Table 2**

<b>CPT Code</b>	<b>Work RVUs</b>	<b>Non-facility PE RVUs</b>	<b>MP RVUs</b>	<b>Total Non-Facility RVUs</b>	<b>Proposed Non-Facility PFS Payment</b>	<b>Proposed OPPS Payment</b>
538X3	5.70	44.54	.71	50.95	\$1,837	\$1,731
53852	5.93	36.29	.70	42.92	\$1,547	\$3,776
53850	5.42	38.25	.64	44.31	\$1,597	\$2,755

The proposed work and malpractice RVUs are about the same for each of these three codes, but the practice expense (PE) RVUs are higher for 538X3, which results in a payment that is 15 to 20 percent higher for 538X3 versus 53852 and 53850. The practice expense RVUs reflect the resource costs associated with these procedures when provided in the physician office setting.

In summary, we believe that the appropriate APC assignment for 538X3 is APC 5375 (Level 5 Urology and Related Services). While reassignment to APC 5374 (Level 4 Urology and Related Services) would be an option, we believe it to be an inadequate one. Furthermore, we would suggest consideration of reassignment of 53850 to

APC 5375 as well. That would resolve the issue of clinical homogeneity and resource similarity by placing all three minimally invasive BPH codes in the APC that most appropriately recognizes their clinical similarity and costs while helping to ensure the access of Medicare beneficiaries suffering from BPH to the minimally invasive treatment that best meets their clinical needs.

#### [CPT Code 538X3 Omitted from 2019 Proposed Rule ASC Payment Rate Spreadsheet, Addendum AA](#)

CPT code 538X3 was not listed in the 2019 proposed rule ASC payment rate spreadsheet, Addendum AA. We expect that this was an oversight. The predecessor code, C9748, is currently listed in the ASC Addendum AA for 2018, and 538X3 is an ASC covered procedure. Therefore, we request that CMS include 538X3 in ASC Addendum AA in the 2019 OPSS/ASC final rule.

#### [Conclusion](#)

The AUA appreciates the opportunity to provide comments on the OPSS/ASC proposed rule for CY 2019. If you have any questions or wish to discuss our comments, please contact Stephanie Stinchcomb, Director of Reimbursement and Regulation, at (410) 689-3786 or [sstinchcomb@auanet.org](mailto:ssinchcomb@auanet.org).

Sincerely,

A handwritten signature in black ink, appearing to read "Chris M. Gonzalez". The signature is fluid and cursive, with a large loop at the end.

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