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September 17, 2021

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445–G
200 Independence Avenue, SW
Washington, D.C. 20201

RE: CY 2022 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Proposed Rule [CMS-1753-P]

Submitted electronically via http://www.regulations.gov

Dear Administrator Brooks-LaSure:

On behalf of our physician members, the American Association of Clinical Urologists (AACU) respectfully submits these comments to the Centers for Medicare & Medicaid Services (CMS) on the CY 2022 Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System Proposed Rule (the "Rule") (86 FR 42018).

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 member urologists, and urologic societies engaged as advocacy affiliates across the United States. 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.

The AACU appreciates many of CMS' proposed updates to the OPPS and ASC payment systems for CY 2022 and shares many of the Biden Administration's goals underlying these updates, such as closing the health equity gap, fighting the COVID-19 public health emergency (PHE) and encouraging price transparency in the health system. The comments that follow focus on the areas where the AACU disagrees with the approach CMS has taken with regard to the proposed Rule.

Inpatient Only List

CMS proposes to reverse last year's plan to eliminate the IPO list and proposes to add back the 298 services previously removed from the IPO list in 2022 while it evaluates the implications for each service on patient safety. The agency proposes to codify the five existing criteria for removal and seeks comment on whether it should eventually eliminate the list completely or scale it back and retain some IPO services based on standards of practice.

The AACU strongly opposes the agency's proposed reinstatement of the IPO list. Advances in technology and medical practice have safely shifted many procedures from the inpatient to the outpatient setting. Eliminating the list does not mean all procedures on the IPO list should be performed in an outpatient setting. Our position is that the list should be phased out so that physicians can make the determination, based on their clinical knowledge and experience and in consultation with their patients, regarding the appropriate setting for the 298 medical procedures on the list.

Finally, there are many effective safeguards for ensuring patient safety and quality of care. In fact, recent academic research has shown that patients treated in an ASC are less likely to be admitted to a hospital or visit an emergency room following outpatient surgery.[1] Urology procedures have been successfully performed in ASCs without any increase in hospital admission or mortality.[2]

ASC Covered Procedures List

The Rule proposes to reinstate safety criteria that was originally used to add covered surgical procedures to the ASC Covered Procedures List (CPL). These criteria were modified in 2021 resulting in the addition of 267 surgical procedures to the ASC CPL. In this year's Rule, CMS proposes removing 258 of these procedures from the list, which includes several urologic procedures. The agency requests comment on whether any of these procedures meet the proposed reinstated criteria.

The AACU rejects this proposal and believes many of these procedures should be performed on an outpatient basis. For example, many urologic laparoscopies, such as surgical prostatectomy (55866) and partial nephrectomy (50543) can be performed robotically in an ASC, which is more efficient, more personalized and has several other advantages to hospital settings.

Robotic surgery is a minimally invasive surgery, which promotes faster convalescence and reduces pain to patients. It is recommended on an outpatient basis as it usually eliminates the need for postoperative hospitalization, which can introduce the risk of nosocomial exposure to COVID and other infections after surgery. Additionally, urologic robotic surgeries often involve cancer patients who have vulnerable immune systems and need surgery without delay. Treating these patients in an ASC protects them from entering hospital units where the majority of seriously ill COVID patients are treated.

ASC-based robotic surgery also produces better patient outcomes, higher patient satisfaction and reduced costs. Patients with less acute symptoms do better in ASCs, an environment that specializes in specific types of surgery, which can lead to more reliable outcomes for patients. In addition, this specialization allows for efficiencies that reduce costs to patients and to the healthcare system at large.

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[1] Munnich EL, Parente ST. Returns to specialization: Evidence from the outpatient surgery market. J Health Econ. 2018 Jan;57:147-167.
[2] Suskind AM, Dunn RL, Zhang Y, et al. Ambulatory surgery centers and outpatient urologic surgery among Medicare beneficiaries. Urology. 2014 Jul;84(1):57-61.

Payment Rates for Urology Procedures

Extracorporeal Shock Wave Lithotripsy (ESWL)

Despite continued correspondence and documentation provided by the Urology community at large regarding the reimbursement rate for extracorporeal shock wave lithotripsy (ESWL) when performed in an ASC, the 2022 Rule fails to address this issue. The AACU urges CMS to update the payment rate for ESWL (HCPCS 50590, APC 5374) to reflect the high equipment acquisition costs for performing the procedure, which are the same whether performed in an ASC or HOPD setting. Updating the rate will demonstrate that the agency is committed to advancing site neutral priorities.

ESWL is a non-invasive ambulatory procedure that is dependent upon the utilization of a lithotripter machine by a highly trained specialist trained in this technique. The typical cost of a lithotripter is around $500,000 and $65,000 annually to maintain the equipment. Due to the prohibitively high cost, urologists and facilities generally lease the equipment rather than purchase it. Industry data suggests that, of nearly 41,000 Medicare ESWL procedures reported annually, over 75% were performed on leased ESWL lithotripters.[3]

As performing ESWL usually requires leasing a lithotripter, most facilities rely on outside contractors to provide the equipment, which costs on average approximately $1,750 per patient. This cost is flat and does not change depending on whether it is used in an HOPD or ASC setting. Thus, due to the discrepancy in reimbursement for ESWL procedures performed in ASC vs. HOPD settings, ASCs lose hundreds of dollars for each ESWL procedure they perform under the existing payment framework. This dynamic has served to shift the procedures towards the costlier HOPD environment, increasing costs to the healthcare system and to beneficiaries.

The current framework has undermined the ability of patients to receive treatment for their kidney stones in a safe, convenient and cost-effective site of care. The AACU urges CMS again to address the inequity of ESWL payments by updating its device-intensive procedure policy to accommodate the unique circumstances of ESWL, which involves high capital costs without the need for an implantable device.

High Intensity Focused Ultrasound (HIFU)

High Intensity Focused Ultrasound (HIFU) is a relatively new, safe and effective technology for the treatment of localized prostate cancer, which is the most prevalent non-skin cancer in men in the United States. HIFU is the least invasive prostate cancer treatment available with a very low rate of complications, such as impotence and incontinence, which are more likely to occur with surgery or radiation. Thus, the procedure has been shown to reduce post-operative care, lower costs for both the government and the beneficiary, and preserve post-surgical patient quality of life.

Unfortunately, this treatment is becoming increasingly inaccessible to Medicare beneficiaries due to CMS lowering HIFU to a level 5 APC code in 2019, which slashed the hospital reimbursement to half of the previous level. The decision was based on claims data from submitted by hospitals that was inaccurate and incomplete and often did not take into account the substantial costs of the disposables used as mandated by the FDA. The dramatic reduction in reimbursement made the procedure unaffordable for hospitals, which now stand to lose several thousand dollars on every HIFU procedure.

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[3] Council for Urologic Interests.

As a result, hospitals have largely refused to allow physicians to do the procedure at their facilities driving patients to non-Medicare contracted facilities.

To ensure this innovative treatment is available to all Medicare beneficiaries with localized prostate cancer, AACU urges CMS reassign HIFU (CPT Code 55880, formerly C9747) to Level 6 APC (5376). This recommendation is supported by OPPS claims data from CY2019 and is even more strongly supported by claims data from CY2020. We believe this APC assignment, which was the original assignment (2017), is clinically appropriate and economically necessary to facilitate access to this technology for the Medicare population.

CMS is encouraged to look at the clinical similarities between CPT Codes 55880 and 55873 (cryosurgical ablation of the prostate, or "Cryo"). These two procedures have the same indication according to the National Comprehensive Cancer Network and are the only two acknowledged treatments for radio current, non-metastatic prostate cancer. Both local therapies have been investigated for the treatment of localized prostate cancer in the initial disease and recurrent settings, with the goal of reducing side effects and matching the cancer control of other therapies. However, Cryo has been in APC 5376 since its implementation in 2000 while HIFU dropped from APC 5376 to APC 5375 in CY2019.

In addition to achieving the same clinical purpose, HIFU has a greater physician work and time requirement than cryotherapy as already recognized by CMS with the RVUs currently assigned to HIFU (17.73) versus cryotherapy (13.60). The wRVU assigned to HIFU and the length of time for the procedure, as well as the clinical complexity are more akin to treatments in APC 5376. When grouped with APC 5375, CPT Code 55880 is a statistical outlier for both wRVU and length of procedure.

Finally, we were very pleased to learn that on August 23, 2021 the CMS Advisory Panel on Hospital Outpatient Payment (HOP) voted unanimously to recommend to CMS that HIFU for localized prostate cancer (55880) be reassigned to Level 6 APC (5376) for CY 2022. We strongly urge CMS to consider the unanimous advice of the HOP Panel, the CY2020 OPPS claims data, and the crosswalk to CPT Code 55873, and reinstate the original hospital reimbursement assigned to HIFU – APC 5376. This APC code is clinically appropriate and economically necessary to facilitate access of this vital technology for CMS's Medicare population.

Conclusion

The AACU appreciates the opportunity to provide comments on the issues detailed above and their impact on urology patients. We look forward to working with CMS to implement policies that support clinicians' ability to deliver high-quality care to their patients. If you have any questions regarding this letter or would like to discuss any of our comments, please contact Yehuda Sugarman, Federal Affairs Manager, at Yehuda@wjweiser.com or (703) 259-6119.

Sincerely,

Elliott Lieberman, M.D.
President
American Association of Clinical Urologists