July 31, 2023

VIA MEARIS PORTAL
Centers for Medicare & Medicaid Services
Ms. Chiquita Brooks-LaSure
Administrator
7500 Security Boulevard
Baltimore, MD 21244

Re: Lithotripsy Procedures and the Impact of APC Configurations 5374 & 5375

Dear Ms. Brooks-LaSure,

The Council for Urological Interests (CUI) is a non-profit, voluntary membership organization, representing more than 40% of all practicing urologists in the United States, and its members form joint ventures with urologists to provide lithotripsy and other urological services to hospitals and ambulatory surgical centers (ASCs). We write to provide our comments regarding the APC configuration affecting lithotripsy procedures, shockwave lithotripsy (SWL; APC 5374), and ureteroscopy with lithotripsy (URS; APC 5375)

In 2010 at the Centers for Medicare & Medicaid Services' (CMS) Baltimore headquarters, CUI leadership met with the leaders of Hospital Outpatient (HOPP) and Ambulatory Surgical Center (ASC) programs. The purpose of the meeting was to try and explain *how Medicare could save itself and taxpayers millions of dollars every year* simply by paying "fairly" for extracorporeal SWL at an ASC. Of course, that is what CMS originally did when it created a separate ASC payment grouping for SWL in the 1990's because of its *unique characteristics: non-invasive, safe, effective, but identically expensive whether at hospital or ASC. The fact is that the same doctor, the same expert lithotripsy tech, the same lithotripter, and the same transportation unit is used wherever the patient is treated for most SWL cases across the US.* Unfortunately for everyone, CMS refused to change its payment scheme simply because it would require CMS to move money that was budgeted for HOPPS, to the bucket of money budgeted for ASCs. A jaw-dropping admission.

In 2018, without notice and/or comment, CMS moved SWL from APC 5375 to APC 5374. This decreased the reimbursement rate for SWL and increased the reimbursement rate for URS. This dramatic adjustment in reimbursement has had the predictable consequence of shifting treatment from the non-invasive SWL, to the more invasive URS, despite the current understanding that recent studies show similar stone-free rates for both procedures, as well as a higher complication rate for URS. Unplanned admissions, infections, septicemia, and ureteral strictures are all more common after URS than SWL and they are not rare: 5% risk of sepsis, 3% of ureteral stricture, and 15% risk of unplanned admission by large scale studies. The risks of general anesthesia must also be considered.

For example, in 2018, both SWL and URS were paid $3,705.77 when done in hospital outpatient departments. That year, 90,572 SWL and URS procedures were performed in the HOPPS venue. SWL made up 47% and URS 53%.

2018	Treatment Received	APC Code	Number of cases	Reimbursement Rate	Cost to CMS
	SWL	5375	42677	$3,705.77	$158,151,146.29
	URS	5375	47895	$3,705.77	$177,487,854.15

By comparison, 2022 data shows that SWL payment was decreased to $3140.04 while URS was increased to $4505.89 at the hospital outpatient department. A total of 97,463 combined cases were performed: 39% SWL and 61% URS. A dramatic swing between procedures.

2022	Treatment Received	APC Code	Number of cases	Reimbursement Rate	Cost to CMS
	SWL	5374	38256	$3,140.04	$120,125,370.24
	URS	5375	59207	$4,505.89	$266,780,229.23

CMS' decision to separate these two procedures into different APC groups may have been well intended, however the result has been that by favoring and incentivizing one procedure over another, on top of Medicare's formulaic rate of 42% of the HOPPS rate for ASCs, many ASCs stopped offering SWL to Medicare patients since the reimbursement was no longer compensatory.

In short, this has meant that most Medicare stone patients will either get SWL at a hospital at a higher cost or get URS at either an ASC or hospital at a much higher cost. Thus, Medicare ends up paying more than double for the same outpatient surgical procedure to be performed in hospital outpatient departments instead of at an ASC. To be clear, there has never been a reason that shock wave lithotripsy needs to be performed in a hospital. Furthermore, CUI presented *an unplanned admission study showing that because of URS's invasiveness, Medicare pays over $200,000 more for every one-hundred Medicare patients that get URS instead of SWL done by a high-volume team of lithotripsy personnel.* This study can be provided upon request.

While this separation of APC groups and the resulting implications has cost CMS and the American taxpayer more, it has also cost Medicare beneficiaries more as well. A Medicare patient is responsible for a 20% co-pay, meaning that treatments at the more expensive hospital settings are more costly to them. For example, when *Medicare patients receive treatment in a HOPD instead of an ASC, the result, based on 2022 reimbursement rates, is an increase of between $340 to $478 dollars additional cost for the Medicare patient for a single procedur*e. Medicare beneficiaries pay a heavy price in pain and potential complications as well when CMS's payment scheme incentives the more invasive URS procedures. Because URS results in an indwelling ureteral stent being left in the patient for up to seven days, many people are in constant misery after the procedure.

In an era where "shared decision-making" with the patient is paramount, CMS's payment scheme becomes even more important, particularly when approximately half of active doctors today work directly for hospitals. Anecdotally, when asked in private what procedure they would choose to have if they had a kidney stone, most urologists answer SWL without hesitation. Even doctors who perform 100% URS on their patients give the same answer when confronted with their personal health. A recent medical podcast had patients speaking who had both SWL and URS, and their conclusion was that they would never have URS again unless SWL failed.

CUI has repeatedly recommended to CMS that SWL should be considered "Device Intensive" because of its cost, regardless of site of service. However, CMS has unfortunately narrowed this category to single use devices and refuses to include SWL. Accordingly, CUI believes the following options would correct the current payment scheme issues facing the lithotripsy industry:

1) Give SWL *Device Intensive status* that was originally recognized by CMS because it's unique. Device Intensive Status was a recognition by CMS that the general principle that ASC costs were lower than hospital outpatient costs did not always apply. In certain cases, a "device" was required in connection with the surgery. The classic example was intra-ocular lenses (IOLs) used in cataract surgery. CMS recognized that while the general overhead was less in an ASC than in an HOPD, the HOPD could not purchase the IOL anymore cheaply than could the ASC. Accordingly, the APC for cataract surgery allowed a Device Intensive supplement to recognize the higher cost of the IOL in the ASC.

   CUI has urged CMS to grant Device Intensive status to SWL in order to recognize the higher cost of a lithotripter, litho tech, truck and maintenance contract, all of which costs the same to an ASC or a HOPD. That fits directly into the intent of the Device Intensive Payment as originally laid out. SWL is an expensive device, regardless of site of service. Thus far CMS has refused *based upon the definition CMS itself adopted limiting Device Intensive status to single-use devices*; or

2) Put SWL and URS back into the same APC grouping.

The time has come to correct this long overdue problem, eliminate the procedure bias, and protect the Medicare beneficiaries from the unintended complications of the current scheme.

Joseph Jenkins MD, JD
Chairman & Executive Director
Council for Urological Interests

*Revised by Request of CMS
Panel Facilitators.
August 9, 2023