UROTRONIC

August 18, 2020 Submitted electronically via www.regulations.gov

Ms. Seema Verma
Center for Medicare and Medicaid Services
Department of Health and Human Services
Attention CMS-1736-P
PO Box 8013
Baltimore, MD 21244-1850

RE: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment and Quality Reporting Programs (CMS-1736-P)

Dear Administrator Verma,

Urotronic, Inc. welcomes the opportunity to provide comment on the Center for Medicare and Medicaid Services' (CMS') proposed regulation, "Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs" (CMS-1736-P).

A. BACKGROUND

Urotronic, Inc. is a medical device company committed to developing less invasive treatments for Benign Prostatic Hyperplasia (BPH) and other urological diseases utilizing drug coated balloon technology. Our specific comments pertain to the Optilume Drug Coated Balloon Catheter System used to treat BPH (Optilume BPH System) described by CPT Code 0619T (Cystoscopy with transurethral anterior prostate commissurotomy and drug delivery, including transrectal ultrasound and fluoroscopy when performed).

In our prior communications with CMS dated January 14, 2020 and February 10, 2020, Urotronic presented it's rationale why CPT 0619T (previously numbered as 0X05T) should be assigned APC 5376 using HCPCS C9740 (Cystoscopy with insertion of transprostatic implants, 4 or more) as a reference code which had been assigned to APC 5376 in CY 2020. The basis for this request was that the clinical characteristics, physician work/ intraoperative intensity, and resource costs including non-device related costs and device related costs were similar to HCPCS C9740. In addition to the aforementioned costs, CPT 0619T had additional non-device costs including transrectal ultrasound, fluoroscopy and use of a rectal stepper device. In the August 4, 2020 Proposed Rule for CY 2021, HCPCS C9740 was maintained in APC 5376 while CPT 0619T was assigned 5375. Urotronic requests that CMS reconsider assigning C0619T to APC 5376 for the below reasons.

B. OPTILUME BPH SYSTEM CONTAINS MULTIPLE COMPLEX COMPONENTS

The Optilume BPH System includes:

1. catheter sizing tool (Precision match of balloon to prostate)

2 specialized non-drug coated pre-dilation balloon

3. specialized drug coated delivery balloon

4. calibrated high-pressure inflation device

5. urethral obturator and sheath for atraumic delivery and removal

The Optilume BPH System consists of two novel hour-glass shaped balloon catheters: a primary non-drug coated pre-dilation balloon used to expand the prostate and a drug coated balloon which transfers drug into the prostate. Both balloons are uniquely designed so that the primary pre-dilation balloon creates the exact forces needed to create an anterior prostate commissurotomy while the drug coated balloon delivers a non-proliferative medication (Paclitaxel) into the prostate tissue to prevent closure of the commissurotomy. (see 'Attachment A' below for product design and the following link to highlight clinical data that was recently published in Urology Times, a leading industry publication.) https://www.urologytimes.com/view/bph-catheter-system-shows-encouraging-outcomes-in-pilot-trial

Both catheters are sized to fit into the urethra side-by-side with a cystoscope. The hour-glass shaped balloon is divided into two lobes separated by a neck section; thereby, creating a cone shaped distal lobe and a cylindrical proximal lobe. The neck section is located approximately 10 mm from the distal end and reinforced with high molecular weight polyethylene fiber to make the neck section non-compliant preventing diameter growth in that area during inflation. The reinforced balloon neck seats in the bladder neck during treatment and prevents migration into the bladder. The distal conical lobe of the balloon is designed to inflate in the bladder and aids in anchoring the device. The proximal cylindrical lobe of the balloon symmetrically dilates the prostatic channel and creates a controlled commissurotomy, which opens the cross-sectional area of the prostatic urethra. The drug eluding balloon has the same geometric shape except that it is coated with Paclitaxel on the entire surface of the proximal lobe and part of the distal lobe. Upon inflation this unique design delivers drug into the prostatic tissue and newly split commissurotomy to prevent the hyperplastic response or reclosure of the obstructing prostatic tissue. Each catheter is individually packaged.

The proximal end of each catheter shaft is designed to interface with a valve which facilitates the connection between the catheter inflation lumen and the calibrated high-pressure inflation device. The proprietary valve design can withstand over six atmospheres of pressure during inflation of the balloons.

C. TOTAL COSTS RELATED TO CPT 0619T ARE APPROPRIATE FOR APC 5376

In the January 14, 2020 and February 10, 2020 communications with CMS, Urotronic utilized CY 2019 data and HCPCS C9740 as a reference code to estimate the total procedure cost of CPT 0619T. Utilizing the more recent data from CY 2020 (published in the CY 2021 Proposed Rule), we have updated our cost estimate. To determine total procedure costs of CPT 0619T, we recommend that CMS use the non-device portion of the estimated cost of C9740 plus the device cost of the Optilume BPH System. In CY 2020, the Geometric Mean Cost of C9740 was $7,930 of which the device costs represent approximately 72%; therefore, the non-device costs for C9740 are estimated to be $2,220 (28% of $7,930). When the cost of the Optilume BPH System ($5,100) is added to the non-device costs ($2,220), the total estimated cost of CPT 0619T is $7,320. Based upon this cost estimate, we believe that the most appropriate APC assignment is APC 5376 with a CY 2021 Projected Geometric Mean Cost of $8,089 rather than APC 5375 with a Projected Geometric Mean Cost of only $4,324.

Furthermore, in the Final CY 2020 portion of APC payment assigned to devices, the device offset for APC 5375 is only 6.02% compared to APC 5376 where it is 55.78%. Since CPT 0619T is device intensive with over 50% of the total estimated cost related to the Optilume BPH System, it would be more appropriate to place 0619T in the more device intensive APC 5376

D. CONCLUSIONS

1. The Optilume BPH System consists of multiple complex components including two specialized shaped balloon catheters which achieve controlled prostate dilation with anterior commissurotomy and drug delivery into the prostate tissue.

2. CPT 0619T is most similar in clinical characteristics, physician work and resource costs to HCPCS C9740.

3. Based upon CY 2020 data, the total estimated costs of 0619T is $7,320 which is more appropriate for APC 5376 with a CY 2021 Projected Geometric Mean Cost of $8,089 rather than APC 5375 of $4,324.

4. CPT 0619T significant device intensive status is more appropriate to APC 5376.

Sincerely,

David Perry
CEO

Attachment A.

The balloon catheter is designed to have a 14.5Fr profile allowing insertion and compatibility with a 19.5 or 20Fr rigid cystoscope sheath.

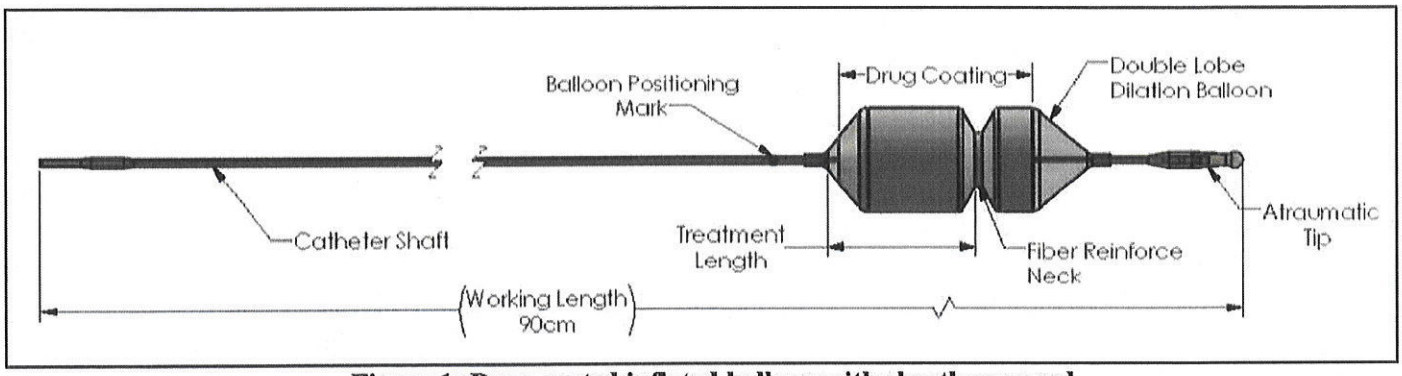

Figure 1: Drug coated inflated balloon with sheath removed

Balloon sizes will be available to fit the entire spectrum of patient anatomy, as outlined in Table 1.

Table 1: Balloon Size Chart

Balloon Diameter		Balloon Treatment Length				Catheter Profile
mm	Fr	mm				
30	90	30	35	40	45	14.5Fr