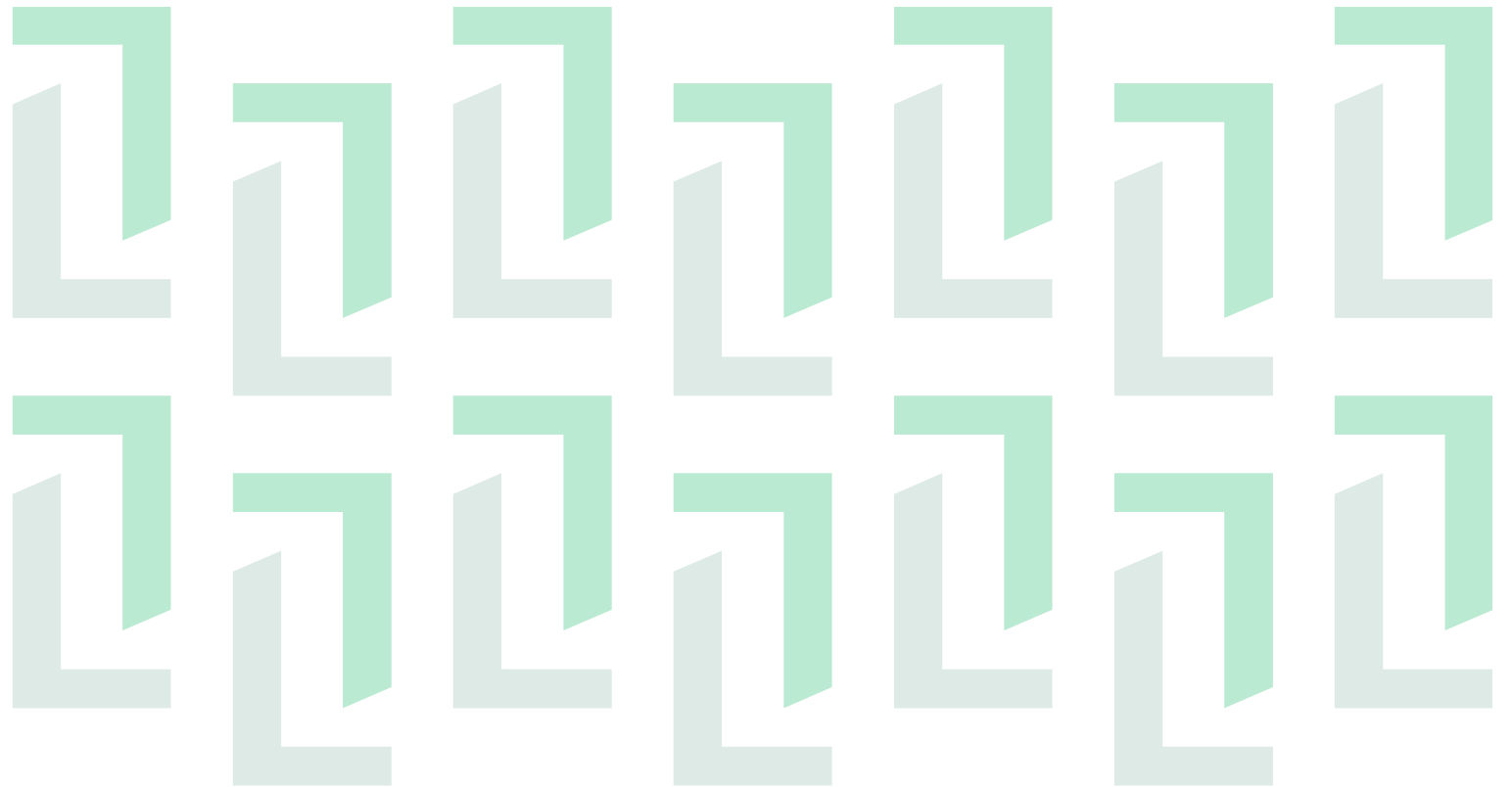


Assignment of 5X000 to APC 5375 and Device Intensive Status for CY 2024

Advisory Panel on Hospital
Outpatient Payment

August 21-22, 2023



OPTILUME® STRICTURE

An exciting, minimally invasive urethral stricture treatment, the Optilume® drug-coated balloon was developed in response to severe patient and physician dissatisfaction with current stricture solutions.

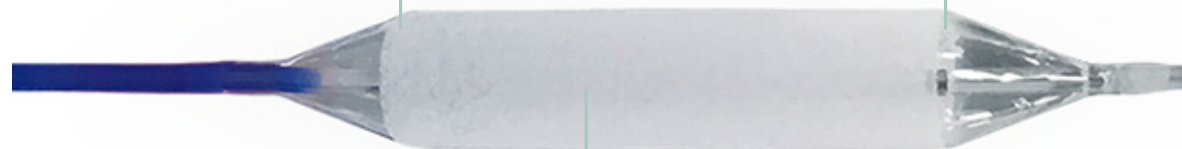
This proprietary technology combines balloon dilation and drug delivery and is well-tolerated by patients.¹

Semi-compliant inflatable balloon

The semi-compliant inflatable balloon expands to create micro-fissures in the tissue, facilitating drug absorption

Radiopaque marker bands

The device has two radiopaque marker bands indicating the working length of the balloon where the drug coating is applied.



Paclitaxel and coating

A novel excipient molecularly binds paclitaxel to the balloon until the balloon inflates and dilates the tissue for rapid, controlled drug release.

Atraumatic tapered tip

Travels easily over the guidewire and can cross tight strictures

CODING

- 0499T (*Cystourethroscopy, with mechanical dilation and urethral therapeutic drug delivery for urethral stricture or stenosis, including fluoroscopy when performed*)
 - Sunsetting December 31, 2023
 - Converting to Category I Current Procedural Terminology (CPT®)* code 5X000 effective January 1, 2024
- Used to report procedure performed with the Optilume device, FDA approved December 2021 and commercially available January 2022
 - Calendar year (CY) 2022 claims data is the first to reflect commercial use of the device outside of the context of a clinical trial

DESCRIPTION OF THE ISSUE

- The Centers for Medicare & Medicaid Services (CMS) proposes to assign CPT code 5X000 to Ambulatory Payment Classification (APC) 5374 (Level 4 Urology and Related Services) without device intensive status
- In the hospital outpatient department setting, this results in assignment that is inconsistent with the claims data, which supports assignment to APC 5375 (Level 5 Urology and Related Services)
 - Geometric mean cost (GMC) of 0499T in CY 2022 claims data is \$4,528.70
 - Higher than nearly all other procedures assigned to APC 5374, and higher than several high-volume procedures proposed to be assigned to APC 5375 (e.g., 52630, 52353, 53750, and 52601)
 - Also disregards clinical coherence with other procedures assigned to APC 5375 (e.g., 0619T, 52346, 52305, and C9739)
- For ASCs, the lack of device intensive status results in payment that is significantly less than the cost of the Optilume device itself, making it unlikely that Medicare beneficiaries will have access to the procedure in an ASC (which is currently the case)
 - Optilume is invoiced at \$2,395, as supported by invoices submitted to CMS
 - Proposed ASC payment rate is \$1,587.88, which is significantly less than the device cost
 - The service is currently not offered in the ASC and will continue to not be available in the ASC setting if payment does not more appropriately reflect costs to furnish the service

RECOMMENDATION REQUESTED

- **We ask the HOP Panel to recommend that CMS:**
 - 1. Assign CPT code 5X000 to APC 5375 and**
 - 2. Designate CPT code 5X000 as device intensive**
 - The device offset should reflect the \$2,395 cost of the Optilume device or, at a minimum, be set at the 31% default device offset until claims data more accurately reflect the cost of the device