



Access to Bladder Cancer Care: The CMS OPPS

AUGUST 2024

**“PACKAGED PAYMENT POLICY”
HARMS CANCER TREATMENT**

PRESENTATION TO APC ADVISORY COMMITTEE

THE ISSUE

- Medicare beneficiaries for the last ten years have received inferior cancer treatment due to CMS “packaged payment” policy
 - In 2014, CMS began packaging certain cancer “drugs that function as a supply when used in a diagnostic procedure” or “. . .when used in a surgical procedure” into procedure payments
 - In 2017, CMS expanded the policy, and included numerous drugs, including the 2014 packaged drugs, into a second “Comprehensive APC” packaging policy (81 Fed. Reg. 79562, 79569 (Nov. 14, 2016))
 - Importantly, packaged drugs are the exception, and there are hundreds of drugs reimbursed “at cost” which remains the rule
- CMS has previously recognized that:
 - *“...packaging payments for certain drugs... might result in inadequate payments to hospitals, which could adversely affect Medicare beneficiary access to medically necessary services.”* 68 Fed. Reg. at 47995 (Aug. 12, 2003)
 - *“.....Packaging policies must achieve a “balance between ensuring that payment is adequate to enable hospitals to provide quality care and establishing incentives for efficiency.”* 76 Fed. Reg. at 74183 (Nov. 30, 2011)

Packaging Cysview into Urology APCs impairs use of innovative cancer treatments – harming care and costing Medicare more

A “PACKAGED PAYMENT” FAILURE: BLADDER CANCER AND UNMET NEED

COMMON (8th most common cancer worldwide^{1a})



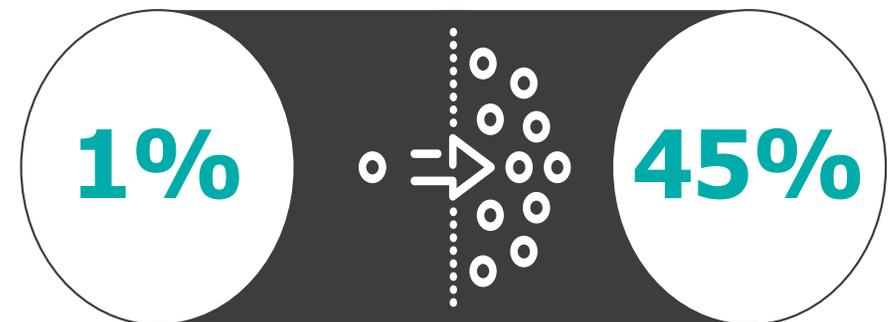
EXPENSIVE



RECURRENT



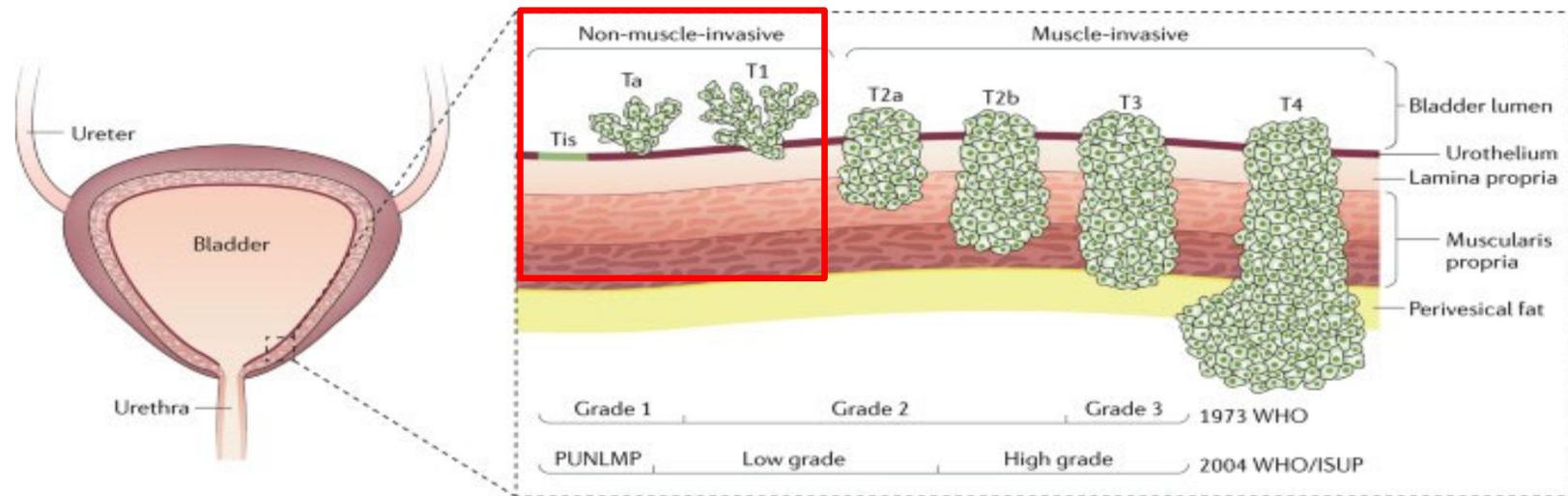
PROGRESSIVE (FROM NMIBC TO MIBC, at 5 years)⁴



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1) Globocan. a) 5-year prevalence / b) incidence/mortality by population. Available at: <https://gco.iarc.fr/today>, accessed [January 2022]. 2) Sievert KD et al. World J Urol 2009;27:295–300 and Bladder Cancer. American Cancer Society. <https://www.cancer.org/cancer/bladder-cancer.html>. 3) Mariotto AB, Yabroff KR, Shao Y, Feuer EJ, Brown ML. Projections of the cost of cancer care in the United States: 2010-2020. J Natl Cancer Inst. 2011;103(2):117-28. 4) Sylvester RJ et al. Eur Urol 2006; 49:466-467 Global Data: Bladder Cancer Report

THE NEED TO TREAT EARLY: NON-MUSCLE INVASIVE BLADDER CANCER

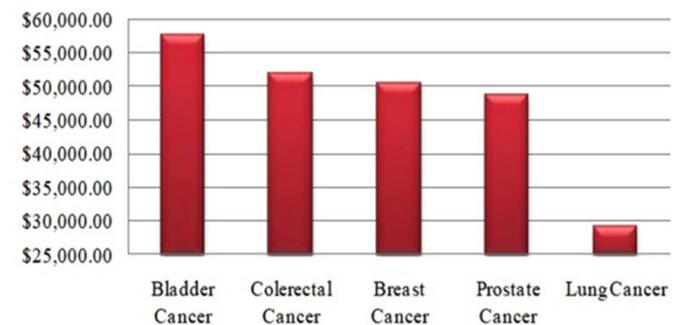


- Bladder cancer typically forms in the lumen and grows into surrounding muscle
- Non-Muscle Invasive bladder cancer (NMIBC) is the earliest and most localized stage of the disease
- NMIBC treatable with curative intent by using Transurethral Resection of Bladder Tumor (TURBT)
- Muscle invasive forms are more advanced and difficult to treat
- Early intervention provides the best clinical outcomes

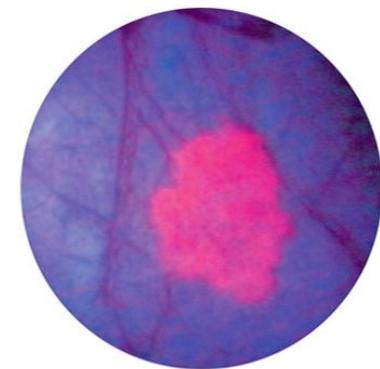
SOLVING THE PROBLEM OF RECURRENCE

- Historically “White Light Cystoscopy” treatment for bladder cancer was state of the art, but results in high cancer recurrence rates^{1,2}
 - Up to 61% at 1 year
 - Up to 78% at 5 years
- Progression to muscle-invasive disease^{1,2}
 - Up to 17% at 1 year
 - Up to 45% at 5 years
- Solution: “Blue Light Cystoscopy with Cysview”
- A better way to visualize bladder cancer:
 - Detects more NMIBC than WL by
fluorescing pink under blue light

Medicare Payment per Patient from Diagnosis Until Death, USD per Person



Bladder image from White Light Cystoscopy



Same image from Blue Light Cystoscopy with Cysview

1. Babjuk M, et al. Eur Urol. 2019; 76(5): 639-657
2. Sylvester, et al. Eur Urol 2006 Mar;49(3):466-5

Clinical Guidelines Endorse Use of Blue Light Cystoscopy

- AUA / SUO - 2020  
 - “In a patient with NMIBC, a clinician should offer blue light cystoscopy at the time of TURBT, if available, to increase detection and decrease recurrence. (Moderate Recommendation; Evidence Strength: Grade B)”
 - “In a patient with a history of NMIBC with normal cystoscopy and positive cytology, a clinician should consider prostatic urethral biopsies and upper tract imaging, as well as enhanced cystoscopic techniques (blue light cystoscopy, when available), ureteroscopy, or random bladder biopsies. (Expert Opinion)”
- NCCN – 2019  National Comprehensive Cancer Network®
 - “Blue Light Cystoscopy with Cysview helps in identifying lesions not visible by White Light Cystoscopy in the primary surgical treatment of Non-Muscle Invasive Bladder Cancer”
- EAU – 2021  European Association of Urology
 - “It has been confirmed that fluorescence-guided biopsy and resection are more sensitive than conventional procedures for the detection of malignant tumors, particularly for CIS”
 - “A systematic review and analysis of 14 randomized controlled trials (RCTs) including 2,906 patients, six using 5-ALA and nine HAL, demonstrated a decreased risk of BC recurrence in the short and long term”

HOW IS THE POLICY WORKING?

- Cysview[®], the bladder cancer drug, provides important evidence that the “packaged payment” policy CONTINUES TO NOT be working for high cost, low volume drugs
- The evidence demonstrates the Packaged Payment Policy is resulting in “inadequate payments to hospitals,” which is “adversely affect[ing] Medicare beneficiary access to medically necessary services”
- As a result of the Packaged Payment Policy, less than 5% of Medicare beneficiaries are receiving needed treatment for bladder cancer

IMPROVEMENT TO COST AND CARE

- Blue Light Cystoscopy with Cysview's dramatically improves patient outcomes:
 - Significantly improves detection of papillary (16-29%) and CIS tumors (32%), detects 96% of all tumors, and significantly reduces tumor recurrence
- Medicare *Could* Save Significant Cost
 - NCI recognized the value: "blue light cystoscopy is the most advanced method of diagnosing and detecting bladder tumors."
 - Cysview patients cost 15% less over five years compared to White Light patients
 - Savings per patient: \$9,097 - \$34,538 (Shore 2022), \$4,600 (Garfield 2013)**
 - Instead, due to packaging, Medicare is wasting money on 1980s care, harming patients and the Trust Fund

The cost-effectiveness of blue light cystoscopy in bladder cancer detection: United States projections based on clinical data showing 4.5 years of follow up after a single hexaminolevulinate hydrochloride instillation

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GARFIELD SS, GAVAGHAN MB, ARMSTRONG SO, JONES JS. The cost-effectiveness of blue light cystoscopy in bladder cancer detection: United States projections based on clinical data showing 4.5 years of follow up after a single hexaminolevulinate hydrochloride instillation. *Cancer J Urol* 2013;20(2): 6682-6689.

Introduction: Several studies, including the recently published phase III study by Stenzl and colleagues have demonstrated that hexaminolevulinate hydrochloride, when used with blue light fluorescence cystoscopy, improves detection of non-muscle invasive bladder tumors compared to white light cystoscopy and transurethral resection of bladder tumors (TURB) alone.
Materials and methods: The objective of this study was to conduct a detailed assessment of the cost-effectiveness of using hexaminolevulinate hydrochloride with blue light cystoscopy as an adjunct to white light versus white light

cystoscopy alone at time of initial TURB in the United States. A probabilistic decision tree model, using TreeAge Pro 2011 software, was developed using base case scenario cost and utility estimates.
Results: Incorporation of hexaminolevulinate hydrochloride into diagnostic cystoscopy results in lower costs over 5 years (\$25,921) as compared to those patients who initially receive white light cystoscopy (\$30,581). Those patients who initially receive hexaminolevulinate hydrochloride blue light TURB also experience a lower overall cancer burden.
Conclusions: Hexaminolevulinate hydrochloride may be cost effective when used at first TURB for patients with suspected new or recurrent non-muscle invasive bladder cancer.

Key Words: white light cystoscopy, bladder cancer, bladder cancer detection, Cysview, cystoscopy, cost-effectiveness, outcomes, utility, cystectomy, transurethral resection of the bladder

Introduction

Bladder cancer is the second most common genitourinary malignancy in the United States and the fifth most

common cancer overall. Approximately 554,347 men and women in the United States have a history of cancer of the urinary bladder (411,234 men and 142,113 women). An estimated 37 per 100,000 men and 8.9 per

Cysview (Hexaminolevulinate Hydrochloride) for Intravesical Solution

Original Sponsor: Sep 05, 2014 10:54 am

Submission Number: NDC104703-01

Notice Type: Preclinical

Synopsis: Added: Sep 03, 2014 10:54 am

Description: The Urologic Oncology Branch (UOB) plans to present on a sub-source basis with Protonics, LLC (Carrigee Center - Suite 204, Princeton, NJ 08542-6276) to provide the optical imaging agent, Cysview (hexaminolevulinate HCl), which is the only FDA approved product for use with blue light cystoscopy. Cysview is an optical imaging agent indicated for use in the cystoscopic detection of non-muscle invasive papillary cancer of the bladder among patients suspected or known to have bladder cancer on the basis of a prior cystoscopy. Cysview is used with the ABL 5100F2 (blue light Cystoscopy) Cystoscopy (CSC) system to perform cystoscopy with the blue light setting as an adjunct to the white light setting. Protonics is the only known source that provides the complete, proprietary source Cysview for Intravesical Solution is a unique optical imaging agent. This material will be processed under FAR Part 12 - Acquisition for Commercial Items and will be made pursuant to the authority in FAR 12.106-10 (1) using the acquisition procedure for commercial acquisitions. The North American Industry Classification System code is 424210 and the business size standard is \$14.2MM/yr.

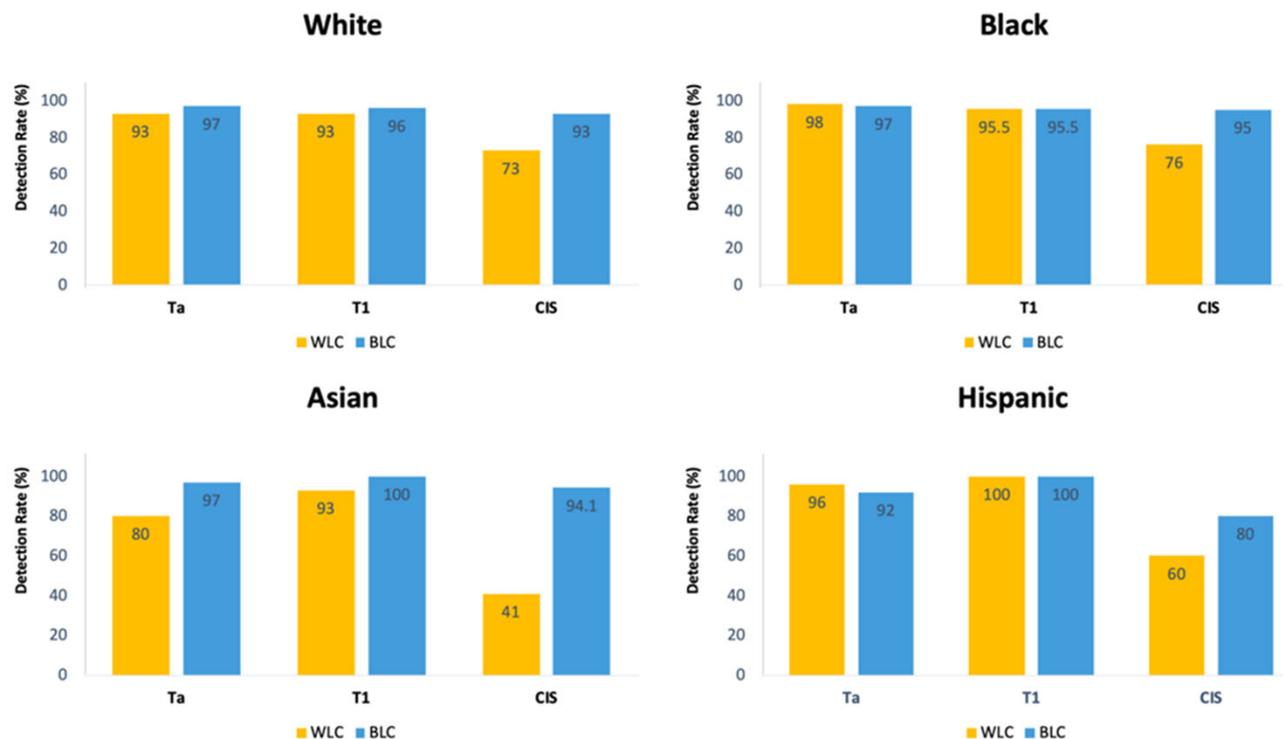
GENERAL INFORMATION: Notice Type: Preclinical
Posted Date: September 3, 2014
Response Date: Sep 05, 2014 12:00 pm Eastern
Archiving Policy: Manual Archive
Archive Date: N/A
Risk Rating: N/A
Classification Code: 14 - Chemicals & Derivatives (Drugs)
NABDS Code: A24 - Molecular Vitamins, Minerals, Steroids, Hormones, Drugs and Diagnostic Reagents, Molecular Vitamins

The Urologic Oncology Branch (UOB) conducts clinical and basic research designed to develop better methods for detection, prevention, and therapy of patients with prostatic and gynecologic cancer. Its primary focus is the study of the genes associated with initiation and progression of kidney, prostate, and bladder cancers. The use of the optical imaging agent Cysview (hexaminolevulinate hydrochloride) for intravesical solution is indicated for photodynamic blue light cystoscopy, as an adjunct to white light cystoscopy for the detection of non-muscle invasive papillary cancer of the bladder in patients suspected or known to have bladder cancer on the basis of a prior cystoscopy. Blue light cystoscopy is the most advanced method of diagnosing and detecting bladder tumors. It has been shown to enhance one's ability to identify bladder tumors over conventional white light cystoscopy. UOB needs to be able to offer blue light cystoscopy to detect and treat bladder tumors for clinical trials and improve patient care. Blue light cystoscopy requires the optical imaging agent Cysview. Cysview is a unique optical imaging agent.

RACIAL DIFFERENCE IN DETECTION RATE OF BLADDER CANCER USING BLUE LIGHT CYSTOSCOPY

- Blue Light Cystoscopy increases percent detection in all races vs. white light standard of care (Das 2023)
- Improvement is especially pronounced in Asian population
- The high-risk tumor carcinoma in situ (CIS) found at much higher rates, especially in Asian populations

	Increase in DR by BLC
Caucasian (n=2011)*	10.6
African American (n=178)*	6
Asian (n=99)*	18.2
Hispanic (n=91)*	1.6
Total (n=2379)*	10.3

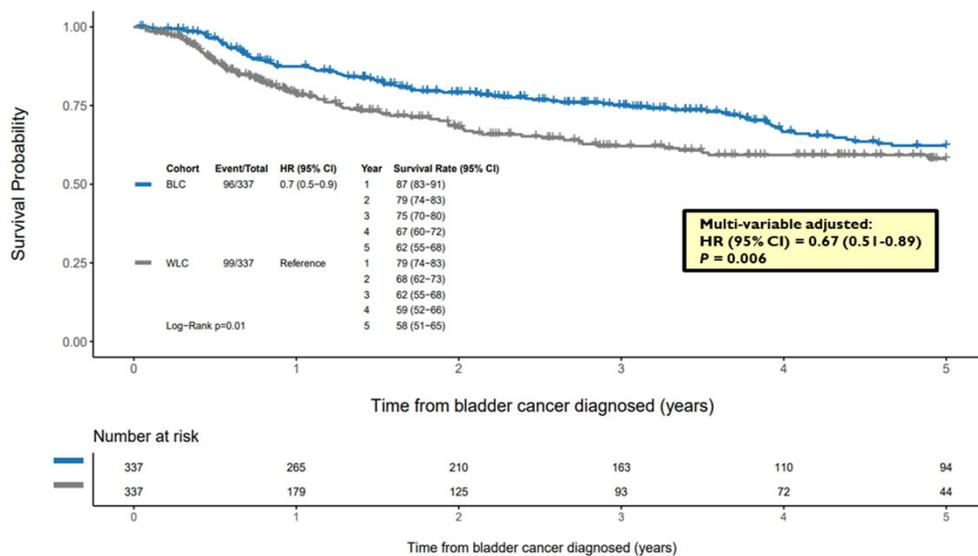


VA BRAVO STUDY:

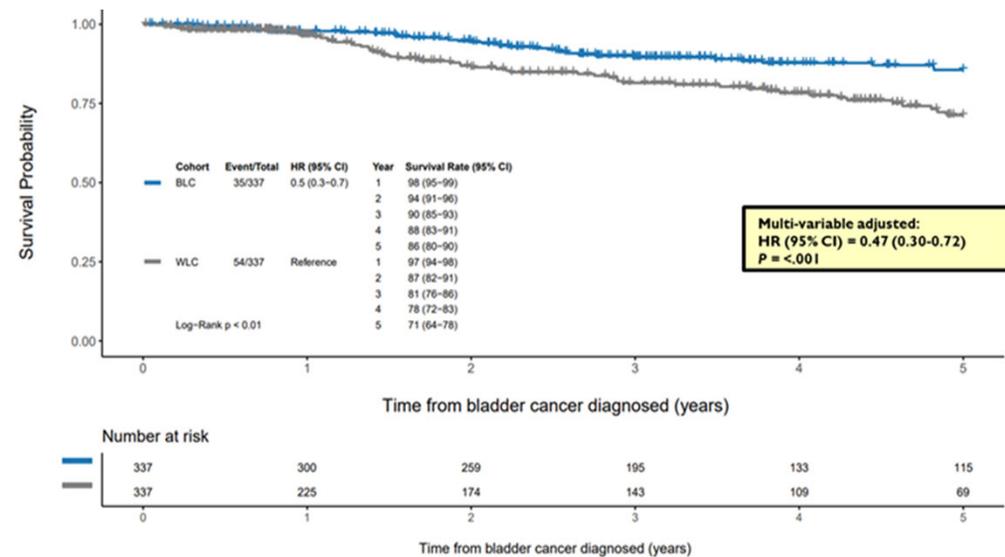
BLADDER CANCER RESEARCH ANALYSIS IN VETERANS AND OUTCOMES

Recurrence and Progression of Bladder Cancer in a Heterogeneous Population in the Veterans Affairs Health Care System: A Retrospective, Multi-Center, Real World Evidence Trial

Delay to Recurrence



Improvement in Overall Survival



PACKAGING DIRECTLY HARMS ACCESS

[REDACTED]
From: [REDACTED]
Sent: [REDACTED]
To: [REDACTED]
Subject: [REDACTED]

FYI

From: [REDACTED]
To: [REDACTED]
Subject: Fwd: [REDACTED]

FYI from [REDACTED] Hospital System Chief of Urology

Begin forwarded message:

Begin forwarded message:

From: [REDACTED]
Date: [REDACTED]
To: [REDACTED]

Kim,
We cannot proceed with using photocure on our bladder cancer patients until the reimbursement issue is settled.

[REDACTED]
Chief, Division of Urology
[REDACTED] University Health System

[REDACTED]

Kim,
We cannot proceed with using photocure on our bladder cancer patients until the reimbursement issue is settled.
[REDACTED]
Chief, Division of Urology
[REDACTED] University Health System

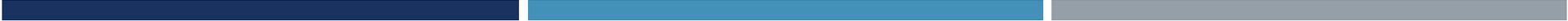
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Why Packaging Drugs Denies Access and Impedes Innovation

- Dilution of payment within the particular type of procedure
 - Procedures “with” and “without” drug are paid at the same rate, and the cost of the drug is diluted across all identical procedures
 - C-APCs with drugs only aggravates the issue
- Dilution of payment across procedures in the APC
 - Bladder Cancer Cystoscopy (APCs 5373 and 5374): over 70 and 100 different procedures, for a wide variety of treatments in the kidney, bladder, prostate, urethra, and other body parts – only 4 of the 100+ procedures could use Cysview (the drug can only be used in the bladder)
- Arbitrary reduction of payment in ASC
 - Complexity adjustment only applies to 2 of 7 relevant CPT codes due to years of historic CMS packaging before it accepted blue light cystoscopy with Cysview as eligible for complexity adjustment

THE ADVISORY COMMITTEE SHOULD RECOMMEND THAT CYSVIEW BE UNPACKAGED AND PAID SEPARATELY

- This Committee has previously recommended unpackaging when warranted by the clinical circumstances. (August 31, 2020 – diagnostic radiopharmaceuticals).
- Blue light cystoscopy with Cysview situation warrants the same recommendation here.
- The Committee should recommend that CMS unpackage and separately pay at cost (ASP+6%) for A9589 (Cysview) when billed with C9738 (blue light cystoscopy).



Discussion and Questions

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