

CMS OPPS

“Packaged Payment Policy”

Presentation to the Office of
Management and Budget, Office of
Information and Regulatory Affairs

April 6, 2017

Why Are We Here

Patient email to Photocure, August 2016:

I am writing to you for two purposes today.

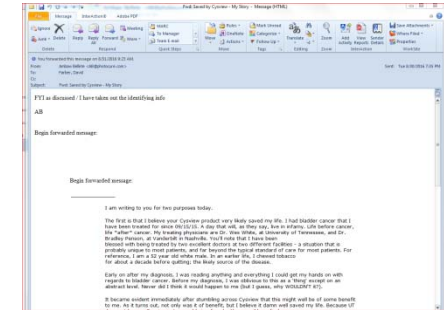
The first is that I believe your Cysview product very likely saved my life. I had bladder cancer that I have been treated for since 09/15/15. A day that will, as they say, live in infamy....

Early on after my diagnosis, I was reading anything and everything I could get my hands on with regards to bladder cancer. Before my diagnosis, I was oblivious to this as a 'thing' except on an abstract level. Never did I think it would happen to me (but I guess, why WOULDN'T it?). It became evident immediately after stumbling across Cysview that this might well be of some benefit to me. As it turns out, not only was it of benefit, but I believe it damn well saved my life. **Because UT does not have a Cysview setup, and being faced with a possible radical cystectomy, I elected to switch to Vanderbilt. First, because of the Cysview technology, but also equally important, because of Dr. Penson and his abilities to treat me. Both of these were critical factors in my and our decision-making process. Vanderbilt is one of only several facilities in the southeast that have Cysview at all, which is amazing to me.**

During I believe it was my 3rd or 4th cystoscopy, Dr. Penson did a second pass around my bladder, which was instilled with Cysview. On this second pass, he found a very, very tiny spot (0.6 cm) that was fluorescing. This spot was actually invading my lamina propria..... I believe that a significant reason for recurrence is because spots like this are missed using WLC. **Had Dr. Penson not had a second go-round, this would have absolutely been lethal to me. Instead of being in the 80 - 90% cohort, I would be in the 20 - 40% 5 year cohort. My cysto was delayed as it was, and any further delay would have meant this would have become muscle invasive. As I sit here now, writing to you, my cytology has come back negative.....**

In case I wasn't clear, Cysview SAVED MY LIFE....Your company and doctors and inventors should be proud of that. Dr. Penson stated to me that he believed Cysview was a 'game changer' - and I couldn't agree more. Had he not seen that single, tiny malignancy, I would probably be dead from this inside of five years, possibly less. And that was all on Cysview.

I am glad I am able to write to you directly. You are welcome to forward my e-mail, without any identifying information, to your staff, as you see fit. You may not often hear directly from the people whose lives you save (or perhaps you do, I don't know, actually) but this is my story.



The Issue

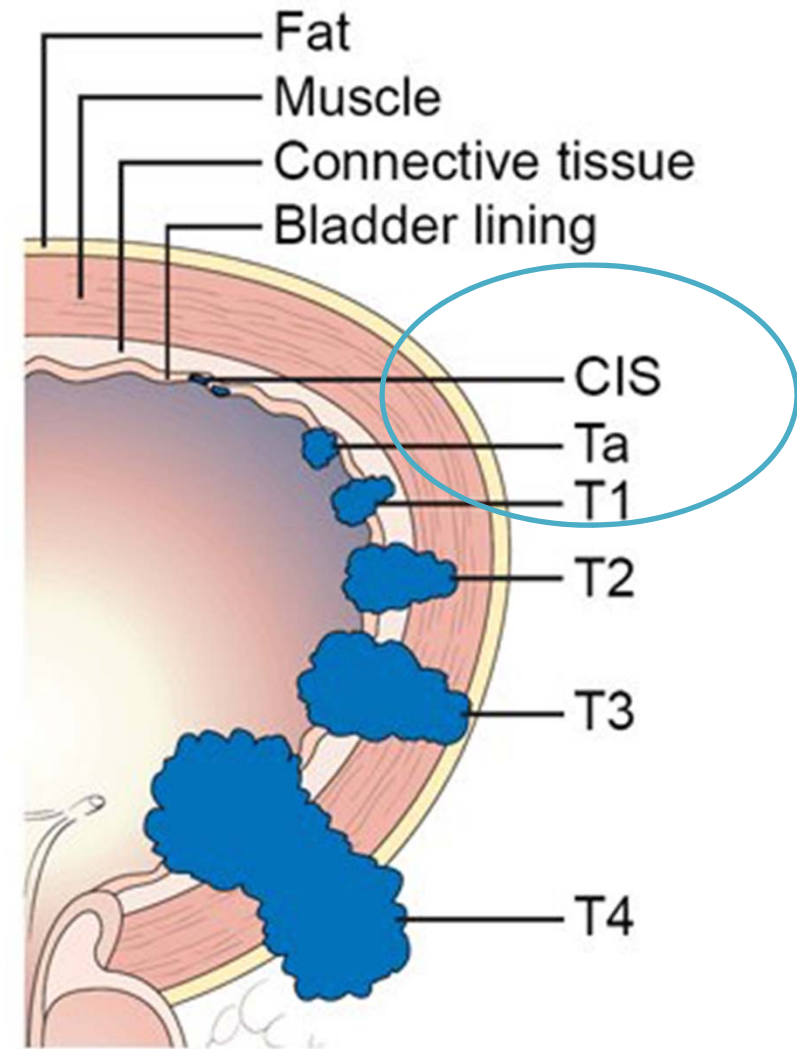
- In 2014, CMS packaged “drugs that function as a supply when used in a diagnostic procedure” or “ . . .when used in a surgical procedure”
- The 10 affected drugs include a bladder cancer drug, pharmacologic stress agents, a glaucoma drug, a cataract surgery drug, and an angioplasty drug, among others
 - Importantly, these 10 drugs are the exception, and there are hundreds of drugs reimbursed “at cost” (using the ASP methodology) which remains the rule
- CMS in CY 2017 Final Rule expanded the policy, and included numerous drugs, including the bladder cancer drug, to the “Comprehensive APC” policy (81 Fed. Reg. 79562, 79569 (Nov. 14, 2016))
 - Multiple parties, including Photocure, Omeros, Astellas, and others commented urging CMS to eliminate packaged payment policy
 - We met with OIRA staff before Final Rule, and were advised to revisit the issue before the CY2018 Rulemaking process
- 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)

With Four Years of Experience, How is the Policy Working?

- Cysview[®], the bladder cancer drug, provides important evidence that the policy CONTINUES TO NOT be working
- 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 3% of Medicare beneficiaries are receiving needed treatment for bladder cancer
- CMS must either
 - eliminate the Packaged Payment Policy and exclude drugs from Comprehensive APCs; or
 - Create specific APCs for procedures “with” and “without” drugs (and address the C-APC issues)

Fast Facts about Bladder Cancer

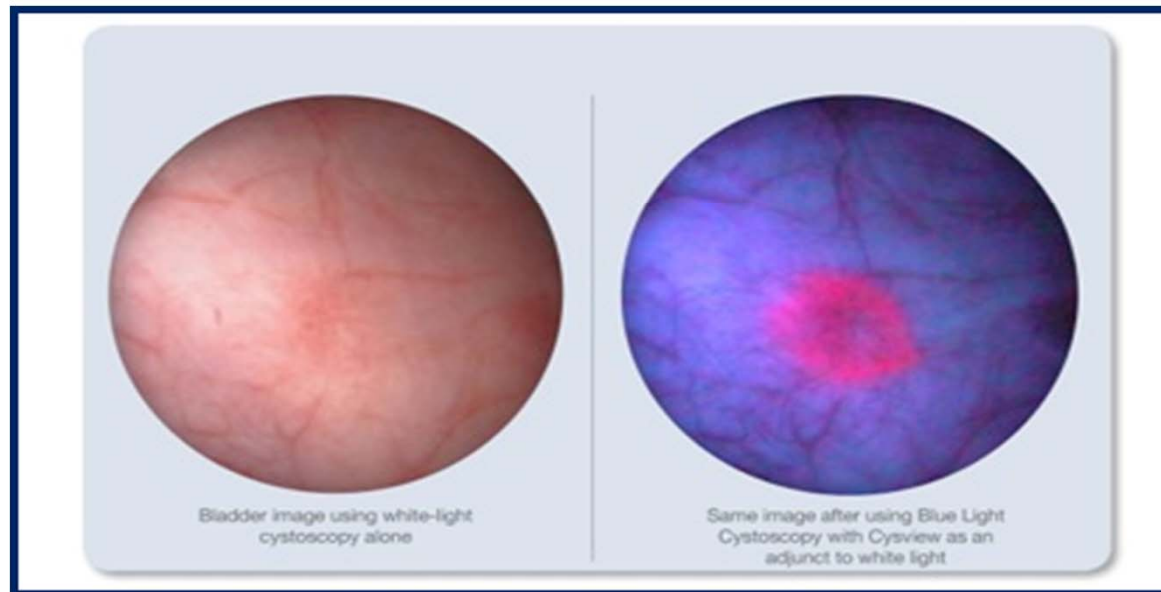
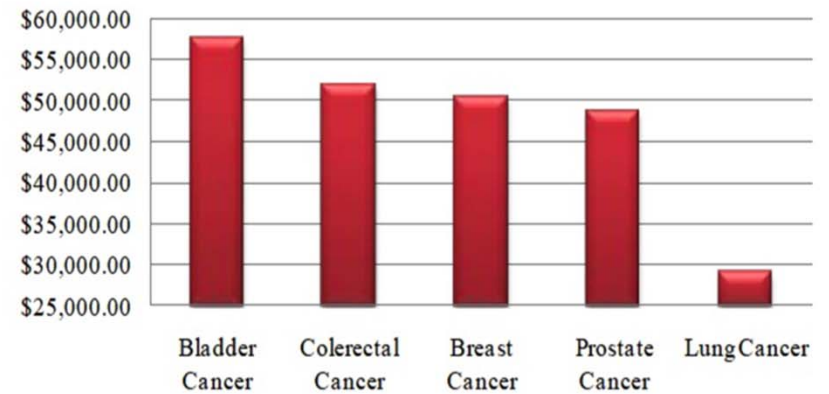
- Bladder cancer epidemiology (US):
 - 5th most common cancer type
 - 76,960 new cases est. by NCI in 2016
 - 16,390 deaths in 2016
 - >570,000 people living with a diagnosis of bladder cancer
- 60% of patients are Medicare beneficiaries
- 70% of patients are diagnosed with non-muscle invasive bladder cancer (NMIBC)
 - 70% Ta
 - 20% T1
 - 5-10% CIS



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
 - Up to 61% at 1 year
 - Up to 78% at 5 years
- Progression to muscle-invasive disease
 - Up to 17% at 1 year
 - Up to 45% at 5 years
- Solution: “Blue Light Cystoscopy with Cysview”

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



Improvement in Care and Cost

- Blue Light Cystoscopy with Cysview's impact on care:
 - Significantly improves detection of papillary (16-29%) and CIS tumors (32%), detects 96% of all tumors, and significantly reduces tumor recurrence
- Beneficial cost savings to health care systems, including Medicare
 - Cysview patients cost 15% less over five years compared to White Light patients
 - Savings per patient: \$4,600 est. (\$30,581 White Light vs. \$25,921 Blue Light with Cysview) (Garfield 2013)
- National Cancer Institute recognizes the value: "blue light cystoscopy is the most advanced method of diagnosing and detecting bladder tumors"

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 MI, 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 hexaminelevulinate hydrochloride instillation. *Can J Urol* 2013;20(2):6682-6689.

Introduction: Several studies, including the recent published phase III study by Sireci and colleagues have demonstrated that hexaminoleuconate 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 (TURBT) alone.

Materials and methods: The objective of this study was to conduct a detailed assessment of the cost effectiveness of using hexamindervallinate hydrochloride with blue light cytoscopy as an adjunct to white light versus white light

Introduction

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

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 hexamethylsilane hydrochloride into diagnostic cytospins results in lower costs over 5 years (\$25,824) as compared to these patients who initially receive white light cytospins (\$30,561). These patients who initially receive hexamethylsilane hydrochloride blue light TURB also experience a lower overall cancer burden.

Conclusions: Hexamethylsilane hydrochloride may be cost effective when used as 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

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

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Packaging Directly Harms Access

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.

Chief, Division of Urology
[REDACTED] University Health System

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

Four “Clinical Guidelines” Call for Use, But Packaging is Blocking Access

- **American Urological Association (AUA) / Society of Urologic Oncology (SUO) Guidelines - 2016**
 - “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)”
 - This is the 4th Guideline to incorporate the treatment (others: NCCN and two European Guidelines)
- **Dozens of studies substantiate support efficacy and benefit**
 - **Mariappan et al.**, “New real life data adding to the growing evidence for the improved patient outcomes of Cysview” (Urology 2015). Cysview-assisted TURB is associated with a significantly lower risk of early recurrence compared with white-light only TURB.
 - **Gakis, et al.**, “Fluorescence-guided bladder tumor resection: impact on survival after radical cystectomy” (World J Urol. 2015) 224 patient retrospective study found that blue light with Cysview in patients who later required radical cystectomy increased overall survival rate.
 - **Daneshmand et al.**, “Hexaminolevulinate blue-light cystoscopy in non-muscle-invasive bladder cancer: review of the clinical evidence and consensus statement on appropriate use in the USA” (Nature Reviews Urology 2014)
 - **Kamat, et al.**, “The Impact of Blue Light Cystoscopy with Hexaminolevulinate (HAL) on Progression of Bladder Cancer – A New Analysis,” (Bladder Cancer 2016) the use of blue light lowers rate of progression in patients moving from Ta to IS disease
 - Another 50+ studies are available both in the U.S. and around the world to the same effect

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): 73 and 102 different procedures, for a wide variety of treatments in the kidney, bladder, prostate, urethra, and other body parts – only 4 of the 73/102 procedures could use Cysview (the drug can only be used in the bladder)
 - Stress Test (APC 5722): 54 distinct procedures, only one of which is a cardiac stress test
 - Cataract Surgery (APC 5491): 62 different procedures, ranging from “remove foreign body from eye” to “detached retina” to “removal of inner eye fluid” the majority of which would never use the packaged drug
- Arbitrary reduction of payment in ASC
 - Drug reimbursement arbitrarily reduced about 40% in ASC, but drug costs the same
- This is not a drug pricing issue

CMS Should Eliminate or Revise its Drug Packaging Policies

- Packaging kills innovation in OPPS
- Packaging does not save Medicare program resources, but actually costs more
- Packaging harms patients by denying access
- Packaging is contrary to CMS precedent
- CMS should either:
 - eliminate the Packaged Payment Policy and C-APCs for “drugs that function as a supply” in “diagnostic” and “surgical” procedures; or
 - Create different APCs for procedures “with” and “without” drugs as exist for contrast agents

DISCUSSION AND QUESTIONS

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