



THE
BLADDER CANCER
COMPANY™

September 15, 2025

VIA ELECTRONIC SUBMISSION

The Honorable Mehmet Oz
Administrator
Centers for Medicare & Medicaid Services
United States Department of Health and Human Services
Attention: CMS-1834-P
P.O. Box 8010
Baltimore, MD 21244-1850

Re: Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs; Overall Hospital Quality Star Ratings; and Hospital Price Transparency (CMS-1834-P, RIN: 0938-AV51)

Dear Administrator Oz:

Photocure appreciates the opportunity to submit comments to the Centers for Medicare & Medicaid Services (“CMS”) on the proposed CY 2026 Hospital Outpatient and Ambulatory Surgical Center Prospective Payment System Proposed Rule, 90 FR Fed. Reg. 33476 (July 17, 2025) (“Proposed Rule”). Photocure is a specialty pharmaceutical company located in Princeton, New Jersey and headquartered in Norway which manufactures Cysview® (hexaminolevulinate HCl, HCPCS code A9589), an FDA-approved drug indicated for use in the cystoscopic detection of carcinoma of the bladder among patients suspected or known to have lesion(s) on the basis of a prior cystoscopy, or in patients undergoing surveillance cystoscopy for carcinoma of the bladder. This procedure is known as Blue Light Cystoscopy (BLC) with Cysview®.

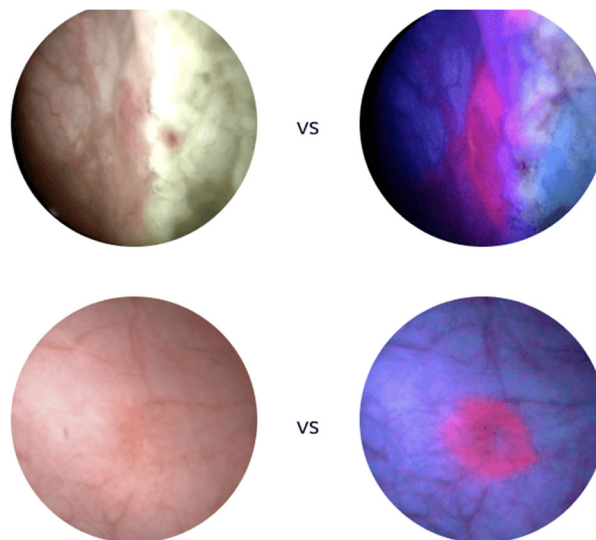
Our comments are in three sections. In Section I, we provide some additional background on blue light cystoscopy with Cysview®, which CMS has reviewed before, as a reminder of what is at stake. In Section II we next address why the CMS reasoning adopted in its CY 2025 Final Rule revising payment for diagnostic radiopharmaceuticals applies with equal, if not more, force, for blue light cystoscopy with Cysview®, and we call on CMS to apply the same separate payment policy for blue light cystoscopy. Section III reiterates our request that blue light cystoscopy be separately paid at cost, and we conclude in Section IV with some final comments.

I. Background

a. Cysview®

Launched in the United States in 2011, Cysview® is a revolutionary cancer drug used with BLC, a new and more resource-intensive procedure than traditional bladder cystoscopy. BLC with Cysview® has improved the ability to remove cancerous lesions, resulting in better treatment and reducing the risk of recurrence of bladder cancer. Dozens of peer-reviewed clinical studies have documented how BLC with Cysview® detects and allows the elimination of up to 30% more bladder cancer tumors and up to 35% more patients with carcinoma in situ as compared to cystoscopy under white light alone, leading to a reduction in recurrence rate at initial follow-up of 56%.¹

The consistency of the studies and the benefits they demonstrate are remarkable. Side-by-side images of older “white light” cystoscopy compared with “blue light” cystoscopy clearly demonstrate how previously undetectable bladder carcinoma can be identified and treated through cystoscopy:



In April 2016, the treatment was incorporated into the Guideline for Diagnosis and Treatment of Non-Muscle Invasive Bladder Cancer, jointly published by the American Urological Association (“AUA”) and the Society for Urologic Oncology (“SUO”) (at the Guideline’s highest rating). The addition of BLC with Cysview® to the Guideline is the definitive validation of the treatment’s efficacy. BLC with Cysview® is also

¹ See, e.g., Mariappan, et al., “Real-life Experience: Early Recurrence With Hexvix Photodynamic Diagnosis-assisted Transurethral Resection of Bladder Tumour (TURBT) vs Good-quality White Light TURBT in New None muscle-invasive Bladder Cancer” (Urology 2015); 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); Chang, et al. Diagnosis and treatment of non-muscle invasive bladder cancer: AUA/SUO guideline. (*J Urology* 2016). There are dozens of such articles available demonstrating the significant improvements of cancer care from Blue Light Cystoscopy with Cysview®.

included in the National Comprehensive Cancer Network (“NCCN”) guidelines for Non-Muscle Invasive Bladder Cancer, as well as other bladder cancer treatment guidelines.

b. CMS Packaging Has Severely Harmed Patient Access

CMS granted BLC with Cysview® “pass-through” status in 2011 for two years. In 2013, however, CMS erroneously chose to “package” Cysview® as a “contrast agent,” following which in 2014 CMS chose to “policy package” Cysview® as a “drug that functions as a supply when used in a diagnostic procedure.” At the same time, CMS also subjected BLC with Cysview® to the “Comprehensive APC” policy. This had the effect for five years of impeding beneficiary access to BLC with Cysview® due to inadequate reimbursement. CMS attempted to address the issue in 2018 by permitting BLC with Cysview® to be subject to a “complexity adjustment.” Unfortunately, however, due to eligibility qualifications and the impact that years of packaging, only two (52204 and 52214) of the seven (52000, 52204, 52214, 52224, 52234, 52235 and 52240) available CPT codes for the procedure were eligible for the adjustment, and in 2021 and 2022 only one of the codes (52204) was currently eligible. In CY 2023, the relevant Urology Level II code, including 52000, was designated a Comprehensive APC and was eligible for the complexity adjustment. As a result of the historic flawed reimbursement methodology, however, hospital outpatient departments still rarely perform the Guidelines-recommended BLC procedure, and less than ten ASCs in the entire country will offer the treatment. As a result, today less than 2% of patients requiring BLC receive treatment, tens of thousands of Medicare beneficiaries receive 1980s-level of care, and Medicare continues to pay for tens of thousands of preventable cases of bladder cancer recurrence, all due to packaged payment.

The cost and utilization of the FDA-approved drug, Cysview®, that must be used in the BLC procedure does not allow the package payment to account for the cost of the treatment given that Cysview® has a significantly higher cost, but lower utilization relative to the other cystoscopy and urology procedures within the APC. The current published “average sales price” for Cysview® (A9589) is \$1,424.33,² which does not account for the cost of the cystoscope or any other costs associated with the BLC procedure. As such, the cost of the drug alone (again not accounting for the remainder of the costs of the procedure) is more than twice the total payment for the Urology Level II (APC 5373, total payment \$650), and 73% of the Urology Level III payment (APC 5374, payment \$1,940.66). Further, when compared to the “Final CY 2025 Portion of APC Payment Associated with ‘Policy Packaged’ Drugs” as reported in the annual CMS OPPIs APC Offset,³ the cost of Cysview® is over 500 times greater than the amount reported by CMS for the Level II Urology APC (APC 5372, \$2.60), 70 times greater than the amount reported by CMS for the Level III Urology APC (APC 5373, \$20.28), and 31 times greater than the offset amount reported by CMS for even the Level IV Urology APC (APC 5374, \$46.22). It is clear that package payment for Cysview® is a relatively

² See CMS, ASP Pricing File, July 2025, available at <https://www.cms.gov/medicare/payment/part-b-drugs/asp-pricing-files>.

³ <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/annual-policy-files/2025>

“high cost” and “low utilization” drug for which packaged payment is inappropriate, and for which separate payment must be made.

II. CMS Should Pay Separately for Cysview® As It Pays Separately for Diagnostic Radiopharmaceuticals.

Providers For a Decade Have Been Urging CMS to Unpackage Cysview®: For the past decade, Photocure, along with dozens of other hospitals, urologists, oncologists, ASC facility operators, and most importantly patients, have written to CMS about the need to unpackage Cysview® (A9589) from the procedure payments for cystoscopy (52000, 52204, 52214, 52224, 52234, 52235 and 52240) because the drug is high cost and has low utilization. These comment letters have repeatedly shown that CMS’s “policy package” policy and the “comprehensive APC” policies, whether applied separately or together, have denied Medicare beneficiary access to care, have cost patients far more both in terms of health and in their financial co-payment obligations, and ironically have even cost the Medicare program more in paying for repeated treatments that the clinical literature demonstrates could have been avoided if blue light cystoscopy with Cysview® had been provided. The letters also demonstrated that due to package payment, Cysview® was not used at all in Ambulatory Surgery Centers (ASCs), and would not be used until the high cost, low utilization drug was unpackaged from the procedure payment.

CMS Should Unpackage Cysview® Just As It Has Diagnostic Radiopharmaceuticals: While we appreciated CMS’s efforts to address this issue in 2018 by applying a “complexity adjustment” to blue light cystoscopy, the CMS efforts have failed, and patient access is not increasing. Clinicians continue to advise Photocure that while they strongly prefer to provide blue light cystoscopy to their patients, neither hospital outpatient departments nor ASCs will do so given the packaged payment system’s skewed financial disincentives. As a result, today less than 5% of eligible beneficiaries are receiving appropriate treatment, patients are experiencing unnecessary cancer recurrence and progression that could have been avoided, Medicare is needlessly paying multiples for these patients, and everyone loses. And in response, CMS continues to repeat that it “believes that packaged policies are inherent principles of the OPPS and are essential to a prospective payment system.” 89 Fed. Reg. at 59214. Whether or not true, these principles are costing bladder cancer patients their lives, and costing the Medicare program money.

For this reason, we were pleased to see that after 16 years CMS finalized its proposal to unpackage diagnostic radiopharmaceuticals, which faced a similar (albeit less obvious or serious) issue. 89 Fed. Reg. 93912, 93950 (Nov. 27, 2024). CMS in the Final Rule recognized (correctly) that package payment policies were diminishing the ability of patients to access such diagnostic treatments and accepted the only solution to the issue was to separately pay for the products with a mean cost over a certain threshold. We urge CMS to do exactly the same with Cysview® when used for blue light cystoscopy – the only indication for the photodynamic agent for the treatment of bladder cancer.

Each of the Final Rule findings CMS made last year made regarding diagnostic radiopharmaceuticals applies with equal or greater force to blue light cystoscopy. For example, CMS noted:

we believe there are certain situations in which the packaged payment amount attributed to the diagnostic radiopharmaceutical used in an imaging procedure assigned to a nuclear medicine APC may not adequately account for the cost of a diagnostic radiopharmaceutical that has a significantly higher cost, but lower utilization relative to the other diagnostic radiopharmaceuticals that may be used with the procedure. In situations where a hospital may have to pay significantly more to purchase a diagnostic radiopharmaceutical than Medicare pays, a hospital may decide not to provide that specific diagnostic radiopharmaceutical imaging agent to Medicare beneficiaries. This could potentially deny access to diagnostic tools for which there is no clinical alternative. To ensure Medicare payment policy is not providing a financial disincentive to using high cost, low utilization diagnostic radiopharmaceuticals, especially when those agents may be the most clinically appropriate, and to ensure appropriate beneficiary access, we believe a subset of diagnostic radiopharmaceuticals with higher per day costs should be paid separately and not packaged into the diagnostic procedure with which the diagnostic radiopharmaceutical is used.

89 Fed. Reg. at 93950. *This statement is equally (if not more) true for BLC with Cysview® – the unique cancer treatment is precisely the situation in which the packaged payment amount attributed to the drug used in a cystoscopy procedure assigned to a urology APC does not adequately account for the cost of a drug that has a significantly higher cost, but lower utilization relative to the other drugs that may be used with the procedure. Given that BLC with Cysview® is one where a hospital will have to pay significantly more to purchase Cysview® than Medicare pays, hospitals and ASCs are deciding not to provide that specific drug and associated BLC treatment to Medicare beneficiaries. This not only has the potential to deny access to cancer treatments for which there is no clinical alternative – it has resulted in Medicare beneficiaries inferior 1980s care which ends up costing the Medicare program significant funds due to avoidable cancer recurrence.*

Just as with diagnostic radiopharmaceuticals, to ensure Medicare payment policy is not providing a financial disincentive to using high cost, low utilization cancer treatments such as BLC with Cysview®, especially when those agents may be the most clinically appropriate, and to ensure appropriate beneficiary access, CMS should modify its payment policy for both policy-package drugs and drugs packaged in a Comprehensive APC and ensure that drugs with higher per day costs should be paid separately and not packaged into the cancer treatment procedure with which the drug is used.

Calculating an “Offset Amount”: For diagnostic radiopharmaceuticals,

CMS also calculated a “volume weighted average policy packaged offset amount” for the relevant APCs, multiplied by 2 and rounded to the nearest \$5 increment to calculate the threshold below which diagnostic radiopharmaceuticals would remain packaged. 89 Fed. Reg. at 93952. This methodology, when applied to Cysview® or other packaged drugs used in the detection or treatment of cancer, should be adopted as well. In fact, CMS could multiply the offset amount by 10, rather than 2, and still find that the cost Cysview® exceeded the volume weighted amount of the offset. Thus, whether 2, 5, or even 10 is used as the multiplier, the cost of Cysview® (combined with its low utilization across the APC) more than satisfies any such threshold calculation to justify separate payment at cost.

Creating a New APC: To facilitate appropriate separate payment, we also urge CMS to create a new APC that would be subject to the “specified covered outpatient drug” (SCOD) rules found at Section 1833(t)(14)(A)(II)(iii)(II) and 1833(t)(14)(B). CMS has taken such actions for diagnostic radiopharmaceuticals with a cost above the offset amount, irrespective of whether the individual products have a “A”, “C” or “Q” HCPCS code. See 89 Fed. Reg. at 93956, 93960. Unlike diagnostic radiopharmaceuticals, however, drugs used for the detection or treatment of cancer, including Cysview®, should have no issues with reliable Average Sales Price (ASP) data, and thus there will be no difficulties with CMS reimbursing providers at the statutory rate.

Summary: In sum, urologists continue to state, as they have for years, that the lack of appropriate payment for Cysview®, a low volume and “high” (relative to the procedure reimbursement) cost drug, is the sole reason that they cannot and will not provide the procedure for cancer treatment. Over the past decade, hundreds of physician and facility comments have been submitted to CMS to this same effect. The CMS packaged payment policy is preventing urologists from correctly diagnosing and treating their patients and the number of bladder cancer deaths continues to rise. Patients lose, CMS loses, and providers’ ability to care for patients is impacted. The 2018 “complexity adjustment” was helpful, but is no longer a solution to this problem – given CMS’s historic packaging and the dynamics of the APCs, even applying a complexity adjustment does not remedy the reimbursement barrier preventing many patients from accessing treatment.

CMS in the past has acknowledged that: “existing cystoscopy CPT codes do not distinguish cystoscopy procedures involving only white light cystoscopy from those involving both white and blue light cystoscopy, which require additional resources compared to white light cystoscopy alone.” 82 Fed. Reg. 59216, 59244 (Dec. 12, 2017). The Agency has also recognized that: “blue light cystoscopy represents [a] . . . distinguishable service as compared to white light cystoscopy that, in some cases, may allow greater detection of bladder tumors in beneficiaries relative to white light cystoscopy alone.” *Id.* Yet, so long as the Agency maintains its current package payment policies, CMS will continue to

overpay for less effective white light cystoscopy, and the policies will cost the Trust Fund millions more in care for avoidable bladder cancer recurrence.

CMS's decision in 2013 to package Cysview® both under the “policy package” and “comprehensive APC” packaging policies continues to result in patients receiving sub-optimal care, and the Agency paying more for less effective treatments. Given the history of this policy and its impacts, we once again urge CMS to separately pay for Cysview® at cost – just as it has done in 2025 for diagnostic radiopharmaceuticals.

III. Unpackaging Cysview®

In the CY 2018 Rule, CMS stated:

Because blue light cystoscopy requires specialized imaging equipment to view cellular uptake of the dye that is not otherwise used in white light cystoscopy procedures, some practitioners consider blue light cystoscopy to be a distinct and adjunctive procedure to white light cystoscopy. However, the current CPT coding structure for cystoscopy procedures does not identify blue light cystoscopy in the coding descriptions separate from white light cystoscopy. Therefore, the existing cystoscopy CPT codes do not distinguish cystoscopy procedures involving only white light cystoscopy from those involving both white and blue light cystoscopy, which require additional resources compared to white light cystoscopy alone. As discussed in the CY 2018 OPPTS/ASC proposed rule, after discussion with our clinical advisors (including a urologist), we believe that blue light cystoscopy represents an additional elective but distinguishable service as compared to white light cystoscopy that, in some cases, may allow greater detection of bladder tumors in beneficiaries relative to white light cystoscopy alone.

82 Fed. Reg. at 59244. The improvement in detection of bladder tumors in beneficiaries relative to white light cystoscopy alone has been well documented in literally dozens of studies,⁴ and is of massive importance to beneficiaries in improving their care. Beyond patient considerations, a 2024 publication demonstrated that the use of BLC with Cysview® saves payers, including the Medicare program, between \$9,097 and \$34,538,

⁴ See, e.g. Cahill, et al., The use of blue-light cystoscopy in the detection and surveillance of nonmuscle invasive bladder cancer, *Current Urology*, (2022) 16, 3, 121–126, <http://dx.doi.org/10.1097/CU9.0000000000000142>; Stout, et al., Clinical Utility of Rigid Blue Light Cystoscopy: Results from a Post Procedure User Survey in a Prospective Multicenter Registry; *AUA Jour.* Vol. 9, 94-100, January 2022, <https://www.auajournals.org/doi/10.1097/UPL.0000000000000280>; Williams, et al, Macro and microeconomics of blue light cystoscopy with CYSVIEW® in non-muscle invasive bladder cancer; *Urologic Oncology: Seminars and Original Investigations* 00 (2021) 1–6, <https://doi.org/10.1016/j.urolonc.2021.05.023>.

per patient, particularly if utilization can be increased in the ASC setting.⁵ Dr. Shore's conclusions could not be clearer:

Modeled results suggest that the Medicare program will incur increased costs, due to the gap between added costs per cystoscopy due to BLC. The current discrepancy in reimbursement disincentivizes community-based ASCs from adopting BLC, resulting in suboptimal patient care while increasing downstream treatment costs to Medicare, necessitated when missed disease progresses to higher stage/grade disease. The findings have important clinical implications for the optimal management of NMIBC and should inform healthcare policies that promote cost-effectiveness and enhanced patient outcomes.

Id. The evidence is clear that subjecting blue light cystoscopy to packaged payment impedes optimal management of bladder cancer care and that CMS must find a way to modify its current policy so that it promotes cost-effectiveness and enhanced patient outcomes. This is precisely the type of situation for which Congress gave the Agency equitable adjustment authority. We urge CMS to exercise that authority, and unpackage Cysview® so that providers can utilize blue light cystoscopy and patients can access treatment.

IV. Conclusion

Dozens of peer-reviewed articles published over the past five years have demonstrated that BLC with Cysview® is a more clinically-effective treatment for Medicare beneficiaries with bladder cancer. Studies have also shown that it is a more cost-effective treatment as well, and the Medicare program's costs will be less, not greater, if Cysview® is separately paid in the HOPD and ASC settings. The evidence was sufficiently compelling to have BLC with Cysview® included in the AUA/SUO Guideline for Diagnosis and Treatment of Non-Muscle Invasive Bladder Cancer. The only barrier to access, improved care, and cost savings is the CMS packaged payment policy.

Photocure appreciates that CMS has heard the concerns of the providers and patients across the country and recognized the negative impact that has resulted from Medicare's packaging policies for drugs. CMS's changes over the years to apply a complexity adjustment and otherwise, however, have proven to be insufficient and patients still are unable to access treatment. We request that CMS unpackage Cysview® altogether – just as it has proposed to do for diagnostic radiopharmaceuticals. No less than the lives of bladder cancer patients stand or fall on the CMS decision.

⁵ Shore, et al., 'Clinical and Economic Impact of Blue Light Cystoscopy in the Management of NMIBC* at U.S. Ambulatory Surgical Centers: What is the Site-of-Service Disparity?', Urol Oncol. 2023 Apr;41(4):207.e9-207.e16. doi: 10.1016/j.urolonc.2022.11.014.

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Thank you for your consideration of these comments. Should you have questions or need additional information, please contact me at ds@photocure.com.

Sincerely,

A handwritten signature in black ink, consisting of a large loop followed by a horizontal line and a small upward stroke.

Daniel Schneider
President and CEO

cc: Jason Bennett (jason.bennett@cms.hhs.gov)
David Rice (david.rice1@cms.hhs.gov)
Representative Dr. Neil Dunn
Representative Dr. Patrick Murphy
Senator Marsha Blackburn