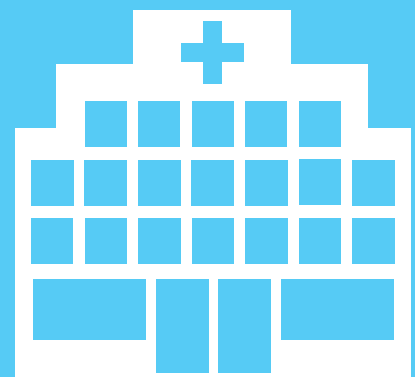


2024 REIMBURSEMENT GUIDE for

FLEXIBLE CYSTOSCOPY in a HOSPITAL OUTPATIENT DEPARTMENT



Billing for
Blue Light Cystoscopy
with Cysview[®]
(hexaminolevulinate hydrochloride)



THE
BLADDER CANCER
COMPANY

Cysview® (hexaminolevulinate hydrochloride) is an optical imaging agent.

- Indicated for use in the cystoscopic detection of carcinoma of the bladder, including carcinoma in situ (CIS), 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.
- Used with the KARL STORZ D-Light C Photodynamic Diagnostic (PDD) system to perform Blue Light Cystoscopy (BLC®) as an adjunct to White Light Cystoscopy.
- Not a replacement for random bladder biopsies or other procedures used in the detection of bladder cancer.

Important Risk & Safety Information

Limitations of Use

Cysview is not a replacement for random bladder biopsies or other procedures used in the detection of bladder cancer.

Warnings and Precautions

Anaphylactoid shock, hypersensitivity reactions, bladder pain, cystitis, and abnormal urinalysis have been reported after administration of Cysview. The most common adverse reactions seen in clinical trials were bladder spasm, dysuria, hematuria, and bladder pain.

Cysview should not be used in patients with porphyria, gross hematuria, or with known hypersensitivity to hexaminolevulinate or any derivative of aminolevulinic acid. Cysview may fail to detect some malignant lesions. False positive fluorescence may occur due to inflammation, cystoscopic trauma, scar tissue, previous bladder biopsy and recent BCG therapy or intravesical chemotherapy. No specific drug interaction studies have been performed.

Use in Specific Populations

Safety and effectiveness have not been established in pediatric patients. There are no available data on Cysview use in pregnant women. Adequate reproductive and developmental toxicity studies in animals have not been performed. Systemic absorption following administration of Cysview is expected to be minimal. There are no data on the presence of hexaminolevulinate in human or animal milk, the effects on a breastfed infant, or the effects on milk production. The development and health benefits of breastfeeding should be considered along with the mother's clinical need for Cysview and any potential adverse effects on the breastfed infant from Cysview or from the underlying maternal condition.

Use of the KARL STORZ D-Light C Photodynamic Diagnostic (PDD) System

Cysview is approved for use with the KARL D-Light C Photodynamic Diagnostic (PDD) system. For system set up and general information for the safe use of the PDD system, please refer to the KARL STORZ instruction manuals for each of the components.

Prior to Cysview administration, read the Full Prescribing Information and follow the preparation and reconstitution instructions.

Photocure has developed the following reimbursement guidance for customers who perform Blue Light Cystoscopy with a flexible cystoscope in a hospital outpatient setting to report the use of Cysview® (hexaminolevulinate hydrochloride) to private commercial payers and Medicare.

The information contained in this guide is provided to help you understand the reimbursement process and is not intended to suggest any manner in which you can increase or maximize reimbursement from any payer. Reimbursement information is gathered from third-party sources and is subject to change. We recommend that you consult with payers for specific coverage and billing requirements.

Disclaimers

The coding and payment data furnished in this guide is for general informational purposes only and should not be relied upon for purposes of determining payer coverage and coding for a specific case or claim for payment. This guide represents no promise, commitment, statement or guarantee by Photocure concerning proper billing or coding practices or levels of reimbursement, payment or charges. The materials referenced and provided are based upon coding experience and research of current general coding practices. The existence of codes does not guarantee coverage or payment for any procedure by any payer. The final decision for coding of any procedure must be made by the provider of care after considering the medical necessity of the services and supplies provided as well as the regulations and local, state, or federal laws that may apply.

All Current Procedural Terminology (CPT®) codes, Healthcare Common Procedural Coding System (HCPCS) codes, Ambulatory Payment Classifications (APCs) and National Drug Codes (NDC) are provided for your information only and Photocure does not represent that these codes are or will be appropriate or that reimbursement will be made if using them or any other codes. CPT® codes and descriptions only are copyrighted by the American Medical Association (AMA). CPT®, APC and other codes do not include fee schedules, relative values or related listings. The Centers for Medicare & Medicaid Services (CMS) updates coverage, coding and payment information frequently, and it is the responsibility of each health service provider to confirm the appropriate billing required by the local Medicare contractor.

Providers should refer to authoritative coding sources, such as the CPT® codes and HCPCS codes. Applicable FARS/DFARS Restrictions Apply to Government Use. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT®, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein.

The information provided in this guide is for informational purposes only. Information included does not guarantee coverage or payment. Payment will vary by geographic locality. It is always the provider's responsibility to determine coding and claims information for the services that were provided.

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2024 Medicare Reimbursement

Site of Service: Hospital Outpatient Department (HOPD)

The HOPD is responsible for billing for the Cysview product in addition to the facility charges that are based on services provided by the physician. Note that if products/services billed by the HOPD do not match the services billed by the physician, Medicare will likely reject the claim.

CMS has determined that Cysview is subject to packaged payment (i.e., payment for Cysview is part of the Ambulatory Payment Classification (APC) procedure payment). As a result, HCPCS code A9589 (Instillation, hexaminolevulinate hydrochloride, 100mg) is designated status “N” (packaged). However, it is essential that HOPDs report HCPCS code A9589 on a separate claim line for each case in which Cysview is utilized. Although the HOPD will not be separately paid for this claim line, CMS uses claims data to calculate APC procedure payments for future years.

In the 2024 OPPS Final Rule, CMS determined that certain Blue Light Cystoscopy procedures are eligible for additional facility reimbursement through a “complexity adjustment.” For these procedures (CPT codes 52000 and 52204), Medicare will provide increased payment when Blue Light Cystoscopy is performed. To facilitate this payment, CMS created an add-on code [HCPCS code C9738 (Adjunctive blue light cystoscopy with fluorescent imaging agent) (List separately in addition to code for primary procedure)] that must be included on a separate claim line for each case in which Blue Light Cystoscopy is performed (whether or not the Blue Light Cystoscopy procedure is eligible for a complexity adjustment). HCPCS code C9738 is designated status “N” (packaged), so payment is part of the APC procedure payment. The HOPD will not be separately paid for this claim line, although it is important to secure a payment under the complexity adjustment.

The following is a summary of 2024 Medicare national payment rates for Blue Light Cystoscopy procedures performed in the HOPD. For each of the procedures, in addition to the applicable CPT code, HCPCS codes A9589 and C9738 must be included on separate claim lines on the facility claim. The most appropriate CPT code for the service performed should be reported on the claim.

Reimbursement information is gathered from third-party sources and is subject to change. This information is provided for illustrative purposes only.

2024 Private Payer Billing Guidance

Photocure recommends that you consult with payers for specific coverage and billing requirements.¹

¹ Blue Light Cystoscopy with Cysview may be covered by private payers when medically necessary. Coverage guidelines and payment levels vary by payer and specific plan. Providers should contact each specific plan to determine coverage and payment.

Hospital Outpatient Departments

Cysview and the KARL STORZ D-Light C PDD system with flexible cystoscope may be used in a hospital outpatient department (HOPD).

- The HOPD is responsible for billing for the Cysview product in addition to the facility charges that are based on services provided by the physician. Note that if products/services billed by the HOPD do not match the services billed by the physician, the claim may be rejected by the payer.
- Claims submitted by a HOPD should report the most appropriate CPT code for the service performed. For Medicare claims, the HOPD should also report C9738 (the Blue Light Cystoscopy procedure code) and A9589 (Instillation, hexaminolevulinate hydrochloride, 100mg). Other payers may have different billing requirements.
- To submit claims in accordance with this guidance:
 - STEP 1: Report the appropriate CPT® code for the procedure for each case in which Cysview with the KARL STORZ D-Light C PDD is used.
 - STEP 2: Report C9738 (Blue Light Cystoscopy procedure) for Medicare claims. Other payers may also require the C9738 code.
 - STEP 3: Report HCPCS code A9589 (Cysview) for Medicare claims. Other payers may require J3490 or that Cysview be reported under a revenue code for the facility.
- Physicians performing Blue Light Cystoscopy with Cysview may report the most appropriate CPT code for the service performed.

Hospital Outpatient Departments

Place of service code = 19 or 22



Procedure codes

- Cystourethroscopy (52000, 52204, 52214)



What to bill

- Procedure code
- + C9738 Blue Light procedure code
- + A9589 for Cysview



Commercial reimbursement

- Procedure and drug may be reimbursed separately
- Cysview at ASP + 6% to 15%



Medicare reimbursement

- Procedure and drug are reimbursed in a packaged Ambulatory Payment Classification (APC) payment
- The complexity adjustment adds approx. \$1,200 to the existing packaged payment for code 52000 and approx. \$1,350 to the existing packaged payment for code 52204

2024 Medicare Reimbursement
Site of Service: Hospital Outpatient Department (HOPD)

CPT® Code	Description	HOPD White Light Procedure Payment	HOPD Blue Light Procedure Payment	Physician Payment
52000	Cystourethroscopy (separate procedure)	\$650.86	\$1,940.66 (APC 5373)	\$77.93
52204	Cystourethroscopy, with biopsy(s)	\$1,940.66	\$3,321.58 (APC 5374)	\$137.20
52214	Cystourethroscopy, with fulguration (including cryosurgery or laser surgery) of trigone, bladder neck, prostatic fossa, urethra, or periurethral glands	\$3,321.58	\$3,321.58 (APC 5374)	\$168.63

Actual payment will vary based on geographic adjustments less any applicable deductible, coinsurance, etc.

Secondary Procedure Code

C9738	Adjunctive blue light cystoscopy with fluorescent imaging agent (list separately in addition to code for primary procedure)
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Drug Code

A9589	Instillation, hexaminolevulinate hydrochloride, 100 mg
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BLUE LIGHT CYSTOSCOPY WITH CYSVIEW[®] (HOPD - MEDICARE)

Relevant Procedure Code

52000 or 52204

Relevant Procedure Code

52214

STEP 1

Relevant Procedure Code

STEP 2

HCPCS Add-on Code C9738
Adjunctive Blue Light
Cystoscopy with Fluorescent
Imaging Agent

STEP 3

HCPCS Code A9589
Instillation, Hexaminolevulinate
Hydrochloride

COMPLEXITY ADJUSTMENT

STEP 1

Relevant Procedure Code

STEP 2

HCPCS Add-on Code C9738
Adjunctive Blue Light
Cystoscopy with Fluorescent
Imaging Agent

STEP 3

HCPCS Code A9589
Instillation, Hexaminolevulinate
Hydrochloride

NO COMPLEXITY ADJUSTMENT

St. Hospital 1234 1 St. Anywhere MA 12345 555-555-1212										2										3a PAT. CNTL. # b. MED. REC. #										P111										4 TYPE OF BILL 0131																																																																					
5 FED. TAX NO. 2222222										6 STATEMENT COVERS PERIOD FROM 1/15/24										7 THROUGH 1/15/24																																																																																									
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50 PAYER NAME A MEDICARE										51 HEALTH PLAN ID 123456789A										52 REL INFO										53 ASG BEN.										54 PRIOR PAYMENTS										55 EST. AMOUNT DUE XXXX XX										56 NPI 22222222										57 OTHER PRV ID																																							
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Sample CMS-1500 Form for HOPD Setting



HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

☐ PICA		PICA ☐	
1. MEDICARE ☒ (Medicare#) ☐ MEDICAID ☐ (Medicaid#) ☐ TRICARE ☐ (ID#/DoD#) ☐ CHAMPVA ☐ (Member ID#) ☐ GROUP HEALTH PLAN ☐ (ID#) ☐ FECA BLK LUNG ☐ (ID#) ☐ OTHER ☐ (ID#)		1a. INSURED'S I.D. NUMBER (For Program in Item 1) 123456789A	
2. PATIENT'S NAME (Last Name, First Name, Middle Initial) JOHN DOE		3. PATIENT'S BIRTH DATE MM DD YY SEX ☒ M ☐ F	
5. PATIENT'S ADDRESS (No., Street) 1234 MAIN ST		6. PATIENT RELATIONSHIP TO INSURED Self ☐ Spouse ☐ Child ☐ Other ☐	
7. INSURED'S ADDRESS (No., Street) CITY STATE ZIP CODE TELEPHONE (Include Area Code)		8. RESERVED FOR NUCC USE	
9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial) NONE		10. IS PATIENT'S CONDITION RELATED TO: a. EMPLOYMENT? (Current or Previous) ☐ YES ☒ NO b. AUTO ACCIDENT? ☐ YES ☒ NO PLACE (State) c. OTHER ACCIDENT? ☐ YES ☒ NO 10d. CLAIM CODES (Designated by NUCC)	
11. INSURED'S POLICY GROUP OR FECA NUMBER a. INSURED'S DATE OF BIRTH MM DD YY SEX ☐ M ☐ F b. OTHER CLAIM ID (Designated by NUCC)		12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below. SIGNED _____ DATE _____	
13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below. SIGNED _____		14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL.	
15. OTHER DATE MM DD YY QUAL.		16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION FROM MM DD YY TO MM DD YY	
17. NAME OF REFERRING PROVIDER OR OTHER SOURCE 17a. 17b. NPI		18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES FROM MM DD YY TO MM DD YY	
19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)		20. OUTSIDE LAB? ☐ YES ☐ NO \$ CHARGES	
21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind.		22. RESUBMISSION CODE ORIGINAL REF. NO.	
A. C67.1 B. C. D. E. F. G. H. I. J. K. L.		23. PRIOR AUTHORIZATION NUMBER	
24. A. DATE(S) OF SERVICE From MM DD YY To MM DD YY B. PLACE OF SERVICE C. EMG D. PROC (Exp CPT/HCM) E. SNOSIS ENTER F. \$ CHARGES G. DAYS OR UNITS H. EPSDT Family Plan I. ID. QUAL. J. RENDERING PROVIDER ID. #		Code for primary procedure performed.	
1 01 15 24 01 15 24 22 52000 1 \$XXXX XX		Establishing charges is the responsibility of the provider. Any dollar figures mentioned in this document are examples only and are not intended to suggest actual amounts that should be charged.	
2 01 15 24 01 15 24 22 C9738 \$XXXX X		Code for the Blue Light Cystoscopy procedure performed.	
3		4	
5		6	
25. FEDERAL TAX I.D. NUMBER SSN EIN ☐ ☒ ☐		26. PATIENT'S ACCOUNT NO. P1111	
27. ACCEPT ASSIGNMENT? (For govt. claims, see back) ☐ YES ☐ NO		28. TOTAL CHARGE \$ \$XXXX XX	
29. AMOUNT PAID \$		30. Rsvd for NUCC Use	
31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.)		32. SERVICE FACILITY LOCATION INFORMATION HOPD 1234 1 ST MA	
33. BILLING PROVIDER INFO & PH # John Smith, MD 1234 1 ST MA		a. 222222 b.	
SIGNED _____ DATE _____		a. 222222 b.	

NUCC Instruction Manual available at: www.nucc.org

PLEASE PRINT OR TYPE

APPROVED OMB-0938-1197 FORM 1500 (02-12)

CARRIER
PATIENT AND INSURED INFORMATION
PHYSICIAN OR SUPPLIER INFORMATION

**2024 Medicare Reimbursement
Relative Value Units – Facility Setting (HOPD)**

CPT® Code	Work RVU	Practice Expense RVU	Malpractice RVU
52000	1.53	0.66	0.19
52204	2.59	1.28	0.32
52214	3.50	1.23	0.42

Replacement of the CPT codes does not affect RVUs.

Photocure is pleased to offer toll-free customer support and documentation for coding and reimbursement related to Cysview.

For additional questions, please contact Photocure's reimbursement helpline at
1-855-CYSVIEW (1-855-297-8439)

Cysview Website

For more information regarding Cysview please visit our website:

[Cysview.com](https://cysview.com)

