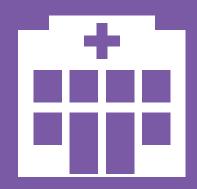
2024 REIMBURSEMENT GUIDE

for

AMBULATORY SURGICAL CENTERS



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



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 in an ambulatory surgical center 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: Ambulatory Surgical Center (ASC)

The ASC 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 ASC 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 APC-based procedure payment). As a result, HCPCS code A9589 (Instillation, hexaminolevulinate hydrochloride, 100mg) is designated status "N" (packaged). However, it is essential that ASCs report HCPCS code A9589 on a separate claim line for each case in which Cysview is utilized. Although the ASC will not be separately paid for this claim line, claims data impacts procedure payments for future years.

In the 2024 Final Rule, CMS determined that certain Blue Light Cystoscopy procedures are eligible for additional ASC facility reimbursement through a "complexity adjustment." For these procedures (CPT codes 52000 and 52204) Medicare will provide increased payment to the ASC when Blue Light Cystoscopy is performed. To facilitate this payment, CMS created new codes [HCPCS code C7554 instead of CPT code 52000, and HCPCS code C7550 instead of CPT code 52204] that must be billed when Blue Light Cystoscopy is performed.

The following is a summary of 2024 Medicare national payment rates for Blue Light Cystoscopy procedures performed in the ASC. For each of the procedures, in addition to the applicable CPT code, HCPCS code A9589 must be included on separate claim lines on the 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.

Ambulatory Surgical Centers

Cysview and the KARL STORZ D-Light C PDD system with flexible cystoscope are what is intended for use in an ambulatory surgical center (ASC).

- The ASC 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 ASC do not match the services billed by the physician, the claim may be rejected by the payer.
- Claims submitted by an ASC should report the most appropriate CPT° code for the service performed.
- 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: When the CPT code 52000 procedure is performed, report HCPCS code C7554 for Medicare claims. When the CPT code 52204 procedure is performed, report HCPCS code C7550 for Medicare claims. For all other cystourethroscopy procedures, report the applicable CPT code.
 - STEP 3: Report C9738 (Blue Light Cystoscopy procedure) for Medicare claims for procedures other than 52000 (for which C7554 is billed) and 52204 (for which C7550 is billed). Other payers may require J3490 or that Cysview be reported under a revenue code for the facility.
 - STEP 4: 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.

Ambulatory Surgical Centers

Place of service code = 24



Procedure codes

- Cystourethroscopy (52000)
- Cystourethroscopy with biopsy or higher (52204, 52214, 52224, 52234, 52235, 52240)



What to bill

- Procedure code (but use C7554 instead of 52000; and C7550 instead of 52204)
- + C9738 Blue Light procedure code (for procedures other than 52000 and 52204)
- + 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

2024 Medicare Reimbursement Site of Service: Ambulatory Surgical Center (ASC)

CPT° Code	Description	ASC Blue Light Procedure Payment	Physician Payment
52000 (C7554)	Cystourethroscopy (separate procedure)	\$929.87 (APC 5373)	\$77.93
52204 (C7550)	Cystourethroscopy, with biopsy(s)	\$1,626.11 (APC 5374)	\$137.20
52214	Cystourethroscopy, with fulguration (including cryosurgery or laser surgery) of trigone, bladder neck, prostatic fossa, urethra, or periurethral glands	\$1,626.11 (APC 5374)	\$168.63
52224	Cystourethroscopy, with fulguration (including cryosurgery or laser surgery) or treatment of MINOR (less than 0.5 cm) lesion(s) with or without biopsy	\$1,626.11 (APC 5374)	\$195.16
52234	Cystourethroscopy, with fulguration (including cryosurgery or laser surgery) and/or resection of SMALL bladder tumor(s) (0.5 up to 2.0 cm)	\$1,626.11 (APC 5374)	\$237.40
52235	Cystourethroscopy, with fulguration (including cryosurgery or laser surgery) and/or resection of MEDIUM bladder tumor(s) (2.0 to 5.0 cm)	\$1,626.11 (APC 5374)	\$278.65
52240	Cystourethroscopy, with fulguration (including cryosurgery or laser surgery) and/or resection of LARGE bladder tumor(s)	\$2,471.16 (APC 5375)	\$378.20

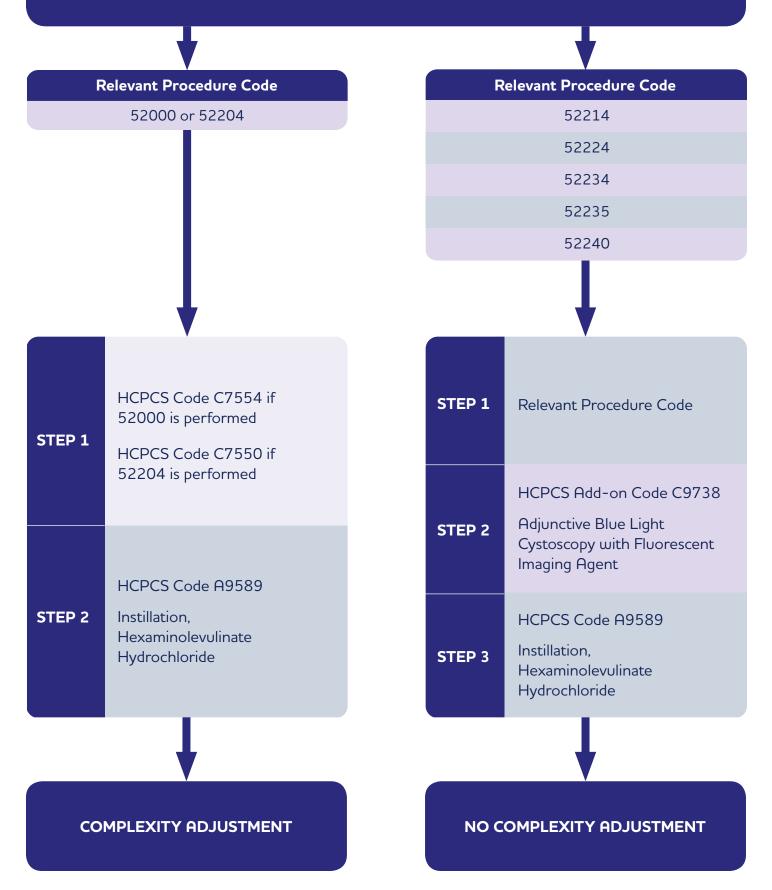
Actual payment will vary based on geographic adjustments less any applicable deductible, coinsurance, etc. ASCs are reimbursed at a percentage of the HOPD rate for the OPPS APC noted.

Secondary Procedure Code

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

Drug Code						
A9589	Instillation, hexaminolevulinate hydrocloride, 100 mg					

BLUE LIGHT CYSTOSCOPY WITH CYSVIEW® (ASC - MEDICARE)



Sample CMS-1500 Form for ASC Charges ASC Setting

IEALTH INSURAN	CE CLAIM	FORM			
PPROVED BY NATIONAL UNIFOR	M CLAIM COMMITT	EE (NUCC) 02/12			
MEDICARE MEDICAID	TRICARE	CHAMPVA	CDOLID EECA OTHER	1a. INSURED'S I.D. NUMBER (For Program in Item 1)	
(Medicare#) (Medicaid#)	(ID#/DoD#)	(Member ID	— HEALTH PLAN — BLK LUNG —	123456789A	
PATIENT'S NAME (Last Name, F	rst Name, Middle Init	tial)	3. PATIENT'S BIRTH DATE SEX	4. INSURED'S NAME (Last Name, First Name, Middle Initial)	
IOHN DOE			01 01 1950 MX F	SAME	
PATIENT'S ADDRESS (No., Street 1234 MAIN ST	t)		6. PATIENT RELATIONSHIP TO INSURED Self Spouse Child Other	7. INSURED'S ADDRESS (No., Street)	
ITY		STATE	Self Spouse Child Other 8. RESERVED FOR NUCC USE	CITY STATE	
ANYWHERE		MA			
	ELEPHONE (Include			ZIP CODE TELEPHONE (Include Area Code)	
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RESERVED FOR NUCC USE			b. AUTO ACCIDENT? PLACE (State) YES X NO	b. OTHER CLAIM ID (Designated by NUCC)	
RESERVED FOR NUCC USE			c. OTHER ACCIDENT?	c. INSURANCE PLAN NAME OR PROGRAM NAME	
			YES X NO		
INSURANCE PLAN NAME OR PR	OGRAM NAME		10d. CLAIM CODES (Designated by NUCC)	d. IS THERE ANOTHER HEALTH BENEFIT PLAN?	
READ BACK OF FORM BEFORE COMPLETING &			& SIGNING THIS FORM	YES NO If yes, complete items 9, 9a, and 9d. 13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize	
2. PATIENT'S OR AUTHORIZED P	ERSON'S SIGNATU	RE I authorize the re	elease of any medical or other information necessary or myself or to the party who accepts assignment	payment of medical benefits to the undersigned physician or supplier for services described below.	
SIGNED			DATE	SIGNED	
14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) 15. OTHER DATE			MM DD VY	16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION MM DD YY MM DD YY	
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			on separate claim lines	amounts that should be charged.	
	1 1				
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1. SIGNATURE OF PHYSICIAN O	SUPPLIER		CILITY LOCATION INFORMATION	33. BILLING PROVIDER INFO & PH # (
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Sample CMS-1500 Form for Physician Billing ASC Setting

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IEALTH INSURAN	ICE CLAIM F	ORM			
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(Medicare#) (Medicaid#)	(ID#/DoD#)	(Member ID:	— HEALTH PLAN — BLK LUNG —		
PATIENT'S NAME (Last Name,	First Name, Middle Initial)		3. PATIENT'S BIRTH DATE SEX	4. INSURED'S NAME (Last Name, First Name, Middle Initial)	
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RESERVED FOR NUCC USE			c. OTHER ACCIDENT? YES X NO	c. INSURANCE PLAN NAME OR PROGRAM NAME	
NSURANCE PLAN NAME OR	PROGRAM NAME		10d. CLAIM CODES (Designated by NUCC)	d. IS THERE ANOTHER HEALTH BENEFIT PLAN?	
				YES NO If yes, complete items 9, 9a, and 9d.	
. PATIENT'S OR AUTHORIZED	PERSON'S SIGNATURE	I authorize the re	& SIGNING THIS FORM. elease of any medical or other information necessary o myself or to the party who accepts assignment	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 DATE			SIGNED		
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QL	AL.	QUA		FROM TO 18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES.	
17. NAME OF REFERRING PROVIDER OR OTHER SOURCE 17a.				FROM TO YY	
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			Cysview should be listed	mentioned in this document are	
			on separate claim lines	examples only and are not	
				intended to suggest actual	
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31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I) Certify that the statements on the reverse			33. BILLING PROVIDER INFO & PH # () John Smith, MD		
(I certify that the statements or apply to this bill and are made		1234 1 S	ST	1234 1 ST	
		MA		MA	

2024 Medicare Reimbursement Relative Value Units – Facility Setting (ASC)

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
52224	4.05	1.42	0.49
52234	4.62	2.07	0.56
52235	5.44	2.40	0.67
52240	7.50	3.13	0.92

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

Cysview Website

For more information regarding Cysview please visit our website: **Cysview.com**



1-855-CYSVIEW (1-855-297-8439)