

Photocure 2018 Reimbursement Guide

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



Cysview (hexaminolevulinate hydrochloride) is an optical imaging drug.

- 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.
- Cysview is used with the KARL STORZ D-Light C Photodynamic Diagnostic (PDD) system to perform Blue Light Cystoscopy (BLC™) as an adjunct to the white light cystoscopy.

Important risk & safety information

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

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.

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.

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 reporting the use of Cysview® (hexaminolevulinate hydrochloride) to private commercial payers for its customers who perform Blue Light Cystoscopy in a hospital outpatient department, ambulatory surgical center or physician office.

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.

This guide contains reimbursement guidance that pertain to commercial payers generally. We recommend that you consult with each private payer organization with regard to its coverage, coding and payment policies as they may differ.

The information in this guide is for informational purposes only, and represents no promise, commitment, statement or guarantee by Photocure concerning proper billing or coding practices or levels of reimbursement, payment or charges.

All Current Procedural Terminology (CPT®), Healthcare Common Procedural Coding System (HCPCS), Ambulatory Payment Classifications (APCs) or National Drug Codes (NDC) codes 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 copyright by the American Medical Association. CPT®, APC and other codes do not include fee schedules, relative values or related listings.

2018 Private Payer Billing Guidance

Reimbursement information is gathered from third-party sources and is subject to change. This information is provided for illustrative purposes only. Photocure recommends that you consult with payers for specific coverage and billing requirements.¹

Hospital Outpatient Departments and Ambulatory Surgical Centers

Cysview and the KARL STORZ D-Light C PDD rigid cystoscope are typically used in a hospital outpatient department (HOPD) or ambulatory surgical center (ASC).

- The HOPD or 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 HOPD or ASC do not match the services billed by the Physician, the claim may be rejected by the payer.
- Claims submitted by a HOPD or ASC may simply report the most appropriate CPT® code for the service performed. Currently, there is no specific CPT® code for only Blue Light Cystoscopy with Cysview, and general cystoscopy codes (illustrated below) may be used.
- Alternatively, a HOPD or ASC may submit both the CPT® code for the cystoscopy services provided and report HCPCS code C9275 (Injection, hexaminolevulinate hydrochloride, 100 mg, per study dose) or J3490 (unclassified drugs) for the actual Cysview product used during the procedure.
- To submit claims in accordance with this guidance:
 - o **STEP 1:** Report the appropriate CPT® code for the procedure listed below for each case in which Cysview with the KARL STORZ D-Light C PDD is used.
 - o **STEP 2:** Report HCPCS code C9275 or J3490. Note that some payers may not accept HCPCS codes and may require that Cysview is 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.

Physician Office

Cysview and the KARL STORZ D-Light C PDD flexible cystoscope are typically used in a physician office setting (although they may also be used in a HOPD or ASC setting).

The physician is responsible for billing for the Cysview product purchased by the physician in addition to the service performed by the physician. Claims submitted by a physician office may simply report the most appropriate CPT code for the service performed. Currently, there is no specific CPT code for only Blue Light Cystoscopy with Cysview, and general cystoscopy codes (illustrated below) must be used. Alternatively, a physician office may submit both the CPT code for the cystoscopy services provided and report HCPCS code J3490 (unclassified drugs) for the actual Cysview product used during the procedure, as there is currently no unique HCPCS J code assigned to Cysview. When reporting J3490, it is important to include the drug name and NDC in Box 19 of the claim. Payers may also request submission of an invoice documenting the physician's purchase of Cysview with the claim.

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.

SELECTED 2018 CPT® CODES FOR BLADDER CYSTOSCOPY

CPT®/ HCPCS Code	Description
52000	Cystourethroscopy (separate procedure)
52204	Cystourethroscopy, with biopsy(s)
52214	Cystourethroscopy, with fulguration (including cryosurgery or laser surgery) of trigone, bladder neck, prostatic fossa, urethra, or periurethral glands
52224	Cystourethroscopy, with fulguration (including cryosurgery or laser surgery) or treatment of MINOR (less than 0.5 cm) lesion(s) with or without biopsy
52234*	Cystourethroscopy, with fulguration (including cryosurgery or laser surgery) and/or resection of SMALL bladder tumor(s) (0.5 to 2.0 cm)
52235*	Cystourethroscopy, with fulguration (including cryosurgery or laser surgery) and/or resection of MEDIUM bladder tumor(s) (2.0 to 5.0 cm)
52240*	Cystourethroscopy, with fulguration (including cryosurgery or laser surgery) and/or resection of LARGE bladder tumor(s)

* These procedures are typically not performed in the physician office setting.

Sample UB Form

St. Hospital 1234 1 St. Anywhere MA 12345 555-555-1212		2		3a PAT. CNTL. # b. MED. REC. #		P111		4 TYPE OF BILL 0131																															
8 PATIENT NAME a John Doe				9 PATIENT ADDRESS a 1234 Main St.																																			
10 BIRTHDATE 01/01/1900		11 SEX M	12 DATE 1/15/18		13 HR 2		14 TYPE 2		15 SRC 01		16 DHR 01		17 STAT 18		19		20		21		22		23		24		25		26		27		28		29 ACDT STATE		30		
31 OCCURRENCE DATE		32 OCCURRENCE DATE		33 OCCURRENCE DATE		34 OCCURRENCE DATE		35 OCCURRENCE DATE		36 OCCURRENCE DATE		37		38		39 VALUE CODES AMOUNT		40 VALUE CODES AMOUNT		41 VALUE CODES AMOUNT		42 REV. CD.		43 DESCRIPTION		44 HCPCS / RATE / HIPPS CODE		45 SERV. DATE		46 SERV. UNITS		47 TOTAL CHARGES		48 NON-COVERED CHARGES		49			
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0360		Blue Light Cystoscopy		C9275		1/15/18		1		XXXX XX																													
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Some payers may require reporting of Blue Light with HCPCS code J3490 or a revenue code.

Sample CMS-1500 Form for HOPD and ASC Setting



HEALTH INSURANCE CLAIM FORM

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

<input type="checkbox"/> PICA PICA <input type="checkbox"/>									
1. MEDICARE <input type="checkbox"/> (Medicare#)					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 01 01 1900 M <input checked="" type="checkbox"/> <input type="checkbox"/>				
4. INSURED'S NAME (Last Name, First Name, Middle Initial) SAME					5. PATIENT'S ADDRESS (No., Street) 1234 MAIN ST				
6. PATIENT RELATIONSHIP TO INSURED Self <input type="checkbox"/> Spouse <input type="checkbox"/> Child <input type="checkbox"/> Other <input type="checkbox"/>					7. INSURED'S ADDRESS (No., Street)				
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) <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO					11. INSURED'S POLICY GROUP OR FECA NUMBER ABC123456				
b. AUTO ACCIDENT? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO PLACE (State)					a. INSURED'S DATE OF BIRTH MM DD YY SEX M <input type="checkbox"/> F <input type="checkbox"/>				
c. OTHER ACCIDENT? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO					b. OTHER CLAIM ID (Designated by NUCC)				
10d. CLAIM CODES (Designated by NUCC)					c. INSURANCE PLAN NAME OR PROGRAM NAME ABC Insurance Company				
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.					d. IS THERE ANOTHER HEALTH BENEFIT PLAN? <input type="checkbox"/> YES <input type="checkbox"/> NO <i>If yes, complete items 9, 9a, and 9d.</i>				
13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.					READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM.				
SIGNED _____ DATE _____					SIGNED _____				
14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL.					15. OTHER DATE MM DD YY QUAL.				
17. NAME OF REFERRING PROVIDER OR OTHER SOURCE					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? <input type="checkbox"/> YES <input type="checkbox"/> 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				
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25. FEDERAL TAX I.D. NUMBER SSN EIN 2222222 <input type="checkbox"/> <input checked="" type="checkbox"/>					26. PATIENT'S ACCOUNT NO. P1111				
27. ACCEPT ASSIGNMENT? (For govt. claims, see back) <input type="checkbox"/> YES <input type="checkbox"/> 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 ST. HOSPITAL 1234 1 ST MA				
33. BILLING PROVIDER INFO & PH # ()					a. 2222222 b.				

Code for primary procedure performed.

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.

CARRIER ↑ PATIENT AND INSURED INFORMATION ↓ PHYSICIAN OR SUPPLIER INFORMATION ↓

Sample CMS-1500 Form for Physician Office Setting



HEALTH INSURANCE CLAIM FORM

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

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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)**

Disclaimers

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. The coding and payment data is furnished 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. Providers should refer to authoritative coding sources, such as the Common Procedural Terminology CPT® codes and Healthcare Common Procedure Coding System (HCPCS) codes.

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For reference only. Information does not guarantee coverage or payment. The information provided in this guide is for informational purposes only. 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.

Cysview® Web Site

For more information regarding Cysview please visit our web site at:

<http://www.cysview.com>

