

2020 Reimbursement Guide for Physician Office

**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.
- 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 customers who perform Blue Light Cystoscopy in a physician office 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 is 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.

CPT® copyright 2012 American Medical Association. All rights reserved. CPT® is a registered trademark of the American Medical Association.

2020 Medicare Reimbursement Site of Service:

Physician Office

Physicians who purchase Cysview® for administration in the office setting are responsible for billing for the Cysview product in addition to the services provided by the physician. There is a unique HCPCS A code assigned to Cysview. Physicians should report HCPCS code A9589 (Instillation, hexaminolevulinate hydrochloride, 100mg) on a separate line on the claim form in addition to the CPT codes identifying the services provided to the patient on that date. The most appropriate CPT codes for the services performed should be reported on the claim.

Medicare Administrative Contractors (MACs) have not yet provided guidance on the payment rate for HCPCS code A9589, which may be based on Average Sales Price, Wholesale Acquisition Cost or invoice price of Cysview. The 2020 payment rates for Blue Light Cystoscopy procedures performed in the office setting are included in this document. These procedures include CPT codes 52000, 52204, 52214 and 52224. CPT codes 52234, 52235 and 52240 are generally not performed in the office setting.

Please consult with your local MAC for specific coverage, coding and payment policies applicable to billing for Blue Light Cystoscopy procedures performed in the physician office setting.

Physician Office

Place of service code = 11



Procedure codes

- Cystoscopy (52000)
- Cystoscopy with biopsy or higher (52204, 52214, 52224)



What to bill

- Procedure code
- + A9589 for Cysview



Commercial reimbursement

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



Medicare reimbursement

- Procedure and drug are reimbursed separately
- Cysview at ASP + 6%

**2020 Medicare Reimbursement
Site of Service: Physician Office**

| CPT® Code | Description | Physician Office Payment |
|----------------------|---|---|
| 52000 | Cystourethroscopy (separate procedure) | \$216.18 |
| 52204 | Cystourethroscopy, with biopsy(s) | \$395.90 |
| 52214 | Cystourethroscopy, with fulguration (including cryosurgery or laser surgery) of trigone, bladder neck, prostatic fossa, urethra, or periurethral glands | \$751.02 |
| 52224 | Cystourethroscopy, with fulguration (including cryosurgery or laser surgery) or treatment of MINOR (less than 0.5 cm) lesion(s) with or without biopsy | \$784.59 |

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

Drug/Supply Code

| | |
|-------|--|
| A9589 | Instillation of hexaminolevulinate HCl |
|-------|--|

2020 Medicare Reimbursement
Relative Value Units – Office (POS 11)

| CPT® Code | Work RVU | Practice Expense RVU | Malpractice RVU |
|------------------|-----------------|-----------------------------|------------------------|
| 52000 | 1.53 | 4.28 | 0.18 |
| 52204 | 2.59 | 8.08 | 0.30 |
| 52214 | 3.50 | 16.90 | 0.41 |
| 52224 | 4.05 | 17.22 | 0.47 |

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://www.cysview.com)