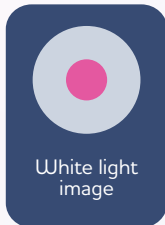


Cystoscopy Fact Sheet

Blue Light Cystoscopy (BLC®) with Cysview® for non-muscle invasive bladder cancer

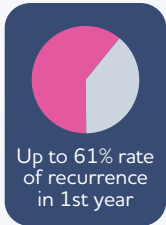
The evolution of bladder cancer detection

Cystoscopy is the gold standard diagnostic tool for bladder cancer detection. This procedure allows a urology HCP to closely examine the lining of a patient's bladder.



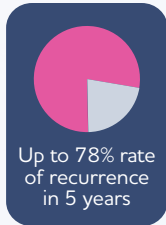
White light
image

Historically, cystoscopy has been performed using only white light to shine in the bladder for the exam.

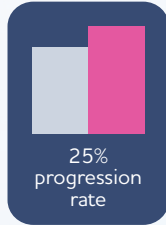


Up to 61% rate
of recurrence
in 1st year

Historically, bladder cancer has had a high risk of recurrence and progression.¹



Up to 78% rate
of recurrence
in 5 years



25%
progression
rate

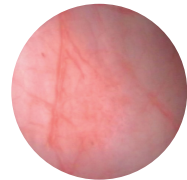


In actuality, some cancer may have recurred, but some cancer may have escaped detection under white light alone.²

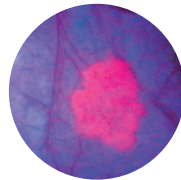
Blue Light Cystoscopy with Cysview detects more non-muscle invasive bladder cancer (NMIBC) than White Light Cystoscopy alone³

This state-of-the-art procedure – Blue Light Cystoscopy with Cysview – helps make cancer more visible.

Cysview may not detect all bladder tumors and is not a replacement for random bladder biopsies. False-positive fluorescence may occur due to inflammation, cystoscopic trauma, scar tissue, previous bladder biopsy, recent BCG immunotherapy or intravesical chemotherapy.



Bladder image from
White Light Cystoscopy



Same image from
Blue Light Cystoscopy
with Cysview

White light and blue light work together

A BLC with Cysview consists of a cystoscopic examination using both white and blue light to explore the bladder lining for tumors. It begins with the instillation of the optical imaging agent Cysview into the patient's bladder to make the abnormal cells glow bright pink in blue light.



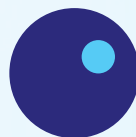
Examine in
white light



View pink lesion
in blue light



Perform procedure/
resect/biopsy in white light



Re-examine margins
in blue light

How Cysview works³

Cysview makes tumor cells glow bright pink in blue light, but it is not a dye. It drives increased production of a natural compound inside cells. Unhealthy cells do not process out the compound as quickly as healthy cells; the resulting accumulation creates a pink glow in blue light. Sufficient accumulation takes about one hour to occur, so patients need to arrive early for a BLC procedure.



Patients must arrive at least one hour before their procedure.



After the usual patient intake process...



a urology HCP reconstitutes Cysview powder into a liquid...



and uses a catheter to place the resulting small amount of liquid into the patient's bladder.



After one hour, the patient's procedure can begin.

Supported by industry guidelines

The clinical value of BLC with Cysview has been recognized by leading urology and cancer care organizations. Categorized as an enhanced cystoscopy technique, BLC is included in the following recommendations.

Diagnosis and Treatment of Non-Muscle Invasive Bladder Cancer: AUA/SUO Joint Guideline (2016; Amended 2020)⁴

Enhanced Cystoscopy

In a patient with NMIBC, a clinician should offer Blue Light Cystoscopy at the time of TURBT, if available, to increase detection and decrease recurrence. (Moderate Recommendation; Evidence Strength: Grade B)

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Bladder Cancer (2021; Amended 2023)^{5*}

Enhanced cystoscopy may be helpful in identifying lesions not visible using white light cystoscopy. Consider enhanced cystoscopy (if available) for initial evaluation or when positive urine cytology.

Please see Important Risk & Safety Information on the back and accompanying Full Prescribing Information.

CYSVIEW®
Hexaminolevulinate HCl

Product Indication for Cysview® (hexaminolevulinate HCl)

Cysview 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 White Light Cystoscopy.

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.

Contraindications

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 STORZ 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.

References

1. Babjuk M, Böhle A, Burger M, et al. EAU Guidelines on Non-Muscle-Invasive Urothelial Carcinoma of The Bladder: Update 2016. *Eur Urol*. 2017;71(3):447-461.
2. Hermann GG, Mogensen K, Carlsson S, et al. Fluorescence-Guided Transurethral Resection of Bladder Tumours Reduces Bladder Tumour Recurrence Due to Less Residual Tumour Tissue in Ta/T1 Patients: A Randomized Two-Centre Study. *BJU Int*. 2011; 108(8b):E297-E30.
3. Cysview [prescribing Information]. 2019:1-4.
4. Chang SS, Boorjian SA, Chou R, et al. Diagnosis and Treatment of Non-Muscle Invasive Bladder Cancer: AUA/SUO Guideline. *J Urol*. 2016;196(4):1021-9.
5. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines-Bladder Cancer. (Version 1.2023). https://www.nccn.org/professionals/physician_gls/pdf/bladder.pdf. Accessed March 16, 2023.

* Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Bladder Cancer. Version 1.2023. © National Comprehensive Cancer Network, Inc. 2023. All rights reserved. Accessed March 16, 2023. To view the most recent and complete version of the guidelines, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.

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April 2023 CYSC20230011

CYSVIEW®
Hexaminolevulinate HCl



THE
BLADDER CANCER
COMPANY