Patient guide to Blue Light Cystoscopy with Cysview® for detection of bladder cancer

Only available by prescription from your healthcare provider.
Facts About Bladder Cancer

• Bladder cancer is one of the most commonly diagnosed cancers, with an estimated 73,500 new cases each year\(^1\)

• In the US, it’s the fourth most common cancer in men and ninth in women\(^2\)

• There are over 520,000 bladder cancer survivors in the US\(^2\)

Cysview\textsuperscript{®} (hexaminolevulinate hydrochloride) for Intravesical Solution Product Information

Product Indication:

Cysview is an optical imaging agent indicated for use in the cystoscopic detection of non-muscle invasive papillary cancer of the bladder among patients suspected or known to have lesion(s) on the basis of a prior cystoscopy. Cysview is used with the KARL STORZ D-Light C Photodynamic Diagnostic (PDD) system to perform cystoscopy with the blue light setting (Mode 2) as an adjunct to the white light setting (Mode 1).

Cysview is not for repetitive use and is not a replacement for random bladder biopsies or other procedures used in the detection of bladder cancer.
What is a cystoscopy?

Cystoscopy is a test that allows your doctor to look directly inside your bladder. A cystoscopy may be used to help find the cause of symptoms, or to treat or monitor conditions. Cystoscopy lets the doctor inspect your bladder lining very closely for any abnormal growths or suspicious areas.

*A glossary of terms is located at the end of this guide.*

What is a cystoscope?

A thin, tube-like telescope called a cystoscope is carefully passed up the urethra (the tube through which urine leaves your body) and into the bladder. Tiny surgical instruments can be passed through the cystoscope so that samples of tissue can be removed (called a biopsy) then sent to the laboratory to be examined.

Cystoscopy also can be used for giving treatment directly to the bladder. Some procedures require a type of anesthesia. You may wish to discuss any questions about anesthesia with your healthcare provider. Your healthcare professional may instruct you to fast or have a light breakfast.
What is a standard cystoscopy?

Standard cystoscopy is a test that allows your doctor to look directly inside your bladder with a scope.

- A cystoscopy may be used to help find the cause of symptoms, to treat or monitor conditions
- Cystoscopy lets the doctor inspect your bladder lining very closely for any abnormal growths or suspicious areas
- Based on the findings of the cystoscopy the doctor may decide to remove the suspicious tumors
- The entire procedure is done under standard white light

How your healthcare professional may see an image during a standard white light cystoscopy

Bladder image using white-light cystoscopy alone
What is a Blue Light Cystoscopy with Cysview?

Blue Light Cystoscopy with Cysview is a technology that significantly improves the detection of non-muscle invasive papillary cancer of the bladder as an adjunct to white light compared to traditional white-light cystoscopy alone:

- Cysview (hexaminolevulinate HCl) is an imaging solution that is placed in the bladder one hour prior to the cystoscopic procedure using a catheter and is absorbed by cancerous tissue.

- The doctor performs the cystoscopy by using both white light and blue light. When the doctor switches to blue light, it makes cancerous tumors more visible and may highlight additional tumors.

- Using Blue Light Cystoscopy with Cysview in conjunction with white light allows the doctor to see more tumors than with standard white light cystoscopy alone.

How your healthcare professional may see the same image during a Blue Light Cystoscopy with Cysview

Same image after using Blue Light Cystoscopy with Cysview as an adjunct to white light.
What Happens During Blue-Light Cystoscopy

Here’s how Blue-Light Cystoscopy with Cysview works:

• The Cysview solution is placed in the patient’s bladder about an hour before the procedure.
• During the procedure, the doctor inserts a long thin tube and uses white light to examine the bladder.
• When the equipment is switched to blue light mode, other hard-to-see tumors that may be present become more visible.
• These tumors stand out against the normal bladder tissue, making it easier for doctors to identify and remove them.

Why Blue Light when added to white light alone improves the detection of lesions

Blue-Light Cystoscopy with Cysview has been shown to outperform white-light cystoscopy alone in detecting tumors:

• In a clinical study of 814 patients, one or more additional Ta or T1 bladder cancer lesions were detected by Cysview in 16.4% of the patients compared white light alone.
• Because doctors can see and remove more tumors, the risk of them returning may be reduced.

Please see Full Prescribing Information enclosed.

A glossary of terms is located at the end of this guide.
**Can Anyone Get Blue-Light Cystoscopy with Cysview?**

Blue-Light Cystoscopy with Cysview is recommended for anyone whose doctor suspects or knows that his or her patient has bladder cancer lesions based on a previous cystoscopy.

**Is Blue-Light Cystoscopy with Cysview Safe?**

Any procedure may have some risks, and you should consult your doctor regarding the risks and benefits of this procedure.

- The most common patient complaints include such problems as bladder spasm and bladder pain, discomfort when urinating, and frequent urination.

- On rare occasions, patients have experienced increased heart rate, chest pain, and fever; hypersensitivity reactions may occur in some patients.

**Ask your doctor if Blue-Light Cystoscopy with Cysview would be right for you**

**Medications**

Be sure to tell your healthcare professional all of the medications you are currently taking. Ask your doctor whether your medications should be taken before or held until after the procedure.
What to expect after the procedure

The following are important things to keep in mind for after your Blue-Light Cystoscopy with Cysview:

- Once the procedure is finished, your bladder will be full of water and it will probably be necessary to pass urine again.
- Most people—including those who have just had local anesthesia—feel ready to go home after a short time; once home, you should plan to rest for the remainder of the day.
- It’s not uncommon to have some bladder spasms after a cystoscopy, which can make you feel like you need to go to the bathroom more often than usual.
- You may feel some stinging when you pass urine for a couple of days.
- Blood in the urine is also common for several days after the procedure, particularly if you have had some cancer cells removed.
- In rare cases, patients may have more difficulty passing urine after their cystoscopy; should that happen, a catheter may be left in the bladder to drain excess fluid until any swelling goes down.
- Some patients may develop a mild infection after cystoscopy; this may usually be treated with antibiotics. Consult your physician if you are concerned.

Drinking plenty of water can help with many of these issues.

When to seek help from your doctor

After 2 or 3 days if you still have blood in the urine, you see blood clots after you have urinated several times, or if any of your symptoms are severe, please contact your healthcare professional for advice.
Standard white light cystoscopy

Blue Light Cystoscopy with Cysview

More information at cysview.com
Glossary

**Anaphylactic shock**
Severe, whole-body allergic reaction.

**BCG treatment (Bacille Calmette-Guerin)**
As it pertains to bladder cancer, weakened tuberculosis bacteria that are placed into the bladder to decrease the recurrence of bladder cancer.

**Bladder**
A hollow organ that collects urine until it can be passed out of the body.

**Chemotherapy**
A type of cancer therapy, which uses anticancer drugs to selectively kill cancer cells.

**Cystitis**
Inflammation of the bladder; may be related to a bacterial infection, viral infection, radiation, or other bladder irritants.

**Cystoscope**
A telescope like instrument that allows examination of the urethra and the inside of the bladder.

**Cystoscopy**
The procedure of using a cystoscope to look into the urethra and bladder.

**Fluorescence**
The property of producing light when acted upon by radiant (shining brightly) energy.

**Instill**
To impart gradually

**Intravesical**
Within the bladder

**Intravesical chemotherapy/cancer therapy**
Medical therapy that is placed into the bladder to kill cancer cells. The therapy is placed into the bladder through a urethral catheter.
Glossary (continued)

Malignant
A cancerous tumor; can invade surrounding structures and spread to a distant site.

PPD (Photodynamic Diagnosis)
A modern type of cystoscopy in which a special drug solution is instilled into the bladder about an hour before the procedure. The drug accumulates in the cancer cells and glows pink under blue light. The tumor cells are highlighted and stand out against the normal bladder tissue which keeps its blue appearance.

Additional patient information

Bladder Cancer Advisory Network (BCAN).
www.bcan.org

BCAN is the first national advocacy organization dedicated to increasing public awareness about bladder cancer; to advancing bladder cancer research; and to providing educational and support services for the bladder cancer community. Founded in May 2005, BCAN is a cooperative effort among bladder cancer survivors, their families and caregivers, and the medical community.

If you have any questions or concerns about your Cysview blue light cystoscopy, ask your doctor right away.

Your doctor will be able to explain every aspect of the procedure and test results. This patient guide is for informational purposes only; it does not replace an open conversation with your doctor.

Please see Full Prescribing Information enclosed.
Important Risk and Safety Information about Cysview

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

Anaphylaxis reactions including 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 in patients receiving intravesical chemotherapy or BCG treatment within 3 months of Cysview photodynamic blue-light cystoscopy. There are no known drug interactions with hexaminolevulinate; however, no specific drug interaction studies have been performed. Using Cysview, fluorescence of non-malignant areas may occur, and Cysview may fail to detect some malignant lesions.

Cysview must be used 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.

Please see Full Prescribing Information enclosed.

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www.cysview.com