BLUE LIGHT CYSTOSCOPY (BLC™) COMMUNICATION KIT

• Educating Local Healthcare Professionals
• Building Community Awareness
• Educating Patients
• Media Relations
• Other Assets
• Reaching Out to the Media

SUPPORTING MATERIAL

• Cystoscopy Fact Sheet
• Understanding Blue Light Cystoscopy with Cysview for the Detection of Bladder Cancer: A Patient Guide
• "Blue Light Cystoscopy with Cysview Available Here" Poster

CYSVIEW®
Hexaminolevulinate HCl
This guide is designed to help you and your institution raise awareness about bladder cancer and the availability of Blue Light Cystoscopy with Cysview® (hexaminolevulinate HCl) at your location. Cysview is approved by the FDA and indicated for the detection of carcinoma of the bladder, among patients suspected or known to have lesion(s) based on a prior cystoscopy or in patients undergoing surveillance cystoscopy for carcinoma of the bladder. Cysview is the only FDA-approved agent for use with Blue Light Cystoscopy.

The first part of this guide includes information about all the customizable materials you will have at your disposal to educate patients and physicians about the availability of Blue Light Cystoscopy (BLC™) with Cysview at your location.

The second part of this guide specifically gives your public relations and/or media relations expert the tips and tools they would need to engage with local media about bladder cancer and Blue Light Cystoscopy with Cysview.

MARKETING AND PATIENT EDUCATION

Educating Local Healthcare Professionals

One of the first steps you will want to take is making sure your local primary care physicians and other referring physicians are aware of the availability of Blue Light Cystoscopy with Cysview at your institution.

**Introductory Letter**

The introductory letter can be emailed or mailed to introduce Blue Light Cystoscopy with Cysview, explaining how it works and encouraging HCPs to refer appropriate patients to undergo the procedure at your institution and invites them to visit your facility to see it in action.

Building Community Awareness

Besides reaching out to area physicians, building an awareness of bladder cancer and the availability of Blue Light Cystoscopy with Cysview at your institution among the broader communities you serve will also be important. For example you may choose to pay for direct advertising or emailing patients, internal promotion with posters and other signage at your institution and holding community-wide events.

One very impactful way to reach potential patients is through the development of a Community Awareness Event that focuses on the risk factors associated with bladder cancer and includes your experts talking about breakthroughs in diagnosis and treatment such as Blue Light Cystoscopy with Cysview.

Specific to supporting a Community Awareness Event, included in the kit are customizable templates for:

**Event Email Templates**

A Community Awareness Event also presents a perfect opportunity to approach your local media. More information about conducting media relations and the materials available to help you with this are included in the second section of this guide.
Educatng Patients
For physicians utilizing Blue Light Cystoscopy with Cysview, educating potential patients about the procedure—how it works and the benefits—will be key. The kit also features several patient education items that can be used by physicians, including:

Email to Patients

Copy for Patient Newsletters

What You Need to know About Bladder Cancer
A slide presentation to aid in the patient discussion

Patient Brochure
Explains bladder cancer, BLC with Cysview, and what to expect

BLC with Cysview Q&A

"BLC with Cysview Available Here" Poster

There are other ways you can incorporate promotion of BLC with Cysview into your marketing programs. These include:

• Dedicate a page or section of your institution's website to the technology
• Include a patient story on your website or in your newsletter (https://www.cysview.com/blc-with-cysview/patient-stories)
• Include a story on BLC with Cysview in any external campaigns you are already using in the community such as newsletters or magazines
• Include information in your institution's internal newsletter
• Partner with your local chapter of the Bladder Cancer Advocacy Network to develop awareness programs and campaigns (www.BCAN.org)
• Promote participation to your community of national efforts such as patient webinars
Media Relations

One of the best ways to inform the community about this important health issue and the latest cutting-edge technology used by your hospital for bladder cancer is through local media relations. This section of the guide provides helpful tips on how to engage with media and specific instructions on how to utilize the template materials.

In order to initiate outreach to the media, it is important to develop core media materials to support your efforts. Effective tools include press releases and fact sheets. Each tool included with the kit is detailed below.

Press Release

The press release template helps provide media with an overview of the story and allows you to feature spokespeople from your institution. This release template focuses on how your institution is an innovator in bladder cancer detection with the adoption of Blue Light Cystoscopy with Cysview, which adds to your reputation as a comprehensive facility committed to the healthcare needs of your community. It is designed to feature your hospital’s team as experts on bladder cancer and Blue Light Cystoscopy with Cysview to the media.

There are other angles you can pursue that can make your story more personal and timely for the media. These could include:

- Highlighting a Patient Story and their firsthand account of diagnosis and treatment. If you use a patient, make sure that you secure the proper written consent.
- Tying your announcement into a Community Awareness Event, such as a free lecture on bladder cancer or National Bladder Cancer Awareness Month in May.

Blue Light Cystoscopy with Cysview® Fact Sheet

This fact sheet provides more detailed information about Blue Light Cystoscopy with Cysview, explaining how the procedure works and the differences between white light cystoscopy used on its own and as an adjunct to blue light. Utilized with the press release and in tandem with a Bladder Cancer Fact Sheet, these materials provide reporters with a complete picture of the technology and its impact on patients.

Other Assets

Photocure has a library of images relevant to BLC with Cysview. Please contact Elaine Harris at EH@photocure.com for more information.
Reaching Out to the Media

Identifying Local Media

Once you have developed your press materials, you will be ready to target the media. Your first step will be to determine the contacts you would like to include in your outreach. To begin, you will need to develop a targeted media list, with names, phone numbers and email addresses of reporters in your area. While each media outlet may be organized differently, you would want to target any health and/or medical editors and reporters.

Most contact information (phone, email and fax numbers) can be found online on the media outlet’s website, though it may also be useful to call the main number for each outlet to ask who the best person is to speak to or email about your story. The larger the media outlet, the busier reporters and editors tend to be, and the more particular they may be with regards to how they want to receive news-related information.

If you are also promoting a bladder cancer event, make sure that you identify and target the editors of print or online community calendar and event news or listings pages so that they can include details publicizing your event in advance. If you are interested in having journalists attend, in the week leading up to your event follow up with the contacts to whom you sent your press release.

Finally, following your initial email, phone call or fax, it is important to reach out by telephone if you have not received a response, as reporters are often working on stories several weeks before a deadline.

Preparing Spokespeople

All news is local, and the best way to interest your media in covering a story on bladder cancer is to make sure you feature patient and healthcare professional spokespersons from your community. Try to have available at least one bladder cancer patient who can share their personal story. In addition, a healthcare professional – ideally an Uro-oncologist with direct experience or familiarity with Blue Light Cystoscopy with Cysview. Other spokespersons may include your institution’s CEO, medical director, a department head or an administrator.

You should prepare your spokespeople in advance of any interviews by helping them anticipate what questions they might be asked. For instance, if you are featuring a bladder cancer patient in your outreach, you may want to develop a list of questions for them that a reporter would likely want to know about their experience. If you are using a physician or other healthcare professional, remind them to use terminology that everyone can understand and refrain from using medical jargon.

Distributing Materials and Media Relations

When the news release has been completed, reviewed and approved by the appropriate people at your institution, the next step is to format it on your institution’s letterhead. The final step is to ensure that the news release has been reviewed and approved by Photocure.

Sending a photograph with your press release will increase the chances that a print publication will cover your story. Please reach out and Photocure will be happy to provide a photo of the Blue Light Cystoscopy with Cysview product to accompany your press release. If you decide to take your own photo of a patient (or a model) undergoing the procedure, be sure to have the patient or model sign a consent form that grants permission to take and use the photo for promotional purposes. The photograph also may be accompanied by an image of how the bladder appears with and without the use of Cysview.

In reaching out to the media you should offer the media a first-hand look at how Blue Light Cystoscopy with Cysview works by offering a site visit. Feel free to invite them to visit your facility for a tour guided by your physician expert.

It is always gratifying when a local media outlet reports on your story. After the story appears, send the editor a thank-you note. This will help you develop an ongoing relationship with that reporter, which will be helpful for future news announcements coming from your institution.
BLUE LIGHT CYSTOSCOPY WITH CYSVIEW® COMMUNICATION KIT

INTRODUCTORY LETTER

PLEASE UTILIZE INSTITUTION LETTERHEAD and/or LOGO

Dear [INSERT RECIPIENT’S NAME]:

With an estimated annual bladder cancer incidence of 81,190 and 696,440 bladder cancer survivors in the US in 2018, the medical need to improve detection and resection of all bladder cancer tumors has never been clearer.1

To that end, [INSTITUTION] is pleased to announce that Blue Light Cystoscopy (BLC™) with Cysview®, which has been proven to significantly increase detection over white light cystoscopy alone is now available at our facility.2

The AUA/SUO 2016 Guideline states that “In a patient with non-muscle invasive bladder cancer (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)3

Cysview is an optical imaging agent indicated for use in the cystoscopic detection of non-muscle invasive bladder cancer including carcinoma in situ (CIS) among patients suspected or known to have lesion(s) on the basis of a prior cystoscopy. Cysview is used with the KARL STORZ Photodynamic Diagnostic (PDD) system to perform BLC™ as an adjunct to the white light cystoscopy.2

BLC with Cysview is now in over 120 US institutions and has been used in over 450,000 patients worldwide.4

Used as an adjunct to white light cystoscopy, BLC with Cysview gives confidence at first sight. It is the only FDA-approved technology that:

• Detects more Ta/T1 bladder cancer lesions than white light cystoscopy alone2
  o At surveillance, lesions in 21% of recurrent patients were only found with Cysview*
  o In the OR, one or more additional Ta or T1 bladder cancer lesions were detected in 16% of patients only by BLC with Cysview**
  o In the OR, CIS in 35% of patients was only found with BLC with Cysview’

• Results in improved tumor resection since better NIMBC detection means more tumors can be removed in that same TURBT5

• Allows for better patient management decisions6

We encourage you to consider the role BLC with Cysview can play in the management of your patients with known or suspected bladder cancer. Your patients can, if appropriate, undergo a BLC with Cysview procedure at [INSTITUTION]. If you wish to visit our facility and see BLC with Cysview for yourself, contact [INSTITUTION]

To learn more about BLC with Cysview at [INSTITUTION], contact [INSTITUTION UROLOGIST] at [INSTITUTION PHONE NUMBER], or go to www.cysview.com.

* A Prospective, Comparative, Within-Patient Controlled Multi-Center Phase 3 Study in the Detection of Bladder Cancer During Surveillance
** A Prospective, Comparative, Within-Patient Controlled Multi-Center Phase 3 Study in the Detection of Ta/T1 NMIBC in patients who had previously undergone a cystoscopy and had suspicion of or confirmed NMIBC

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 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.

**Event Email**

**Please Utilize Institution Letterhead and/or Logo**

Subject: Bladder cancer detection breakthrough to be featured at [Institution]

Learn about the breakthrough technology that improves bladder cancer detection at the [Institution] [Event Name].

If you or anyone you know has or is at risk for bladder cancer, this is an important event you won’t want to miss!

Join us on [Event Date] at the [Institution] [Event Name] to learn about the latest healthcare trends and breakthroughs, including a new technology that increases the detection of bladder cancer.

- Improves detection – so that your doctor can see and remove more cancerous tumors
- Allows better disease management
  - better detection means more tumors can be removed
  - more complete disease staging and grading

Here’s your opportunity to talk to the professionals and learn more about this breakthrough technology! Don’t miss it!

[Event Name] [Event Date] [Event Time]

[Institution Information]

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**References:**

Blue Light Cystoscopy (BLC™) with Cysview® is Now available to Bladder Cancer Patients

Bladder cancer is the fifth most commonly diagnosed cancer in the US and is the fourth most common cancer found in men.\(^1\) Estimates state 81,190 new cases of bladder cancer in 2018.\(^1\) More information can be found on bladder cancer at www.bcan.org, the website for the Bladder Cancer Advocacy Network.

[INSTITUTION] is among a select number of institutions around the country to offer this revolutionary approach, Blue Light Cystoscopy with Cysview, which is included in bladder cancer American Urological Association (AUA) and the Society of Urological Oncology (SUO) guidelines.\(^2\) [INSTITUTION WEBSITE]

In [MONTH, YEAR, PHYSICIAN] started using BLC with Cysview. “As a urologist specializing in treating patients with cancer you always want to be able to tell your patients, with confidence, that you were able to remove as much cancer as possible. I felt reassured from the moment that the blue light was switched on and I could see additional lesions I couldn’t see with my previous cystoscope. Patients have appreciated this technology and I know it will make a difference going forward.”

When symptoms and blood tests suggest that you may have bladder cancer, doctors perform a visual inspection of the interior wall of the bladder using a cystoscope — a thin tube with a light and video camera on the end — in a procedure called a cystoscopy.

With BLC with Cysview doctors use a cystoscope equipped with both white and blue light. Before the procedure Cysview (hexaminolevulinate HCl) is instilled into the bladder. Cysview makes the cancer cells glow bright fluorescent pink in blue light and stand out against the blue of the healthy tissue. This results in the improvement of the visualization and detection of non-muscle invasive bladder cancer (NMIBC) lesions. Studies have found that there is a significant increase in the detection of non-muscle invasive bladder cancer using this state-of-the-art technology.\(^3\) For more information on the procedure please go to www.cysview.com.

BLC with Cysview is FDA approved for use during surgery and for follow-up cystoscopies. For the appropriate bladder cancer patients, [INSTITUTION] now offers this revolutionary approach. For an appointment call [INSTITUTION PHONE], or visit our website [INSTITUTION WEBSITE].

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.

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References:
Patients seeking treatment for bladder cancer have many choices on where to go for their care. There are more diagnostic tools and treatments now than ever before. Today, patients have an additional option when undergoing a biopsy or surgical removal (called a resection) of a suspected or known bladder cancer or for their follow-up check-up cystoscopies. BLC with Cysview is an important tool that can aid in the diagnosis and management of bladder cancer. Finding a center that offers this option can make a difference. Doctors at your institution are now using BLC with Cysview to better detect patients’ bladder cancer.

Below are the answers to some common questions about BLC with Cysview.

**Q: What is BLC with Cysview?**

In the earliest stages of bladder cancer, cancer cells are located on the surface layer of the bladder wall. Identifying this kind of cancer, which is called non-muscle invasive bladder cancer (NMIBC), requires a correct and thorough work-up, and diagnosis is a key component of successful treatment. Understanding the stage and grade of the cancer is essential to deciding on the best treatment path.

To diagnose this disease, surgeons inspect the inside of the bladder using a long, thin tube called a cystoscope that includes a video camera on the end. In the past, the only option was white light cystoscopes, which do not always easily show tumors or cancerous lesions.

BLC with Cysview uses a cystoscope equipped with both white and blue light for visual inspection inside the bladder. A small amount (less than 2 oz.) of the prescription imaging agent Cysview is placed into the bladder using a catheter before the procedure. Together the medication and device are used to detect significantly more bladder cancer in more patients.

**Q: How is Cysview administered and how does it work?**

With BLC with Cysview doctors use a cystoscope equipped with both white and blue light. Before the procedure Cysview (hexaminolevulinate HCl) is instilled into the bladder. Cysview makes the cancer cells glow bright fluorescent pink in blue light and stand out against the blue of the healthy tissue. This results in the improved detection of non-muscle invasive bladder cancer (NMIBC) lesions. Studies have found that there is a significant increase in the detection of non-muscle invasive bladder cancer.

**Q: How many patients have had BLC with Cysview?**

BLC with Cysview has been used in over 450,000 patients. It was approved in the US in 2010 and was included in the American Urological Association (AUA) and Society of Urologic Oncology (SUO) guideline for the management of patients with non-muscle invasive bladder cancer in 2016. Over 120 centers in the US use BLC with Cysview. We at [INSTITUTION] have been using it since [YEAR], (add if participated in clinical studies or have published).

**Q: Does BLC with Cysview work better than white light? What are the benefits of using Cysview?**

BLC with Cysview does work better than white light alone. Because Cysview causes bladder cancer cells to glow bright fluorescent pink in blue light, surgeons are better able to see smaller tumors and flat lesions that may not be seen with white light. The surgeon can immediately remove diseased tissue (called a resection), ideally leaving a clean margin of healthy tissue around the resection site. Cysview gives urologic surgeons the ability to better evaluate, identify, and remove hard-to-see tumors more accurately.

By seeing more lesions, the stage and grade of the patient can be more accurately determined and appropriate management and treatment offered.
**Q: Can Cysview be used as a diagnostic tool on all types of bladder cancer?**

No. It is not suitable for muscle invasive bladder cancer and some patients with non-muscle invasive bladder cancer (NMIBC) after initial diagnosis and follow-up.

Bladder cancer falls into two general categories:

- **Non-muscle invasive bladder cancer (NMIBC):** About 70 percent of all bladder cancers fall into this category, in which a tumor (also called a lesion) is still in the inner layer of cells of the bladder’s inside wall. Subtypes include Ta, carcinoma in situ (CIS) and T1 lesions.6
- **Muscle invasive bladder cancer (MIBC):** This disease, which is less common than non-muscle invasive, occurs when the cancer has grown into deeper layers of the bladder wall. This disease is more likely to spread to other organs and is more difficult to treat. These cancers include the subtypes T2, T3, and T4.7

Cysview readily detects the first type, NMIBC, which may be hard to distinguish from healthy tissue. Due to their more advanced nature, MIBC tumors are detected through white light cystoscopy, biopsies, a manual exam, imaging and other diagnostic tests.1

**Q: What are the limitations of BLC with Cysview?**

Cysview is not a replacement for random biopsies, which still need to be done to check whether there is any disease that has not been detected under white or blue light during the cystoscopic examination. Cysview is not used for the detection of MIBC.

**Q: Who is eligible for Cysview? Is Cysview right for me?**

Anyone who is suspected of having or is known to have bladder cancer (from a previous cystoscopy) can have BLC with Cysview. As with all medical situations, your physician will work with you to determine if Cysview is right for your particular situation.

**Q: Is Cysview with Blue Light Cystoscopy safe?**

Clinical studies have shown that BLC with Cysview is safe and well-tolerated. However, no surgical procedure is free of any risk, so you should consult your doctor regarding the risks and benefits of this procedure for your individual circumstances.

Most people are ready to go home shortly after a routine procedure. Your doctor will advise you on how much rest and care you will need afterward.
Q: What are the side effects associated with Blue Light Cystoscopy with Cysview?

Side effects of both blue light and white light cystoscopies are generally the same. They may include:

- Bladder spasms
- Bladder pain
- Discomfort while urinating
- Frequent urination
- Blood in your urine

Rare side effects may include:

- Difficulty passing urine, which may require a catheter
- A mild infection, which is usually treated with a standard course of antibiotics
- Hypersensitivity reactions to the Cysview medication, which could include an increased heart rate, chest pain and fever.

Be sure to consult your physician if you are concerned about any effects you may experience after the procedure.

Q: Do physicians need to special training in this procedure?

Yes, surgeons require special training to use Cysview and the cystoscope that has both white and blue light. [INSTITUTION] is now among a select number of organizations around the country and [ONE OF TWO IN THE IMMEDIATE AREA]. The approach is included in bladder cancer guidelines published by the AUA and SUO.

Q: How much will it cost? Is it covered by insurance?

Many insurance plans do cover Cysview, but coverage can vary widely. Some insurance plans do not cover it at all. Medicare covers it in certain circumstances.

We recommend working with the Photocure Patient Financial Services Department regarding your situation. They can help you determine how Cysview will be covered under your policy, if there are any co-pays, and how/if it qualifies under your plan’s deductible structure.

For questions or comments, please contact us at [INSTITUTION]

Important risk & safety information

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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.

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Prior to Cysview administration, read the Full Prescribing Information and follow the preparation and reconstitution instructions.

References:
[INSTITUTION] ADOPTS INNOVATIVE IMAGING AGENT TO IMPROVE DETECTION OF CERTAIN BLADDER CANCERS

Blue Light Cystoscopy with Cysview® May Detect Certain Bladder Cancer Tumors More than the Use of Standard Diagnostic Technology

[LOCATION, DATE] – [INSTITUTION] is one of a number of medical centers nationwide offering Blue Light Cystoscopy with Cysview® (hexaminolevulinate hydrochloride) is an optical imaging agent indicated for use in the cystoscopic detection of non-muscle invasive bladder cancer including carcinoma in situ (CIS) among patients suspected or known to have lesion(s) on the basis of a prior cystoscopy.¹

[SAMPLE QUOTE:]
“Bladder cancer is difficult to detect and has a high rate of recurrence. An inaccurate diagnosis can result in incomplete treatment, which may lead to serious complications and a lower chance of survival for patients with potentially aggressive tumors,” noted [PHYSICIAN SPOKESPERSON, TITLE]. “Blue Light Cystoscopy with Cysview represents an important advancement in diagnostic technology, enabling more accurate diagnosis of non-muscle invasive bladder tumors compared to the standard technique.”

Bladder cancer is the sixth most commonly diagnosed cancer in the United States. The American Cancer Society estimates that 81,190 new cases of bladder cancer are diagnosed in the U.S. each year.² [INSERT STATE OR OTHER LOCAL STATISTIC, IF AVAILABLE]. Up to 50% of patients will have their bladder cancer recur -- that's the highest recurrence rate of any form of cancer.³

White light cystoscopy has long been the gold standard for detecting suspicious lesions during transurethral resection of bladder tumor (TURBT) procedures.⁴ Often bladder cancer lesions are hard to see and can be missed.

Now the gold standard is becoming Blue Light Cystoscopy (BLC™) with Cysview. For BLC, Cysview is placed into the bladder using a catheter about an hour prior to the cystoscopy. After first using white light, the doctor will switch to blue light mode. Because Cysview makes the cancer cells glow bright fluorescent pink in blue light, the doctor can more easily identify and remove tumors.¹

[SAMPLE QUOTE:]
“The availability of Blue Light Cystoscopy with Cysview is in keeping with our commitment to advancing patient care,” said [INSTITUTION SPOKESPERSON].

“At [INSTITUTION] patients with known or suspected bladder cancer can now undergo diagnostic procedures performed by physicians who have been specially trained in the use of this innovative technology.”

Cysview is an optical imaging agent indicated for use in the cystoscopic detection of non-muscle invasive bladder cancer including carcinoma in situ (CIS) among patients suspected or known to have lesion(s) on the basis of a prior cystoscopy. Cysview is used with the KARL STORZ Photodynamic Diagnostic (PDD) system to perform Blue Light Cystoscopy (BLC™) as an adjunct to the white light cystoscopy.¹

For an appointment call [INSTITUTION PHONE], or visit our website [INSTITUTION WEBSITE].
Important risk & safety information

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References:
[INSTITUTION] is pleased to announce that Blue Light Cystoscopy (BLC™) with Cysview® which is proven to significantly increase the detection\(^1\) of non-muscle invasive bladder cancer is now available at our center.\(^1\)

BLC with Cysview can detect more NMIBC in more patients and it is now included in the AUA/SUO guideline.\(^2\)

We encourage you to make an appointment to discuss Blue Light Cystoscopy with Cysview and to learn more about BLC with Cysview at [INSTITUTION]. You can also go to www.cysview.com and www.bcan.org to learn more about bladder cancer and its management.

BLUE LIGHT CYSTOSCOPY
WITH CYSVIEW®

Available Here

ASK YOUR DOCTOR

Cysview is not a replacement for random bladder biopsies or other procedures used in the detection of bladder cancer.
See Full Prescribing Information on reverse
**CLINICAL STUDIES**

**NONCLINICAL TOXICOLOGY**

**12.1 Mechanism of Action**

Cysview (hexaminolevulinate hydrochloride) for Intravesical Solution is a light-activated iminoester photosensitizer. The light source enables both white light cystoscopy and blue light (wavelength 360 – 450 nm) cystoscopy. The light is activated by the photosensitizer, Cysview. After excitation with light at wavelengths between 360 and 450 nm, PpIX and other porphyrins are generated in the neoplastic cells. After bladder instillation of Cysview for approximately 20 minutes, PpIX accumulates in neoplastic cells, compared to normal urothelium. In the human bladder, a greater accumulation of porphyrins is proposed in neoplastic or carcinoma-related pathology, including dysplasia. In a study of patients treated with recent BCG immunotherapy or intravesical chemotherapy, the percentage of patients with carcinoma-related pathology, including dysplasia, was higher in the study group, compared to the control group (85% vs 66%).

**8 USE IN SPECIFIC POPULATIONS**

**8.1 Pregnancy**

Pregnancy Category C

Cysview was studied in pregnant rats in the late stages of gestation and in rabbits early in gestation. The animals were treated with repeated doses of Cysview. At postmortem examination, the offspring revealed no anomalies. However, the clinical significance of these studies is not known. Because animal reproduction studies are not always predictive of human response, Cysview should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

**8.2 Lactation**

It is not known whether Cysview is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Cysview is administered to a nursing woman.

**8.3 Children**

The safety and efficacy of Cysview in children have not been established.

**8.4 Adverse Reactions**

The most common adverse reaction during cystoscopic examination was bladder pain. (6.2)

**5 WARNINGS AND PRECAUTIONS**

**5.1 Sensitivity Reactions**

The development of anaphylaxis to Cysview is extremely rare, but has been reported. The development of anaphylaxis has been associated with use of the photosensitizer, hexaminolevulinate hydrochloride. Individuals with a prior history of sensitivity to hexaminolevulinate hydrochloride, hexaminolevulinate, or other porphyrins should not use Cysview.

**5.2 Failed Detection**

Cysview may fail to detect some bladder tumors, including malignant lesions. Cysview is not a substitute for standard bladder examination techniques, and is not effective for the detection of certain bladder tumors.

**3 DOSAGE FORMS AND STRENGTHS**

**3.2 Prefilled Syringe**

Diluent for Cysview, 50 mL, in a plastic prefilled syringe.

**2 DOSAGE AND ADMINISTRATION**

**2.3 Bladder Instillation of Cysview**

Cystoscopic examination with the aid of a D-Light flexible PDD Videoscope System or a KARL STORZ D-Light C Photodynamic Diagnostic (PDD) System, with a source of white light or blue light (wavelength 360 – 450 nm), is performed after intravesical instillation of Cysview. The principal indication for the use of Cysview is for visualizing bladder anomalies, including bladder tumors. In this manner, Cysview may aid in the detection of bladder anomalies prior to resection or other intervention (Figure 9).

**2.4 Use of the KARL STORZ D-Light C Photodynamic Diagnostic (PDD) System**

Flexible PDD Videoscope System. Suspected malignant lesions were counted and evaluated. Lesions were considered to be malignant if they were visualized in red fluorescence using blue light. The primary indication for the use of the D-Light C PDD System is for evaluation of lesions suspicious for malignancy.

**2.5 Cystoscopic Examination**

Cystoscopic examination with the aid of a D-Light flexible PDD Videoscope System or a KARL STORZ D-Light C Photodynamic Diagnostic (PDD) System, with a source of white light or blue light (wavelength 360 – 450 nm), is performed after intravesical instillation of Cysview. The principal indication for the use of Cysview is for visualizing bladder anomalies, including bladder tumors. In this manner, Cysview may aid in the detection of bladder anomalies prior to resection or other intervention (Figure 9).

**11 PHARMACOKINETICS**

**11.1 Absorption**

Cysview is rapidly absorbed following oral ingestion. Absorption is not affected by food.

**11.2 Distribution**

In humans, Cysview is distributed into the intracellular fluid compartment. Cysview concentration in the intracellular fluid compartment is 10-100 times higher than in the extracellular fluid compartment. Cysview is concentrated in the blades of plants and the liver of animals exposed to porphyrin-producing bacteria.

**11.3 Metabolism**

Cysview undergoes metabolism in the liver, where it is converted to porphyrins. The porphyrins are then excreted in urine and bile. The metabolism of Cysview is not influenced by the presence or absence of bacteria.

**11.4 Excretion**

Cysview is excreted in the urine and bile of humans. The half-life of Cysview in urine is approximately 24 hours. The half-life of Cysview in bile is approximately 168 hours. Cysview is not excreted in the feces.

**10 CLINICAL PHARMACOLOGY**

**10.1 Mechanism of Action**

Cysview (hexaminolevulinate hydrochloride) for Intravesical Solution is a light-activated iminoester photosensitizer. The light source enables both white light cystoscopy and blue light (wavelength 360 – 450 nm) cystoscopy. The light is activated by the photosensitizer, Cysview. After excitation with light at wavelengths between 360 and 450 nm, PpIX and other porphyrins are generated in the neoplastic cells. After bladder instillation of Cysview for approximately 20 minutes, PpIX accumulates in neoplastic cells, compared to normal urothelium.
Blue Light Cystoscopy (BLC™) with Cysview® (hexaminolevulinate HCl) for Bladder Cancer

Bladder Cancer Detection
Cystoscopy is the gold standard diagnostic tool for bladder cancer detection. Doctors who suspect patients may have bladder cancer use this procedure to look inside the bladder. A cystoscope lets the doctor inspect the bladder lining very closely for any abnormal growths or suspicious areas. Historically, cystoscopy was performed using only white light for visualizing suspicious lesions. Unfortunately, there is a high risk of recurrence in bladder cancer and 30-44% of all patients have evidence of tumor on repeat TURBT until 8 weeks. This may be due to doctors being unable to detect, and therefore remove, all of the cancer during the initial resection.

Blue Light Cystoscopy with Cysview®
Blue Light Cystoscopy (BLC™) with Cysview® is a technology that significantly improves the detection of non-muscle invasive bladder cancer compared to traditional White Light Cystoscopy alone.
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 taken up by cancer cells in the bladder making them glow bright pink under blue light. Because of this, BLC™ with Cysview improves the detection of tumors and therefore can lead to a more complete resection, less residual tumors and better management decisions.

- A solution containing the drug is placed in the bladder using a catheter one hour prior to the cystoscopic procedure. During this time Cysview is absorbed by cancerous tissue.
- The doctor performs the cystoscopy by using both white light and blue light.

Inclusion of BLC with Cysview in Guidelines
The clinical value of BLC with Cysview has been included in several guidelines. Guidelines and recommendations have been published by the following organizations:

- American Urological Association (AUA), Society of Urological Oncology (SUO) (2016) – in the enhanced cystoscopy section, Blue Light Cystoscopy is recommended (Moderate Recommendation; Evidence Strength: Grade B) for use in patients with NMIBC at the time of transurethral resection of bladder cancer tumors (TURBT) to increase detection and decrease recurrence.

Clinical Overview
- Phase III studies using BLC with Cysview demonstrated a statistically significant difference in the detection of:
  - Ta/T1 tumors, with additional tumors detected in 16.4% of patients using BLC with Cysview
  - CIS, with 34.6% patients who recurred with CIS were detected with BLC only
  - recurrence, with 20.6% recurrent patients were found with Cysview alone through flexible cystoscopy

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

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 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 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

UNDERSTANDING BLUE LIGHT CYSTOSCOPY WITH CYSVIEW FOR DETECTION OF BLADDER CANCER

Cysview can only be used by qualified healthcare providers.

CYSVIEW®
Hexaminolevulinate HCl

VISIT CYSVIEW.COM
Facts About Bladder Cancer

81,190 new cases of bladder cancer each year\(^3\)

Bladder cancer incidence is about four times higher in men than in women\(^3\)

Over 696,440 bladder cancer survivors in the US\(^3\)

Important risk & safety information

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What is a cystoscopy?

A cystoscopy is a procedure that your doctor may use to examine your bladder to help find the cause of symptoms, or to treat or monitor conditions. This procedure allows your doctor to look directly inside your bladder and inspect the lining very closely.

If during a cystoscopy any abnormal growths or suspicious areas are seen, your doctor may remove tissue samples (biopsy) and send them to the laboratory to be examined.

A cystoscopy can be done while you are asleep under anesthesia or while you are awake with moderate sedation and/or pain management. Your doctor may instruct you to fast or have a light breakfast depending on whether you will be awake or asleep. Be sure to tell your doctor all the medications you currently take. Ask whether you should take them before your procedure or hold them until after.

What is a cystoscope?

A cystoscope is a thin, tube-like telescope that is carefully passed up the urethra (the tube through which urine leaves your body) and into the bladder. The cystoscope is a hollow tube that creates a path for surgical instruments to pass through for use in a cystoscopy.
A standard cystoscopy uses white light

During a cystoscopy procedure, the cystoscope shines light inside the bladder to aid in visibility. In a standard procedure, the light is regular white light—the type we all use every day to light a room.

White light helps your doctor visually assess the general health of your bladder and find irregularities to be further evaluated.
A cystoscopy can also use blue light with Cysview®

Your doctor also has the option of enhancing a cystoscopy by adding blue light and Cysview to the procedure. Called Blue Light Cystoscopy (BLC™) with Cysview®, this technology significantly improves the detection of non-muscle invasive bladder cancer (NMIBC).

With a standard cystoscopy procedure, your doctor can see some indicators of cancer under white light. With the addition of blue light and Cysview, the procedure offers significantly improved detection of suspicious areas compared to white light. The Cysview causes cancerous cells to glow bright pink under blue light.
What happens during Blue Light Cystoscopy with Cysview®

• One hour prior to a cystoscopy, a healthcare professional uses a catheter to place about 2 oz of Cysview in the bladder where it is absorbed by cancerous tissue

• For the procedure, your doctor inserts a long, thin tube (a cystoscope) and uses white light to examine the bladder

• When the doctor switches to blue light, the Cysview is taken up by cancerous tumors and glows bright pink—making them more visible and possibly also revealing additional tumors not visible under white light

• With Cysview, all tumors stand out against normal bladder tissue, so they are easier for your doctor to identify and remove completely

Blue Light Cystoscopy with Cysview has been shown to detect more bladder tumors than White Light Cystoscopy alone.²
Is BLC™ with Cysview® safe?²

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

- The most common patient complaints include 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

Who can have BLC with Cysview?²

Anyone who is suspected of having or is known to have bladder cancer (from a previous cystoscopy) can have BLC with Cysview.

Ask your doctor if BLC with Cysview would be right for you.
What to expect after the procedure

Here are some important things to keep in mind for after your cystoscopy:

• Once the procedure is finished, your bladder will be full, so you may need to urinate

• 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 is common to have some bladder spasms, which can make you feel like you need to urinate more often than usual

• For a couple days you may feel some pain or discomfort when you urinate

• Blood in the urine is common for several days after the procedure, particularly if you had any bladder tissue removed

• In rare cases, patients may have difficulty urinating after their cystoscopy; if that happens, your doctor may choose to discharge you with a urinary catheter in your bladder to drain excess fluid until any swelling goes down

• Some patients may develop a mild infection after a cystoscopy—watch for fever, chills, unrelieved nausea and/or vomiting, or inability to urinate; an infection may be treated with antibiotics. Consult your doctor if you are concerned

• In some cases your doctor may prescribe additional therapy, including intravesical chemotherapy (placed directly into the bladder)

*Drinking plenty of water can help with many of the common issues experienced after a cystoscopy.*

When to contact your doctor

Follow your doctor’s discharge instructions carefully. If after 2 or 3 days you still have blood in the urine, you see blood clots after you have urinated several times, or if you have severe symptoms of any kind, please contact your doctor’s office immediately.
Bladder images under white and blue light

**Standard White Light Cystoscopy**

**Blue Light Cystoscopy with Cysview**
Additional patient resources

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.

For more information about BLC with Cysview
www.Cysview.com

If you have any questions or concerns about your Blue Light Cystoscopy with Cysview, ask your doctor right away. Your doctor will be able to explain every aspect of the procedure.
This patient guide is for informational purposes only; it does not replace a conversation with your doctor.

Please see Full Prescribing Information enclosed.
References