[Month, day, year]

[To:
Name
Title
Department
Facility
Street address
City, State, Zip]

Dear [(name) or (To whom it may concern)],

I am writing to ask whether you are planning to make the flexible Blue Light Cystoscopy procedure available at [facility name].

I am sure that many patients would find it beneficial to have this procedure in the [office/clinic] rather than having to go into the operating room if not medically needed.

These are some of the benefits of using the flexible procedure.

- Comfortable atmosphere
- No need for general anesthesia
- Potentially less restrictive visitor/companion policy vs. hospital
- Easier for patient to have procedure in office/clinic than in a hospital outpatient department
- Patient can see what the HCP sees during the examination
- Patient pays co-pay instead of deductible and co-insurance
- Patients report having had a positive experience with Cysview and would do the procedure again.

I am asking that you consider how this procedure might prove very beneficial to your patients with non-muscle invasive bladder cancer.

Best regards,
(SIGNATURE)

P.S. Please review the following information to consider flexible Blue Light Cystoscopy with Cysview as a new procedure at your facility.

This procedure uses special cystoscopy equipment and an FDA-approved optical imaging agent, Cysview® (hexaminolevulinate HCl), for enhanced visibility of non-muscle invasive bladder cancer (NMIBC) tumors during a Blue Light Cystoscopy (BLC®) with Cysview.

A Blue Light Cystoscopy uses both white and blue light sources. First the urologist examines the bladder walls in regular white light; then switches to blue light for a different view. Cysview makes NMIBC glow bright pink in blue light for enhanced visibility during examinations and TURBTs.

Cysview is 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 as an adjunct to White Light Cystoscopy.

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Cysview is a class of diagnostic imaging agents that should be used with blue light during cystoscopy for the detection of bladder cancer. Cysview works by exploiting the fluorescent properties of naturally occurring molecules called photoactive porphyrins (PAPs). This improves the visibility of lesions in the bladder as compared to standard White Light Cystoscopy. Since White Light Cystoscopy and Blue Light Cystoscopy have different properties, Blue Light Cystoscopy with Cysview includes use of both white and blue light sources to deliver a full complement of visibility.

Blue Light Cystoscopy with Cysview involves instilling Cysview into the bladder approximately one hour before the cystoscopic examination, then evacuating it shortly beforehand. During the procedure, the bladder is mapped using both white light and blue light. Switching between the two modes can be done easily during the procedure. In this way, additional lesions can be identified under blue light; biopsies taken from suspect tissue and all macroscopic tumors resected under standard light; then the resected areas re-examined under blue light to check for remaining malignant tissue.

The clinical value of Cysview is that it improves detection of non-muscle invasive bladder cancer, including hard-to-detect smaller or flat non-papillary tumors as compared to White Light Cystoscopy alone. Improved tumor detection with Cysview fluorescence can lead to more accurate risk categorization that may impact treatment decisions.

A number of hospitals, ambulatory surgery centers, and urology clinics throughout the United States are using this exciting diagnostic agent and are seeing improved detection that benefits patients. It has currently been used in over 500,000 patients globally and is well tolerated, with a safety profile similar to that seen with standard 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.