



THE
BLADDER CANCER
COMPANY

New study publication reinforces the clinical benefits of Blue Light Cystoscopy in the ASC setting; supports ongoing initiatives to further improve reimbursement

Press release – Oslo, Norway, January 3, 2023: Photocure ASA, The Bladder Cancer Company, announces the publication of the study “Clinical and Economic Impact of Blue Light Cystoscopy in the Management of NMIBC* at U.S. Ambulatory Surgical Centers: What is the Site-of-Service Disparity?” in Urologic Oncology this week. The research objective was to quantify the clinical and economic impact of the incorporation of BLC in the management of NMIBC in ambulatory surgical centers (ASCs) considering 2022 Center for Medicare Services (CMS) patient-physician coverage and reimbursement.

The study authors Neal Shore**, MD, FACS and Meghan B. Gavaghan, MPH, built a budget impact model to assess projected ASC costs for a cohort of newly diagnosed bladder cancer patients over a 2-year follow-up comparing white light cystoscopy (WLC) alone versus WLC + blue light cystoscopy (BLC®). Treatment and surveillance intervals were based on AUA/SUO clinical guidelines. Clinical and cost metrics for staging and biopsy rates were assessed, with cost inputs based on Medicare reimbursement rates. Photocure supported this research with an unrestricted grant.

In the U.S., BLC for NMIBC surveillance in the ASC setting involves a flexible cystoscopy, an outpatient procedure without need of general anesthesia, allowing additional OR time for other hospital procedures. In the published clinical and health economic model, use of BLC resulted in the identification of 5 additional NMIBC recurrences compared to white light cystoscopy alone. There was an associated increased cost of performing BLC in an ASC setting, with a net increase in the total cost of care for NMIBC of \$110 per cystoscopy over a two-year period. If recurrences missed using WLC alone were to progress prior to detection, the model projects an increase in treatment costs borne by Medicare of \$9,097-\$34,538 due to more intensive treatments required for more advanced disease.

The authors conclude that due to the modeled results, “the Medicare program will incur increased costs. ... The current discrepancy in reimbursement disincentivizing community-based ASCs from adopting BLC, resulting in suboptimal patient care while increasing downstream treatment costs to Medicare, necessitated when missed disease progresses to higher stage/grade disease. The findings have important clinical implications for the optimal

management of NMIBC and should inform healthcare policies that promote cost-effectiveness and enhanced patient outcomes.”

“The findings of this paper highlight the benefits of BLC when patients receive this option for bladder cancer care in ambulatory surgery centers,” said Dan Schneider, President and Chief Executive Officer of Photocure ASA. *“The paper also reinforces the need for fair and equitable reimbursement in all sites of care, with Medicare payment rates increasing in January 2023, but favoring use of blue light in hospital outpatient departments (HOPDs) over ASCs. While we are pleased with the historic step by CMS to provide higher payment rates in both settings, feedback from ASC accounts is that payment would need to be increased further before patients treated in this site of care will be offered broad access to BLC. As a result, Photocure will continue to partner with the medical community to advocate for improved Medicare coverage in the ASC setting.”*

Read the full article here: <http://authors.elsevier.com/a/1gI7K3r93nVECK>

*NMIBC: Non-muscle invasive bladder cancer

**Dr. Shore is Medical Director for the Carolina Urologic Research Center and is a Fellow of the American College of Surgeons. He joined Photocure’s Board of Directors in May 2022.

Note to editors

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About Bladder Cancer

Bladder cancer ranks as the 8th most common cancer worldwide – the 5th most common in men – with 1 720 000 prevalent cases (5-year prevalence rate)^{1a}, 573 000 new cases and more than 200 000 deaths annually in 2020.^{1b}

Approx. 75% of all bladder cancer cases occur in men.¹ It has a high recurrence rate, with up to 61% in year one and up to 78% over five years.² Bladder cancer has the highest lifetime treatment costs per patient of all cancers.³

Bladder cancer is a costly, potentially progressive disease for which patients have to undergo multiple cystoscopies due to the high risk of recurrence. There is an urgent need to improve both the diagnosis and the management of bladder cancer for the benefit of patients and healthcare systems alike.

Bladder cancer is classified into two types, non-muscle invasive bladder cancer (NMIBC) and muscle-invasive bladder cancer (MIBC), depending on the depth of invasion in the bladder wall. NMIBC remains in the inner layer of cells lining the bladder. These cancers are the most common (75%) of all cases and include the subtypes Ta, carcinoma in situ (CIS), and T1 lesions. In MIBC, the cancer has grown into deeper layers of the bladder wall. These cancers, including subtypes T2, T3, and T4, are more likely to spread and are harder to treat.⁴

¹ Globocan. a) 5-year prevalence / b) incidence/mortality by population. Available at: <http://gco.iarc.fr/today>, accessed [January 2022].

² Babjuk M, et al. Eur Urol. 2019; 76(5): 639-657

³ Sievert KD et al. World J Urol 2009;27:295–300

⁴ Bladder Cancer. American Cancer Society. <http://www.cancer.org/cancer/bladder-cancer.html>

About Hexvix[®]/Cysview[®] (hexaminolevulinate HCl)

Hexvix/Cysview is a drug that preferentially accumulates in cancer cells in the bladder, making them glow bright pink during Blue Light Cystoscopy (BLC®). BLC with Hexvix/Cysview, compared to standard white light cystoscopy alone, improves the detection of tumors and leads to more complete resection, fewer residual tumors, and better management decisions.

Cysview is the tradename in the U.S. and Canada, Hexvix is the tradename in all other markets. Photocure is commercializing Cysview/Hexvix directly in the U.S. and Europe and has strategic partnerships for the commercialization of Hexvix/Cysview in China, Chile, Australia, New Zealand and Israel. Please refer to <http://photocure.com/partners/our-partners> for further information on our commercial partners.

About Photocure ASA

Photocure: The Bladder Cancer Company delivers transformative solutions to improve the lives of bladder cancer patients. Our unique technology, making cancer cells glow bright pink, has led to better health outcomes for patients worldwide. Photocure is headquartered in Oslo, Norway, and listed on the Oslo Stock Exchange (OSE: PHO). For more information, please visit us at www.photocure.com, www.hexvix.com, www.cysview.com

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