

# New budget impact model study in 4 European countries concludes that BLC use offers a clinically meaningful and economically rational approach to NMIBC management

Press Release – Oslo, Norway, November 19, 2025: Photocure ASA (OSE: PHO), the Bladder Cancer Company, announces the publication of the study "Hexaminolevulinate-enhanced photodynamic diagnosis in the management of non-muscle-invasive bladder cancer (NMIBC): The influence of differing European health care payment systems on the potential financial impact of adoption." in the Journal of Medical Economics this week. The research objective was to compare the economic implications of blue light cystoscopy (BLC®) adoption in line with national guideline recommendations in four European markets. The analysis further explores the impact of the different health care payment systems on the budgetary impact of BLC adoption by a hospital.

Methods: A <u>previously published budget impact model</u> was adapted to allow for the exploration of costs across four different payment environments: Denmark, France, Italy and Finland. Using the same set of clinical assumptions around disease risk profiles, recurrence rates and usage of PDD, but applying local treatment guidelines and country-specific costs per country, the net budget impact per patient with NMIBC was estimated for each over a 3-year time horizon. The analysis was carried out from the perspective of a hospital with a protocol-driven strategy for BLC adoption.

Results: In Denmark, with a differential tariff system between BLC and white light cystoscopy (WLC), the additional cost of the technology was fully offset by the tariff, with a net surplus of €170 per patient. In France and Italy, both of which have a flat-rate tariff for BLC and WLC, there was a net cost of €108 and €120 per patient respectively. In Finland, with a block contract system, the net cost per patient was €206.

Conclusions: Diagnostic technologies like BLC often present unique challenges for economic evaluation, requiring linkage between improved detection and downstream clinical and economic outcomes. In this study, incorporating predicted clinical outcomes and subsequently modelling the costs based on risk stratification, guideline recommendations and funding mechanisms, provides a useful tool to predicting overall cost for patient populations per country. Future studies for such technologies should integrate economic endpoints at the trial design stage, enabling better-informed decisions and faster time-to-adoption for patients.

The authors conclude that BLC offers a clinically meaningful and economically rational approach to NMIBC management across diverse European healthcare environments. Through flexible, locally tailored BIMs, stakeholders are better equipped to assess where and how BLC can be integrated into care pathways - supporting both improved patient outcomes and sustainable healthcare resource allocation.

"This multi-country budget impact analyses of blue light cystoscopy using hexaminolevulinate, otherwise known as Photodynamic Diagnosis, in the management of non-muscle-invasive bladder cancer, demonstrates the consistent clinical and economic value of enhanced diagnostic accuracy in reducing recurrence risk. Despite important structural differences across European healthcare systems—ranging from various tariff-based reimbursement models in Denmark, France and Italy to block contract systems in Finland—the reduction in the requirement for early repeat TURBT is an important clinical benefit. This clinical benefit inevitably carries both capacity and cost offset implications for hospitals, regardless of whether this gain is reflected in the local healthcare payment system," said Dr. Jonathan Belsey, Health Economics expert and one of the study authors.

"The growing number of approved treatment options and advances in technology and AI are accelerating the growth of precision diagnostics in bladder cancer. The pharmaceutical advancements, with emerging immune and gene therapies, are transforming care. This requires a more precise diagnosis to better select patients, predict and monitor treatment response and thus ensure the right treatment for the individual patient. Photocure's expertise in bladder cancer diagnostics, extensive data and knowledge, strong relationships with key stakeholders and deep understanding of their needs make us uniquely positioned to driving progress in uro-oncology precision diagnostics," said Anders Neijber, Photocure's Chief Medical Officer.

Read the full publication here: http://doi.org/10.1080/13696998.2025.2588728

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# **About Bladder Cancer**

Bladder cancer ranks as the 8<sup>th</sup> most common cancer worldwide – the 5<sup>th</sup> most common in men – with 1 949 000 prevalent cases (5-year prevalence rate)<sup>1a</sup>, 614 000 new cases and more than 220 000 deaths in 2022.<sup>1b</sup>

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 BC 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.<sup>4</sup>

# **About Hexvix®/Cysview® (hexaminolevulinate HCI)**

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.

The following safety information is solely included to comply with U.S. regulatory requirements: Important Risk & Safety Information for Cysview® (hexaminolevulinate HCl)

### **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/news.

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<sup>&</sup>lt;sup>1</sup> Globocan. a) 5-year prevalence / b) incidence/mortality by population. Available at: http://gco.iarc.fr/today, accessed [February 2024].

<sup>&</sup>lt;sup>2</sup> Babjuk M, et al. Eur Urol. 2019; 76(5): 639-657

<sup>&</sup>lt;sup>3</sup> Sievert KD et al. World J Urol 2009;27:295–300

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