



THE
BLADDER CANCER
COMPANY

New Health Economic analysis in France concludes there is insignificant cost difference between White Light and Blue Light Cystoscopy use when applying ccAFU guidelines

Press release – Oslo, Norway, October 6, 2023: Photocure ASA, The Bladder Cancer Company, announces the publication of “A cost-consequences and budget impact analysis of blue light-guided cystoscopy with Hexvix® in patients diagnosed with non-muscle-invasive bladder cancer in France” in the peer-reviewed international Journal of Medical Economics this week. This health economic analysis aims to assess the financial impact of widely adopting Blue Light Cystoscopy (BLC®) as recommended in the French ccAFU guidelines. A budget impact model (BIM) was developed, that simulates the overall costs of implementing a range of strategies involving the use of BLC, with analyses then undertaken to determine the cost consequences for individual hospitals if implementing the recommended management approach.

The analysis, led by Dr. Jonathan Belsey, [Health Economist & Managing Director of JB Medical Ltd), details that clinical evidence, such as published in the recent Cochrane review, supports the benefits of BLC over White Light Cystoscopies (WLC) alone on the detection of bladder tumors and time to first recurrence as well as an extended time to disease progression in patients managed with BLC-assisted TURBT*.

The most recent ccAFU (Comité de cancérologie de l'Association française d'urologie) guidelines recommend the use of BLC in a number of different positions in the care pathway for NMIBC. The study authors explain: *“The health economic impact of this strategy has been evaluated using a cost-utility analysis, from the perspective of the French healthcare system, and was found to be dominant over WLC – meaning that its use results in better outcomes and lower costs overall. Despite the existence of a clear clinical and economic evidence base, however, concerns around the potential budgetary impact of the widespread adoption of BLC have led to a degree of reluctance to adopt the technology.”*

ccAFU guidelines are detailed as follows: *“...the French guidelines make strong recommendations that BLC should be used: for the initial diagnostic TURBT in all but the smallest unifocal tumors; for the second look cystoscopy when cytology and the absence of papillary lesions with WLC suggest the presence of CIS; for treating recurrent NMIBC** in all*

low-risk patients, Small Ta low grade tumors in intermediate-risk patients, Suspicion of CIS in high-risk patients."

The budget impact model was developed as an interactive tool to provide organisation-specific results. For illustrative purposes, results have been analysed for 2 different theoretical scenarios: 1.) a large public hospital implementing the specific BLC recommendations within the ccAFU guidelines for 300 new patients per year and 2.) a small private hospital, using BLC in a more high-risk targeted subgroup from a cohort of 100 new patients per year.

The study publication presents the model results estimating the financial consequences of implementing this strategy for an individual hospital within the French healthcare system. Although BLC incurs an additional cost of €360 per case for the Hexvix instillation, this cost is partially offset by a reduced requirement for subsequent TURBT, attributable to the anticipated reduction in disease recurrence rates. Based on the two scenarios explored in this paper, full implementation of the ccAFU guideline recommendations would be expected to yield a net cost increase of around €269 per procedure, while a more targeted strategy based on a higher risk subgroup treated in the private sector was shown to yield a net cost differential of €133 per patient. Given that in France the mean overall cost of care for these patients ranges from €1,991 in the private sector to €3,376 in the public sector, it can be seen that the use of BLC is likely to be associated with an incremental cost of around 5-10% of the index procedural cost.

The BIM focused on direct medical costs incurred in the French healthcare system. Recurrence rates for BLC-assisted patients were estimated by applying a single overall hazard ratio estimate to all patient groups. All the published data for this outcome, however, relate to the time to the first episode of recurrence. Any residual benefit of BLC in reducing the risk of second or subsequent recurrences will therefore not have been captured in this analysis, potentially underestimating the total cost savings relating to reduced future event rates. In addition, impact of BLC on disease progression was also excluded from the calculation. The authors conclude: *"Given the high costs of managing progression to MIBC***, this will have potentially had a significant negative impact on the cost offset calculated by the model... Using a model of patient care that reflects the current recommendations of the ccAFU in France, we have shown that the additional expenditure required to implement BLC-assisted TURBT within individual hospitals is modest and not disproportionate to the overall cost of care for these patients. More nuanced targeting of BLC use has the potential to further improve the budget impact, while future research relating to subsequent event rates and progression risk offer the potential to move towards cost neutrality."*

Read the full publication here: <http://doi.org/10.1080/13696998.2023.2267929>

*TURBT: Transurethral resection of bladder tumor

**NMIBC: Non-muscle invasive bladder cancer

***MIBC: Muscle invasive bladder cancer

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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 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 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.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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