The Cxbladder Bulletin

Dear Customers and Friends of Cxbladder,

Welcome to the October 2023 edition of the Cxbladder Bulletin. In this issue:

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Medicare coverage update

Leading US Urological Societies call for LCD revision as submission period concludes. Cxbladder remains a covered test as we wait for a verdict

Pacific Edge is confident we have made the best possible legal and clinical arguments for Cxbladder to retain Medicare coverage during the open public meetings and the written comment period for the draft Local Coverage Determination (LCD) 'Genetic testing for oncology' (DL39365).

Our representations to Novitas were strongly supported by the leading professional societies in urology - the American Urological Association (AUA), the Large Urology Group Practice Association (LUGPA) and the American Association of Clinical Urologists (AACU) – and by our industry partners, the Coalition for 21st Century Medicine (C21), the American Clinical Laboratory Association (ACLA) and by many other key urologic opinion leaders.

The submission period ended on 9 September and now Novitas must consider and respond publicly to all of the comments presented during the notice and comment period. Novitas has given no indication on when it is likely to finalise the LCD, but it is statutorily required to do so (or withdraw the LCD) within 365 days of the original publication date. An LCD becomes effective 45 days after it is finalised.

In the meantime, Cxbladder Detect and Cxbladder Monitor remain Medicare covered tests.

The presentations given at the open meetings and details of written submissions are available on our website: https://www.pacificedgedx.com/investors/presentations/

New data from Kaiser Permanente highlights the utility of Cxbladder Triage and Cxbladder Monitor

In September, our written arguments to Novitas for continued Medicare coverage of Cxbladder were significantly bolstered by the release of unpublished non-peer-reviewed data from Kaiser Permanente. The study, documented in a letter to Novitas from the AUA, LUGPA and AACU, highlighted the role Cxbladder has played in substantially reducing the number of cystoscopies Kaiser undertakes each year.

The data illustrates how Cxbladder Triage safely excluded 78% of 1,932 Kaiser patients presenting with haematuria from a cystoscopy. It also shows similarly positive results for Cxbladder Monitor in relation to 394 Kaiser patients under surveillance for the recurrence of bladder cancer.

Cxbladder Detect⁺ clears first commercialisation hurdle

Detect⁺ is a next generation Cxbladder test that combines an analysis of 5 core mRNA biomarkers with DNA markers to provide enhanced clinical utility. As a single test that builds on the strengths and capabilities of both Cxbladder Triage and Detect, Cxbladder Detect⁺ further extends accuracy for the detection and rule out of urothelial cancer in patients presenting with haematuria.

Pacific Edge was notified in late September that Cxbladder Detect⁺ was included in the latest CPT coding schedule release by the AMA with code 0420U. Consequently, Pacific Edge has completed the first of the three requirements for reimbursement: coding, coverage and pricing. Our Market Access Team will continue to work on pricing, targeting June 2024 for inclusion in the Clinical Lab Fee Schedule potentially effective January 2025.

Concurrently, as we build evidence to support use of the test, we will seek to obtain Medicare coverage. As a foundation, the groundbreaking Lotan et al (2023) study delivered compelling evidence of the test's analytical validity. We are now looking forward to the results of DRIVE, AUSSIE, microDRIVE and the pooled analysis of these studies to deliver evidence of clinical validity. We expect our new CREDIBLE study (see page 4) to deliver evidence of the test's clinical utility.

Cxbladder budget impact model demonstrates significant per patient savings

A budget impact model for Cxbladder Detect, developed by Pacific Edge and authors from the Mayo Clinic and Germany's Coreva using national average data, has demonstrated median savings of $521.94 in direct costs per patient annually, through the routine use of the test in the evaluation of patients presenting with haematuria.

The model compares the AUA guidelines as a Standard of Care pathway to a Cxbladder clinical pathway. Haematuria patients in the Standard of Care pathway are stratified per AUA guidelines based on clinical factors into low risk, intermediate risk and high risk, while patients in the Cxbladder clinical pathway are risk stratified into AUA high risk (Cxbladder Detect positive) and AUA low risk (Cxbladder Detect negative).

The authors noted this cost saving strengthens the argument on the clinical value of deferring or avoiding cystoscopies and imaging, sparing thousands of patients these unnecessary procedures.

"This study shows for the first time that doing the right thing for the patient is also cost effective for the health system payers," says Pacific Edge Senior Medical Director Daniel Shoskes, who is a co-author of the study and Emeritus Professor of Urology at the Cleveland Clinic.

"Furthermore, this model does not account for indirect and opportunity savings such as decreased waiting times for appointments and procedures, the cost and inconvenience for patients of coming in for unnecessary visits, and the environmental impact of eliminating the carbon footprint and medical waste from unnecessary medical procedures."

Clinical program update: new study CREDIBLE commencing

Pacific Edge is commencing a new study for demonstrating the clinical utility of Cxbladder Detect⁺ in haematuria evaluation. CREDIBLE (**C**ystoscopic **RED**uction **I**n **BL**adder **E**valuations for microhaematuria) will follow at the conclusion of our microDRIVE study. CREDIBLE is a randomised, controlled study that will compare patients in the control arm risk stratified by AUA Standard of Care using clinical factors into high, intermediate and low with patients in the test arm risk stratified by Cxbladder Detect and managed as AUA high risk (Detect⁺ positive) and AUA low risk (Detect⁺ negative).

The primary endpoint for the study will compare the number of cystoscopies between the test and control arms. The number of tumours on each arm will be collected and analysed as part of the secondary outcomes of the study. The expectation is that the number of tumours would not be significantly different between the test and control arms, while the number of cystoscopies will be significantly reduced in the test arm compared to the control arm. We are targeting the completion of CREDIBLE in mid 2026 with the goal of publication in late 2026.

Cxbladder live in the Philippines

Distribution agreements have now been signed in the Philippines, Vietnam, Israel, Argentina, Uruguay, and Venezuela.

Cxbladder is now live in the Philippines following the signing of a distribution agreement with a local partner Hi-Precision Diagnostics (HPD), one of the country's largest medical laboratories, in June. HPD's sales team numbers more than 50+ people nationally and the company has more than 70 sites across the country providing strong exposure of Cxbladder to the 900+ urologists practicing in the Philippines.

The agreement with HPD builds on similar agreements signed in Vietnam, Israel, and Latin America. In each case, Pacific Edge initiates logistical test shipments, works on any country specific registration or market access requirements, translates marketing material with our partners as necessary, and updates our billing processes. In all cases, our Distribution Partners have exclusive sales and marketing rights and are expected to drive the integration of Cxbladder into local standards of care by leveraging their strong relationships with clinicians and Pacific Edge's peer-reviewed and published clinical evidence.

Upcoming events

Come and see us at an upcoming event:

Date	Event Name	Location
Nov 2-4	USANZ NSW Section Meeting	Newcastle, NSW, Aust.
Nov 24-25	32nd Malaysian Urological Conference	Kuala Lumpur, Malaysia

Contact us

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