The Cxbladder Bulletin

Dear Customers and Friends of Cxbladder,

Welcome to the December 2024 edition of the Cxbladder Bulletin. In this issue:

Lumea Digital announces availability of Cxbladder tests on its BxLink™ platform

Earlier this month, we were excited to announce the integration of our Cxbladder suite of tests into Lumea's BxLink™ digital pathology platform. Lumea Digital are a recognized leader in the digital pathology field and this partnership empowers US healthcare providers with streamlined access to Cxbladder's advanced diagnostic capabilities, further enhancing patient care and clinical efficiency.

"At Lumea, we're thrilled to integrate the proven reliability of Cxbladder into our advanced digital pathology platform, BxLink," said Jim Pack, Lumea CEO. "By combining seamless tissue handling with sophisticated AI tools and analytics, Lumea continues to deliver proven solutions to the industry. This partnership underscores our commitment to advancing digital pathology and modern diagnostic care."

The Cxbladder suite of urine-based tests provide a solution for the risk stratification of UC in patients presenting with hematuria and those being monitored for recurrent non-muscle invasive bladder cancer (NMIBC). The tests help prioritize time and clinical resources for those who need it the most, streamlining practice workflow and increasing overall efficiency. Non-invasive sampling, coupled with the option of in-home sample collection, ensures patients get the best experience possible.

Lumea customers who currently order Cxbladder can now streamline and simplify their workflow by requesting the test digitally. Additionally, customers new to Cxbladder can quickly begin ordering the test and explore its use with eligible patient types.

"The ability to order Cxbladder tests through the BxLink digital pathology platform from Lumea is a great example of Pacific Edge's digitalization strategy to improve the customer experience with elegant ordering and resulting of our tests," says Pacific Edge's CEO, Dr Peter Meintjes. "This will

result in more satisfied customers who we hope will more consistently order our Cxbladder tests on eligible patient types for microhematuria and bladder cancer surveillance. In particular, BxLink is a 'one-to-many' interface, where a single integration makes Cxbladder available to every Lumea customer already using BxLink simultaneously with a single deployment."

Providers using BxLink can easily access Cxbladder's suite of tests, allowing faster integration of these groundbreaking diagnostics into everyday practice. The platform's advanced capabilities ensure that every step of the process—from test ordering to result retrieval is as seamless as possible, allowing clinicians to focus on what matters most: their patients.

To enable Cxbladder ordering within BxLink, US clinicians should contact Lumea to activate the function and their Cxbladder Account Executive to finalize integration. US Clinicians who aren't current Cxbladder users but would like to access the test through BxLink should call 1-855-292-5237, Option 1, to initiate the integration process.

Cxbladder well positioned for inclusion in the AUA Microhematuria Guidelines

Pacific Edge continues to await the outcome of the American Urological Association (AUA) review of its Microhematuria Guidelines. The recent publication of the STRATA study in the Journal of Urology has helped to position Cxbladder for inclusion.

STRATA[1], a randomized controlled trial - the first study of this kind for a urine biomarker in hematuria evaluation – has delivered the evidence that meets the standard typically required for guideline committees to consider a change to standards of care.

Earlier this year, an editorial published in the September issue[2] of the Journal of Urology entitled 'What Is the Future of Cystoscopy for Detecting Urothelial Carcinoma?' cited the STRATA study as evidence of the clinical value of Cxbladder Triage in helping clinicians to evaluate patients both presenting with hematuria and those under surveillance for bladder cancer recurrence.

The editorial notes: "Although these novel biomarker studies raise important questions about evaluating patients at risk for urothelial bladder cancer (UCB), these tests have the potential to improve the management of our patients with suspected UCB who would otherwise require an invasive procedure for diagnosis. This also holds true for non-muscle invasive bladder cancer patients who require cystoscopic surveillance."

Authored by Journal of Urology Assistant Editor Christopher Anderson, the editorial first critiques the AUA's guidelines for the evaluation of asymptomatic microscopic hematuria, which it says results in urologists performing many unnecessary cystoscopies and missing opportunities to evaluate at-risk patients.

It then focuses on the clinical evidence to overcome these limitations, regularly referencing Pacific Edge's STRATA study, which was published in the May edition of the Journal of Urology. The study showed clinicians undertook 59% fewer cystoscopies if they were able to use the information generated by a Cxbladder Triage test.

The editorial also notes the potential cost savings that come from reducing unnecessary procedures using non-invasive urine-based biomarkers such as Cxbladder. The editorial concludes by acknowledging the continued need for cystoscopy in bladder cancer diagnosis

but underscores the importance of reducing negative cystoscopies.

“If these biomarkers are employed in the first-line setting, it may ultimately improve appropriate hematuria referrals to urology and avoid the referral delays that some hematuria patients face... we are challenged to understand these tests, educate patients about them, and determine how to best incorporate them into our practice.”

1 Lotan et al. A Multicenter Prospective Randomized Controlled Trial Comparing Cxbladder Triage to Cystoscopy in Patients With Microhematuria. The Safe Testing of Risk for Asymptomatic Microhematuria Trial. The Journal of Urology Vol 212 1-8 Jul 2024.

CREDIBLE RCT study set for launch

Pacific Edge is set to commence its CREDIBLE study in January following a meeting of Principal Investigators and study coordinators at SUO 2024 in Dallas earlier in December.

CREDIBLE aims to demonstrate the clinical utility of Cxbladder Triage Plus in risk stratifying patients with microhematuria, reducing the volume of unnecessary cystoscopies and imaging procedures while maintaining diagnostic accuracy.

Cxbladder Triage Plus[1] is a second generation Cxbladder test with added DNA markers to better risk stratify microhematuria patients and identify those with lowest and highest risk of urothelial carcinoma (UC).

CREDIBLE’s team of Principal Investigators includes 15 urologists, 5 from leading US universities and 10 from community urological centers. The study is the largest randomized control trial for hematuria evaluation to date, targeting the enrolment of 1,000 participants. Final outcomes are anticipated by late 2025.

CREDIBLE is a prospectively enrolled randomized clinical trial: one group is assessed using the American Urological Association (AUA) Standard of Care guidelines, and the other using Cxbladder Triage Plus.

Key endpoints include a comparison of cystoscopy rates and tumor detection outcomes between the two groups.

[1] Timings for a commercial launch of Cxbladder Triage Plus are still to be confirmed.

Video: From science to clinical utility: Cxbladder Monitor: bladder cancer surveillance for patients with urothelial carcinoma

Dr Neal Shore, Dr Joshua Meeks, and Dr Tamer Aboushwareb, Chief Medical Officer, Pacific Edge. Click the image below or this link to launch the video in a browser window.

A note to those that have been impacted by the US cystoscopy supply shortage

An important note to all those US clinicians who have been impacted by the recent supply shortage and forced to delay or reschedule cystoscopies. Cxbladder can help provide a solution.

Cxbladder is a suite of non-invasive genomic urine tests optimized for the risk stratification of urothelial cancer in patients presenting with hematuria and those being monitored for recurrent disease.

As highlighted in a September Journal of Urology editorial[1], Cxbladder is ideal for:

- Risk stratifying microhematuria patients
- Reducing the frequency of cystoscopy in NMIBC surveillance patients
- Increasing patient comfort while helping to prioritize those that require care

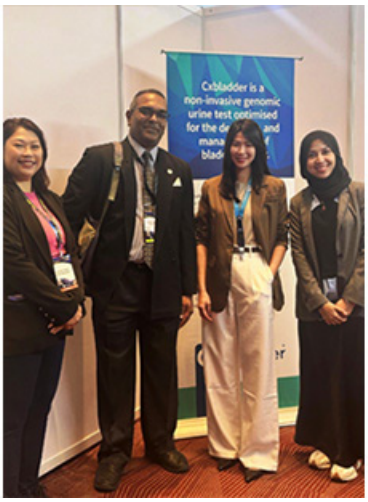
For more information, please email us at cs-pedusa@pacificedgedx.com. Cxbladder is covered by Medicare and comes with the option of in-home sampling.

[1] Anderson. The Future of Cystoscopy for Detecting Urothelial Carcinoma Vol. 212, 399-400, September 2024.

Interest in Cxbladder high at Southeast Asian events

From September through November, the Cxbladder Team attended several events in Southeast Asia, including UAA 2024 in Bali, the Malaysian Urology Conference in Penang, and the Philippine Urological Association's Annual Meeting in Manila. Interest in Cxbladder was high and we thank all those clinicians who stopped by our booth to learn more about the suite.





Medicare update

Cxbladder continues to remain a covered test as we wait for Novitas to finalize its draft LCD following the conclusion of the comment period in September 2023 and a CMS authorized extension from July 26, 365 days from the original publication of the draft and the date Novitas was statutorily obliged to finalize or withdraw the LCD.

Our representations to Novitas were strongly supported by leading US Urological Societies - the AUA, LUGPA, and AACU; alongside our industry partners, the Coalition for 21st Century Medicine (C21); and by the American Clinical Laboratory Association (ACLA). A number of key urologic opinion leaders also voiced their support through formal submissions.

We believe the environment is now more favorable for Pacific Edge given the publication of the STRATA[1] study on the clinical utility of Triage, its reception within the broader urology community, and the potential for it to influence inclusion in the AUA Microhematuria Guidelines. Furthermore, we have informed Novitas of our latest publication in the journal 'Diagnostics' on the Analytical Validation of Triage, Detect and Monitor that was developed after a recent update to our protocols.[2]

[1] Lotan et al. A multicenter prospective randomized controlled trial comparing Cxbladder triage to cystoscopy in patients with microhematuria. The safe testing of risk for asymptomatic microhematuria trial. J Urol. Published online May 3, 2024

[2] Harvey et al. Analytical Validation of Cxbladder Detect, Triage, and Monitor: Assays for Detection and Management of Urothelial Carcinoma. Diagnostics, 2024; 14(18):2061.

Wishing you **Happy Holidays** and a wonderful New Year!

Contact Us

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