Cxbladder Bulletin: June 2026

Dear Customers and Friends of Cxbladder,

Welcome to the June 2026 edition of the Cxbladder Bulletin. In this issue:

Draft LCD Proposes US Medicare Coverage For Cxbladder Triage and Triage Plus

Earlier this month a draft Local Coverage Determination (LCD) with foundational medical policy for urine-based biomarkers for microhematuria evaluation was published to the US Medicare Coverage Database.

The draft LCD '*Urine-based Biomarkers in Patients with Microhematuria*' (DL40378) establishes microhematuria evaluation as a covered US Medicare benefit for the first time and importantly distinguishes hematuria patients as eligible for Cxbladder Triage and Triage Plus.

In the rationale section of the draft LCD, Novitas[1] states: "*Given the low prevalence of malignancy in patients with MH, the limited diagnostic performance of urine cytology and earlier generation UBBs, and the emerging body of evidence supporting select multi-analyte rule-out assays, limited coverage for UBB testing is supported when applied within a narrowly defined clinical context. Specifically, use of validated multi-analyte UBBs may be reasonable and necessary to support risk-stratification in appropriately counseled, intermediate-risk patients with MH who are considering deferral of cystoscopy.*"

Pacific Edge Chief Executive Dr Peter Meintjes said: "This result reflects the substantial body of clinical evidence Pacific Edge has developed in recent years and the clinical needs described by the panel of experts assembled by Novitas for its recent CAC Meeting[2]. It's an excellent outcome for Medicare patients, urologists, and the broader healthcare system, supporting access to appropriate care while balancing clinical and economic considerations."

Learn more

New Evidence Presented at AUA 2026 Reinforces Patient Preference for Cxbladder Monitor

The American Urological Association (AUA) Annual Meeting, the largest and most influential event in the US and global urological calendar, provides an important opportunity to present and discuss new clinical evidence and endorsement. This year the event was held in Washington DC.

Alongside the publication of the draft LCD - which was released a day before the event began – we were pleased to discuss a new Mayo Clinic study[3], presented as

a poster – '*A Randomized Multicenter Crossover Study to Evaluate Patient Preference and Satisfaction With Urine-Based Molecular Testing vs Cystoscopy for Surveillance of Non-Muscle-Invasive Bladder Cancer*'. The study, now published as an article in the Journal of Urology, reinforces the utility of Cxbladder Monitor as a complement or alternative to cystoscopy in bladder cancer surveillance, demonstrating that patients value the comfort, convenience, and non invasive nature of Cxbladder Monitor and that they can use the test while maintaining confidence in their cancer surveillance regime.

The prospective crossover study randomized participants to receive surveillance with Monitor followed by cystoscopy, or cystoscopy followed by Monitor at 3-month and 6-month assessment periods. The study enrolled 107 patients with 97 completing both assessment periods.

Outcomes were measured across preference, satisfaction, convenience, work disruption, urinary symptoms, and fear of recurrence. The 'crossover' design of the study, with each person receiving both a cystoscopy and Monitor test, enhanced its statistical power because it meant patients effectively acted as their own control.

The key findings of the study were:

- A strong patient preference for Monitor with 74% of patients[4] indicating they preferred Monitor over cystoscopy, only 19% preferring cystoscopy, and 6% had no preference.
- Monitor was associated with markedly less pain, greater convenience, and no instances of missed work compared to cystoscopy. Five recurrences (5.2%) were detected, all non-invasive with no missed high-grade events.

The study's authors concluded: "Patients strongly preferred CxbM (Cxbladder Monitor) over cystoscopy, providing less pain, more convenience, and improved satisfaction while maintaining comparable diagnostic performance, quality of life, and fear of cancer recurrence. Incorporating CxbM into NMIBC surveillance may enhance patient adherence and experience without compromising oncologic safety."

Review the study, published as an article in the Journal of Urology.

The Cxbladder Team at AUA 2026 in Washington DC

Kaiser Permanente Study Supports Use of Cxbladder

In January Pacific Edge welcomed the publication, in the journal Urology Practice, of a Kaiser Permanente study demonstrating the real-world Clinical Utility of Cxbladder Triage in the largest ever urine-based biomarker study on patients presenting with hematuria[5].

The publication, which used a 3,353-patient risk-matched cohort (n=6,706) to determine the real-world reduction in cystoscopies and imaging (CT scans), concluded that Cxbladder Triage avoided 952 cystoscopies and 70 CT scans reinforcing the previously published findings of 59% relative reduction in cystoscopies from the prospectively enrolled, randomized controlled STRATA Study[6].

The authors concluded: “Cxbladder Triage testing significantly decreased cystoscopy and imaging utilization among low-risk microscopic hematuria patients while simultaneously increased use among higher-risk patients. Cancer detection was consistent among patients in both groups.”

View the peer-reviewed publication.

View a Urology Times webinar led by Kaiser Permanente’s Dr Christopher Filson "*Using Cxbladder Triage to Risk-Align Cystoscopy in Microhematuria*". Dr Filson discusses key findings from the study.

View the Urology Times webinar

DRIVE Study Validates Cxbladder Triage Plus for Hematuria Evaluation

Triage Plus is a genomic urine test that employs a novel combination of mRNA and DNA biomarkers to enhance the risk stratification and rule out of patients presenting with hematuria.

The DRIVE Study, now published in the Journal of Urologic Oncology[7], provides clinical validation of Triage Plus. The study, comparing Triage Plus to white light cystoscopy, combined with a histopathologic confirmation of urothelial cancer, confirms the performance characteristics of Triage Plus established via the Analytical Validation publication (Harvey et al. 2025[8]). It also confirms performance in a patient population independent of the development dataset utilised in the proof-of-concept study (Lotan et al. 2023[9]).

The authors of the DRIVE study concluded: “Cxbladder Triage Plus demonstrated clinical validity in this veterans population [presenting with gross hematuria or microhematuria] with high sensitivity and specificity. These findings indicate that Triage Plus may be safely used to rule out or detect [urothelial cancer] in patients with hematuria.”

Access the DRIVE study.
View a Urology Times article reviewing the study.

Supporting BEAT Bladder Cancer Australia in May

BEAT Bladder Cancer Australia are the leading national patient body for bladder cancer patients and caregivers. BEAT work hard to promote awareness of the disease and its care in the community, while supporting and empowering patients. They also play an important role educating health professionals, and advocating for improved national health outcomes. Traditionally focused on Australia, BEAT are now extending their efforts and footprint to New Zealand.

In May, as part of Bladder Cancer Awareness Month, BEAT run their program of Anna's Walk community events. The walks are designed to promote awareness of the disease while remembering those who have been lost and giving survivors a voice.

They're great events and this year we were proud to support the Wellington walk. It was inspiring to see so much support from the community.

Contact Us

For further information on any of the articles above or the Cxbladder suite, we invite you to email us at info@cxbladder.com or to reach out to your local Cxbladder representative.

[1] Novitas is the Medicare Administrative Contractor (MAC) with jurisdiction of Pacific Edge's laboratory operations in Pennsylvania.

[2] Novitas convened a panel of experts for a Contractor Advisory Committee (CAC) Meeting on 19 February, 2026 to consider the evidence for urine-based biomarkers in the evaluation of hematuria. You can view a recording of the meeting here.

[3] Mestas, L. A., Mi, L., Ferguson, C., Lyon, T., Zganjar, A., Renteria, M., & Tyson, M. (2026). IP02-17. A Randomized Multicenter Crossover Study To Evaluate Patient Preference And Satisfaction With Urine-Based Molecular Testing Versus Cystoscopy For Surveillance Of Non-Muscle-Invasive Bladder Cancer (NMIBC). Journal of Urology, 215(5S), e67. https://doi.org/10.1097/01.JU.0001191276.85430.b0.17.

[4] Patients for whom there was complete data.

[5] Filson et al. (2026). Real-World Utility of Cxbladder Triage for Patients with Microhematuria: A Matched Cohort Study, Urology Practice (2026), doi: 10.1097/UPJ.0000000000000972.

[6] Lotan et al. (2024). A Multicenter Prospective Randomized Controlled Trial Comparing Cxbladder Triage to Cystoscopy in Patients With Microhematuria. Journal of Urology, 211(5S), e176. https://doi.org/10.1097/01.JU.0001008576.33217.96.08.

[7] Savage et al. (2025) Diagnostic Performance of Cxbladder® Triage Plus for the Identification and Stratification of Patients at Risk for Urothelial Carcinoma: The Multicenter, Prospective, Observational DRIVE Study. Urologic Oncology, S1078-1439(25)00405-3.

[8] Harvey, J.C. et al. (2025) Analytical Validation of the Cxbladder® Triage Plus Assay for Risk Stratification of Hematuria Patients for Urothelial Carcinoma. Diagnostics 2025, 15, 1739.

[9] Lotan et al., (2023). Urinary Analysis of FGFR3 and TERT Gene Mutations Enhances Performance of Cxbladder Tests and Improves Patient Risk Stratification. The Journal of Urology, 10-1097.