Cxbladder

US CLINICIANS

Cxbladder Bulletin: November 2026

Coverage news, clinical evidence, and practice updates from the Cxbladder team.

Dear Colleagues,

Welcome to the November 2026 edition of the Cxbladder Bulletin.

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COVERAGE POLICY

Medicare coverage for Triage Plus and Triage confirmed

Last week we were pleased to announce the publication of a final LCD for Urine-based Biomarkers in Patients with Microhematuria (DL40378), confirming Medicare coverage for Cxbladder Triage Plus and Triage in the evaluation of appropriately counseled intermediate-risk patients. The policy takes effect on December 20, 2026.

What does this mean for clinical practice?

Cxbladder Triage Plus and Triage are the only tests covered within the LCD, and the final policy, once effective, will streamline the use and reimbursement of the tests in eligible Medicare patients.

> *"The final LCD is a significant milestone for Pacific Edge, Medicare patients, urologists, and the broader healthcare system. It provides clear guidance on the eligible hematuria patients for which Triage and Triage Plus should be reimbursed and recognizes the important role that validated, non-invasive urine-based biomarkers can play in helping physicians make better-informed decisions about cystoscopy."*
>
> — Dr Peter Meintjes, Chief Executive, Pacific Edge

We'll be providing further information shortly ahead of the December 20 effective date. In the meantime, we welcome any questions. Please call us at 1-855-292-5237 or email **cs-pedusa@pacificedgedx.com**.

Review the LCD

- The final LCD "Urine-based Biomarkers in Patients with Microhematuria" (L40378) can be accessed via **this link**.
- The final LCA for billing and coding (L60424) can be accessed via **this link**.
- The response to comments article (L60570) can be accessed via **this link**.

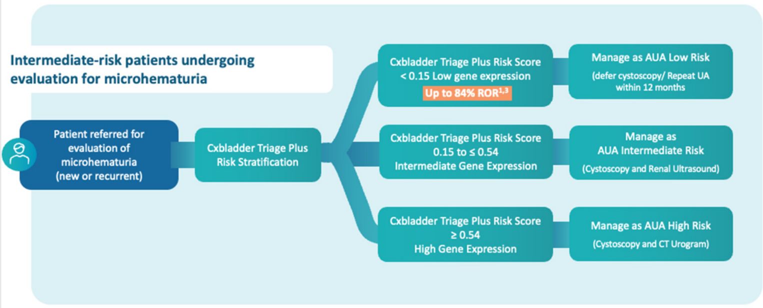
CLINICAL PRACTICE

The case for implementing Triage Plus within urological practice

While hematuria is the most common symptom of urothelial cancer, the incidence is low among microhematuria patients — between 0% and 6.3% risk of malignancy based on the 2025 AUA/SUFU Risk Stratification System — and around 95% of those cystoscopies yield a negative result.

- With an NPV of 99% or greater, Triage Plus increases the rate of UC rule out in patients with a low probability of disease (71–84% ROR[1,3]), allowing you to defer those patients who do not stand to benefit from an invasive cystoscopy.
- Triage Plus enables the identification of high-risk patients with high specificity and PPV (98% specificity and up to 75% PPV when the higher 0.54 cut point on the test report is used).
- Triage Plus builds on the performance of Cxbladder Triage, a test now included in the AUA/SUFU Microhematuria Guideline[4], supported with "Grade A" evidence.

Suggested Triage Plus pathway



Intermediate-risk patients undergoing evaluation for microhematuria
Patient referred for evaluation of microhematuria (new or recurrent)
Cxbladder Triage Plus Risk Stratification
Cxbladder Triage Plus Risk Score < 0.15 Low gene expression
Up to 84% ROR1,3
Manage as AUA Low Risk (defer cystoscopy/ Repeat UA within 12 months
Cxbladder Triage Plus Risk Score 0.15 to ≤ 0.54 Intermediate Gene Expression
Manage as AUA Intermediate Risk (Cystoscopy and Renal Ultrasound)
Cxbladder Triage Plus Risk Score ≥ 0.54 High Gene Expression
Manage as AUA High Risk (Cystoscopy and CT Urogram)

Contact us to learn more →

CLINICAL ADOPTION

Pacific Edge secures first blanket agreement within the VA system

In September Pacific Edge secured its first facility-level Blanket Purchase Agreement

(BPA) within the Veterans Administration (VA) system — a five-year BPA allocating ~US$1.3M for Cxbladder testing with the Marion, Illinois VA for Triage Plus and Monitor.

Department of Veterans Affairs

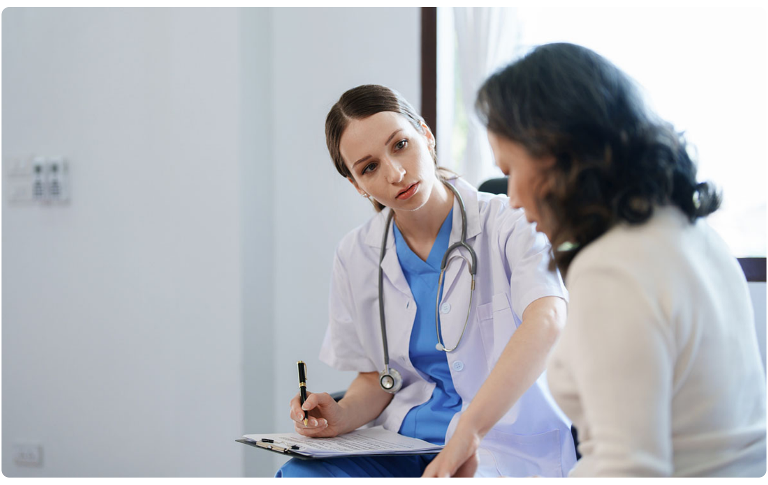
BPAs are not required for VA facilities to order Cxbladder, but they provide an important practical step, streamlining test access and allocating funding. Furthermore, given the predominantly high-risk VA patient population, the BPA demonstrates demand for Cxbladder testing, while generating additional real-world clinical evidence in this population to complement the core evidence established through the DRIVE study[1].

CLINICAL FOCUS

Streamlining the evaluation of microhematuria in women

In the US, 75% of intermediate risk microhematuria patients are women[5] — which highlights the utility of Cxbladder testing for clinicians focused on female care, including UroGyns and URPS specialists.

The importance of early diagnosis in women is reinforced by clinical data. While bladder cancer is more prevalent in men, studies have shown that women are more likely to present with more advanced tumors at diagnosis[6], with outcomes and survival rates lagging behind those of men at all stages of the disease[7].



The utility of Cxbladder genomic testing centers on the ability to streamline risk stratification and potentially accelerate early diagnosis of UC in women. Microhematuria is often one of many symptoms patients present with. The ability to defer cystoscopy in patients with a low probability of UC using a urine-based test allows clinicians to focus resource on the evaluation of other symptoms and those patients who require further care.

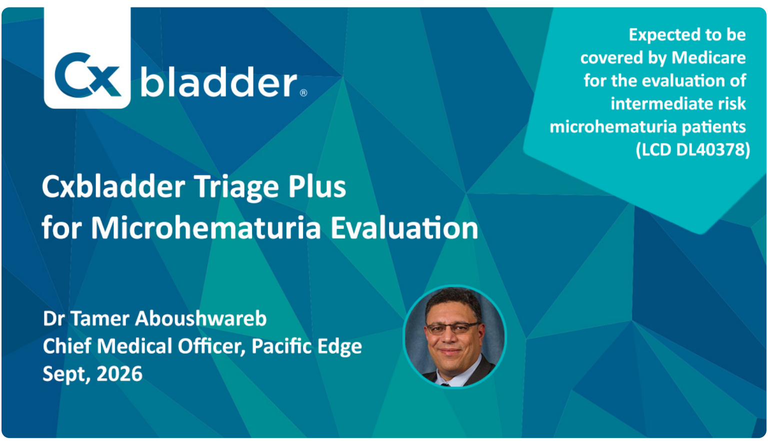
To raise awareness of Cxbladder testing among female-focused specialists, we attended the American Urogynecologic Society's (AUGS) annual meeting earlier this month. Interest in genomic testing was high, and the team took the opportunity to discuss supporting clinical evidence and suggested pathways.

VIDEO WEBINAR

Triage Plus for microhematuria evaluation

In September, Pacific Edge Chief Medical Officer Dr Tamer Aboushwareb presented an overview of Triage Plus for doctors and clinical teams. During the session he discussed:

- Nuances in hematuria evaluation and the impact of recent AUA/SUFU Microhematuria Guideline changes[4]
- The advantages of urine-based genomic testing supported with real world evidence
- The development and clinical validation of Triage Plus, our second generation Cxbladder test for hematuria evaluation, including active studies
- Practical considerations in the use of Triage Plus, now expected to be covered by Medicare for the evaluation of appropriately counseled intermediate risk microhematuria patients (via the publication of LCD DL40378)



Expected to be covered by Medicare for the evaluation of intermediate risk microhematuria patients (LCD DL40378)

Cxbladder Triage Plus for Microhematuria Evaluation

Dr Tamer Aboushwareb
Chief Medical Officer, Pacific Edge
Sept, 2026

Watch the video →

CLINICAL EVIDENCE

AUSSIE study validates Triage Plus in Australian patients

Last month we were pleased to confirm the publication of the AUSSIE study in *BJU International*[8]. The Australian study provides important new evidence that Cxbladder Triage Plus performs consistently across different patient populations and health systems, and further strengthens the clinical case for usage in the risk stratification of patients presenting with hematuria.

The study — the second peer reviewed clinical validation of Triage Plus and the first in an Australian population — reproduces the performance seen in the DRIVE study[1] and gives clinicians and hospitals local peer-reviewed evidence supporting use of the test to help rule out urothelial cancer and defer an invasive cystoscopy and unnecessary imaging in patients with a low probability of disease.

The AUSSIE study enrolled 691 evaluable patients presenting with visible (gross) or non-visible (micro) hematuria across four Australian hospital urology clinics between September 2023 and August 2025:

- The test-negative rate (anticipated rule-out rate) was 74%. This highlights the potential economic value of Triage Plus for health providers, as a higher test negative rate creates greater opportunity for health systems to avoid unnecessary cystoscopies and their associated costs.
- The study analyzed microhematuria and gross hematuria patients separately, with test-negative rates of 81% in microhematuria (NPV 100%) and 70% in gross hematuria (NPV 98%).
- Within the microhematuria population, test-negative rates were 100% in low-risk patients (NPV 100%), 89% in intermediate-risk patients (NPV 100%), and 76% in high-risk patients (NPV 99%) — a clear demonstration of the utility of Triage Plus across the spectrum of hematuria risk.
- NPV remained at or above 99% across all microhematuria risk categories, while the proportion of patients testing negative appropriately declined as underlying disease risk increased.

Read the study in BJU International →

REAL-WORLD DATA

New Zealand pathway evidence shows faster, more efficient care

In September, a new real world experience study from the Canterbury Health System in New Zealand was published in the *ANZ Journal of Surgery*[9].

The study, building on the clinical utility previously established by Davidson et al (2019 and 2020[10]), described the key benefits of clinical use in a real public health system, following the 2018 decision in Canterbury to replace urine cytology with Cxbladder Triage and upper tract imaging as the first-line primary care work-up for hematuria. The key outcomes for patients, physicians and health systems were clear: faster access to specialist care, faster time to first operative treatment for bladder cancer, and fewer avoidable referrals.

Christchurch Hospital, New Zealand

Eaton and colleagues audited 4,512 hematuria referrals to Christchurch Hospital between March 2013 and December 2021, comparing the period before and after Cxbladder Triage was added to the Canterbury pathway. Under that pathway, patients with a negative Cxbladder Triage result and normal upper tract imaging were considered at very low probability of bladder cancer and did not require referral for specialist assessment and cystoscopy, unless symptoms persisted and repeat investigation was required.

The results were clinically impactful:

- Median waiting time from primary care referral to urological specialist appointment reduced by 14.8 days, from 57.8 days to 43.0 days.
- Median waiting time from referral to first operative treatment for bladder cancer reduced by 15.0 days, from 78.0 days to 63.0 days.
- Monthly hematuria referrals to specialist urology fell from 45.7 to 38.8 — a reduction of 6.9 referrals per month, or approximately 83 fewer referrals per year, driving economic savings for hospitals.

> *"*
>
> ***The authors concluded:** these published data are directly relevant to other capitated systems like the integrated delivery networks (IDNs) in the US and payers. The results suggest Cxbladder can reduce unnecessary procedures, and free urologist capacity without compromising cancer detection.*

DIGITAL CONNECTIVITY

Paperless ordering and resulting: the Cxbladder Customer Portal

The CxConnect Customer Portal is a secure platform designed to streamline the online ordering and resulting of tests within the Cxbladder suite. The Portal, designed to function as a centralized hub with a fully paperless workflow, is ideal for community-based urology clinics, and access is provided to all customers as a practice benefit at no cost.

Key features of the portal include:

- An easy step-by-step workflow guiding users through the ordering process. Required documentation can be uploaded, while digital signatures are supported by DocuSign.
- Quick and secure access to Cxbladder results from both desktop and mobile devices.
- Test status and results searchable via clinician, patient name, date range, and test type.
- Past results pre-loaded upon registration, and portal access to results from all Cxbladder tests ordered from that point on regardless of where the order originated.
- An accessible learning and resource area to support test usage in-clinic and enhance the value Cxbladder can offer your practice and your patients.

For more information on the Cxbladder Customer Portal, access, and further planned enhancements, please **contact us**. We're here to help.

Contact us

P: 1-855-292-5237

Contact us or visit us online at **www.cxbladder.com**

PacificEdge®
CANCER DIAGNOSTICS

[1] Savage et al. (2026). 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, 44(1), 65.e13–65.e20. https://doi.org/10.1016/j.urolonc.2025.10.008.

[2] Triage Plus delivers significant improvement in NPV, Sensitivity, PPV and Specificity over our established Cxbladder Triage and Detect tests.

[3] Harvey et al. (2025). Analytical Validation of the Cxbladder® Triage Plus Assay for Risk Stratification of Hematuria Patients for Urothelial Carcinoma. Diagnostics. 2025; 15(14):1739. https://doi.org/10.3390/diagnostics15141739.

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[5] Percentage of patients based on AUA risk category by sex (at birth). Management estimates derived from referred hematuria data in Woldu et al (2021).

[6] Pignot, G., Barthélémy, P., & Borchiellini, D. (2024). Sex Disparities in Bladder Cancer Diagnosis and Treatment. Cancers, 16(23), 4100. https://doi.org/10.3390/cancers16234100.

[7] Mungan N, Kiemeney L, van Dijck J, van der Poel H, Witjes J. (2000) Gender differences in stage distribution of bladder cancer. Urology, 55, 368-371.

[8] Buhariwalla, V., Sethi, K., Vela, I., Hayne, D., Atchia, Z., de Lange, M., Lough, T., White, A. and Ranasinghe, W. (2026), Validation of Cxbladder Triage Plus in Australian patients with haematuria: the AUSSIE study. BJU Int. https://doi.org/10.1111/bju.70504.

[9] Eaton, D., Kerdemelidis, M., Losco, G., Mark, S., Patu, M., Elliot, N., & Frampton, C. (2026). Cxbladder triage in haematuria assessment reduces time from referral to specialist assessment and bladder cancer treatment and improves equity for Māori. ANZ Journal of Surgery.

[10] Davidson, PJ, McGeoch, G, Shand, B. Inclusion of a molecular marker of bladder cancer in a clinical pathway for investigation of haematuria may reduce the need for cystoscopy. NZ Med J 2019; 132:1497; Davidson P, McGeoch G, Shand B. Assessment of a clinical pathway for investigation of haematuria that reduces the need for cystoscopy. NZ Med J 2020. 133:1527.