Cxbladder Bulletin: March 2026

Dear Customers and Friends of Cxbladder,

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

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Expert CAC Panel Expresses Clear Support For Urine-Based Biomarkers in Hematuria Evaluation

On February 19, Novitas, the MAC with jurisdiction of Pacific Edge's laboratory operations in Pennsylvania, led a Contractor Advisory Committee (CAC) meeting, inviting an expert panel of urology professionals to discuss the value of using urine-based biomarker tests in the evaluation of hematuria.

CACs are typically convened ahead of developing new or substantially revised Medicare policy and the opinions expressed by the panel clearly endorsed the use of urine-based biomarkers as medically reasonable and necessary, and appropriate for coverage by Medicare.

The strength of evidence supporting Cxbladder Triage and Cxbladder Triage Plus[1] was mentioned regularly throughout the call (most notably the STRATA RCT[2] and the recent Kaiser Study[3]), and among other things, the panelists called for appropriately validated biomarkers to be covered for expanded indications beyond intermediate risk microhematuria patients.

Specifically, the panelists noted the value of clinically validated biomarkers for:

- routine evaluation of all risk categories of hematuria to rule out bladder cancer.
- repeat use to rule out bladder cancer in patients with recurrent microhematuria of unknown origin.
- providing patients who may be resistant to undergoing a cystoscopy with a non-invasive and medically reliable alternative.

Similarly, the panelists highlighted the following logistical and economic benefits of urine-based biomarkers:

- improving the healthcare outcomes for patients living in the 63%[4] of rural counties that do not have urological care.
- earlier detection of bladder cancer through increasing compliance and referral thus reducing the potential of more invasive disease (MIBC).
- better serving women, who frequently have hematuria symptoms dismissed as UTI.

The expert panel was comprised of seven urologists and one pathologist[5] covering private practice, academic institutions, the Veterans Administration, and Kaiser Permanente.

Highlighting the critical need for non-invasive alternatives panelist Dr. Jason Hafron, Chief Medical Officer and Medical Director of Clinical Research at Michigan Institute of Urology, citing a recent study[6], noted: “only 13% of patients with high-risk microhematuria actually underwent cystoscopy… that is why a biomarker could be so appealing”. In saying this Dr Hafron reinforced the use of biomarkers as an ideal diagnostic tool for physicians concerned about bladder cancer and wanting to enhance early detection. Among other factors, patient resistance to invasive testing continues to impact compliance.

The panel session concluded with a direct appeal to Novitas from Dr Yair Lotan, UT Southwestern Professor and member of the committee that published the 2025 update to the AUA/SUFU Microhematuria Guideline[7], incorporating Cxbladder Triage with supporting grade A evidence. Dr Lotan strongly advocated for Medicare reimbursement given the clinical significance of these urine-based biomarkers and several other panelists followed that lead summarizing the clinical significance of these tests.

“We're all used to using markers in prostate cancer for many years. There's quite a plethora of them. If you look overall, they don't perform as well as most of these urine markers, but they have been widely available…. we are all fairly frustrated when we find this disease [bladder cancer] late and these patients don't do well because this is a very aggressive cancer,” Dr Lotan said.

“So, I'm very hopeful that this [session] does lead to access to these markers, which I do think will help identify this disease early. Most of our patients accept cystoscopy, but prefer not to have it. And if we have ways to increase efficacy of evaluation and also at the same time reduce cystoscopy, I think there will be a lot of potential benefits.”

For more analysis of the CAC meeting, please contact your local Cxbladder representative or email us directly at cs-pedusa@pacificedgedx.com.

View a recording of the session.

View a transcript of the session: (those based in the US only)

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[3].

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[2].

The retrospective study considered patients evaluated according to the new clinical pathway that includes Cxbladder Triage against a risk-matched cohort of patients from the same time period that did not receive Cxbladder Triage. The primary endpoints of the study were to compare the number of cystoscopies and imaging procedures (CT scans) between the new standard of care incorporating Cxbladder Triage and the prior standard of care, while monitoring cancer detection rates. Its key findings were:

- The cystoscopy rate of patients classified by Cxbladder Triage as having a 'Low Probability' of urothelial cancer, was just 3.8%, compared with 46.5%in the risk-matched group.
- The cystoscopy rate in patients with 'High Probability' Triage scores was 73.4%, versus 45.7% in the standard-of-care group, indicating more appropriate use of invasive procedures in those most at risk.
- Overall bladder cancer detection rates between the Cxbladder Triage patients and the standard-of-care patients were similar (0.6% vs 0.7%), confirming that unnecessary procedures were reduced without compromising cancer detection.

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.

Video Webinar: Using Cxbladder Triage to Risk-Align Cystoscopy in Microhematuria

Speaking with Urology Times, Dr Christopher Filson discusses key findings from the recent Kaiser Permanente study[3] evaluating the real-world utility of Cxbladder Triage when incorporated into the diagnostic workflow for microhematuria.

To view the webinar, cick the image below.

Leading Singapore Hospital Now Ordering Cxbladder

Earlier this month Pacific Edge signed a service agreement with Singapore General Hospital (SGH), an important milestone in the company's strategy to drive the adoption of its tests in the Asia Pacific.

Physicians and clinicians at SGH may now order Cxbladder Triage or Triage Plus for the evaluation of patients presenting with hematuria, and Cxbladder Monitor for the surveillance of bladder cancer recurrence.

SGH is government funded, and the largest and oldest hospital in Singapore, serving a population of more than 1 million patients annually[8].

SGH is committed to reducing unnecessary or unwanted cystoscopies, and the initial clinical implementation will focus on offering microhematuria patients Triage Plus and offering Monitor to lower risk NMIBC patients on surveillance as an alternative to reduce the frequency of cystoscopy. Patients may be required to pay for the tests, so will be given the choice of a cystoscopy or Cxbladder.

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[1] Triage Plus is the next generation test from Pacific Edge – a multi-modal (RNA and DNA) urine-based genomic test with substantially improved performance characteristics when contrasted with Pacific Edge's first-generation tests, Triage and Detect for hematuria evaluation

[2] Lotan et al., (2024) The Journal of Urology Vol 212 1-8 Jul 2024

[3] 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

[4] Nolaszco (2025) Curr Urol. 2025 Jul 7;19(5):357–358. doi: 10.1097/CU9.0000000000000292

[5] The participants were: Prof Yair Lotan at UT Southwestern; Dr Bogdana Schmidt at University of Utah and Salt Lake City VA Medical Center; Dr Abhishek Srivastava at Atlantic Urology Specialists; Prof John Sfakianos at Mt Sinai; Urologist Dr Terrance Regan; Dr Jason Hafron at Michigan Institute of Urology; Dr Katy Rezaei at Moffitt Cancer Center and Dr Chris Filson at the Southern California Permanente Medical Group

[6] Elias, K., Svatek, R. S., Gupta, S., Ho, R., & Lotan, Y. (2010). High-risk patients with hematuria are not evaluated according to guideline recommendations. Cancer, 116(12), 2954–2959 https://doi.org/10.1002/cncr.25048

[7] Barocas et al., Updates to Microhematuria: AUA/SUFU Guideline (2025). J Urol. 0(0). doi: 10.1097/JU.0000000000004490

[8] https://www.sgh.com.sg/about-sgh/who-we-are