23 February 2026

EXPERT PANEL EXPRESSES CLEAR SUPPORT FOR URINE-BASED BIOMARKERS IN HEMATURIA EVALUATION

DUNEDIN, New Zealand – Cancer diagnostics company Pacific Edge (NZX, ASX: PEB) today summarizes the opinions expressed by the panel of experts during the Contractor Advisory Committee (CAC) meeting organized by Novitas[1] on Thursday 19 February 2026 (US time) regarding the use of urine-based biomarker tests in the evaluation of hematuria. CACs are typically convened ahead of developing new or substantially revised Medicare policy.

Pacific Edge considers the weight of the opinions expressed by the panel was a clear endorsement of urine-based biomarkers as medically reasonable and necessary, and appropriate for coverage by Medicare. The evidence supporting Cxbladder Triage and Triage Plus was mentioned regularly throughout the call (most notably STRATA[2] and the 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
- reflexive use (after cystoscopy or cytology) when those methods do not yield a result
- limited adjunctive use (at the same time as cystoscopy) in situations where it is difficult to visualize the bladder due to inflammation, redness or blood, including some cases of gross hematuria
- 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 logistical and economic benefits of urine-based biomarkers, particularly when tests are ordered from primary care, including:

- improving the healthcare outcomes for patients living in the 63%[4] of rural counties that do not have urological care
- prioritizing referral of higher-risk patients to urologists
- earlier detection of bladder cancer through increasing compliance and referral thus reducing the potential of more invasive disease (MIBC)[5]
- better serving women, who frequently have hematuria symptoms dismissed as UTI

---

[1] Novitas is the Medicare Administrative Contractor (MAC) with jurisdiction of Pacific Edge's laboratory operations in Pennsylvania
[2] Lotan et al., (2024) The Journal of Urology Vol 212 1-8 Jul 2024
[3] Filson et al., (2026) doi: 10.1097/UPJ.0000000000000972
[4] Nolaszco (2025) Curr Urol. 2025 Jul 7;19(5):357–358. doi: 10.1097/CU9.0000000000000292
[5] MIBC is muscle-invasive bladder cancer

Pacific Edge Chief Executive Dr Peter Meintjes said: “The clear sentiment from the panelists was that the sum of the published evidence available to Novitas, and the 2025 update to the AUA Microhematuria Guideline demonstrate that Cxbladder Triage and Triage Plus[6] are medically reasonable and necessary under the Social Securities Act and given their demonstrated clinical utility, these tests would be appropriate for Medicare coverage”

Panelist Dr John Sfakianos, Assistant Professor of Urology from the Ichan School of Medicine at Mount Sinai in New York, echoing the views of many of the panelists, said: “In the setting of a primary care office, family medicine office… something like Cxbladder that has a [high] Negative Predictive Value, I think could be useful because we could avoid referrals that are not necessary.”

Dr Meintjes said the meeting featured several important and meaningful highlights.

“Many of the comments were notably positive, because they reflect the strength of the underlying evidence and the genuine clinical need. The support from the panel to use biomarkers for hematuria patients of all risk categories, including gross hematuria in select cases; the endorsement of their use to support a wide range of clinical decision making, the specific endorsement of Cxbladder Triage and Triage Plus and the evidence-based plea for access to these tests as medically necessary in the management of hematuria patients was encouraging.”

Dr Meintjes said the dialogue was constructive and balanced, with panelists’ responses to Novitas’ questions firmly based in clinical evidence, including references to STRATA, the first ever randomized control trial of a urine biomarker and the Kaiser Study, the largest real world comparative study on urine-based biomarkers for hematuria evaluation.

“We thank Novitas for lending credibility to the ongoing process of establishing Medicare coverage policy for urine-based biomarkers in hematuria evaluation. We sincerely thank all CAC members for providing their expert opinions to advance the standard of care available to Medicare patients,” Dr Meintjes said.

The panel was comprised of seven urologists and one pathologist[7] covering private practice, academic institutions, the Veterans Administration and Kaiser Permanente. Dr Megan Landsverk led the Novitas Medical Affairs Team on the call and asked a series of questions made available to the panelists and the public in advance.

Pacific Edge noted the panelists were aligned regarding the utility of biomarkers, the strength of the evidence for urine-based biomarkers, with specific mentions of Cxbladder Triage and Triage Plus, the need for Medicare to cover the tests (often referred to as “access” [to the

---

[6] Cxbladder Triage has analytical validation (AV), clinical validation (CV), clinical utility (CU) and AUA Guideline inclusion while Cxbladder Triage Plus has AV and CV, and is yet to be reviewed for inclusion in the AUA Guideline.

[7] 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.

tests]), and the desire to implement these tests for maximum impact to patient care by implementation in primary care.

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, noted: “only 13% of patients with high-risk hematuria actually underwent cystoscopy… so that is why a biomarker could be so appealing”, meaning that biomarkers are the ideal diagnostic tool for physicians concerned about bladder banker.

UT Southwestern Professor Yair Lotan, a principal investigator on a number of Pacific Edge trials, and a member of the committee that wrote the update to the 2025 AUA Microhematuria Guideline noted: "The vast majority of patients with microhematuria in the US are not getting referred to urologists or any evaluation whatsoever… the consequence is that many patients are getting *delayed in diagnosis*”.

In an unanticipated conclusion of the panel, Dr Lotan initiated a direct appeal to Novitas 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.”

At the conclusion of the meeting, Novitas’ Dr Megan Landsverk said the feedback from the panelists, alongside the published evidence and the AUA Microhematuria Guideline would be used to determine if LCD development is warranted.

Pacific Edge does not control if or when Novitas will develop a new or substantially revised draft LCD supporting the reimbursement of Cxbladder. Pacific Edge maintains the view that generating compelling clinical evidence in a rigid framework of analytical validation, clinical validation and clinical utility and the unmet clinical need as articulated by the expert panel provides Novitas with the appropriate evidence and motivation to develop this policy expediently. Pacific Edge estimates the timelines for draft coverage are within approximately six months and final-effective coverage within a further approximately six months, noting Novitas has up to 12 months from the published draft to finalize or retire any draft LCD.

Novitas is expected to publish a full transcript of its meeting to its website in the coming months.

Released for and on behalf of Pacific Edge by Grant Gibson Chief Financial Officer.

Pacific Edge: www.pacificedgedx.com

Pacific Edge Limited (NZX/ ASX: PEB) is a global cancer diagnostics company leading the way in the development and commercialization of bladder cancer diagnostic and prognostic tests for patients presenting with hematuria or surveillance of recurrent disease. Headquartered in Dunedin, New Zealand, the company provides its suite of Cxbladder tests globally through its wholly owned, and CLIA certified, laboratories in New Zealand and the USA.

Cxbladder: www.cxbladder.com

Cxbladder is a suite of non-invasive genomic urine tests optimized for the risk stratification of urothelial cancer in patients presenting with microhematuria and those being monitored for recurrent disease. The tests help improve the overall patient experience, while prioritizing time and clinical resources to optimize practice workflow and improve efficiency.

Supported by over 20 years of research, Cxbladder's evidence portfolio extends to more than 30 peer reviewed publications, and Cxbladder Triage is now included in the American Urological Association's Microhematuria Guideline. To drive increased adoption and improved patient health outcomes, Cxbladder is the focal point of numerous ongoing and planned studies designed to generate further clinical utility evidence.

Cxbladder is available in the US, Australasia, and Israel and in markets throughout Asia and South America. In the US, the test has been used by over 5,000 urologists who have ordered more than 130,000 tests. In New Zealand, Cxbladder is accessible to around 70% of the population via public healthcare and all residents have the option of buying the test online.