

15 SEPTEMBER 2025

NOVITAS PROPOSES EXPERT PANEL IN RESPONSE TO 2025 AUA GUIDELINE

DUNEDIN, New Zealand – Pacific Edge (NZX, ASX: PEB) today announces it has received notification from Medicare Administrative Contractor (MAC) Novitas that it intends to convene an expert panel to consider coverage for tests mentioned in the 2025 update to the American Urological Association (AUA) microhematuria guideline, including Cxbladder Triage.

The panel — known as a Contractor Advisory Committee (CAC) — is likely to be convened in early 2026. It will be comprised of urology subject matter experts and will be tasked with considering how to bring Medicare policy into alignment with the 2025 update to the AUA guideline.

Pacific Edge notes that under the Medicare Program Integrity Manual, CAC meetings are initiated by the MAC and generally precede the draft issuance of a new or substantially revised Local Coverage Determination (LCD).

Pacific Edge Chief Executive Dr Peter Meintjes said: “We are pleased that Novitas has acknowledged the importance of the AUA microhematuria guideline and is taking a robust and credible approach to policy development by convening a panel of urologists who understand the latest update to the guideline. It is also recognition of the important role that randomized controlled trials like our STRATA¹ study and guidelines play in the development of medical policy like LCDs.”

Investors:

Dr Peter Meintjes
Chief Executive
Pacific Edge
P: 022 032 1263

Media:

Richard Inder
The Project
P: +64 21 645 643

OVERVIEW

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

¹ Lotan et al. (2024). 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.

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 25 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.