15 May 2026

DRAFT LCD PROPOSES MEDICARE COVERAGE FOR TRIAGE AND TRIAGE PLUS

DUNEDIN, New Zealand – Cancer diagnostics company Pacific Edge (NZX/ASX: PEB) today notes that a draft Local Coverage Determination (LCD) with foundational medical policy for urine-based biomarkers for hematuria evaluation (DL40378) has been published to the Medicare Coverage Database, with explicit coding guidance for Cxbladder Triage and Triage Plus in the associated Local Coverage Article (LCA) (DA60424).

The draft LCD 'Urine-based Biomarkers in Patients with Microhematuria' (DL40378) establishes hematuria evaluation as a covered Medicare benefit for the first time and importantly distinguishes hematuria patients as eligible for Cxbladder Triage and Triage Plus when contrasted with the existing non-coverage LCD 'Genetic Testing in Oncology: Specific Tests' which is for a different patient population, i.e. 'patients with cancer or substantiated suspicion of cancer'.

In the rationale section of the draft LCD, Novitas states: "*Given the low prevalence of malignancy in patients with MH[1], the limited diagnostic performance of urine cytology and earlier generation UBBs[1], 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.*"

Importantly, the associated draft article for billing and coding guidance (DA60424) makes clear that both Cxbladder Triage (0363U) and Cxbladder Triage Plus (0420U) are proposed to be reimbursable under this policy. No other urine-based biomarkers are included in the draft coding article creating a moat around our microhematuria business.

Pacific Edge Chief Executive Dr Peter Meintjes said: "This new draft LCD establishes hematuria evaluation as a covered Medicare benefit for the first time. The draft language clearly distinguishes microhematuria patients as eligible for urine-biomarker testing and notes positive coverage for Cxbladder Triage and Triage Plus. 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].

"We welcome Novitas' decision to expediently address our reconsideration requests and those of the AUA[3] and other clinicians. This is an excellent outcome for Medicare patients, urologists,

[1] MH means Microhematuria and UBB means Urine-based Biomarkers
[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
[3] AUA is the American Urological Association

and the broader healthcare system, supporting access to appropriate care while balancing clinical and economic considerations.

“The draft LCD and LCA confirm our position as the first mover and market leader in non-invasive diagnostics for microhematuria patients suspected of bladder cancer, and Pacific Edge now stands on the cusp of a major commercial inflection point with the only two tests covered for microhematuria evaluation.

“Importantly, as Triage Plus has been included in the draft coverage language, we have the opportunity to shift our customers over to i) a test with higher clinical utility, ii) a test that works on a broader range of patient types, iii) a test that continues to have a cost benefit for healthcare systems and payers, and iv) a test that shifts the economics of Pacific Edge towards operating profitably given the Medicare price of US$1,328 per test, a 75% improvement over the US$760 received for the legacy Cxbladder products,” Dr Meintjes said.

While an LCD, when finalized, directly enables reimbursement for over 66 million Medicare patients, the clarity in draft coverage language provides a template for US commercial payers to adopt in their own medical policies for the 223 million US lives they collectively insure. The Company also expects this news to provide a tailwind to the adoption of our tests in international markets.

Publishing the draft LCD marks the beginning of a well-defined process governed by the Medicare Program Integrity Manual[4]. This begins with a ‘Notice and Comment’ period of a minimum of 45 days during which Novitas[5] will hold a public meeting and accept written comments. Within 12 months from today, Novitas must address the comments and publish a final version of the LCD or withdraw the draft LCD. If it finalizes the draft LCD, it will become effective 45 days after it is published.

“Noting the strength of the underlying clinical evidence, the alignment to AUA guidelines and the clinical opinion expressed on the CAC, Pacific Edge looks forward to Novitas addressing comments and publishing the final LCD,” Dr Meintjes said.

“Given this draft LCD clearly distinguishes microhematuria patients as covered and as distinct from cancer patients in the non-coverage LCD (L39365), Pacific Edge will engage with Novitas to seek reimbursement for Triage and Triage Plus on a claim-by-claim basis during the draft period.”

Dr Meintjes said the language in the draft LCD reflects the strength of Pacific Edge’s value creation strategy that is founded on generating the compelling clinical evidence required to drive behavior change in physicians.

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[4] The Medicare Program Integrity Manual (MPIM) can be downloaded at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c13.pdf

[5] Novitas is the Medicare Administrative Contractor (MAC) with jurisdiction over Pacific Edge’s laboratory in Pennsylvania

"We produce evidence that is founded on the frameworks of AV, CV, CU[6], on defined patient populations, with statistically significant sample sizes and measuring the appropriate endpoints that drive change in medical policy. Creating value for investors through evidence development is a core expertise that Pacific Edge can repeat for Cxbladder Triage Plus, for Surveillance Plus and future products beyond bladder cancer."

Pacific Edge notes that its retail offer to eligible existing shareholders to raise up to NZ$6 million, with the ability to accept oversubscriptions at Pacific Edge's discretion (Retail Offer), opened on Thursday, 14 May 2026 and closes at 5:00pm NZST on Thursday, 28 May 2026. The Retail Offer is open to "Eligible Shareholders", who are all persons recorded on Pacific Edge's share register at 7:00pm NZST on Friday, 8 May 2026 as being a holder of Pacific Edge shares and having an address in New Zealand.

The Retail Offer follows Pacific Edge's successful placement (the Placement) of NZ$25.4 million of new ordinary shares to certain investors at a price of NZ$0.17 per share, which closed on Tuesday, 12 May 2026. Over 90% of the shares to be issued under the Placement will be issued to existing Pacific Edge shareholders, who were prioritized in the Placement.

Eligible Shareholders who wish to participate in the Retail Offer are able to apply for up to a maximum of NZ$50,000 of new shares per shareholder at NZ$0.17 per share, the same price per share offered to investors under the Placement. Further information on the Retail Offer, including the Retail Offer Document that contains the terms and conditions of the Retail Offer, and information on how to apply for shares under the Retail Offer, is available at www.nzx.com and www.asx.com.au under ticker code "PEB".

The draft LCD Urine-based Biomarkers in Patients with Microhematuria (DL40378) can be accessed via the following link: https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=40377

The draft LCA Billing and Coding: Urine-based Biomarkers in Patients with Microhematuria (DL60424) can be accessed via the following link: https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=60423

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

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[6] Analytical Validity (AV), Clinical Validity (CV), and Clinical Utility (CU),

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

Cxbladder is a suite of non-invasive genomic urine tests optimized for the risk stratification of urothelial cancer in patients presenting with hematuria 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 twenty-five 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.