

29 July 2024



NOVITAS CONFIRMS MEDICARE COVERAGE REVIEW EXTENSION

DUNEDIN, New Zealand – Cancer diagnostics company Pacific Edge (NZX, ASX: PEB) notes that Novitas, the Medicare Administrative Contractor (MAC) with responsibility for Pacific Edge’s US lab, has confirmed that it has been granted an extension to finalize or withdraw the Local Coverage Determination (LCD) ‘Genetic Testing for Oncology’ (DL 39365).

In a post on its website on Friday (Saturday morning NZDT), the MAC noted: “Novitas is considering all the feedback from interested parties regarding the Genetic Testing for Oncology LCD. An extension has been granted by the [Centers for Medicare & Medicaid Services¹] in order for all comments to be considered thoroughly. Future updates will be published to this website and the Medicare Coverage Database.”

Pacific Edge expected the LCD, which could impact Medicare coverage of its Cxbladder tests, to be withdrawn or finalized last Thursday evening (NZDT), i.e. within 365 days of the initial posting.

The continued deliberation on the LCD means that Pacific Edge’s tests Cxbladder Triage, Detect and Monitor continue to receive reimbursement from Medicare and Medicare Advantage payers in line with historical reimbursement rates, subject to medical necessity guidelines.

Pacific Edge continues to expect Novitas to finalize the LCD, but the timeframe is unknown. It will update shareholders as it gains certainty on the status of the LCD and the timeline for its resolution, but will not be making further comment on the matter until then.

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

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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

¹ The Centers for Medicare and Medicaid Services (CMS) delegates to Novitas the power to make the coverage determination. Novitas is accountable to CMS for the decision.

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 urine-based genomic biomarker test optimized for the detection and surveillance of bladder cancer. The Cxbladder evidence portfolio developed over the past 14 years includes more than twenty peer reviewed publications for primary detection, surveillance, adjudication of atypical urine cytology and equivocal cystoscopy. Cxbladder is the focal point of numerous ongoing and planned clinical studies to generate an ever-increasing body of clinical utility evidence supporting adoption and use in the clinic to improve patient health outcomes. Cxbladder has been trusted by over 4,400 US urologists in the diagnosis and management of more than 100,000 patients, including the option for in-home sample collection. In New Zealand, Cxbladder is accessible to 75% of the population via public healthcare and all residents have the option of buying the test online.