

## PACIFIC EDGE WELCOMES STAY OF NOVITAS LCD

**DUNEDIN, New Zealand** – Cancer diagnostics company Pacific Edge (NZX, ASX: PEB) today welcomes a decision from Novitas<sup>1</sup> and First Coast to delay the implementation of the Local Coverage Determination (LCD, L39365) released in early June that would have seen Medicare coverage of Cxbladder cease in the US on 17 July 2023.

In an email received by Pacific Edge from our US lawyers, the US Department of Health and Human Services Associate General Counsel Janice L Hoffman said: "Details are being worked out but there is a commitment from these two MACs (same parent company) that the LCD will not proceed as is and that the LCD will go through the LCD process again with an open meeting and public comment period".

No time frame has been provided for the process.

Pacific Edge Chief Executive Dr Meintjes said Pacific Edge was pleased with the outcome. Speaking from the USA, he said "we are confirmed in our position that a more robust procedure that includes an open meeting and public comment was needed and thank Novitas for the opportunity to discuss the substance of their evidentiary review of Cxbladder products with them.

"We support efforts to ensure the Medicare program only pays for genetic testing services that are analytically valid, clinically valid, and clinically useful," Dr Meintjes said.

"We will update investors as we gain further information on Cxbladder's Medicare coverage status."

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

## For more information:

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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 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

<sup>&</sup>lt;sup>1</sup> Novitas is the Medicare Administrative Contractor (MAC) with responsibility for Pacific Edge's US laboratory.

20 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.