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NOVITAS RELEASES NEW DRAFT LCD

DUNEDIN, New Zealand – Cancer diagnostics company Pacific Edge (NZX, ASX: PEB) notes the release overnight of a new proposed Local Coverage Determination (LCD) governing the reimbursement of its Cxbladder tests by Medicare, the US National Health Insurance provider.

The proposed LCD (DL39365) released by the Medicare Administrative Contractor (MAC) Novitas[1], notes the Cxbladder tests are 'not considered medically reasonable and necessary', the threshold required for coverage under the US Social Security Act. It follows substantially the same approach as the LCD 'Genetic Testing for Oncology' (L39365), which was released in early June and then withdrawn in early July following a concerted legal and political campaign from Pacific Edge and its industry partners that focused on several procedural issues.

Notably, and in contrast to the prior finalized LCD, Novitas has now provided for the statutory requirement for a 45-day notice and comment period commencing 27 July 2023* and finishing 9 September 2023*, during which time all interested stakeholders may submit comments to Novitas. The notice and comment period will also include an Open Public Meeting on 11 August 2023*, where Novitas has advised Pacific Edge in a direct communication that DL39365 is confirmed on the agenda.

Pacific Edge Chief Executive Dr Peter Meintjes said: "Pacific Edge supports Novitas' efforts to ensure that Medicare only pays for analytically valid, clinically valid and clinically useful tests. Our Pacific Edge Diagnostics USA Team and our US-based Key Opinion Leaders (KOLs) are well prepared for the Novitas Open Meeting where we will focus on the clinical value of Cxbladder to Medicare patients in the context of the standard of care in urology and the importance of physician choice when determining patient care. We will summarize our published clinical evidence, maintaining the view that it is sufficient to support continued Medicare coverage for our Triage, Detect and Monitor tests."

While the Open Public Meeting is an important part of the process, the written submissions are ultimately the most crucial, as Novitas is required to respond to all comments in a process that is also reviewed by the Centers for Medicare and Medicaid Services (CMS). Novitas may take up to 365 days from the original publication date (27 July 2023*) to withdraw or finalize the LCD including a response to those comments. When finalized, Novitas must provide a minimum of 45 days' notice before the LCD becomes effective.

"We continue to believe the evidentiary review of DL39365 and its predecessor L39365 appear to misunderstand the intended use of the Cxbladder tests, which is to "rule out" patients who would otherwise receive an unnecessary cystoscopy and that this has significant clinical value to physicians, patients and payers like Medicare," Dr Meintjes said.

"Pacific Edge and its KOLs will take the opportunity at the Open Meeting to present Novitas with important bladder cancer-specific medical knowledge regarding how clinical diagnostic tests such as Cxbladder with high negative predictive value, when used on patients that have a substantiated suspicion of cancer after presenting with hematuria, are a benefit to those patients and the Medicare Program."

Pacific Edge is continuing to bill and receive reimbursement by Medicare and Medicare Advantage for its tests under reimbursement arrangements that have been in place since 2020.

[1] Novitas is the MAC with jurisdiction for Pacific Edge's US laboratory

The Draft LCD and the associated Local Coverage Article can be found at the CMS website here: https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=39667&ver=9&contractorName=6&contractorNumber=all&updatePeriod=1053&sortBy=updated&bc=13

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

**All dates with an Asterix refer to US dates*

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OVERVIEW

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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 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 is reimbursed by CMS and 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.