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PACIFIC EDGE RELEASES SUBMISSIONS ON MEDICARE LCD

DUNEDIN, New Zealand – Cancer diagnostics company Pacific Edge (NZX, ASX: PEB) today releases details of written submissions on the draft local coverage determination (LCD) that proposes non-coverage of Cxbladder tests by Medicare, the US national health insurance provider.

The written submissions argue Cxbladder Triage, Detect and Monitor tests should retain Medicare coverage based on the clinical value they offer to patients, clinicians, and healthcare payers.

Written submissions are the second element of the notice and comment period required when proposing a new LCD. The details released today concern the draft LCD DL39365 proposed by Novitas the Medicare Administrative Contractor (MAC) with jurisdiction for Pacific Edge's US laboratory on July 27, 2023, and its sister MAC First Coast Service Options (FCSO).

Pacific Edge Chief Executive Dr Peter Meintjes said: "Pacific Edge believes there is no new information in these submissions, but they provide further context of a sensitive process and show the weight of opinion supporting the arguments for continued Medicare coverage Cxbladder."

The material released can be found attached and includes:

- A Pacific Edge letter to Novitas Medical Director Dr Patrick Mann MD summarizing the submissions on the draft LCD of which the company is aware.
- Pacific Edge's medical rebuttal of Novitas' evidentiary review of the clinical evidence supporting Cxbladder tests.
- A letter from the American Urological Association (AUA), the Large Urology Group Practice Association (LUGPA), and the American Association of Clinical Urologists (AACU) - the three most influential urological organizations in the US, covering every practicing urologist in the country. The letter includes unpublished non-peer-reviewed results from Kaiser Permanente that shows Cxbladder Triage safely excluded 78% of the patients presenting with hematuria from a cystoscopy. It also showed similarly positive results for Cxbladder Monitor for patients under surveillance for the recurrence of bladder cancer.
- A submission from the diagnostic technology industry group 'The Coalition for 21st Century Medicine' which provides a detailed critique on the structure and approach of the draft LCD.
- An open letter from long-time Pacific Edge research collaborator Dr Yair Lotan Professor of Urology at University of Texas Southwestern Medical Center, and 13 other key urologic opinion leaders supporting the use of urine bladder cancer markers. This letter has also been accepted for publication in the journal "Bladder Cancer", the official journal of the US advocacy group, the Bladder Cancer Advocacy Network.

The written submissions follow the presentations made during the open public meetings held in August. The written comments are important, because MACs are required to respond to all comments in a process that is also reviewed by the Centers for Medicare and Medicaid Services (CMS).

Written submissions closed in the US on 9 September. Novitas and FCSO may take up to 365 days from the original US publication date (27 July 2023) to withdraw or finalize the LCD including a response to written comments. When finalized, the MACs must provide a minimum of 45 days' notice before the LCD becomes effective.

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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 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.