24 April 2025

# US COURT LACKS JURISDICTION TO HEAR PACIFIC EDGE CLAIM

**DUNEDIN, New Zealand** – Cancer diagnostics company Pacific Edge (NZX, ASX: PEB) notes the US District Court for the Middle District of Pennsylvania has determined that it does not have jurisdiction to conduct judicial review of 'Genetic Testing in Oncology: Specific Tests' (L39365) Local Coverage Determination.

The judgment means the court is not able to consider the merits of Pacific Edge's legal complaint filed in the US District Court on 19 February 2025 about the LCD, despite Judge Neary noting in her ruling that *"the company has also marshalled incredibly compelling facts for why its test is a medical marvel."*

The judgment was published around 4:15pm ET on 23 April 2025 and means the remaining avenue for L39365 not to become effective on 24 April 2025 in the USA is a policy action by the Center of Medicare and Medicaid Services (CMS).

CMS has the authority to unilaterally extend the effective date of L39365 independent of the Court's ruling. Pacific Edge and associated parties have made the case for retirement of the LCD or extension of the effective date to the incoming political appointees within CMS[1], HHS[2] and OGC[3]. Pacific Edge is continuing to watch closely to determine what action, if any, CMS will take and we will update the market as we receive further information.

*Released for an 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 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.

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[1] Center for Medicare and Medicaid Services
[2] The Department of Health and Human Services
[3] Office of the General Counsel (of the Department of Health and Human Services)

**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 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.