28 April 2025

MEDICARE LCD EFFECTIVE; PACIFIC EDGE SEEKS RECOVERAGE

DUNEDIN, New Zealand – Cancer diagnostics company Pacific Edge (NZX, ASX: PEB) notes the 'Genetic Testing in Oncology: Specific Tests' (L39365) Local Coverage Determination became effective on 24 April 2025 in the US, halting Medicare coverage of Cxbladder tests.

Pacific Edge filed for a preliminary injunction and undertook political advocacy efforts directed at the incoming political appointees within CMS[1], HHS[2] and OGC[3] that included substantial support from the American Urological Association (AUA). However, on Wednesday 23 April 2025 a Pennsylvania District Court Judge ruled that her court lacks jurisdiction to hear Pacific Edge's claim against Medicare Administrative Contractor Novitas and CMS. Meanwhile, the lobbying efforts have not yielded a change to the effective date or retirement of the LCD.

Pacific Edge, which currently generates ~60% of its US revenue from Medicare, will now focus on the paths available, which include Medicare appeals for Cxbladder Triage to get paid based on its inclusion in the AUA microhematuria guideline[4], despite the non-coverage determination and reconsideration requests for Triage and Monitor.

Pacific Edge submitted a reconsideration request for Cxbladder Triage under 'Biomarkers for Oncology' LCD (L35396) on 21 March 2025, a request that has already been deemed valid by Novitas, meaning they will now assess the evidence submitted. It also expects to submit a reconsideration request for Cxbladder Monitor under 'Genetic Testing in Oncology: Specific Tests' (L39365) as soon as possible and request non-coverage to be removed.

However, Pacific Edge will not seek re-coverage of Cxbladder Detect as no new evidence has been published that can be submitted for reconsideration. Detect users will be required to move over to Triage in an acceleration of a plan intended to coincide with the commercial launch of Triage Plus.

Novitas controls the timeline for these reconsideration requests and is not bound by any maximum period to complete this work. Industry experts typically estimate the time at 6-9 months for a valid submission of a single product with only a small number of new supporting publications and not the protracted period of consultation that results from creating a new LCD as was done with L39365.

Regarding Cxbladder Triage Plus, the company will continue to develop, publish and subsequently submit a reconsideration request in line with our previously published roadmap – those activities remain on track. The company will also continue to work with Kaiser

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[1] Centers 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)
[4] Under current legislation, MACs are required to consider consensus statements and/or guidelines in determining coverage.

Permanente on a peer-reviewed publication confirming the real-world utility of Cxbladder Triage. The preliminary data was presented as a poster at the AUA 2025 annual meeting (April 26–29) in Las Vegas and will be used for future reconsideration requests when published.

While the impact of 'Genetic Testing for Oncology: Specific Tests' (L39365) is expected to have a significant impact on testing volume, Pacific Edge expects to continue to bill and receive reimbursement from contracted commercial US payers without interruption, notably Kaiser Permanente, the US Veterans Administration, various Blue Cross Blue Shield plans under the group purchasing agreement and from non-contracted private payers in line with historic reimbursement rates. Similarly, Pacific Edge expects collections from our enhanced patient responsibility and patient assistance programs to continue in line with the rates since the introduction of that program in July 2023.

Pacific Edge Chief Executive Dr Peter Meintjes said: "This finalization is a poor outcome for Medicare patients and urologists, as it removes coverage for guideline-recommended testing and followed a flawed process that failed to review the most-current evidence.

"We are obviously disappointed we have been unable to maintain coverage of our tests in the short term. However, as we noted when the final LCD was published in mid-January 2025, we have planned for this possibility. We will update shareholders as these plans are finalized, though our focus will remain on further evidence generation in parallel with the reconsideration pathway made available to all providers seeking Medicare coverage of their tests."

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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 suite of non-invasive genomic urine tests optimized for the risk stratification of urothelial cancer in patients presenting with microhematuria and those being monitored for recurrent disease. The tests help improve the overall patient experience, while prioritizing time and clinical resources to optimize practice workflow and improve efficiency.

Supported by over 20 years of research, Cxbladder's evidence portfolio extends to more than 25 peer reviewed publications, and Cxbladder Triage is now included in the American Urological Association's Microhematuria Guideline. To drive increased adoption and improved patient health outcomes, Cxbladder is the focal point of numerous ongoing and planned studies designed to generate further clinical utility evidence.

Cxbladder is available in the US, Australasia, and Israel and in markets throughout Asia and South America. In the US, the test has been used by over 5,000 urologists who have ordered more than 130,000 tests. In New Zealand, Cxbladder is accessible to around 70% of the population via public healthcare and all residents have the option of buying the test online.