13 January 2025

NOVITAS FINALIZES NON-COVERAGE DETERMINATION

DUNEDIN, New Zealand – Cancer diagnostics company Pacific Edge (NZX, ASX: PEB) today notes that Novitas, the Medicare Administrative Contractor with jurisdiction for our US laboratory, on Thursday 9 January 2025 finalized a non-coverage determination that would end reimbursement for Cxbladder Triage, Detect and Monitor by Medicare.

The draft Local Coverage Determination (LCD) 'Genetic testing for oncology' (DL39365) has been finalized under a new title 'Genetic Testing in Oncology: Specific Tests' (L39365). The LCD reverses Novitas' July 2020 determination[1] that provided for Medicare coverage of Cxbladder. If not challenged, the finalized LCD would become effective in 45 days from the date of publishing, with reimbursement of Pacific Edge's Cxbladder tests Triage, Detect and Monitor ceasing on 23 February 2025.

The new 'Genetic Testing in Oncology: Specific Tests' (L39365), acknowledges some shortcomings of the original draft LCD (DL39365), but remains flawed, particularly in its review of the clinical evidence underpinning Cxbladder tests.

Specifically, Novitas:

- Continues to misunderstand the current standard of care in evaluating hematuria patients, and the important role that biomarkers can play in stratifying patients with hematuria into those that would benefit from further potentially more invasive medical attention and those that would not.
- Fails to consider new peer reviewed evidence supporting the use of Cxbladder published since the revised draft determination in July 2023, despite having been notified of the evidence and stating in writing that it would incorporate that evidence in the review. Specifically, Novitas has not reviewed or cited:
    - the ground-breaking STRATA[2] randomized control study published in July 2024, which demonstrated the Clinical Utility (CU) of Cxbladder Triage and importantly that this study showed that clinicians undertook 59% fewer cystoscopies, when provided with a Triage test result; and
    - the analytical validation data of Cxbladder Detect, Triage and Monitor published in September 2024[3].

[1] Pacific Edge was informed by Novitas that its tests were covered in July 2020 (A58529)
[2] Lotan et al (2024). A Multicenter Prospective Randomized Controlled Trial Comparing Cxbladder Triage to Cystoscopy in Patients With Microhematuria. The Safe Testing of Risk for Asymptomatic Microhematuria Trial. J Urol 2024.
[3] Harvey et al (2024) Analytical Validation of Cxbladder® Detect, Triage, and Monitor: Assays for Detection and Management of Urothelial Carcinoma. Diagnostics. 2024; 14(18):2061.

- Repeats its flawed analysis of the existing clinical evidence for Cxbladder tests by focusing on the biomarker discovery study by Holyoake et al in 2008[4] and creates confounded conclusions by lumping the evidence in future publications from all assays together and not the clinical evidence supporting the individual products.

Pacific Edge Chairman Chris Gallaher said: “We are disappointed by Novitas’ determination, which has been made despite strong representations from Pacific Edge, many key opinion leaders in urology, bladder cancer patient advocates and the molecular diagnostics industry.

“Nevertheless, it is an outcome for which Pacific Edge has prepared. Following the release of the draft determination (DL39365) in late July 2023, and in recognition of the elevated risk of a decision such as this, we restructured our business to reduce our cash burn.

“With the LCD finalized, we are now activating the contingency plans and strategies to further reduce our expense base until we regain reliable Medicare coverage. With $28.5 million in reserves as at the end of December 2024, the company the company is well placed to fund the re-coverage process if necessary and regain reimbursement for our tests,” Mr Gallaher said.

Pacific Edge Chief Executive Dr Peter Meintjes said: “We are disappointed by a finalized LCD that misunderstands the science of biomarker discovery and diagnostic test development in the context of the standard of care in urology. We are do not understand its framing of Cxbladder as a screening test of asymptomatic patients and at the failure to acknowledge the views of the American Urological Association (AUA) and the practicing clinicians that derive value from the test.

“Furthermore, we cannot believe that Novitas would commit in writing to review our most recent evidence (the STRATA study and recent analytical validation data) as part of developing this LCD and then fail to do so. Ignoring a randomized controlled trial (classified as Level 1 Evidence) published during the lengthy deliberations on the LCD and the consensus of the urology community runs counter to the mandate of a US government health insurance program, Dr Meintjes said.

“Regardless, we are prepared to continue to do what is best for our investors, physicians and patients.”

Dr Meintjes said the go-forward plans may include the following:

- Pursuing a preliminary injunction and legal challenge to the finalization of the LCD. Pacific Edge notes and recognizes the inherent uncertainty of success in these endeavors.

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[4] Holyoake et al (2008) Development of a multiplex RNA urine test for the detection and stratification of transitional cell carcinoma of the bladder. Clin Cancer Res 2008;14:742–9.

- Further review the structure of our operations and our strategy to reduce cash burn in line with our plan to regain reliable Medicare coverage.
- Submit to Novitas a Medicare coverage reconsideration request on the basis of the Journal of Urology's publication of the STRATA study and the updated Analytical Validation studies of Triage, Detect and Monitor.
- Continue to explore other strategic alternatives for Pacific Edge that could support the company through to regaining reliable Medicare coverage and advancing the commercialization of Cxbladder globally.

Dr Meintjes emphasized that the long-term focus of the company remains unchanged and that the team is looking forward to the outcome of the AUA's ongoing review of its microhematuria guideline following the publication of the STRATA study. The possibility of AUA Guidelines inclusion creates additional potential for a reconsideration request for Medicare coverage to Novitas.

Pacific Edge is currently unable to fully determine the impact of the new LCD on test volumes in the US market for the remainder of the 2025 financial year and beyond, but in 1H 25 Medicare and Medicare Advantage delivered ~5,300 commercial tests (~54% of US commercial tests) and ~$6.5m NZD in total operating revenue.

The company expects to continue to bill and receive reimbursement from contracted US payers without interruption, notably Kaiser Permanente and the US Veterans Administration, and from non-contracted private payers in line with historic reimbursement rates. Similarly, Pacific Edge expects collections from the enhanced patient responsibility and patient assistance programs to continue in line with the rates since the introduction of that program in July 2023.

Dr Meintjes said: "While this determination will have an impact on our current and future commercialization plans, it simultaneously emphasizes that our focus on rigorous clinical evidence generation as a path to gaining coverage certainty through guidelines inclusion is the right focus for our business. This program is at the center of our efforts to regain Medicare coverage.'

Pacific Edge will be hosting a conference call and webcast to discuss the determination today (Monday 13 January 2025) at 11.00am NZST:

This update will be available via webcast by the following link:
www.virtualmeeting.co.nz/pebiu25 or by phone on the following toll-free numbers:

- New Zealand: 0800 005 652
- Australia: 1800 953 093

Questions
Questions can be submitted online in writing via the Webcast platform or verbally via the audio call when prompted.

The new 'Genetic Testing in Oncology: Specific Tests' (L39365) LCD can be accessed HERE

The response to comments on the draft LCD 'Genetic Testing for Oncology' (DL39365) can be accessed: HERE

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

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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 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.