7 June 2023

MEDICARE COVERAGE OF CXBLADDER EXPECTED TO CEASE

DUNEDIN, New Zealand – Cancer diagnostics company Pacific Edge (NZX, ASX: PEB) today announces Medicare coverage of Cxbladder tests in the US market is expected to cease from 17 July 2023.

This development follows the finalization of a Local Coverage Determination (LCD) (L39365) by Novitas, the Medicare Administrative Contractor (MAC) with jurisdiction for Pacific Edge's laboratory in Hershey Pennsylvania.

The finalized LCD, which includes Cxbladder and tests provided by other companies, specifically notes the Cxbladder tests Triage, Detect, Monitor, Resolve and Detect^{+} as 'not considered medically reasonable and necessary', the threshold required for coverage under the US Social Security Act. A number of other companies are also affected by the LCD.

Over the coming days Pacific Edge will seek to explore all available legal options (including a potential appeal) with our US-based lawyers, the key opinion leaders among our customers, our partners at The Coalition for 21st Century Medicine, and other impacted companies.

As a direct result of the LCD, Pacific Edge's revenue is expected to reduce substantially from current levels until Cxbladder tests regain coverage. In the year ended March 2023 (FY 23), tests for Medicare and Medicare Advantage were ~60% of US commercial tests, or ~13,800 tests, and generated ~$15.3 million, or 77.3%, of FY23 total operating revenue. Post 17 July 2023 all of these tests are expected to be impacted by this determination from Novitas.

Pacific Edge Chief Executive Dr Peter Meintjes says the company is surprised and disappointed with the finalized LCD. He says the local coverage determination appears to materially misunderstand the important role that biomarkers can play in "first line" diagnostics for risk stratifying patients with hematuria into those that would benefit from further potentially more invasive medical attention and those that would not.

Pacific Edge has consistently sought to enhance and to strengthen its research and evidence base with a particular focus on its clinical evidence generation program over the last 18 months under the company's new CEO, Peter Meintjes, further accelerated since Dr. Tamer Aboushwareb joined as the VP of Medical Affairs, now leading the medical organization as CMO. The current program focuses on analytical validity (AV), clinical validity (CV) and clinical utility (CU) in defined patient populations, with conventional end points and at sufficient sample size for future inclusion in guidelines.

"While Novitas appears to have reviewed all available evidence for Cxbladder, we believe that Novitas' analysis has sought to predominantly emphasize negative comments in Cxbladder publications. We believe that focusing predominantly on only negative comments likely mischaracterizes issues or confounding factors with our evidence that were addressed in subsequent publications and routine commercial testing, while also dismissing the support Cxbladder receives from key opinion leading urologists, and the US patient advocacy group BCAN (Bladder Cancer Advocacy Network). Importantly, urologists have identified the value for themselves and their patients as demonstrated by the record number of urologists using the test, 1,151 in FY23Q4, and the record growth in Cxbladder testing volume at 43% CAGR for the last two years.

“Molecular diagnostics is a developing field, and this LCD has made an unprecedented move to change the threshold regarding what’s acceptable evidence and what’s not, by relying on third-party databases[1] that do not adequately cover the current standard of care in bladder cancer diagnosis. Consequently, Novitas does not appear to acknowledge that Pacific Edge’s products improve the standard of care in bladder cancer diagnosis and does not appear to consider the benefits of non-invasive testing alternatives and may result in worse outcomes for patients” Dr Meintjes says.

Private healthcare payers in the USA make independent medical policy decisions and consequently Pacific Edge expects to continue to bill and receive reimbursement from contracted US payers without interruption and from non-contracted private payers in line with historic reimbursement rates. Notably, our largest US customer Kaiser Permanente is expected to continue payment for our Triage and Monitor products, irrespective of the Novitas determination. We also expect continued reimbursement for the small proportion of patients insured by the US Veterans Administration and other direct bill payers.

Pacific Edge is currently unable to fully determine the impact of the new LCD on test volumes in the US market for the 2024 financial year. For the immediate future, the company will continue to promote Cxbladder and process all tests ordered by US clinicians whilst it further considers its strategy and future options.

The company believes that in the short term it is prudent to continue to support Cxbladder as it determines the best path forward, but the approach will be accompanied by cost containment initiatives including, but not limited to an immediate hiring freeze and a halt on discretionary spending and new capital expenditure.

“We see this LCD as a delay to our future commercialization plans. Now that Novitas has codified their views in a finalized LCD, we are able to consider and assess the potential necessary adjustments required to regain Medicare coverage. The generation of clinical evidence that supports the further integration of Cxbladder into clinical practice is expected to be at the foundation of these efforts.

Chief Medical Officer, Dr Tamer Aboushwareb notes: “The language and framework adopted in this LCD has reinforced our recent decision to develop and commercialize Cxbladder Detect^{+} as a single test for hematuria evaluation. The clinical evidence for Detect^{+} has, and will be, developed in a more structured framework for AV, CV and CU, using a defined patient population, conventional end points and a sample size sufficient for future inclusion in guidelines.

“By building a solid and focused clinical development plan based on the foundations of AV, CV and CU (which are requirements for guidelines inclusion and coverage), the Detect^{+} test will likely be the strongest candidate for future potential inclusion in both the NCCN[2] and AUA[2] guidelines for the stratification of microscopic hematuria patients. We have an ongoing study (DRIVE) expected to be ready for publication by early 2024 and another two validation studies (microDRIVE, and AUSSIE) set to start soon with a target completion date at the end 2024,” Dr Tamer Aboushwareb says.

In light of this new LCD, management and the Board at Pacific Edge are reviewing the scenario planning commenced last year to determine a strategic path forward that potentially includes: a) legal challenges

[1] The finalized LCD relies on three knowledge bases to determine coverage. They are Clinical Genome Resource (ClinGen); National Comprehensive Cancer Network (NCCN); Oncology Knowledge Base (OncoKB) knowledge bases.
[2] NCCN: National Comprehensive Cancer Network; AUA American Urological Association.

or appeals, b) seeking to regain coverage through Novitas, c) seeking to be awarded coverage through an alternative MAC, d) alternative billing practices that would increase patient responsibility and e) remaining open to other strategic alternatives.

Which of these we adopt, will be determined by considering a number of factors including the potential impact on revenue, expenditure and cash reserves, the time and resources required to regain coverage, shareholder value implications, and the expected likelihood of success.

Chairman Chris Gallaher notes: “Pacific Edge is well funded with cash and cash equivalents and short-term deposits of $77.8 million at the end of March 2023. Despite this current setback, the company believes that it can still deliver on the significant opportunities we see for Cxbladder in the US and around the world. We will update the market as we gain greater clarity and have determined our strategic path forward.”

A copy of the LCD can be downloaded from the following link: HERE

Pacific Edge is holding a conference call at 11.00am (NZT) today (Wednesday 7 June 2023)

Webcast link: www.virtualmeeting.co.nz/pebjun23

Phone participation: NZ: 0800 449 170; AUS 1800 896 574

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

For more information:

Investors:

Dr Peter Meintjes
Chief Executive
Pacific Edge
P: 022 032 1263

Media:

Richard Inder
The Project
P: +64 21 645 643

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 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.