

PACIFIC EDGE NOTIFIED OF POSITIVE LCD DECISION IN USA

Transformational reimbursement milestone for Pacific Edge with notification of LCD coverage for CMS patients in the USA. The LCD coverage facilitates reimbursement for CMS patients using Cxbladder Detect and Cxbladder Monitor.

New Zealand bladder cancer diagnostics provider, Pacific Edge Limited (NZX: PEB), has been notified by Novitas¹ that the LCD: Biomarkers for Oncology (L35396) provides coverage for Cxbladder, CPT codes 0012M (Cxbladder Detect) and 0013M (Cxbladder Monitor), for tests performed on or after July 1, 2020 that are medically necessary.

This includes reimbursement for all Cxbladder tests performed for patients covered by the Centers for Medicare and Medicaid Services (CMS) across the USA, at the already determined national CMS price for Cxbladder of US\$760 per test. The CMS provides healthcare coverage for all US citizens over 65 years, as well as assistance for healthcare coverage to people with low incomes. CMS tests currently make up approximately 40% of Pacific Edge's current Commercial Tests in the USA. Pacific Edge will also be seeking to negotiate reimbursement for the Cxbladder tests that have previously been completed and invoiced for CMS patients.

CEO of Pacific Edge, David Darling, said: "This is a transformational milestone for Pacific Edge and the result of a number of years of hard work and effort from our teams in New Zealand and the USA. This long awaited outcome results from the generation of substantial clinical evidence, publication of numerous clinical papers demonstrating the compelling clinical utility and outperformance of Cxbladder, and growing commercial use of our tests by urologists in the USA and other markets.

"Coverage under the LCD for our two Cxbladder tests with CPT codes² will unlock access to the CMS revenue which currently represents approximately 40% of Pacific Edge's commercial sales in the US. The coverage decision is also expected to positively impact on demand and positive reimbursement decisions from other healthcare organisations and payers as well. It signals a new phase in Pacific Edge's commercial journey and we will be pushing hard on the back of this announcement to gain adoption of Cxbladder by other large scale healthcare organisations."

The LCD coverage notification comes hot on the heels of the signing of a commercial agreement with Kaiser Permanente, one of the largest non-profit healthcare providers in the USA, which was announced by Pacific Edge on 17 June 2020. Kaiser Permanente is one of the largest non-profit healthcare providers in the US, with over 12

¹ NOVITAS is the CMS's Medicare Administrative Contractor (MAC) for Pacific Edge's USA commercial reimbursement for CMS patients. MACs regionally manage policy and payment related to reimbursement and act as the fiscal intermediary for Medicare. MACs manage provider claims for payment and establish regional policy guidelines, called Local Coverage Determinations (LCDs).

² Administrative MAAA CPT Codes are issued by the American Medical Association (AMA) Current Procedural Terminology (CPT®) Editorial Panel and are a key component of the reimbursement process in the USA.

million members and annual operating revenue of \$84.5b³. It operates 39 hospitals, 714 medical offices and employs approximately 23,000 physicians.

Cxbladder is already in commercial use by the majority of the public healthcare providers in New Zealand and many have adopted it into their guidelines for both the evaluation of haematuria and in the monitoring for recurrence of urothelial cancer.

Chair of Pacific Edge, Chris Gallaher, said: "The LCD coverage signals a major step change for our company with the successful completion of the major reimbursement milestones in the USA. For a company from New Zealand, this is a huge achievement and one of which we are very proud. On behalf of the Board, I would like to thank our team who have worked tirelessly to make this happen and shareholders for their patience and support as we have worked to commercialise our Cxbladder technology."

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OVERVIEW www.pacificedge.co.nz www.pacifiedgedx.com

Pacific Edge Limited (NZX: PEB) is a New Zealand publicly listed, cancer diagnostic company specialising in the discovery and commercialisation of diagnostic and prognostic tests for better detection and management of cancer. Its Cxbladder suite of non-invasive, simple to use and accurate diagnostic tests provide actionable results, and better detection and management of urothelial cancer. The company is developing and commercialising its range of Cxbladder bladder cancer tests globally through its wholly owned central laboratories in New Zealand and the USA. The company's products have been tested and validated in international multi-centre clinical studies.

ABOUT Cxbladder Triage www.cxbladder.com

Cxbladder Triage combines the power of the genomic biomarkers with additional phenotypic and clinical risk factors to accurately identify patients with haematuria who have a low probability of bladder cancer and may not require a more extensive urological evaluation. Cxbladder Triage is a tool for use by clinicians and physicians in primary evaluation of patients with haematuria and is intended to reduce the need for an expensive and invasive work-up in patients who have a low probability of having urothelial carcinoma.

ABOUT Cxbladder Detect www.cxbladder.com

Cxbladder Detect enables the non-invasive detection of bladder and other urinary tract cancers from a small volume of a patients' urine. Cxbladder Detect provides clinicians with a quick, cost effective and accurate measure of the presence of the cancer as an effective adjunct to cystoscopy.

ABOUT Cxbladder Monitor www.cxbladder.com

³ Kaiser Permanente Fast Facts <https://about.kaiserpermanente.org/who-we-are/fast-facts>

Cxbladder Monitor allows urologists to monitor bladder cancer patients for recurrence of the disease. Bladder cancer has a recurrence rate of 50-80% and requires life-long surveillance. Cxbladder Monitor accurately identifies patients with a prior history of urothelial cancer (UC) whose Cxbladder Monitor score shows that they have a low probability of recurrent urothelial carcinoma. Cxbladder Monitor is designed to be used as the preferred adjunct test to cystoscopy in the management of patients for ongoing evaluation of recurrent bladder cancer.

ABOUT Cxbladder Resolve www.cxbladder.com

Cxbladder Resolve identifies those patients who are likely to have aggressive or more advanced bladder cancer. Cxbladder Resolve, when used as part of the primary evaluation of haematuria and/or in conjunction with other Cxbladder tests (Triage, Detect), is designed to assist clinicians by accurately identifying patients with a high probability of having high grade or late stage bladder cancer, for whom alternative or expedited treatment options may be warranted, or who can be prioritised for further investigation in high throughput settings.

Refer to www.cxbladder.com for more information.