

## PACIFIC EDGE RECEIVES NOTIFICATION OF CXBLADDER NATIONAL CMS REIMBURSEMENT RATE IN THE USA

### **Major US reimbursement milestone achieved by Pacific Edge**

Cancer diagnostics company, Pacific Edge (NZX: PEB) is pleased to advise that the preliminary national CMS reimbursement rate of US\$760 (NZ\$ 1,166) has been publicly notified. The national reimbursement rate covers the Cxbladder tests awarded national CPT codes in the USA earlier this year,

The national CMS reimbursement rate is for all patients covered under the Centers for Medicare and Medicaid Services (CMS) and will apply to Cxbladder test claims submitted to CMS once Pacific Edge receives inclusion in the Local Coverage Determination (LCD) for Medicare coverage.

The rate, set by the Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests, will be open for public comment until 22 October 2018 and will be published in the Clinical Laboratory Fee Schedule in November 2018 and effective from 1 January 2019.

CEO of Pacific Edge, David Darling, said: "This is a major reimbursement milestone and the second of the three significant components of the US reimbursement process which Pacific Edge has now achieved. The reimbursement rate of US\$760 per test is within an acceptable commercial range and in line with other similar molecular diagnostic laboratory tests in the US."

The first component in the reimbursement process was the granting of dedicated CPT codes by the American Medical Association, which was achieved earlier in 2018. These national codes are only issued for tests that have entered the mainstream, where the volume of tests used by physicians has been shown to be indicative of significant adoption and for which the clinical efficacy of the test is well established and documented in peer reviewed literature.

The second component is the notification of the national reimbursement rate associated with the Codes, and the third is inclusion in the Local Coverage Determination (LCD) for CMS coverage. The national reimbursement rate will set the reimbursement rate for tests ordered by physicians for CMS patients, once the LCD inclusion is received.

David Darling said: "We have been working hard to complete the reimbursement milestones in the US and we are delighted with this achievement. Once the LCD is attained, we will receive more consistent reimbursement for CMS claims. Having the national CMS reimbursement rate in place on the Clinical Laboratory Test Fee Schedule is expected to positively impact negotiations with private insurers and funders in the USA to gain coverage for our tests in their insurance plans."

**ENDS**

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Company Announcement



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**OVERVIEW** [www.pacifedge.co.nz](http://www.pacifedge.co.nz) [www.pacifedgedx.com](http://www.pacifedgedx.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](http://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](http://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](http://www.cxbladder.com)

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](http://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](http://www.cxbladder.com) for more information.