Company Announcement
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PACIFIC EDGE COMMENTS ON PROPOSED NOVITAS LCD

DUNEDIN, New Zealand – Pacific Edge (NZX, ASX: PEB) today provides further information for shareholders on proposed changes to the Medicare Local Coverage Determination (LCD)[1] that governs the reimbursement of Cxbladder in the US. This follows the decision by Pacific Edge to request a trading halt on Friday 29 July 2022 to ensure investors were well informed on the draft proposals.

The proposed changes to the LCD by Novitas, the Medicare Administrative Contractor (MAC) with jurisdiction for Pacific Edge's US laboratory, have the potential to disrupt the reimbursement of Cxbladder.

Having consulted with our US-based advisers and industry experts, Pacific Edge believes the proposed changes are unlikely to survive the ongoing review process in their current form. The consensus view we received was that the proposed changes to the LCD are contrary to US legal requirements and precedent. The proposed changes also fundamentally change the process for determining coverage for specific tests and could deprive US clinicians and Medicare patients access to diagnostic tools with proven, peer-reviewed clinical utility.

If the proposed LCD and LCA were approved unchanged, Cxbladder would not qualify for coverage from Novitas for tests reimbursed by the US Centers for Medicare & Medicaid Services (CMS). These tests represent a significant portion of current Cxbladder testing revenue. Multiple companies with dozens of diagnostic tests that have existing coverage or are seeking coverage, would similarly be impacted by this proposal.

Pacific Edge Chief Executive Dr Peter Meintjes says, "We commend the broader initiative to simplify and streamline the coverage process. However, given the explicit prior coverage and payment history for Cxbladder tests, we have presented our initial concerns to Novitas.

"We will work with CMS and its contractors to make the necessary changes to the drafts to ensure that there is no disruption to the coverage of Cxbladder, as far as we are able. We will also be encouraging the many clinicians and healthcare providers already using our tests to support our position. We will update shareholders as we progress this matter."

Since Cxbladder gained CMS reimbursement coverage in 2020, Pacific Edge has received CMS reimbursement for over 10,000 tests. Cxbladder has also been adopted by some of the US' largest integrated care networks and has been incorporated into their clinical treatment guidelines.

To date more than 80,000 patients globally have benefitted from our tests, while the volume of clinical evidence supporting the tests continues to grow. The evidence continues to show how Cxbladder tests can assist clinicians to safely intensify or de-intensify the clinical workup for patients presenting with

[1] LCDs are decisions made by a Medicare Administrative Contractor (MAC) whether to cover a particular item or service in a MAC's jurisdiction (region) in accordance with section 1862(a)(1)(A) of the US Social Security Act.

hematuria, resolve diagnostic dilemmas during hematuria evaluation, and monitor for the recurrence of urothelial cancer in post-treatment patients.

Novitas has extended the period for public comments on the proposals until 6 September 2022. Novitas has not provided a specific date for a decision, however we understand it must either publish or withdraw the draft LCD within a year of the end of the public comment period. Regardless of a positive or negative determination, we understand CMS is required to give Pacific Edge at least 45 days' notice of the effective determination date.

Chairman Chris Gallaher says, "Pacific Edge remains well capitalized and positioned to execute on our long-term strategic objectives."

Pacific Edge will continue to update shareholders on this matter as further information becomes available.

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

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FREQUENTLY ASKED QUESTIONS

Is Cxbladder still being reimbursed in the US?

Yes. But Novitas, the Medicare Administrative Contractor (MAC) with jurisdiction for Pacific Edge's US laboratory in Hummelstown, Pennsylvania, has proposed changes to the Local Coverage Determination (LCD) that governs the reimbursement of Cxbladder tests in the US. These proposed changes have the potential to disrupt reimbursement for patients with Medicare and Medicare Advantage plans accounting for a significant part of the current Cxbladder testing revenue.

What is a Medicare Administrative Contractor (MAC)?

The Centers for Medicare and Medicaid Services (CMS), relies on a network of MACs to serve as the primary operational contact between the Medicare fee for service (FFS) program and the health care providers enrolled in the program. MACs perform many activities including establishing Local Coverage Determinations (LCDs), which are decisions to cover a particular item or service in a MAC's jurisdiction.

What is a Proposed LCD?

MACs such as Novitas, periodically propose new LCDs on whether to cover a particular item or service in a MAC jurisdiction (region). As Novitas notes on its website: "Proposed LCDs are works in progress that are available on the Medicare Coverage Database site for public review. Proposed LCDs are not necessarily a reflection of the current policies or practices of the contractor".

What has Novitas proposed?

In June Novitas proposed to fundamentally change its approach to determining if a genetic/genomic test should be reimbursed for Medicare patients in the US. Specifically, Novitas has proposed a new approach to coverage in a draft LCD (DL39365/DL3967) and a draft Local Coverage Article (LCA, DA59125)[2] for Genetic Testing in Oncology. Under its current local coverage determination, Novitas reviews the clinical evidence for individual diagnostic products. Going forward, Novitas is proposing that it will determine which tests to cover by relying solely on criteria established by third party external knowledge bases: (1) Clinical Genome Resource (ClinGen); (2) National Comprehensive Cancer Network (NCCN); or (3) Oncology Knowledge Base (OncoKB).

How does the new approach impact Cxbladder and Pacific Edge?

If the proposed LCD and LCA were approved unchanged, Cxbladder would no longer receive reimbursement for Cxbladder from Novitas as the tests are not specifically mentioned in any of the three knowledge bases that Novitas has identified. OncoKB and ClinGen are "SNP[3]-only" databases, meaning that they are unsuitable for multi-analyte assays with algorithmic analyses (MAAAs), so advanced gene expression tests would only be able to obtain coverage by inclusion in NCCN guidelines.

[2] Local Coverage Articles are a type of educational document published by the Medicare Administrative Contractors (MACs). Articles often contain coding or other guidelines that are related to a Local Coverage Determination (LCD).
[3]Single nucleotide polymorphisms.

What does Pacific Edge think of the LCD and LCA?

Pacific Edge believes the proposed LCD and LCA will not survive in their current form because:

- They do not meet the statutory requirements for an LCD.
- They do not comply with CMS' requirements for the development of LCDs.
- Their new approach of using knowledge bases as a determinant for CMS coverage is not well supported within the draft LCD.
- The proposed LCD and LCA are insufficient to allow stakeholders to understand whether tests are covered and would inappropriately restrict coverage for tests.

What is Pacific Edge doing to change the Novitas proposal?

Pacific Edge has presented in person to Novitas and has made a detailed submission comprehensively setting out its concerns and the drawbacks of this new approach. It is also sharing insight with other biotech companies that could be similarly affected by the new approach to make their concerns known to Novitas before the end of the consultation period, and engaging with industry advocates.

If the draft LCD was first published in June, why did Pacific Edge only notify the NZX and ASX and call a trading halt on Friday 29 July 2022?

In June the draft proposals did not appear to affect Pacific Edge since there was no indication that coverage for Cxbladder under its existing LCD was changing. Additionally, Cxbladder was not explicitly mentioned in the proposed LCD. However, on Friday morning on 29 July 2022 (NZT), the company became aware that the latest revision of the draft explicitly excluded Cxbladder from reimbursement. In consultation with the NZX, Pacific Edge decided a trading halt was appropriate because there was information in the public domain that needed clarification and context. Given the time differences between New Zealand and the United States, where the subject matter experts are based, and the complexity of the proposals, a full and complete response was not able to be completed within a reasonable time, resulting in a request for a trading halt.

When will Pacific Edge know if the proposed LCD is finalized?

Novitas is required to give Pacific Edge at least 45 days' notice of the effective determination date. Novitas is consulting interested parties on the proposals until 6 September 2022. Novitas has not provided a specific date for a decision, but it must either publish or withdraw the draft LCD within a year of the end of the public comment period.

OVERVIEW 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.

About Cxbladder www.cxbladder.com

Cxbladder is a non-invasive genomic urine test optimized for the detection and management 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 2,000 US urologists

in the diagnosis and management of more than 80,000 patients, including the option for in-home sample collection. In New Zealand, Cxbladder is accessible to 70% of the population via public healthcare and all residents have the option of buying the test online.