13 SEPTEMBER 2024

AUA MICRO-HEMATURIA GUIDELINE AND MEDICARE TIMELINES

DUNEDIN, New Zealand – Cancer diagnostics company Pacific Edge (NZX, ASX: PEB) today notes the American Urological Association (AUA) is seeking urologist feedback on a draft standard of care guideline for the evaluation of microhematuria. The consultation is taking place under strict conditions of non-disclosure with the process commencing after 15 September 2024.

Pacific Edge also notes the Centers for Medicare & Medicaid Services (CMS) has indicated - through a meeting with stakeholders that included The Coalition for 21st Century Medicine (C21) - that it had agreed to an extension to deliberations on the draft Local Coverage Determination (LCD) 'Genetic Testing for Oncology' (DL 39365) to ensure Pacific Edge's Medicare Administrative Contractor, Novitas, had time to respond to a large volume of detailed comments and because the LCD raises unique issues. Novitas confirmed it had been granted an extension to finalize, retire or start over on the draft LCD in late July.

Given these developments Pacific Edge does not expect these matters to be resolved ahead of the company's Annual Shareholder Meeting (ASM) in Auckland on 24 September 2024, which contrasts to the previous expectations communicated in Pacific Edge's Q1 24 investor update released to the NZX and ASX on 10 July 2024.

The review of the AUA microhematuria guideline, which was last amended 2020, is potentially significant as guidelines play a substantial role in medical reimbursement policy for Medicare and all other payers. They also have a significant influence over the practices of individual urologists.

Pacific Edge Chief Medical Officer Dr Tamer Aboushwareb is contributing to the AUA's consultation on the microhematuria guideline. Dr Aboushwareb's contribution to the process is subject to the terms of the strict and personal AUA confidentiality agreement.

Despite the deliberations over the draft LCD, Pacific Edge continues to receive reimbursement for tests performed for Medicare and Medicaid patients – as it has without interruption since July 2020 including more than two years since the draft LCD was first published. In the event of a total or partial non-coverage determination, reimbursement will continue until at least 45 days after the LCD is publicly notified.

In the Q1 24 investor update Pacific Edge also noted CMS could make a pricing decision on the company's Cxbladder Detect+ test before the ASM on September 24. That remains a possibility.

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

For more information:

Investors:
Dr Peter Meintjes
Chief Executive
Pacific Edge
P: +64 22 032 1263

Media:
Richard Inder
The Project
P: +64 21 645 643

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 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.