29 April 2024

TRIAGE PLUS PRICE SET TO LIFT PACIFIC EDGE'S ECONOMICS

DUNEDIN, New Zealand – Cancer diagnostics company Pacific Edge (NZX, ASX: PEB) notes today that the draft 'Gapfill' prices for Cxbladder Triage Plus[1] have been published by the US Centers for Medicare & Medicaid Services (CMS) proposing a draft price for the test of US$1,018.44.

When finalized, the CMS price for Triage Plus sets the amount Pacific Edge will be reimbursed for all patients with Medicare and Medicare Advantage insurance. This will be subject to Pacific Edge's Medicare Administrative Contractor (MAC), Novitas, providing coverage of the test. The test is currently listed as non-covered on Novitas' 'Genetic Testing in Oncology: Specific Tests (L39365)' Local Coverage Determination (LCD). Private health insurance companies make separate coverage and pricing decisions based on their own medical policy and contracting for a test.

In the Gapfill process CMS asks each MAC to propose prices for any new testing services based on estimates of the resources needed to develop and run the test, then recommends the median of those prices as its final price. The seven MACs responsible for processing Medicare claims across various jurisdictions in the United States have published their draft pricing for Triage Plus. While Novitas priced Triage Plus at US$1,587.69, due to its agreements with multiple MACs, the price provided by MolDX[2] is the *de facto* median price, because MolDX pricing is used in 28 of the 50 states. The draft pricing for MolDX was US$1,018.44, and subject to public comments that are due by 28 June 2025, and some possible adjustment based on those comments, CMS is expected to make that price effective on 1 January 2026.

Hematuria evaluation tests currently represent around 81% of Pacific Edge's total US laboratory throughput[3]. The US$1,018.44 price is a meaningful increase compared to the US$760 CMS price of our existing tests, because it increases the margin and margin percentage per test and improves the profitability of operating our front-line sales force. When coverage of Triage Plus is established, Pacific Edge will make migration from Triage a priority, noting that Detect tests are being migrated to Triage tests effective immediately given the February 2025 inclusion of Triage in the American Urological Association's microhematuria guideline.

Pacific Edge expects to submit a reconsideration request for coverage of Triage Plus as soon as the analytical validation (AV) and clinical validation (CV) studies have been published. The

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[1] Cxbladder Triage Plus has CPT Code 0420U and has not yet completed the administrative name change from Cxbladder Detect+

[2] MolDX is a coverage and reimbursement program run by the Palmetto MAC that provides unique test registrations and technical assessments for molecular diagnostics products to which other MACs can subscribe. The majority of MACs have elected to do so, but Novitas and National Government Services do not.

[3] Half year to 30 September 2024.

AV publication is being reviewed by the submitting authors and the CV publication, the DRIVE study[4], has already been submitted for publication.

Pacific Edge Chief Executive Dr Peter Meintjes said: “We are very pleased that both MolDX and Novitas have recognized the novelty of Triage Plus in their pricing determinations with prices of US$1,018.44 and US$1,587.69 respectively. We have invested significant resources in Triage Plus – a multimodal test that combines DNA and RNA workflows with the outputs analyzed by a novel algorithm that provides dramatic performance improvement over existing tests and can be used on a broader patient population to assist clinicians to manage their hematuria patients as high, intermediate or low risk.

“The resources needed to develop, validate and operate Triage Plus commercially are substantial, thus necessitating a higher price, but importantly when Triage Plus’ performance characteristics[5] are used in our existing budget impact model[6] we observe that the improved performance characteristics has the potential for even greater savings to the Medicare system by reducing more unnecessary procedures and allowing clinicians to spend more time and clinical resources on those who need it most.”

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[4] Detection and Risk stratification In Veterans presenting with hematuria: Savage S.J., et al (2025) The Prognostic Performance of Cxbladder Triage Plus for the Identification and Priority Evaluation of Veterans at Risk for Urothelial Carcinoma: The Drive Study, Abstract submitted to the AUA 2025 meeting.

[5] Lotan Y, Raman JD, Konety B, Daneshmand S, Schroeck F, Shariat SF, Black P, de Lange M, Asroff S, Goldfischer E, Efros M, Chong KT, Huang E, Chua HL, Wu QH, Yeow S, Lau W, Yong J, Eng M. Urinary Analysis of FGFR3 and TERT Gene Mutations Enhances Performance of Cxbladder Tests and Improves Patient Risk Stratification. J Urol. 2022 Dec 30:101097 JU0000000000003126

[6] Tyson MD, Abouassaly R, Durant A, Smith AB, Seemann K, Shoskes DA. Budgetary Impact of Including the Urinary Genomic Marker Cxbladder Detect in the Evaluation of Microhematuria Patients. Urol Pract. 2024 Jan;11(1):54-60. doi: 10.1097/UPJ.0000000000000489. Epub 2023 Nov 1. PMID: 37914255.

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 suite of non-invasive genomic urine tests optimized for the risk stratification of urothelial cancer in patients presenting with microhematuria and those being monitored for recurrent disease. The tests help improve the overall patient experience, while prioritizing time and clinical resources to optimize practice workflow and improve efficiency.

Supported by over 20 years of research, Cxbladder's evidence portfolio extends to more than 25 peer reviewed publications, and Cxbladder Triage is now included in the American Urological Association's Microhematuria Guideline. To drive increased adoption and improved patient health outcomes, Cxbladder is the focal point of numerous ongoing and planned studies designed to generate further clinical utility evidence.

Cxbladder is available in the US, Australasia, and Israel and in markets throughout Asia and South America. In the US, the test has been used by over 5,000 urologists who have ordered more than 130,000 tests. In New Zealand, Cxbladder is accessible to around 70% of the population via public healthcare and all residents have the option of buying the test online.