10 September 2025

CMS RECOMMENDS US$1,328 PRICE FOR TRIAGE PLUS

DUNEDIN, New Zealand – Cancer diagnostics company Pacific Edge (NZX, ASX: PEB) notes today that the recommended final 'Gapfill' price for Cxbladder Triage Plus[1] has been published by the US Centers for Medicare & Medicaid Services (CMS) proposing a US$1,328.32 price – a higher price than the US$1,018 draft price proposed in April this year.

The CMS price sets the amount Pacific Edge will be reimbursed for all patients with Medicare and Medicare Advantage insurance for Triage Plus 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), but Pacific Edge is preparing to submit a reconsideration request for Triage Plus shortly after the publication of the DRIVE Study[2] that is currently in peer review.

Hematuria evaluation tests currently represent around 83% of Pacific Edge's total US laboratory throughput[3]. The US$1,328.32 price is a meaningful increase compared to the US$760 CMS price of our existing tests and compared to the $1,018 draft price proposed by MolDX in April. When coverage of Triage Plus is established, Pacific Edge will make migration from Triage to Triage Plus a priority, noting that Detect tests have already been migrated to Triage tests since the February 2025 inclusion of Triage in the American Urological Association's microhematuria guideline.

Pacific Edge Chief Executive Dr Peter Meintjes said: "We are very pleased that MolDX has recognized the novelty of Triage Plus in their pricing determination with an increase to $1,328.32 and that CMS has recommended this as a final price. 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

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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] 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.

[3] Half year to 30 September 2024.

characteristics[4] are used in our existing budget impact model[5] 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."

The CMS final price for Triage Plus is still subject to 60 days of notice and comment but is typically not expected to change, and is expected to become effective from 1 January 2026.

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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.

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[4] 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

[5] 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.

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.