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22 January 2025

PACIFIC EDGE RELEASES QUARTERLY VOLUMES FOR Q3 FY25

Cxbladder test volumes steady amid seasonal slow down

DUNEDIN, New Zealand – Cancer diagnostics company Pacific Edge (NZX, ASX: PEB) today announces tests processed at its laboratories in the three months to the end of December 2024 (Q3 25) were steady on the prior quarter (Q2 25).

Novitas' deliberations remained the overriding challenge to test volume growth, although the seasonal holiday slowdown also impacted volumes in the quarter. Against this, the addition of one FTE to the US sales team for the last month of the period, steady demand from our US customer Kaiser Permanente, the sustained benefits of our sales force efficiency gains, and an uplift in demand from the US clinicians most supportive of our tests diluted the impact of these factors.

Total laboratory throughput (TLT) in Q3 25 rose 0.7% to 7,092 tests from 7,042 tests in Q2 25[1]. US TLT was 5,808 tests up 2.2% on the 5,682 in Q2 25. Our sales force efficiency metric was 379 tests per sales FTE, flat on the prior quarter.

Tests per unique US ordering clinician (our preferred metric for measuring customer commitment to Cxbladder) was up 9.1% in Q3 25 to 7.0 compared to 6.4 in Q2 25, while unique ordering clinicians in the quarter fell to 834 down from 890 in Q2 25.

These trends reflect the ongoing impact of Medicare uncertainty and the sales force efforts to maximise demand from Cxbladder's strongest supporters. Asia Pacific volumes were down 5.6% to 1,284 tests from 1,360[1] in Q2 25, a move that largely reflected the seasonal holiday slowdown in New Zealand.

The Q3 25 investor update also provides a detailed analysis of the finalized 'Genetic Testing in Oncology: Specific Tests' (L39365) Local Coverage Determination released on Thursday 9 January, and Pacific Edge's response to it including:

1. Our determination to pursue a preliminary injunction if our efforts to negotiate a withdrawal or revision to the finalized LCD prove unsuccessful
2. The path the company has set to regaining reimbursement certainty and our confidence of achieving that goal

We also highlight the recent successes we have had contracting with the BlueCross Blue Shield network of health insurers to make our tests 'in-network, creating a new non-Medicare revenue stream in the US.

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

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[1] APAC test volumes for Q2 25 have been revised to 1,360 from the 1,363 reported in the October 2024 Investor Update.

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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 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.

PacificEdge

INVESTOR UPDATE

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JANUARY 2025

INSIDE

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LETTER FROM THE CEO

2025: Mounting a multifaceted challenge to a flawed LCD

Dear Shareholders,

Pacific Edge enters the New Year facing the loss of Medicare coverage of our Cxbladder tests, an outcome we had strenuously fought for more than two years to avoid.

Prior to Novitas[1] finalizing the draft 'Genetic Testing for Oncology' (DL 39365) on 9 January as a non-coverage determination under the new name 'Genetic Testing in Oncology: Specific Tests' (L39365), we believed we had mounted a compelling argument to retain our existing coverage arrangements.

However, in making its decision – one that has impacted other companies as well as Pacific Edge – Novitas has relied on its flawed understanding of how our tests are used in clinical practice (the risk stratification of patients presenting with hematuria). It has relied on a flawed review of the high quality peer reviewed evidence supporting the use of our tests. It also ignored the compelling new evidence that has emerged since it published the revised draft determination in July 2023 (our STRATA[2] study and new Analytical Validation data[3]) despite having been notified of the evidence and also stating in writing that it would incorporate that evidence in the review (see page 5).

Novitas' evidentiary review is particularly disappointing because it questions Pacific Edge's steadfast commitment to producing only the highest standard of clinical evidence. We are determined that this should not go unchallenged. As a matter of best practice, we have requested a review of Novitas' L39365 from an independent consulting medical director to provide an objective 3rd party analysis to consider that we will publish on our website and use as needed for internal and external purposes.

The new issues now evident through the finalization of the LCD, combined with the significant harm this determination could do to Pacific Edge, provide standing for a legal challenge and we have resolved to escalate should our attempts to negotiate a better solution fail.

Our goal is to retire the LCD and/or remove the non-coverage language of Cxbladder tests

Our goal is to retire the LCD and/or remove the non-coverage language of Cxbladder tests. We will seek to engage with Novitas' Medical Affairs, its parent company GuideWell and other stakeholders including the Centers for Medicare & Medicaid Services (CMS) and the US Department of Health and Human Services Office of the General Counsel (OGC).

As the test volumes we release today show (see page 4) the uncertainty over the draft LCD has significantly hampered our growth, principally because it has forced us to reduce investment in our commercial team to preserve capital in case of a decision such as the one we have now received. With Medicare accounting for circa 54% of our US commercial tests, this LCD has profound implications for the future of the business.

The LCD is a setback, but we continue to bill and expect to receive continued reimbursement from contracted US payers without interruption, notably Kaiser Permanente and the US Veterans Administration. Moreover we are receiving reimbursement from an increasing number of Blue Cross Blue Shield plans (see page 9), as well as non-contracted private payers in line with historic reimbursement rates. Meanwhile, we see many potential short and medium term developments, in addition to a successful legal challenge, that could catalyze progress towards our goal of establishing Cxbladder in clinical practice for bladder cancer diagnosis.

Principal among these is the American Urological Association's (AUA) ongoing review of its microhematuria guideline. This review, prompted by our STRATA study, has the potential to establish guideline inclusion supporting the use of Cxbladder in the evaluation of patients presenting with microhematuria. Guideline revisions are typically published as a peer-reviewed article in the AUA's Journal of Urology, which is released monthly, but would be available online immediately when accepted for publication. We would expect to leverage such inclusion in our ongoing conversations with CMS

[1] Novitas is the Medicare Administrative Contractor (MAC) charged by the centers for Medicare & Medicaid Services for making Medicare policy decisions in the region where our US laboratory is located.
[2] Lotan et al (2024). A Multicenter Prospective Randomized Controlled Trial Comparing Cxbladder Triage to Cystoscopy in Patients With Microhematuria. The Safe Testing of Risk for Asymptomatic Microhematuria Trial. J Urol 2024.
[3] Harvey et al (2024) Analytical Validation of Cxbladder® Detect, Triage, and Monitor: Assays for Detection and Management of Urothelial Carcinoma. Diagnostics. 2024; 14(18):2061.

and Novitas and, if necessary, will be used as part of a reconsideration request. Our STRATA study and the new analytical validation data we published in September will be used in a similar fashion will be used as part of a reconsideration request.

We remain confident that over the longer term that reliable reimbursement is a consequence of our clinical evidence generation program (see page 7) and the clinical evidence being generated externally. Notably, we are on track to submit the results of our DRIVE study for publication ahead of the AUA meeting in April, while Kaiser Permanente is also set to present real world evidence of Cxbladder Triage at the same meeting as a moderated poster (see page 8).

Importantly, we expect the DRIVE study, which is targeted at demonstrating the clinical validity of Cxbladder Triage Plus in a clearly defined patient population of micro and gross hematuria patients, to also provide the grounds for a reconsideration request. With the DRIVE study focused on demonstrating validity within a US veterans' population, it will also bolster our case for the Veteran's Administration - one of the largest healthcare providers in the US after Medicare and Medicaid - to include Cxbladder in its medical policy.

Longer term our CREDIBLE study – a randomized control trial aimed at demonstrating the clinical utility of Cxbladder Triage Plus, will seek to entrench Cxbladder in clinical practice. The study is gearing up to enroll its first patient in February 2025 after the meeting of the principal investigators at the Society of Urologic Oncology (SUO) Annual Meeting in Dallas, Texas in December 2024 (see page 8).

We thank you for your ongoing support as we drive these initiatives forward and work towards realizing the significant potential we see for Pacific Edge and Cxbladder.

We wish you a happy and productive start to the New Year and look forward to updating you on our progress.

Best regards

Dr Peter Meintjes
Chief Executive

TEST VOLUMES

Test volumes hold steady

Tests processed through Pacific Edge's laboratories in the three months to the end of December 2024 (Q3 25) were steady on the prior quarter (Q2 25) as we awaited clarity on Medicare coverage of our tests.

Novitas' deliberations remained the overiding challenge to test volume growth, although the seasonal holiday slowdown also impacted volumes in the quarter. Against this, the addition of one FTE to the US sales team for the last month of the period, steady demand from our US customer Kaiser Permanente, the sustained benefits of our sales force efficiency gains, and an uplift in demand from the US clinicians most supportive of our tests diluted the impact of these factors.

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[1] APAC test volumes for Q2 25 have been revised to 1,360 from the 1,363 reported in the October 2024 Investor Update.

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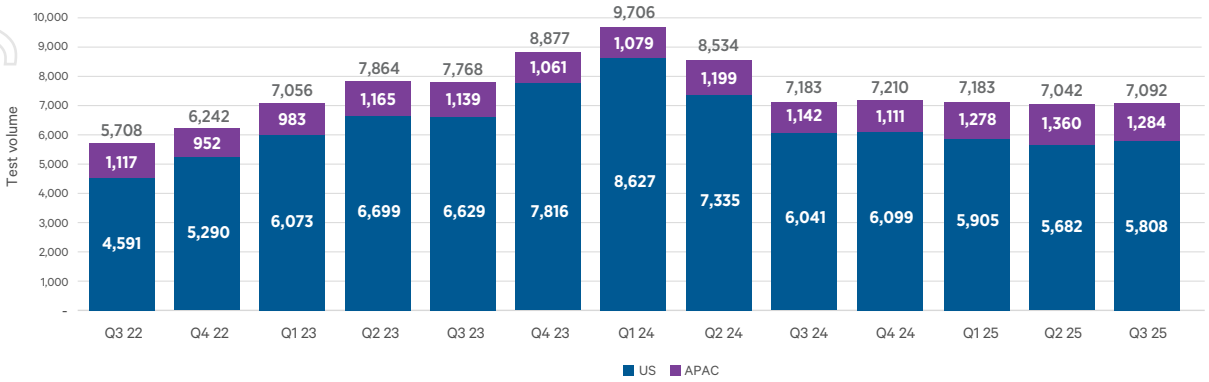
FIGURE 1: TOTAL TEST VOLUMES[1]



[1] Volumes in some prior quarters of FY24 are marginally different from those reported in earlier investor updates reflecting post period adjustments.

FIGURE 2: CXBLADDER CLINICAL ADOPTION

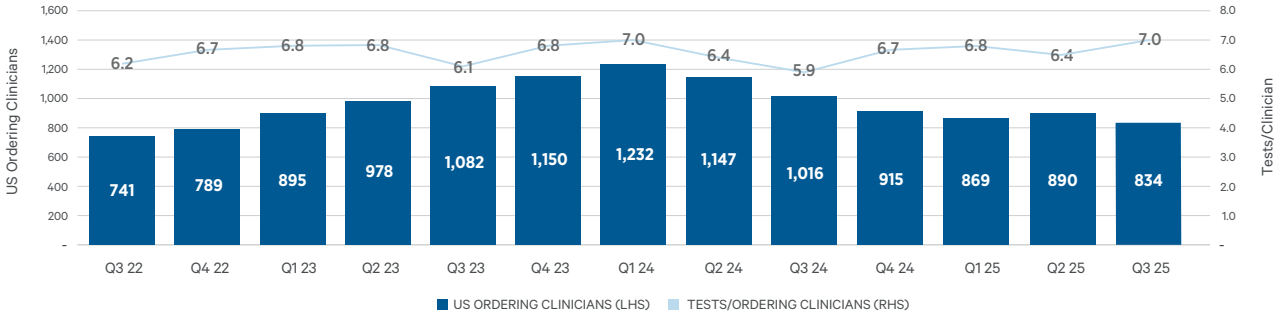
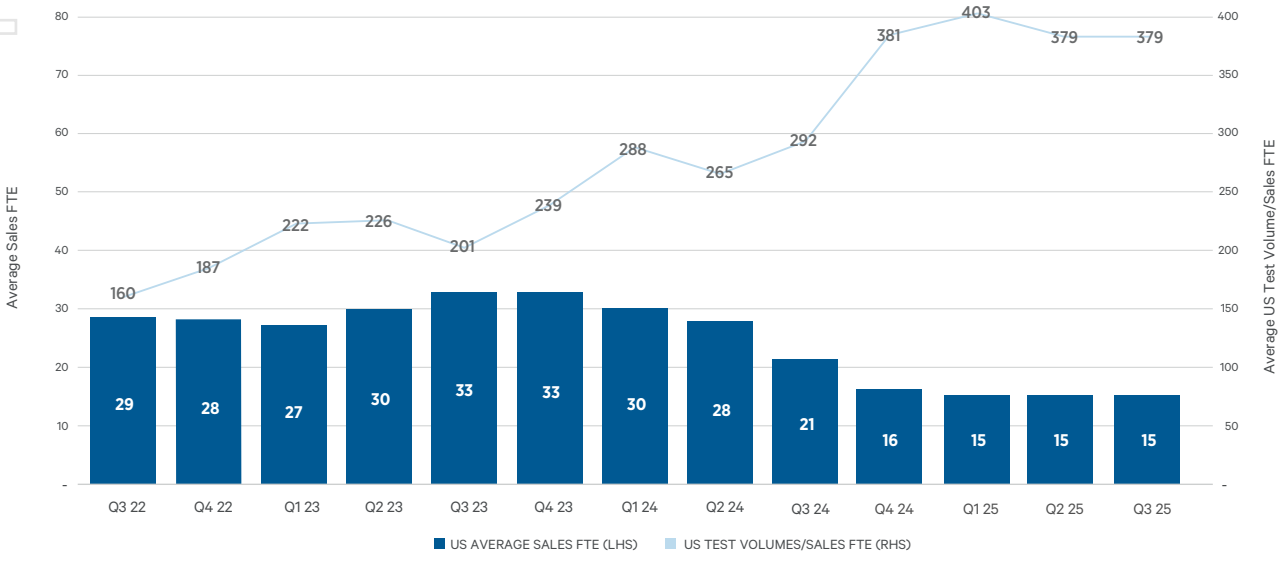


FIGURE 3: US SALES FORCE EFFICIENCY



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A FLAWED MEDICARE DETERMINATION

Novitas has followed a flawed process in finalizing the Genetic Testing in Oncology: Specific Tests" (L39365)' Local Coverage Determination. In making its decision it has also relied on its flawed understanding of how our tests are used in clinical practice (the risk stratification of patients presenting with hematuria), and its flawed review of the high-quality peer review evidence supporting the use of our tests.

A fundamental departure from the 'Genetic testing for oncology' draft

The 'Genetic Testing in Oncology: Specific Tests' (L39365)' LCD fundamentally departs from the structure of the draft 'Genetic Testing for Oncology' (DL 39365) determination.

It now amounts to an evidentiary review and a non-coverage determination of specific tests including Cxbladder. It no longer preemptively excludes tests that have not yet been commercialized and excludes the draft's reliance on third-party databases for Medicare coverage determinations.

Its conclusion that "Cxbladder [Triage, Detect and Monitor] are not reasonable and necessary to support positive outcomes in the management of bladder cancer" is meanwhile based on flawed assumptions and a misunderstanding of how our tests are integrated into clinical practice.

Specifically, it conflates hematuria evaluation with cancer screening, focusing on Cxbladder's low Positive Predictive Value (PPV) and its potential to deliver false positives rather than the clinical utility of our tests in risk stratifying patients into those that would benefit from a more invasive medical evaluation and those that would not.

It repeats its flawed analysis of the existing Cxbladder test evidence that conflates biomarker discovery with test development resulting in a substantial misunderstanding on the clinical validation of our tests. It also failed to consider new peer reviewed evidence supporting the use of Cxbladder published since the revised draft determination in July 2023, despite having been notified of the evidence and stating in writing that it would incorporate that evidence in the review.

This evidence included: the ground-breaking STRATA randomized control study published early last year, which demonstrated the Clinical Utility of Cxbladder Triage, and showed that clinicians substantially reduced the number of cystoscopies they undertook it they were able to use the results of the test in their evaluation. The analytical validation data of Cxbladder Detect, Triage and Monitor published in September 2024 was also ignored.

Seeking a fair hearing before pursuing legal action

Our immediate focus is to seek a negotiated revision or withdrawal of the finalized LCD, but we have resolved to escalate and seek immediate relief on the basis of the irreparable harm it will do to our business via a preliminary injunction in the US Federal District Court if our concerns are not heard and acted upon.

We are seeking immediate dialogue with Novitas and its parent company Guidewell over the significant shortcomings we see with the LCD. We are making similar representations to the Centers for Medicare & Medicaid Services (CMS) and its Coverage and Analysis Group, which develops national policies regarding Medicare coverage and oversees contractor performance and integrity of the Medicare Program.

We are also seeking to engage with the US Department of Health and Human Services (HHS) Office of the General Counsel (OGC), which serves as the chief legal advisor to the department and plays a crucial role in ensuring the lawful and effective operation of HHS programs, including those administered by CMS.

With these organizations we will highlight what we see as fundamental process errors in finalizing the LCD, in addition to our concerns over Novitas' misunderstanding of how Cxbladder is incorporated into clinical practice, the flaws in the LCD's evidentiary review, and the LCD's failure to consider new evidence.

We are hopeful that all parties involved in the process will seek an evidence-based outcome that respects established practice in urology, established definitions of screening by Medicare and the United States Preventative Services Task Force (USPSTF) and the logic of our views. However, if they do not, we have resolved to seek a preliminary injunction to the LCD based on these points and the fact that the finalized LCD will likely extinguish most demand for Cxbladder tests, hurting Medicare patients and physicians and in the process causing irreparable harm to Pacific Edge.

Delivering the clinical evidence policy makers require

Pacific Edge is at its heart an evidence-based organization. We rely on evidence in our scientific discovery and research.

Our research is focused on producing clinical evidence that is founded on the frameworks of Analytical Validity, Clinical Validity, and Clinical Utility in defined patient populations. We undertake our studies with sample sizes with the appropriate statistical power and a focus on endpoints that can change clinical practice, medical policy and patient outcomes. This framework will ultimately see our tests integrated into clinical guidelines and gain reimbursement.

The LCD makes a fundamental attack on the credibility of our research and the frameworks we use to guide it. In response we have requested a review of Novitas' L39365 from an independent consulting medical director to further expose its flaws. This will be published on our website and used in various market access activities.

We have already established a clinical evidence generation program to achieve our long term goals and it remains on track. In the absence of Novitas withdrawing the LCD, this evidence provides multiple opportunities for Pacific Edge to seek a reconsideration request for Medicare coverage.

Our first reconsideration request will include all previously unreviewed clinical evidence, including the STRATA Study and our Analytical Validation study of Triage, Detect and Monitor, both of which Novitas said it would consider as part of the evidentiary review but failed to do so. The DRIVE Study, which has been closed out and is targeted for publication in time for the AUA annual conference, coupled with an independent real world evidence of Triage's Clinical Utility from our US customer Kaiser Permanente will follow. These, as the table on the following page shows, are the immediate short term opportunities that should be sufficient to re-establish coverage, but the longer term program continues the approach to strengthen policy and guideline language for greater coverage certainty and improved reimbursement.

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Evidence to drive clinical practice change

Our clinical study program is at the foundation of Pacific Edge's value. We are focused on generating the compelling clinical evidence required to drive behavior change in physicians. Specifically, we seek to produce evidence that is founded on the frameworks of Analytical Validity, Clinical Validity, and Clinical Utility, with the endpoints and sample sizes required for coverage decisions and guideline inclusion.

STUDY	GOAL	POPULATION AND USE	STATUS
STRATA **S**afe **T**esting of **R**isk for **A**symptoma**T**ic Microhematuri**A**	• CU for Triage • CV/CU for Triage Plus (retrospective)	• Microhematuria (MH) • Risk stratification	- Recruitment closed with 555 patients including 223 low risk patients (test and control) with interim analysis results published in Journal of Urology - Monitoring for final analysis completed mid-Aug, some re-work needed. Database lock March 2025 and final Clinical Study Report (CSR) expected Sep 2025
DRIVE **D**etection and **R**isk stratification **I**n **VE**terans presenting with hematuria	• CV for Triage Plus for a Veterans' cohort • Data for MH pooled analysis	• MH and gross hematuria (GH) • Risk stratification	- Enrolment closed with 710 patients enrolled including 48 tumor confirmed patients (target was 45) from across 10 US VA sites - Database lock completed and publication submission expected by March 2025
microDRIVE **D**etection and **R**isk stratification **I**n **VE**terans presenting with microhematuria	• CV of Triage Plus • Data for MH pooled analysis	• MH • Detection	- Currently a decentralised study across all VAMCs coordinated through a single US VA Medical Center. Protocol amendment provides for addition of 4 more sites to increase enrolment - 447 patients have consented for the study with 224 samples received to date - The target is 1000 patients with 35 tumor confirmed patients - Last patient in is now projected to be Q3-2025
AUSSIE **A**ustralian **U**rologic risk **S**tratification of patient**S** w**I**th h**E**maturia	• CV of Triage Plus (Australian cohort) • Data for MH pooled analysis	• MH and GH • Risk stratification	- The target is 35 UC confirmed patients including a minimum of 10 MH patients - Currently 456 subjects enrolled with 29 UC confirmed including 5 MH patients - Last patient in projected to be Q2-2025
POOLED ANALYSIS	• CV of Triage Plus	• MH and GH • Risk stratification	- MH (and separately GH patient data where available) from DRIVE, AUSSIE and microDRIVE will be pooled and performance determined - Paper submission is one quarter after publication of DRIVE, microDRIVE and AUSSIE
LOBSTER **LO**ngitudinal **B**ladder cancer **S**tudy for **T**umor **R**ecurrence	• CV of Monitor and Monitor+	• Surveillance • Risk stratification	- Enrolment will be complete when 75 UC recurrences are observed across 10–15 sites - Enrolment is 413 subjects providing 810 samples with 48 UC recurrences observed to date and expected completion is Q3-2026
CREDIBLE **C**ystoscopic **RED**uction **I**n **BL**adder **E**valuations for microhematuria	• CU of Triage Plus	• MH • Risk stratification	- Protocol IRB approved for 14 and contracts finalized for 6 of expected 15 sites - Interim analysis will occur at 600 to determine if incidence is <5% and if so will continue until 1000 are enrolled - Enrolment due to commence February 2025

*Quarterly dates are calendar year not financial years

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Triage Plus clinical utility study on the launch pad

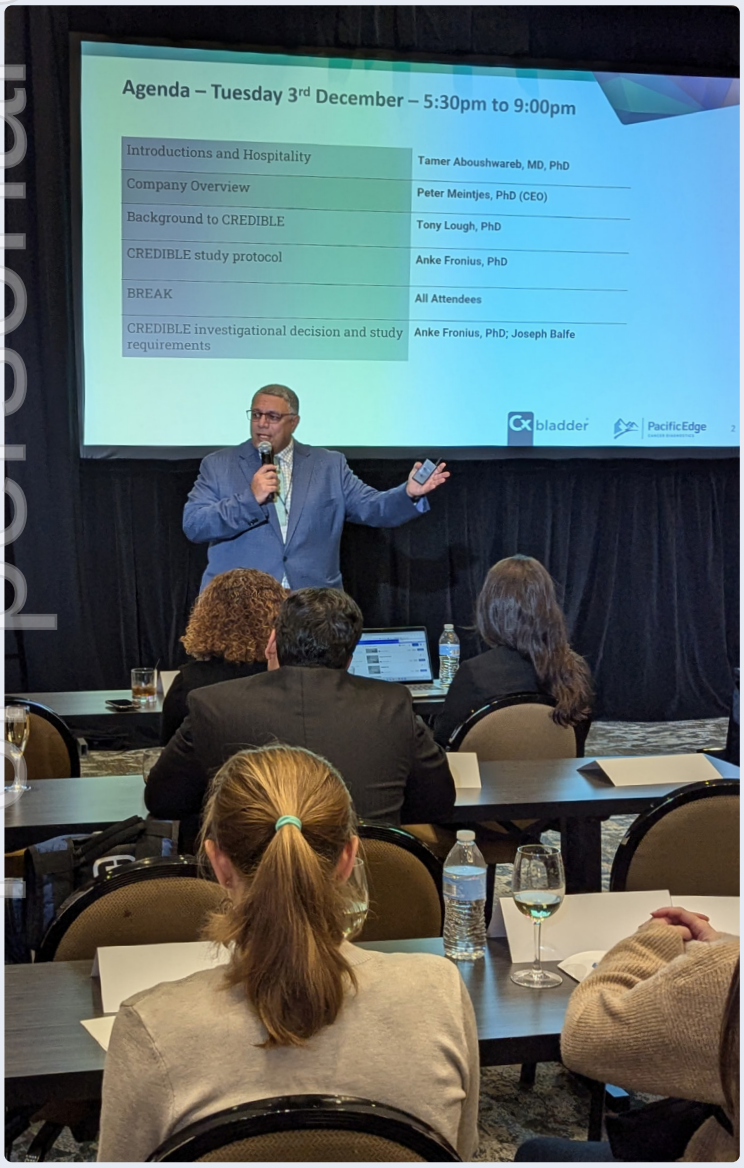
Pacific Edge is set to commence the CREDIBLE study next month following a meeting of the principal investigators at the Society of Urologic Oncology (SUO) Annual Meeting in Dallas, Texas in early December.

CREDIBLE aims to demonstrate the clinical utility of Cxbladder Triage Plus in evaluating patients with microhematuria, focusing on reducing unnecessary cystoscopies while maintaining diagnostic accuracy. Its team of principal investigators includes 15 urologists, including 5 from leading universities across the US and the remainder from community urological centers.

The SUO conference, a key event for professionals in urologic oncology, offered an opportunity for the investigators to review the study's protocol and timeline and align themselves on study goals and execution strategies.

The study is a randomized control trial, targeting the enrolment of 1,000 participants, with an interim analysis after 600 participants with final outcomes anticipated by late 2025. It is designed to generate high-quality evidence of the test's clinical utility sufficient to influence standard of care guidelines, healthcare payer medical and reimbursement policies, and specialist clinical practice.

CREDIBLE is a prospectively enrolled randomized clinical trial: one group is assessed using the American Urological Association (AUA) Standard of Care guidelines, and the other using Cxbladder Triage Plus. The eligible patient population include those presenting with microhematuria. Key endpoints include comparing cystoscopy rates and tumor detection outcomes between the two groups.



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BCBS AGREEMENTS TO SUPPORT NON-MEDICARE REVENUE

Pacific Edge has signed commercial contracting agreements with Blue Cross Blue Shield of Texas (BCBSTX), Blue Cross Blue Shield of Illinois (BCBSIL) and Wellmark (a BCBS entity covering Iowa and South Dakota), granting the company 'in-network' status.

The contracts will increase the certainty of payment to Pacific Edge at the allowed price for Cxbladder tests performed on patients covered by the insurer and provide an alternative revenue stream in the absence of coverage policy with Medicare and Medicare Advantage.

Blue Cross Blue Shield of Texas (BCBSTX) is the largest health benefits provider in Texas, covering nearly eight million members. BCBSIL is the largest commercial carrier in the state of Illinois covering 8,380,136 lives. Nationally, BCBS and its affiliates provide coverage for 115 million members in all 50 US states as well as Washington DC, and Puerto Rico.

The agreement establishes a contracted price for Cxbladder tests that BCBSTX, BCBSIL and Wellmark will pay Pacific Edge (less a small processing fee) rather than establishing an 'allowable' that typically does not benefit Pacific Edge. These are the first agreements with state-wide plans following the Master agreement the company established with the BCBS Group Purchasing Organization in August 2024, which defined an agreed process for payment of Cxbladder tests.

The success of the negotiations with BCBSTX, BCBSIL and Wellmark reflects the effectiveness of clinical utility data from our STRATA study, a prospectively enrolled randomized clinical trial that demonstrated Cxbladder's clinical utility in helping clinicians to safely and more effectively risk-stratify low-risk hematuria patients when compared to AUA guidelines. For healthcare payers, the study highlighted the benefits of using Cxbladder to improve patient care and optimize resource use.

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Cxbladder Triage Plus

CMS CENTERS FOR MEDICARE & MEDICAID SERVICES

TRIAGE PLUS COMMERCIALIZATION

CMS confirms Gapfill to price Triage Plus

The Centers for Medicare and Medicaid Services (CMS) has affirmed it will follow a Gapfill process to price Cxbladder Triage Plus, the company's second generation Cxbladder test for hematuria evaluation. The CMS price for Triage Plus sets the amount Pacific Edge will be reimbursed for all patients with Medicare and Medicare Advantage insurance.

CMS agreed with the Pricing Panel that Gapfilling Triage Plus was more appropriate given its view that there were no suitable crosswalk candidates in the current CMS Clinical Lab Fee Schedule. Gapfill requires all Medicare Administrative Contractors to recommend an initial price each year in April, and to follow a notice and comment process that is only finalized in late November.

We continue to focus on preparing our US laboratory for running Triage Plus at scale and will work with Novitas on provisional pricing for Triage Plus to ensure that a Gapfill recommendation is not limiting our ability to launch the new test with reliable reimbursement. We remain confident Triage Plus will achieve a price that will deliver a greater margin both in nominal and percentage terms than the current generation of products, underpinning our drive towards long-term financial sustainability.

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ABOUT US

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.

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