The Cxbladder Bulletin

Dear Customers and Friends of Cxbladder,

Welcome to the December 2023 edition of the Cxbladder Bulletin. In this issue:

Kaiser Permanente EMR Integration Goes Live

In November, we were pleased to announce the launch of the integration of Cxbladder tests within HealthConnect - the Electronic Medical Records (EMR) system of Kaiser Permanente.

The integration, which has gone live within all 15 urology medical centers of the Southern California Permanente Medical Group (Kaiser Permanente SoCal), is a significant improvement to patient access for Cxbladder with sample collection at Kaiser facilities and offers electronic management of test ordering and resulting for simpler patient care.

Kaiser Permanente urologists can now electronically order Cxbladder Triage for patients referred for hematuria evaluation and Cxbladder Monitor for those under surveillance for the recurrence of bladder cancer, based on pre-specified patient types agreed by Kaiser Permanence SoCal's Urology Section Chiefs. Results are returned directly to a patient's EMR.

Following a test ordered through the EMR, patients will be able to have their urine samples collected at 29 separate facilities where Kaiser Permanente staff are being trained on sample collection and stabilization to ensure samples received in the lab are of the highest quality. Additionally, Cxbladder urine collection kits will be stored at each of these facilities and managed by site-specific logistics and restocking processes to optimize needs-based availability of Cxbladder kits for optimized operations.

The integration of Cxbladder into these pathways, according to a Kaiser Permanente study, could allow the organization to safely avoid more than 70% of these examinations, saving money, reducing waitlists, reducing unnecessary time in the operating room and sparing the vast majority of patients with symptoms, but without cancer from the risks and discomfort of the invasive procedure[1].

Pacific Edge Chief Executive Dr Peter Meintjes says: “We are excited to have completed this important partnership together with Kaiser Permanente – a project that spanned many teams and many person-hours across the Kaiser system, our team in the US, and our team in New Zealand. The patients of Kaiser Permanente SoCal will be among the first in the US to benefit from a standardized clinical approach to hematuria evaluation and monitoring for the recurrence of bladder cancer.”

Dr Meintjes noted that this milestone indicates the commitment to a standard clinical pathway and represents a significant opportunity to optimize the evaluation and management of bladder cancer.

Dr Eugene Rhee, MD MBA, National Chair of Urology for Kaiser Permanente and Regional Chief of Urology for The Southern California Permanente Medical Group, said Cxbladder tests have greatly improved Kaiser Permanente’s ability to safely work up and provide surveillance to a highly vulnerable population of patients.

“In addition, these tests have improved access to urology care. The very high negative predictive value of the Cxbladder tests have allowed us to improve access by safely reducing overwhelming demand for hematuria evaluation and surveillance cystoscopy. It’s proven to be a quadruple win: convenient and preferred by our members, high quality - reliable results, adding additional capacity for the organization, and a sustainable way to improve the wellbeing of our healthcare teams,” Dr Rhee said.

“For our members this means fewer invasive, uncomfortable, and time-consuming cystoscopies and timely and efficient diagnosis. With the system integration complete we are now well positioned to roll out Cxbladder tests across our network. We are delighted with the way the Kaiser Permanente and Pacific Edge teams have worked together and look forward to building on this relationship in the future.”

[1] AUA, LUGPA, AACU Joint Response to Novitas DL 39365.

Published Economic Model Demonstrates Significant Savings for Healthcare Payers

A budget impact model on the health economics of Cxbladder Detect has now been published in the American Urological Association (AUA) Journal "Urology Practice"

The model shows that routine use of Cxbladder offers healthcare payers substantial savings for the evaluation and treatment of patients presenting to clinicians with microhematuria.

The budget impact model for Cxbladder Detect, developed by Pacific Edge, and authors from the Mayo Clinic, Cleveland Clinic, and independent healthcare consultancy Coreva using national average data, has demonstrated median savings of $559 in direct costs per patient.

View the Study Abstract on PubMed.

Video: The Promise, Potential, and Practicality of Cxbladder in Modern Urologic Oncology

Host Dr Zach Klaassen and the Mayo Clinic's Dr Mark Tyson discuss the economic and clinical outcomes of incorporating Cxbladder into diagnostic pathways. View the video on UroToday.

Medicare Coverage Update

Cxbladder remains a covered test as we continue to wait for a decision

Leading US Urological Societies called for a revision of LCD (DL39365) as the comment period concluded in early September. Our representations to Novitas were strongly supported by the leading professional societies in urology - the American Urological Association (AUA), the Large Urology Group Practice Association (LUGPA) and the American Association of Clinical Urologists (AACU) – and by our industry partners, the Coalition for 21st Century Medicine (C21), the American Clinical Laboratory Association (ACLA) and by many other key urologic opinion leaders.

Novitas must now consider and respond publicly to all of the comments presented during the notice and comment period. The MAC has given no indication on when it is likely to finalize the LCD, but it is statutorily required to do so (or withdraw the LCD) within 365 days of the original publication date. An LCD becomes effective 45 days after it is finalized.

The presentations given at the open meetings and details of written submissions are available on our website.

An Update From SUO 2023

Thanks to all of those that took the time to speak with us at the SUO Annual Meeting in Washington DC two week ago. As always there was plenty of productive and informative discussion, with bladder cancer and molecular markers both popular topics of conservation.

While our Field Representatives managed a booth in the main hall, our Medical Affairs Team used the event to run several planning meetings and an Advisory Board focused on confirming the protocol for our upcoming CREDIBLE study. CREDIBLE (**C**ystoscopic **RED**uction In **BL**adder **E**valuations for Microhematuria) is a randomized, controlled study designed to demonstrate the clinical utility of Cxbladder Detect^{+} (CxbD^{+}) in a microhematuria population.

By adding DNA biomarkers, we have developed CxbD^{+} as a next generation Cxbladder test and single product for hematuria evaluation that extends best in class performance, increasing the rate of urothelial cancer rule out in patients presenting with microhematuria. CxbD^{+} is the first combined RNA and DNA biomarker test for the rule out of bladder cancer.

Practical Guidelines: Cxbladder In-Clinic Sampling Process

Cxbladder is an advanced genomic test that analyses biomarker genes to help rule out urothelial cancer. To help ensure a high-quality sample reaches our laboratory it's important to keep the following points in mind during sample collection.

- Voided urine only (2nd void or later preferred)
- The sample must be from a natural bladder
- You must collect urine in the Cxbladder cup
- Please transfer to Cxbladder tube as soon as possible, preferably within 15 minutes
- Please ensure there's no visible blood in the urine sample
- No dip sticks or fixative in the Cxbladder urine sample please

To learn more, we invite you to watch this video which demonstrates the in-clinic sampling process.

Cxbladder®

Wishing you
Happy Holidays
and a wonderful
New Year!

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