

From: David Sosa | Pacific Edge <david.sosa@pacifiedgedx.com>

Sent: Friday, November 7, 2025 8:31 AM

To: Medical Affairs <MedicalAffairs@guidewellsource.com>

Cc: David Sosa | Pacific Edge <david.sosa@pacifiedgedx.com>

Subject: New LCD Request-Use of urinary molecular biomarkers for patients with hematuria being evaluated for bladder cancer

Good afternoon.

This is a formal request for the establishment of a new local coverage determination for the use of urinary molecular biomarkers for patients with hematuria that are being evaluated for bladder cancer.

This request is coming from Pacific Edge Diagnostics USA LTD, an ancillary healthcare provider located in Hummelstown PA.

The request is being submitted in writing and includes the language that is being requested for this new LCD.

Attached we have included the evidence and sources of information that support our request, including medical literature that has not been reviewed by the contractor in the past.

This email includes 5 attachments:

- New Local Coverage Determination request for the establishment of a benefit for Medicare recipients to include coverage for the use of molecular urinary biomarkers indicated for patients presenting with hematuria that are being evaluated for bladder cancer.
- Harvey JC, Cambridge LM, Ellen CW, Colonval M, Hazlett JA, Newell J, Zhou X, Guilford PJ. Analytical Validation of Cxbladder® Detect, Triage, and Monitor: Assays for Detection and Management of Urothelial Carcinoma. *Diagnostics (Basel)*. 2024 Sep 17;14(18):2061. doi: 10.3390/diagnostics14182061. PMID: 39335740; PMCID: PMC11431456.
- Harvey JC, Fletcher D, Ellen CW, Colonval M, Hazlett JA, Zhou X, Newell JM. Analytical Validation of the Cxbladder® Triage Plus Assay for Risk Stratification of Hematuria Patients for Urothelial Carcinoma. *Diagnostics (Basel)*. 2025 Jul 8;15(14):1739. doi: 10.3390/diagnostics15141739. PMID: 40722489; PMCID: PMC12293762.
- Lotan Y, Daneshmand S, Shore N, Black P, Scarpato KR, Patel A, Lough T, Shoskes DA, Raman JD. 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 Jul;212(1):41-51. doi: 10.1097/JU.0000000000003991. Epub 2024 May 3. PMID: 38700731.

- Savage SJ, Ercole CE, Hemstreet G, Leone A, Masterson T, McWilliams G, Risk M, Schroeck FR, Stratton K, Lough T, de Lange M, Sakamoto K. Diagnostic performance of Cxbladder Triage Plus for the identification and stratification of patients at risk for urothelial carcinoma: The multicenter, prospective, observational DRIVE study. Urol Oncol. 2025 Oct 31:S1078-1439(25)00405-3. doi: 10.1016/j.urolonc.2025.10.008. Epub ahead of print. PMID: 41176469.

Thank you for your consideration.

Respectfully,

David

David Sosa

VP Market Access & Reimbursement | [Pacific Edge Diagnostics USA Ltd](#)

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