American Urological Association

June 13, 2025

Office of the Contractor Medical Director
Novitas Solutions
Medical Affairs Department
2020 Technology Parkway, Suite 100
Mechanicsburg, PA 17050

RE: Reconsideration Request for LCD L39365 – Genetic Testing for Oncology
Submitted Electronically to medicalaffairs@guidewellsource.com on June 17, 2025

Thank you for meeting with us on March 28, 2025 to discuss LCD L39365. We appreciate the collaboration with you and look forward to working with Novitas to craft an LCD that will give Medicare beneficiaries access to genetic testing. As discussed during the meeting, we are submitting this formal reconsideration request for LCD L39365.

The AUA is a globally engaged organization with more than 22,000 physicians, physician assistants, and advanced practice nursing members practicing in more than 100 countries. Our members represent the world's largest collection of expertise and insight into the treatment of urologic disease. Of the total AUA membership, more than 15,000 are based in the United States and provide invaluable support to the urologic community by fostering the highest standards of urologic care through education, research, and the formulation of health policy.

The AUA is submitting a **reconsideration request for LCD L39365 - *Genetic Testing for Oncology* to be revised to include:**

1. **Coverage for urinary biomarker tests for the evaluation of microhematuria**, especially as initial evaluations including imaging or cytology can be inconclusive.
2. **Urinary biomarker tests for risk stratification to determine the necessity of invasive diagnostic procedures.** Recent evidence and updated clinical guidelines support the clinical utility of these tests in evaluating patients with suspected urothelial carcinoma.

Headquarters

Michael T. Sheppard, CPA, CAE
Chief Executive Officer

1000 Corporate Boulevard
Linthicum, MD 21090

U.S. Toll Free: 1-866-RING-AUA (1-866-746-4282)
Phone: 410-689-3700
Fax: 410-689-3800
Email: AUA@AUAnet.org
Websites: AUAnet.org
UrologyHealth.org
UrologicHistory.museum

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Updated Clinical Guidelines
The AUA recently updated its guidelines in February 2025 to incorporate new evidence that supports the use of certain urinary biomarker tests in the evaluation of microhematuria. The updated guideline includes recommendations that in appropriately counselled intermediate risk microhematuria patients, biomarker testing is appropriate as an alternative to immediate cystoscopy. The new guideline, Updates to Microhematuria: AUA/SUFU Guideline (2025), is attached to this request and includes a list of biomarkers recommended for testing.

The AUA Guidelines Committee engages in a thorough process which includes a review of all available published literature and the extensive clinical experience of Guidelines Committee members. The AUA Guidelines provide a recommendation that promotes the highest level of urologic patient care supported by published evidence. Urologists look to the AUA Guidelines to manage patient care; therefore, it is imperative that reimbursement policy accurately reflects established clinical guidelines.

Clinical Utility of Urinary Biomarkers and Impact on Value-Based Care
Urinary biomarker tests have shown strong clinical value in helping stratify a patient's risk for urothelial carcinoma, supporting more informed decisions about whether invasive procedures like cystoscopy are truly necessary. By identifying risk earlier and more accurately, these tests can lead to timelier diagnoses and better outcomes for patients.

Ensuring access to and coverage of these tools is critical to improving patient care. Biomarkers represent a smart, targeted approach to diagnostics—allowing clinicians to detect disease in patients with microhematuria more efficiently while reducing the need for invasive procedures in low-risk cases. Their use reflects the principles of value-based care: improving clinical precision, reducing unnecessary interventions, and optimizing resource use.

Real-World Validation: *The Kaiser Permanente Southern California Study*

The STRATA: Safe Testing of Risk for Asymptomatic Microhematuria trial in partnership with Kaiser Permanente Southern California, compared the standard-of-care evaluation for microhematuria in which patients were offered cystoscopy and imaging as compared to a biomarker strategy. Among 3,353 matched patients, Cxbladder Triage reduced cystoscopy rates in low-risk patients from 46.5% to just 3.8%, without compromising cancer detection (0.6% vs 0.7%). In higher risk patients, Cxbladder results increased appropriate cystoscopy use (73.4% with test vs 45.7% without the test), enhancing targeted diagnostic prediction.

Due to this study, Kaiser Permanente avoided 952 unnecessary cystoscopes and 70 CT urograms, contributing to safer patient experiences and reduced exposure to radiation The STRATA randomized controlled trial found that using the Cxbladder Triage test reduced cystoscopy use by 59% in low-risk patients without compromising diagnostic accuracy. With a 99% negative predictive value, biomarker testing improves triage, minimizes patient burden, and lowers overall healthcare costs. CxBladder enables non-invasive genomics-based risk assessments to stratify patients with microhematuria; the test addresses overuse in low-risk groups while maintaining detection efficacy for urothelial cancer – an optimal balance of quality, safety, and resource stewardship. This aligns with Kaiser Permanente's strategy and urologists' goals to deliver high-value care through appropriate diagnostic intensity. Cxbladder enables precision triage, improving

operational efficiency in urology by: 1). Reducing procedural backlog, 2). Prioritizing high-risk cases, and 3). Minimizing invasive diagnostics in low-yield populations. Tests such as Cxbladder, reduces disparities in access and evaluation – especially in women and minorities who frequently face underdiagnosis and delays.

Sustaining Access to Urologic Care Through Diagnostics

Integrating urinary biomarkers into the diagnostic pathway also helps address long-standing workforce challenges in urology. With uneven provider distribution, rising demand for urologic services, and persistent workforce shortages, it's more important than ever to optimize how and where specialist resources are used. Coverage for efficient, noninvasive tools like biomarkers allows urologists to triage more effectively, focusing attention on patients who most need in-depth or urgent care.

This kind of resource allocation is critical to maintaining timely access to care, particularly for Medicare patients in rural and underserved communities where delays in diagnosis can have serious consequences.

The AUA strongly urges Novitas Solutions to reconsider the current limitations of LCD L39365 and incorporate coverage for urinary biomarker tests in the evaluation of microhematuria. Utilizing these types of biomarker tests can lead to earlier detection of cancers, potentially improving patient outcomes with timely intervention. Access to and coverage of these tests is critical to improve patients' health and wellbeing. This revision will align the LCD with current clinical guidelines and practice, enhancing patient care.

If you have any questions, please contact Bhavika Patel, Physician Payment and Reimbursement Manager, at bpatel@auanet.org.

Mark Edney, MD, MBA
Chair, AUA Public Policy Committee

Attachments:
AUA Guidelines
STRATA Study