Veracyte Secures Medicare Coverage for TrueMRD Monitoring Test in Muscle-Invasive Bladder Cancer

May 15, 2026

Marks the first Medicare coverage decision for Veracyte's whole-genome sequencing-based TrueMRD platform and launch of the first test

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--May 15, 2026-- Veracyte, Inc. (Nasdaq: VCYT), a leading cancer diagnostics company, today announced that its TrueMRD Monitoring Test has received coverage from the Centers for Medicare & Medicaid Services' (CMS) Molecular Diagnostics Services Program (MolDX) for patients with muscle-invasive bladder cancer (MIBC). The TrueMRD Test is covered for recurrence monitoring following definitive treatment with curative intent in patients with MIBC. It will be available for clinicians to order on June 1, 2026, marking the commercial launch of Veracyte's first minimal residual disease (MRD) offering and the only commercially available truly whole-genome MRD test to come to market, expanding the company's reach into cancer recurrence monitoring.

"Securing Medicare coverage and launching our first TrueMRD Test are significant milestones for Veracyte and important steps in enabling access to our MRD testing platform," said Marc Stapley, Veracyte's chief executive officer. "This decision validates the clinical utility of our TrueMRD testing approach and the rigor of our whole-genome sequencing MRD workflow while also positioning us to support clinicians with earlier detection of recurrence and more informed treatment decisions for patients with muscle-invasive bladder cancer. We see tremendous opportunity to expand our TrueMRD platform across multiple cancer types over the coming years."

Bladder cancer is the sixth most common cancer in the United States with an estimated 85,000 people expected to be diagnosed each year.[1] MIBC accounts for approximately 25% of all new bladder cancer diagnoses and carries a worse prognosis than non-muscle-invasive disease. [2] Up to half of MIBC patients experience recurrence within two years of initial treatment.[3] Current surveillance relies primarily on imaging, which may not detect recurrence until the disease has significantly progressed.

Veracyte's TrueMRD platform is supported by expanding clinical evidence, including PAGER, a pivotal prospective study published in *European Urology* that evaluated over 900 blood and tissue samples from 112 patients with MIBC treated with neoadjuvant chemotherapy and radical cystectomy. In this study, the TrueMRD MIBC Test detected disease recurrence a median of 131 days earlier than imaging. The TrueMRD platform is being used in significant ongoing research in MIBC, including the TOMBOLA trial, which is evaluating ctDNA-guided use of adjuvant immunotherapy with check point inhibitors, and the NEO-BLAST trial, which aims to spare patients from unnecessary surgery. This innovative study investigates whether MIBC patients who have no remaining cancer after neoadjuvant therapy can safely opt for active surveillance rather than immediate radical cystectomy.

"Surveillance for muscle-invasive bladder cancer relies heavily on imaging right now, which has real limitations in detecting early recurrence. A whole-genome MRD test that can help identify disease recurrence, often months before imaging, gives clinicians a powerful new tool," said Matthew Galsky, M.D., Professor of Medicine, Icahn School of Medicine at Mount Sinai and Deputy Director, Mount Sinai Tisch Cancer Center. "The expanding clinical evidence behind Veracyte's MRD platform is compelling, and Medicare coverage brings this test to patients at a pivotal time when the landscape of treatment for muscle-invasive bladder cancer is rapidly changing with the development of more effective systemic therapies and expanding bladder-sparing approaches."

Unlike approaches that track a limited set of genetic targets, TrueMRD analyzes patient-specific tumor variants across the entire genome in every sample tested. This whole-genome, tumor-informed approach has the potential for tracking tumor clonality and molecular evolution longitudinally, which may be especially important for patients who initially respond to therapy but then experience recurrent disease.

For more information on Veracyte's TrueMRD Monitoring Test for patients with MIBC, visit https://www.veracyte.com/tests/truemrd-mibc/.

About Veracyte

Veracyte (Nasdaq: VCYT) is a global diagnostics company with a vision to transform cancer care for patients around the world. The company's molecular tests assess the unique biology of each patient's tumor to help clinicians answer essential questions about cancer care. Veracyte's Diagnostics Platform combines broad genomic and clinical data, advanced bioinformatics and AI, and a powerful evidence-generation engine to support continued innovation and pipeline development. The company's portfolio includes the Afirma® Genomic Sequencing Classifier test, Decipher® Bladder Genomic Classifier test, Decipher® Prostate Genomic Classifier test, Prosigna® Breast Risk of Recurrence test, and the TrueMRD™ Monitoring Test for MIBCFor more information, visit Veracyte's website or follow the company on LinkedIn or X (Twitter).

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements, including, but not limited to statements regarding the potential impact, adoption, and benefits of Veracyte's TrueMRD Platform; the ability of the TrueMRD Platform to support earlier detection of recurrence and more informed treatment decisions for patients with MIBC; the potential expansion of the TrueMRD Platform across multiple cancer types; and Veracyte's plans to commercially launch the TrueMRD Monitoring Test for MIBC. Forward-looking statements can be identified by words such as: "appears," "anticipate," "intend," "plan," "expect," "believe," "should," "may," "will," "enable," "positioned," "offers," "designed," "ultimately," and similar references to future periods. Actual results may differ materially from those projected or suggested in any forward-looking statements. These statements involve risks and uncertainties, which could cause actual results to differ materially from our predictions. Additional factors that may impact these forward-looking statements can be found under the caption "Risk Factors" in our Annual Report on Form 10-K filed on February 26, 2026, as well as in other documents that we may file from time to time with the Securities and Exchange Commission. Copies of these documents, when available, may be found in the Investors section of our website at investor.veracyte.com. These forward-looking statements speak only as of the date hereof and, except as required by law, we specifically disclaim any obligation to update these forward-looking statements or reasons why actual results might differ, whether as a result of new information, future events or otherwise.

References

1. National Cancer Institute, Surveillance, Epidemiology and End Results (SEER) Program. *SEER Cancer Stat Facts: Common Cancer Sites.* https://seer.cancer.gov/statfacts/html/common.html
2. Attanasio G, et al. *Histological and immunohistochemical approaches to molecular subtyping of muscle-invasive bladder cancer.* Frontiers in Oncology. 2025.
3. Esteban-Villarrubia J, et al. Current and Future Landscape of Perioperative Treatment for Muscle-Invasive Bladder Cancer. Cancers (Basel). 2023;15(3):566.

View source version on businesswire.com: https://www.businesswire.com/news/home/20260515626790/en/

Investors:
Kelly Gura
investors@veracyte.com

Media:
Molly Cornbleet
media@veracyte.com

Source: Veracyte, Inc.