



BillionToOne Announces Medicare Coverage for Northstar Select®

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MENLO PARK, Calif., April 16, 2025 /PRNewswire/ -- BillionToOne, a molecular diagnostics company with a mission to create powerful and accurate tests that are accessible to all, announced today that its comprehensive genomic profiling assay Northstar Select® has met Medicare coverage criteria established by Palmetto GBA, a Medicare administrative contractor that administers the Molecular Diagnostics Services program (MoIDx). This coverage, which is effective as of February 14, 2025, ensures Medicare beneficiaries will have access to BillionToOne's liquid biopsy test for cancer therapy selection.

Northstar Select® is an ultra-sensitive, 84-gene next-generation sequencing (NGS)-based ctDNA panel that helps oncologists identify genomic alterations in patients with advanced solid tumors to guide therapy selection. This non-invasive, blood-based test incorporates BillionToOne's patented Quantitative Counting Template™ (QCT™) technology, which enables single-molecule detection and quantification. The comprehensive panel interrogates guideline-recommended alterations and covers 82 genes for SNVs/indels, 19 for copy number amplification, 5 for copy number loss, and 9 for fusions, while also providing microsatellite instability (MSI) status. Designed for any late-stage solid tumors, it offers exceptional sensitivity that detects clinically actionable alterations at levels much lower than other conventional liquid biopsy tests.

"Receiving Medicare coverage for Northstar Select® represents a significant milestone and advancement in making the latest precision oncology tools more accessible to patients who need it most," said Oguzhan Atay, Ph.D., Co-Founder and CEO of BillionToOne. "This coverage further supports the clinical utility of our technology and will help ensure that more patients with advanced cancer can benefit from uncovering more personalized treatment approaches."

The MoIDx approval follows rigorous review of evidence demonstrating the test's analytical validity, clinical validity, and clinical utility. Notably, the clinical validation data submitted as part of the MoIDx evaluation included a head-to-head concordance study, which demonstrated the superior sensitivity of Northstar Select over other commercially available liquid biopsy tests by identifying 51% more

clinically actionable alterations, most of which were found below the comparator assays' 95% limit of detection.¹ Medicare coverage will apply to eligible beneficiaries with advanced solid tumors who meet the coverage criteria outlined in the MoIDx local coverage determination (L38043).

"We believe Northstar Select[®] offers unique advantages in the field of precision oncology," said Gary Palmer, Chief Medical Officer, Oncology at BillionToOne. "Our QCT[™] technology enables best-in-class sensitivity and precision, enabling oncologists to make more informed treatment decisions by potentially uncovering more clinically actionable alterations that may be missed by other tests."

Northstar Select[®] is part of BillionToOne's growing oncology portfolio, which also includes Northstar Response[®], a tissue-free, methylation-based test designed for monitoring treatment response in patients with advanced cancers. Together, these tests provide oncologists with powerful tools for both therapy selection and treatment monitoring through non-invasive liquid biopsies.

For more information about Northstar Select[®] and Northstar Response[®], visit northstaronc.com.

About BillionToOne

Headquartered in Menlo Park, California, BillionToOne is a precision diagnostics company on a mission to make molecular diagnostics more accurate, efficient, and accessible for all. The company's single-molecule NGS (smNGS) platform, which includes the patented Quantitative Counting Template (QCT) technology, is the only multiplex methodology that can accurately count DNA molecules at the single-molecule level. For more information, please visit

www.billiontoone.com.

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¹ Xavier Bower et al., Clinical validation of Northstar Select, a novel liquid biopsy assay for comprehensive genomic profiling of solid tumors. JCO 42, 3072-3072(2024).DOI:10.1200/JCO.2024.42.16_suppl.3072

SOURCE BillionToOne