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June 18, 2021

Natera Awarded Advanced Diagnostic Laboratory Test (ADLT) Status for its Signatera® MRD Test From CMS

AUSTIN, Texas, June 18, 2021 /PRNewswire/ — Natera, Inc. (NASDAQ: NTRA), a pioneer and global leader in cell-free DNA testing, today announced that the Centers for Medicare & Medicaid Services (CMS) has granted ADLT status for the Signatera molecular residual disease (MRD) test.



Obtaining ADLT status confirms that Signatera meets the highly selective criteria established under the Protecting Access to Medicare Act of 2014 (PAMA). The initial ADLT rate established by CMS is \$3,500 for each Signatera assay used in the recurrence monitoring setting. Signatera received Medicare coverage for use in stage II-III colorectal cancer in late 2020, while finalization of a draft local coverage determination for use in immunotherapy response monitoring is anticipated for release in late 2021.

"Receiving ADLT status represents a major milestone in our commercialization efforts and confirms the unique nature of the Signatera assay," said John Fesko, chief business officer at Natera. "We are committed to working closely with CMS to expand access to MRD testing to ensure CMS members, physicians and healthcare systems can fully benefit from this revolutionary technology."

Signatera is used for treatment monitoring and MRD assessment and can detect cancer recurrence up to two years before conventional imaging.¹ To date, Signatera has been studied in over 3,000 patients and in 12 peer-reviewed publications, including multi-site, prospective, randomized trials, across more than 25 different tumor types. The test has also been granted three Breakthrough Device Designations by the FDA.

About Signatera

Signatera is a custom-built circulating tumor DNA (ctDNA) test for treatment monitoring and molecular residual disease (MRD) assessment in patients previously diagnosed with

cancer. The test is available for both clinical and research use, and has been granted three Breakthrough Device Designations by the FDA for multiple cancer types and indications. The Signatera test is personalized and tumor-informed, providing each individual with a customized blood test tailored to fit the unique signature of clonal mutations found in that individual's tumor. This maximizes accuracy for detecting the presence or absence of residual disease in a blood sample, even at levels down to a single tumor molecule in a tube of blood. Signatera is intended to detect and quantify how much cancer is left in the body, to detect recurrence earlier and to help optimize treatment decisions.

Signatera test performance has been clinically validated in multiple cancer types including colorectal, non-small cell lung, breast, and bladder cancers. Signatera has been developed and its performance characteristics determined by Natera, the CLIA-certified laboratory performing the test. The test has not been cleared or approved by the US Food and Drug Administration (FDA). CAP accredited, ISO 13485 certified, and CLIA certified.

About Natera

Natera is a pioneer and global leader in cell-free DNA testing from a simple blood draw. The mission of the company is to change the management of disease worldwide with a focus on women's health, oncology, and organ health. Natera operates ISO 13485-certified and CAP-accredited laboratories certified under the Clinical Laboratory Improvement Amendments (CLIA) in Austin, Texas and San Carlos, California. It offers proprietary genetic testing services to inform obstetricians, transplant physicians, oncologists, and cancer researchers, including biopharmaceutical companies, and genetic laboratories through its cloud-based software platform. For more information, visit [natera.com](https://www.natera.com). Follow Natera on [LinkedIn](#).

Forward-Looking Statements

All statements other than statements of historical facts contained in this press release are forward-looking statements and are not a representation that Natera's plans, estimates, or expectations will be achieved. These forward-looking statements represent Natera's expectations as of the date of this press release, and Natera disclaims any obligation to update the forward-looking statements. These forward-looking statements are subject to known and unknown risks and uncertainties that may cause actual results to differ materially, including with respect to our efforts to develop and commercialize new product offerings, whether the results of clinical or other studies will support the use of our product offerings, our ability to successfully increase demand for and grow revenues for our product offerings, our expectations regarding the reliability, accuracy and performance of our screening tests, or regarding the benefits of our screening tests and product offerings to patients, providers and payers, or coverage and reimbursement determinations from third-party payers. Additional risks and uncertainties are discussed in greater detail in "Risk Factors" in Natera's recent filings on Forms 10-K and 10-Q and in other filings Natera makes with the SEC from time to time. These documents are available at www.natera.com/investors and www.sec.gov.

NATERA EX2007

NeoGenomics v. Natera, IPR2024-00346

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1. Reinert T, Henriksen TV, Christensen E, et al. Analysis of plasma cell-free DNA by ultradeep sequencing in patients with stages I to III colorectal cancer. *JAMA Oncol.* 2019;5(8):1124–1131.

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