



NEWS RELEASE

Natera Announces Medicare Coverage of Signatera™ for Surveillance in Lung Cancer

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AUSTIN, Texas--(BUSINESS WIRE)-- **Natera, Inc.** (NASDAQ: NTRA), a global leader in cell-free DNA and genetic testing, today announced that its Signatera test has met coverage requirements from the Centers for Medicare & Medicaid Services' (CMS) Molecular Diagnostics Services Program (MoIDX) for patients with non-small cell lung cancer (NSCLC). This coverage applies to patients with stage I-III NSCLC with resectable or unresectable disease in the surveillance setting. It expands upon preexisting Medicare coverage of Signatera for monitoring of immunotherapy, a common form of treatment for NSCLC in both the adjuvant and metastatic settings.

Lung cancer is the leading cause of cancer death in the U.S., accounting for about 1 in 5 of all cancer deaths. In 2025, it will have an estimated incidence and mortality of 226,650 and 124,730, respectively, and an average age at diagnosis of 70 years old.¹ While significant advances have been made in the treatment of NSCLC in recent years, the 5-year overall survival rate remains poor (28% for all SEER stages combined).²

Several limitations exist with existing surveillance tools, including limited sensitivity,³ difficulty in interpretation of CT scan results,⁴ and non-specific findings,⁵ This highlights the need for sensitive and specific biomarkers to support early detection of recurrence before the onset of disease-related symptoms, at a time when therapy might provide greater clinical benefit.

Signatera test performance and utility in the surveillance setting for stage I-III NSCLC was validated in three independent peer-reviewed studies,⁶⁻⁸ to support this Medicare coverage determination. Across these studies, longitudinal sensitivity to extracranial recurrence ranged between 93-100%, with specificity ranging from 96-100% and an observed lead time up to one year ahead of imaging (median 5 months).

"CMS's coverage decision expands access to Signatera for patients with the most lethal and one of the most common forms of cancer in the U.S.," said Alexey Aleshin, M.D., corporate chief medical officer and general



manager of oncology at Natera. “The body of evidence continues to grow demonstrating Signatera’s value in risk stratification, treatment response monitoring, and early detection of recurrence to inform treatment decisions across a broad range of cancer indications.”

In addition to the coverage in NSCLC, Signatera is also covered by Medicare for adjuvant and recurrence monitoring in colorectal cancer, muscle-invasive bladder cancer, breast cancer, and ovarian cancer; neoadjuvant treatment monitoring in breast cancer; and pan-cancer immunotherapy response monitoring.

About Signatera

Signatera is a personalized, tumor-informed, molecular residual disease test for patients previously diagnosed with cancer. Custom-built for each individual, Signatera uses circulating tumor DNA to detect and quantify cancer left in the body, identify recurrence earlier than standard of care tools, and help optimize treatment decisions. The test is available for clinical and research use and has coverage by Medicare across a broad range of indications. Signatera has been clinically validated across multiple cancer types and indications, with published evidence in more than 100 peer-reviewed papers.

About Natera

Natera™ is a global leader in cell-free DNA and genetic testing, dedicated to oncology, women’s health, and organ health. We aim to make personalized genetic testing and diagnostics part of the standard-of-care to protect health and inform earlier, more targeted interventions that help lead to longer, healthier lives. Natera’s tests are supported by more than 250 peer-reviewed publications that demonstrate excellent performance. Natera operates ISO 13485-certified and CAP-accredited laboratories certified under the Clinical Laboratory Improvement Amendments (CLIA) in Austin, Texas, and San Carlos, California. For more information, visit www.natera.com.

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 whether the results of clinical or other studies will support the use of our product offerings, the impact of results of such studies, our expectations of the reliability, accuracy and performance of our tests, or of the benefits of our tests and product offerings to patients, providers and 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.

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