



NEWS RELEASE

# Medicare Extends Coverage of Natera's Signatera™ MRD Test to Ovarian Cancer and Neoadjuvant Breast Cancer

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AUSTIN, Texas--(BUSINESS WIRE)-- Natera, Inc. (NASDAQ: NTRA), a global leader in cell-free DNA testing, today announced that its personalized and tumor-informed molecular residual disease (MRD) test, Signatera, has met coverage requirements from the Centers for Medicare & Medicaid Services' (CMS) Molecular Diagnostics Services Program (MoIDX) in two new indications: ovarian cancer in the adjuvant and surveillance settings, and breast cancer in the neoadjuvant setting.

These determinations add to a growing list of covered indications for Signatera, including adjuvant and recurrence monitoring coverage in colorectal cancer, muscle-invasive bladder cancer, and breast cancer; and pan-cancer immunotherapy response monitoring.

## Ovarian Cancer

The MoIDX coverage decision applies to patients with ovarian cancer, in both the adjuvant and surveillance settings.

Ovarian cancer is the 5th leading cause of cancer-related death among women, with an estimated 2022 incidence and mortality of 19,880 and 12,810, respectively, and a median age at diagnosis of 63 years.<sup>1</sup> While multiple new treatment options have been introduced in recent years, physicians have had to rely on imperfect biomarkers to determine who is likely to benefit from these more intensive regimens, and recurrence risk remains high<sup>2</sup>. Additionally, current guidelines for surveillance are limited and providers often rely on tools with low sensitivity and specificity, such that a significant unmet need remains for these patients.<sup>3</sup>

Signatera performance in ovarian cancer was validated in a blinded, multi-site study published in *Gynecologic*



Oncology.<sup>4</sup> The study analyzed 163 plasma samples from 69 patients with stage I-IV ovarian cancer. Test performance was evaluated at multiple time points: pre-surgery, post-surgery prior to adjuvant treatment, and longitudinally. With longitudinal testing, recurrence was detected with 100% sensitivity, 100% specificity, and an average lead time of 10 months ahead of imaging.

### Breast Cancer (neoadjuvant setting)

This MoDx coverage decision applies to patients with breast cancer in the neoadjuvant setting across all subtypes of the disease, including hormone receptor (HR)-positive, HER2-positive, and triple negative breast cancers.

Up to 50% of newly diagnosed breast cancer patients receive neoadjuvant therapy (NAT).<sup>5</sup> Guidelines recommend routine assessment of tumor response to neoadjuvant therapy but acknowledge that this is “difficult” using currently available diagnostic tools.<sup>6</sup> Signatera has been validated to address this unmet need.

The coverage decision was based on clinical evidence published in Cancer Cell 7 from the I-SPY2 trial, which reported on 283 patients and 1,024 plasma samples, with a median of more than 3 years of clinical follow up and a maximum of more than 7.5 years. The study demonstrated that early ctDNA clearance during NAT was a significant predictor of therapy response ( $p=0.0002$ ), and Signatera negativity after NAT was significantly associated with improved distant recurrence-free survival (DRFS), even in patients with residual cancer burden at surgery ( $p<0.0001$ ). By contrast, persistent Signatera positivity during and after NAT was significantly associated with therapy non-response and inferior DRFS ( $p=0.02$  to  $p<0.0001$ ).

“These important Medicare decisions support our ability to personalize disease management for patients with ovarian cancer, the most lethal gynecologic malignancy worldwide, and extend existing coverage in breast cancer to the neoadjuvant setting,” said Minetta Liu, M.D., chief medical officer of oncology at Natera. “Clinical evidence continues to demonstrate the value of Signatera across various settings of disease, which can help clinicians make timely decisions and may improve outcomes for patients. We are incredibly proud of this milestone, and look forward to continuing to work with Medicare to make Signatera more widely accessible for people affected by cancer.”

### 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 is covered by Medicare for patients with colorectal cancer, breast cancer, ovarian cancer and muscle invasive bladder cancer, as well as for immunotherapy monitoring of any solid tumor. Signatera has been clinically validated across multiple cancer types and indications, with published evidence in more than 65 peer-reviewed papers.

## About Natera

Natera™ is a global leader in cell-free DNA 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 validated in approximately 175 peer-reviewed publications that demonstrate high accuracy. 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](http://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](http://www.natera.com/investors) and [www.sec.gov](http://www.sec.gov).

## References

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