



NEWS RELEASE

# Natera Announces Commercial Payor Coverage for Signatera™

3/2/2023

Pan-cancer policy from Blue Shield of California covers adjuvant, recurrence monitoring, and treatment monitoring

Multi-cancer policy from BCBS of Louisiana covers CRC, Bladder, and IO monitoring

AUSTIN, Texas--(BUSINESS WIRE)-- **Natera, Inc.** (NASDAQ: NTRA), a global leader in cell-free DNA testing, today announced the Company's first commercial coverage policies for its molecular residual disease test, Signatera, including its first pan-cancer coverage policy for adjuvant, recurrence monitoring, and treatment monitoring.

Effective March 1, 2023, Blue Shield of California now provides commercial coverage of Signatera for plan members diagnosed with any solid tumors. Specifically, the policy describes tumor-informed ctDNA testing with Signatera as medically necessary for patients with stage I-IV cancer to provide information for (1) adjuvant or targeted therapy; and/or (2) monitoring for relapse or progression, including but not limited to the use of immunotherapy.

In addition, effective January 1, 2023, Blue Cross and Blue Shield of Louisiana is providing coverage of serial testing with Signatera for plan members diagnosed with colorectal and muscle invasive bladder cancer and for pan-cancer immunotherapy monitoring.

"Following the recent breast cancer coverage decision by Medicare, achieving our first commercial coverage policies for Signatera – including one that encompasses pan-cancer coverage – is another major milestone for Natera and the patients who will now have enhanced access to tumor-informed ctDNA testing," said John Fesko, chief business officer. "These developments underscore the medical necessity of Signatera to inform critical treatment decisions and detect recurrence earlier."

Data supporting the clinical validity and utility of Signatera has been published in approximately 40 peer-reviewed publications, including validation across multiple cancer types to detect recurrence earlier than standard diagnostic tools<sup>1,2</sup> and to improve the assessment of treatment response in conjunction with imaging.<sup>3</sup>

## 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. Signatera is intended to detect and quantify cancer left in the body, at levels down to a single tumor molecule in a tube of blood, to identify recurrence earlier and to help optimize treatment decisions.

## 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 by more than 100 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 our expectations of the reliability, accuracy and performance of our tests, or our expectations 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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2. Coombes RC, Page K, Salari R, et al. Personalized detection of circulating tumor DNA antedates breast cancer metastatic recurrence. *Clin Cancer Res.* 2019;25(14):4255-4263.
3. Bratman SV, Yang SYC, Iafolla MAJ, et al. Personalized circulating tumor DNA analysis as a predictive biomarker in solid tumor patients treated with pembrolizumab. *Nat. Cancer.* 2020;1(9):873-881.

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