Medicare Extends Coverage of Natera's Signatera™ MRD Test to Breast Cancer
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Coverage to include serial monitoring in all subtypes, including hormone receptor-positive, HER2-positive, and triple negative breast cancers

AUSTIN, Texas–(BUSINESS WIRE)– Natera, Inc. (NASDAQ: NTRA), a global leader in cell-free DNA testing, today announced that it has received written confirmation from the Centers for Medicare & Medicaid Services' (CMS) Molecular Diagnostics Services Program (MolDX) that Natera's Signatera molecular residual disease (MRD) test has met coverage requirements for adjuvant and recurrence monitoring in patients with stage IIb or higher breast cancer. The coverage applies across all subtypes of the disease, including hormone receptor (HR)-positive, HER2-positive, and triple negative breast cancers. This decision adds to Medicare's prior coverage of Signatera in colorectal cancer, muscle-invasive bladder cancer, and pan-cancer immunotherapy monitoring.

"Signatera is a critical innovation that can help us to enhance care management for patients with breast cancer," said Jenny C. Chang, M.D., treating oncologist and director of the Houston Methodist Dr. Mary and Ron Neal Cancer Center. "The five-year recurrence rates for breast cancer are estimated to be as high as 30 percent,and traditional methods for detecting recurrence can be inaccurate. Signatera addresses a critical unmet need and improves our ability to accurately predict recurrence risk from breast cancer."

The decision by CMS was primarily based on evidence from the Exploratory Breast Lead Interval Study (EBLIS), published in Clinical Cancer Research.[1] In the study, patients with breast cancer across all subtypes were monitored with Signatera every 6 months after surgery, resulting in early relapse detection with 89% sensitivity, 100% specificity, and a diagnostic lead time of up to 2 years (median 8.9 months) ahead of radiographic imaging. Signatera MRD status was also found to be the most significant risk factor for recurrence across all subtypes of disease. This study is one of several that support the use of Signatera in breast cancer, and one of over 40 peer-reviewed publications across solid tumors.

In addition to detecting recurrence and helping to inform patient management decisions, Signatera can offer peace of mind to those patients who test serially negative. According to Chloe Crampton, a Signatera patient living with breast cancer, "Signatera has given me and my care team more information about my disease, but most importantly, it has allowed me to live a life with less anxiety and more hope."

Breast cancer is the most common cancer in women in the United States, with an estimated 2022 incidence and mortality of 287,850 and 43,250, respectively. There are more than 3.8 million women with a history of breast cancer in the U.S.[2] The median age of diagnosis is approximately 60 years, and over 40% of patients are diagnosed at age 65 years or older.[3]

"Extending Medicare coverage for Signatera to patients with breast cancer, irrespective of subtype, is a real milestone for precision oncology and a game changer for patients," said Minetta Liu, M.D., chief medical officer of oncology at Natera. "Our tumor-informed assay enables oncologists to more confidently identify patients at high risk of recurrence, informing decisions related to active surveillance via imaging, as well as decisions to escalate or de-escalate treatment."