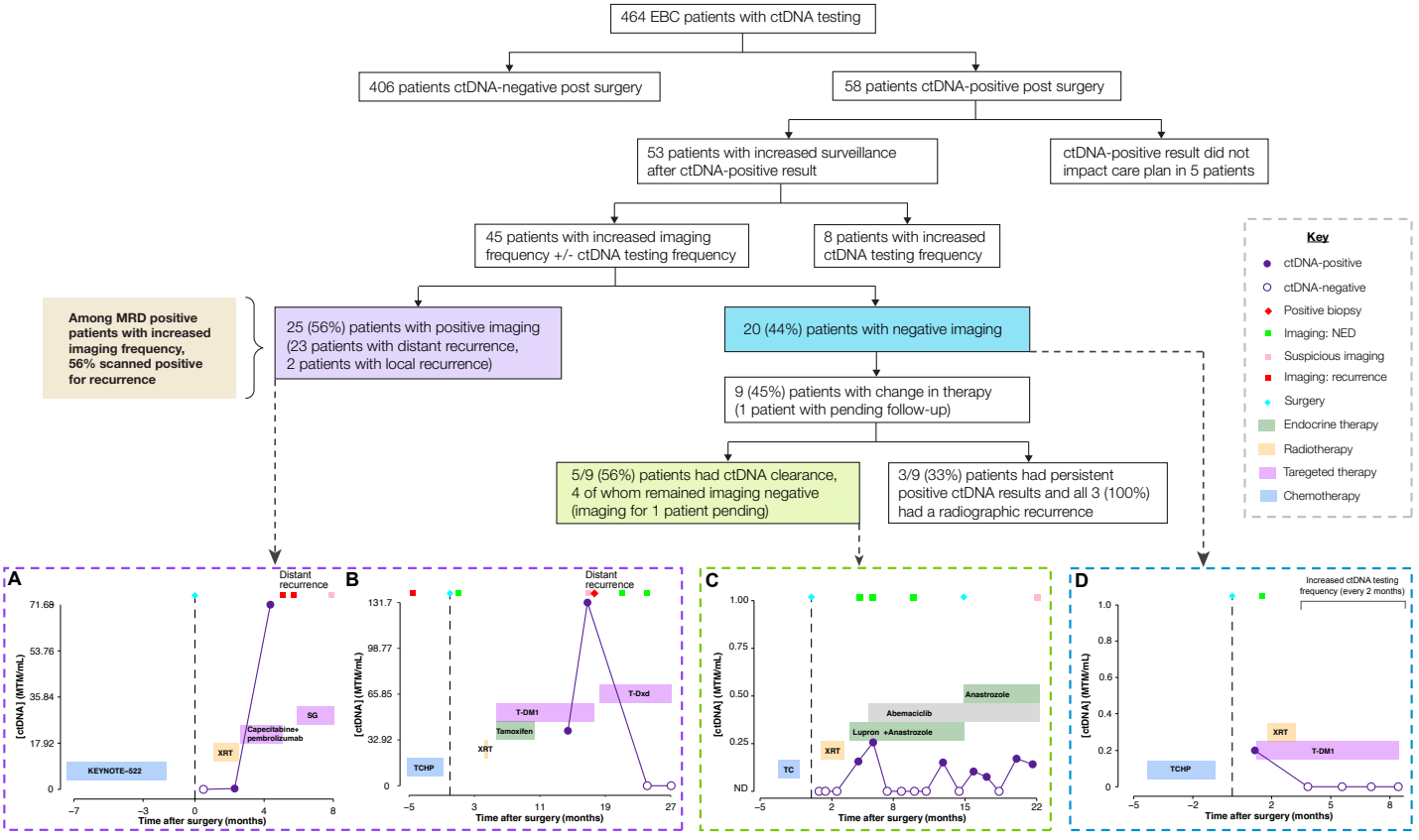
natera™ | Signatera™ Residual disease test (MRD)

Covered by Medicare for patients with stage II-IV breast cancer

ASCO 2024: New data shows how leading oncologists treated EBC patients with molecular residual disease (MRD), potentially impacting the trajectory of the disease

Background:

- The presence of ctDNA has been strongly associated with recurrence yet the clinical impact of early ctDNA detection in terms of therapeutic intervention remains unclear[1,2]
- In this multi-institution (4 geographic US regions) retrospective real-world analysis, ctDNA detection in the adjuvant setting was investigated to determine the impact on patients with stage I-III early breast cancer (testing was conducted between 11/2020 - 01/2024)[3]

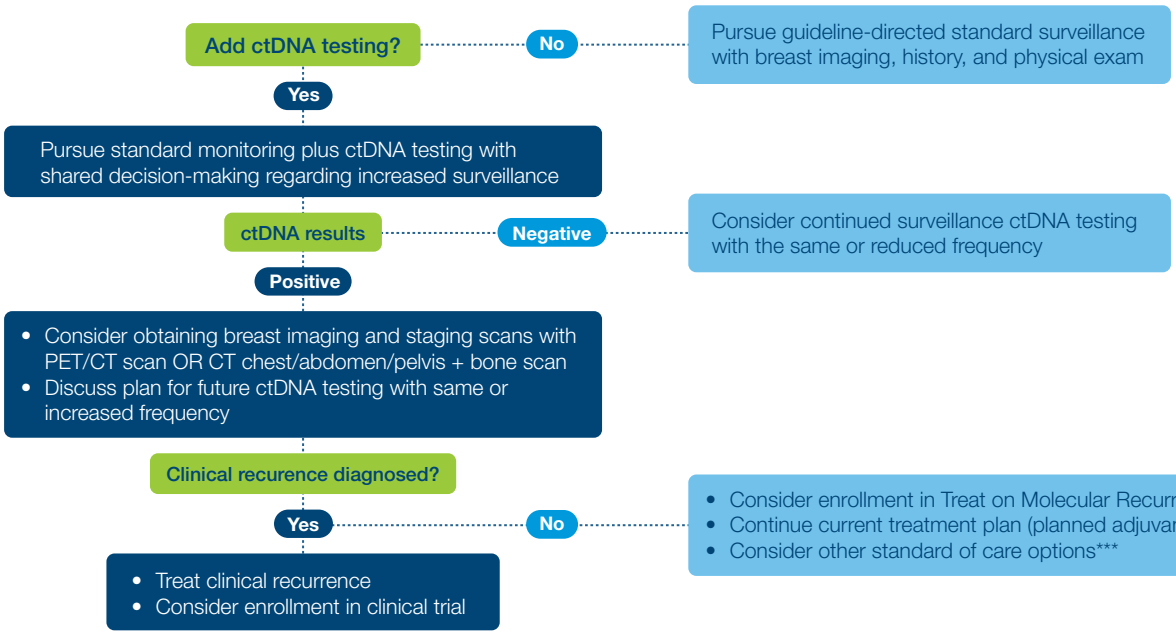


- 45% of patients with negative imaging were shown to have MRD which led to a change in therapy; 56% of these patients achieved ctDNA clearance
- A subset of patients who had a change in systemic therapy with subsequent ctDNA clearance was associated with better prognosis, compared to those patients without ctDNA clearance

ctDNA detection informed shared decision-making and impacted routine clinical care for **91% of Signatera™ positive patients with EBC**

Real world clinical use of positive ctDNA testing in adjuvant surveillance of patients with early breast cancer

Patient/provider shared decision-making regarding plan for adjuvant surveillance*



*Contributing considerations include stage, grade, tumor subtype, recurrence risk, treatment options, patient preference, and others. Shared decision-making should include discussion of potential benefits, risk, and clinical actionability associated with ctDNA testing.
**Preferred
***Some providers in this cohort elected to: change endocrine therapy (ie: tamoxifen to aromatase inhibitor + ovarian suppression), start treatment with adjuvant CDK4/inhibitor, starts treatment with adjuvant PARK inhibitor) for patients with BRCA mutations)

Ordering Signatera™ for your breast cancer patients: Can be run at any time point from diagnosis through survivorship, using either the core biopsy or surgical resection

Medicare coverage: Signatera™ is covered by Medicare for monitoring disease progression, disease recurrence, or relapse for patients with: stage II-IV breast cancer in the neoadjuvant setting, regardless of subtype; stage IIb and higher breast cancer in the adjuvant and recurrence monitoring setting

Natera's Oncology Portfolio:

Altera™
Tumor genomic profile

Add on **Altera™ Genomic Profiling test** which utilizes whole-exome and whole-transcriptome sequencing to identify clinically relevant biomarkers that may help guide treatment selection for advanced cancer patients: no additional sample needed

Empower™
Hereditary cancer test

Empower™ for hereditary cancer testing (saliva or plasma only needed) which analyzes up to 81 genes across 12+ common hereditary cancers (panel can also be customizable, up to 190 genes) and more commonly known genes associated with breast cancer including *BRCA1, BRCA2, TP53, PALB2, ATM, CHEK2, STK11, PTEN* to help guide surgical and therapeutic decisions.

References:

1. Coombes C et al. Personalized Detection of Circulating Tumor DNA Antedates Breast Cancer Metastatic Recurrence. *Clinical Cancer Research.* 2019;25(14):4255-4263.
2. Shaw JA et al. Serial postoperative circulating tumor DNA assessment has strong prognostic value during long-term follow-up in patients with breast cancer. *JCO Precis Oncol.* 2024;8:e2300456.
3. Marla Lipsyc-Sharf et al. Impact of circulating tumor DNA (ctDNA) surveillance on clinical care for patients with stage I-III breast cancer: Findings from a multi-institutional study. ASCO Annual Meeting 2024

Discover more here

13011 McCallen Pass, Building A Suite 100 | Austin, TX 78753 | natera.com

natera™