

Unlocking new treatment options for Patients with Metastatic Breast Cancer

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Recommend Molecular Testing in Breast Cancer¹

- 1 | Therapeutic options are available for amplified and/or mutated **ERBB2 (HER2)**
- 2 | Testing for germline **BRCA1** and **BRCA2** mutations should be considered in patients with HER2- metastatic breast cancer under consideration for chemotherapy
- 3 | Assess for **PIK3CA** mutation with tumor or liquid biopsy if patient has HR+/HER2- metastatic breast cancer
- 4 | For patients with metastatic triple-negative breast cancer (TNBC) assess PD-L1 biomarker status

Our portfolio of tests analyzes guideline recommended genes for relevant alterations in patients with breast cancer including **ERBB2 (HER2)**, **BRCA1**,² **BRCA2**,² and **PIK3CA** and offer a supplemental IHC-test for PD-L1.

Value of Comprehensive Genomic Profiling with Foundation Medicine:



Our tests detect additional alterations in genes known to be relevant in breast cancer, **such as, NTRK³, ESR1, AKT1**, as well as alterations in genes involved in the cell cycle pathway and the PI3K-AKT-mTOR and **HER2/FGFR** pathways.



Conveniently order supplemental PD-L1 testing that is the companion diagnostic for atezolizumab with your comprehensive tissue-based test all from one partner.



Breast cancer patients from all sub-types who have TMB ≥ 9 may benefit from cancer immunotherapy independent of their PD-L1 status or prior therapies.⁴

Alva AS, Mangat PK.,
Garrett-Mayer R, et al.,
*Incidence of high tumor
mutational burden...*

EMERGING DATA:

FoundationOne®CDx has received FDA-approval for a new companion diagnostic (CDx) claim for PIQRAY® (apfelisib) detection of **PIK3CA** alterations in HR+/HER2- advanced breast cancer patients.

Advancing Therapy Options in Breast Cancer

FDA-Approved therapies⁵, including the **bolded therapies** for which FoundationOne CDx is the companion diagnostic

BIOMARKER	FDA-APPROVED THERAPY
ERBB2 (HER2) amplification	Herceptin® (trastuzumab) Perjeta® (pertuzumab) Kadcyla® (ado-trastuzumab-emtansine)
PIK3CA alterations	Piqray® (apfelisib)
HER2- and BRCA1/2+	Lynparza® (olaparib) Talzenna® (talazoparib)
MSI-H	Keytruda® (pembrolizumab)
NTRK fusions	Vitrakvi® (larotrectinib) Rozlytrek® (entrectonib)
PD-L1 expression ⁷	Tecentriq® (atezolizumab) in combination with Abraxane®

Growing Therapy Options in Breast Cancer

Genomic alterations and relevance for clinical trials with novel therapies⁷

MOLECULAR ALTERATION	SUBTYPE CONSIDERATION	DRUG CLASS
<i>ERBB2</i> mutation	2%–4% breast cancer	HER2 Tyrosine kinase inhibitors (TKI)
<i>AKT1</i> mutation	2%–5% breast cancer	<i>AKT</i> inhibitor, mTor inhibitor
<i>ESR1</i> mutation	30%–40% <i>ER</i> +/ <i>HER2</i> - after aromatase inhibitors (AI)	Selective estrogen receptor degrader
TMB ≥9	8–12% breast cancers ⁴	Immune checkpoint inhibitor

A portfolio of tests to help identify more treatment options



TISSUE BIOPSY

FoundationOne CDx is our only FDA-approved test and includes Medicare coverage for qualifying Medicare patients⁸.

- Analyzes 324 genes
- Reports TMB and MSI



LIQUID BIOPSY

FoundationOne Liquid is a laboratory developed test that delivers high-quality answers from a simple blood draw.

- Analyzes 70 genes
- Reports MSI-H status



TO LEARN MORE:

Visit www.foundationmedicine.com

TO SIGN UP OR ORDER A TEST:

Visit www.foundationmedicine.com/signup

FoundationOne[®]CDx is the only FDA-approved in vitro diagnostic test by Foundation Medicine. FoundationOne Liquid and FoundationOne Heme were developed and their performance characteristics determined by Foundation Medicine. They have not been cleared or approved by the U.S. Food and Drug Administration. For more information on our laboratory developed tests please see Technical Specifications at www.foundationmedicine.com.

FoundationOne[®]CDx is a next-generation sequencing based in vitro test intended for use by healthcare professionals for advanced cancer patients with solid tumors. The test analyzes 324 genes as well as genomic signatures including microsatellite instability (MSI) and tumor mutational burden (TMB) and is FDA-approved as a companion diagnostic to identify patients who may benefit from treatment with a specific list of therapies (listed in Table 1 in the Technical Information at <http://www.foundationmedicine.com/flcdx>) in accordance with the approved therapeutic product labeling. Additional genomic findings, other than those listed in Table 1, may be reported and are not prescriptive or conclusive for labeled use of any specific therapeutic product. Use of the test does not guarantee a patient will be matched to a treatment or clinical trial option, or that all relevant alterations will be detected. Some patients may require a biopsy. For the complete label, including important risk information, please visit <http://www.foundationmedicine.com/flcdx>.

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References:

1. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines[®]) for Breast Cancer V.3.2019. © National Comprehensive Cancer Network, Inc. 2019. All rights reserved. Accessed September 6, 2019. To view the most recent and complete version of the guideline, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.
2. Foundation Medicine detects both somatic and germline alterations but does not differentiate between the two on reports.
3. NTRK genes currently tested on FoundationOne CDx and FoundationOne Heme only
4. Alva AS, Mangat PK, Garrett-Mayer E, et al: Pembrolizumab (P) in patients (pts) with metastatic breast cancer (MBC) with high tumor mutational burden (HTMB): Results from the Targeted Agent and Profiling Utilization Registry (TAPUR) Study. J Clin Oncol 37, 2019 (suppl; abstr 1014)
5. Herceptin[®], Perjeta[®], and Kadcyla[®] are registered trademarks of Genentech, Inc. Lynparza[®] is a registered trademark of the AstraZeneca group of companies. Talzenna[®] is a registered trademark of Pfizer Inc. Brandname[®] is a registered trademark of Novartis. Keytruda[®] is a registered trademark of Merck Sharp & Dohme Corp. a subsidiary of Merck & Co., Inc. Vitakvi[®] is a registered trademark of Bayer. Piqray[®] is a registered trademark of Novartis.
6. VENTANA PD-L1 (SP142) assay is the companion diagnostic for atezolizumab and can be ordered a supplemental test to tissue-based testing with Foundation Medicine.
7. Kratz, J et al. Incorporating Genomics Into the Care of Patients With Advanced Breast Cancer American Society of Clinical Oncology Educational Book 2018 :38, 56-64
8. Medicare and Medicare Advantage members have coverage of FoundationOne CDx in accordance with the Centers for Medicare and Medicaid Services (CMS) national coverage determination (NCD) criteria.