Unlocking New Treatment Options for Patients with Metastatic Prostate Cancer

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Recommend Molecular Testing in Metastatic Prostate Cancer

Homologous recombination (HRD) pathway genes: BRCA1, BRCA2, ATM, PALB2, FANCA, RAD51D, CHEK2 and CDK12 for genetic counseling, early use of platinum chemotherapy, olaparib, and/or eligibility for clinical trials (e.g., PARP inhibitors).

Microsatellite instability (MSI) or mismatch repair deficiency (dMMR): If MSI is used, testing using an NGS assay validated for prostate cancer is preferred. MSI or dMMR indicate eligibility for pembrolizumab in later lines of treatment for CRPC (castrate-resistant prostate cancer).†

Our portfolio of tests analyzes all guideline recommended genes and biomarkers for relevant alterations in patients with prostate cancer including: BRCA1, BRCA2, ATM, PALB2, FANCA, RAD51D, CHEK2, CDK12 and MSI*.

Advancing Therapy Options for Metastatic Prostate Cancer Patients

<table>
<thead>
<tr>
<th>BIOMARKER</th>
<th>FDA-APPROVED THERAPY</th>
<th>FOUNDATION MEDICINE COMPANION DIAGNOSTIC</th>
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</thead>
<tbody>
<tr>
<td>Homologous Recombination Repair (HRR) gene (BRCA1, BRCA2, ATM, BARD1, BRIP1, CDK12, CHEK1, CHEK2, FANCL, PALB2, RAD51B, RAD51C, RAD51D and RAD54L) alterations</td>
<td>Lynparza® (olaparib)</td>
<td>FoundationOne®CDx</td>
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<tr>
<td>BRCA1, BRCA2</td>
<td>Rubraca® (rucaparib)</td>
<td>FoundationOne®Liquid CDx</td>
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As of June 2020

Lynparza® is a registered trademark of the AstraZeneca group of companies.
Rubraca® is a registered trademark of Clovis Oncology

The Value of Comprehensive Genomic Profiling with Foundation Medicine:

FoundationOne Liquid CDx is the only FDA-approved comprehensive genomic profiling test that can identify prostate cancer patients who are likely to respond to Rubraca® (rucaparib) from a simple blood draw.

By testing for all mutations, regardless of germline or somatic, our portfolio of tests can identify more than twice as many men who may benefit from PARP inhibitor therapy than conventional germline-only testing.

A blood-based comprehensive genomic profiling test is an important option to consider for mCRPC patients due to tissue sample issues, as demonstrated in the TRITON2 trial for rucaparib where liquid biopsy identified an additional 22.5% of patients with a BRCA1/2 alteration for whom tissue was sample unavailable, and in the PROfound trial for olaparib where 31% of tissue samples were unable to be successfully sequenced for comprehensive genomic profiling testing.

Due to genomic variance in metastatic sites, liquid biopsies may have advantages over individual metastatic site biopsies in their ability to capture the entire range of therapeutic opportunities for prostate cancer patients.

* FoundationOne Liquid only reports MSI when determined to be high
† MSI/dMMR testing should be considered in patients with metastatic castration-naïve prostate cancer and is recommended in patients with metastatic CRPC.
FDA-approved portfolio of tests to help identify more treatment options:

**FOUNDATIONONE® CDx**

**TISSUE BIOPSY**

FoundationOne CDx is FDA-approved and covered by Medicare for qualifying patients.

- Analyzes 324 genes
- Reports TMB and MSI

**FOUNDATIONONE® LIQUID CDx**

**LIQUID BIOPSY**

FoundationOne Liquid CDx is FDA-approved and covered by Medicare for qualifying patients.

- Analyzes 324 genes
- bTMB, MSI-High, and tumor fraction

References:

1. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Prostate Cancer V.2.2020 © National Comprehensive Cancer Network, Inc. 2020. All rights reserved. Accessed May 27, 2020. 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.


5. Necchi, Andrea et al. Comprehensive genomic profiling (CGP) in post-systemic treatment (Post) metastatic sites (MET) and pretreatment (Pre) primary tumors (PT) of metastatic prostate cancer (mPC). Journal of Clinical Oncology 38, no. 6_suppl (February 20, 2020) 175-175. DOI: 10.1200/JCO.2020.38.6_suppl.175

6. The Centers for Medicare & Medicaid Services (CMS) Decision Memo for Next Generation Sequencing (NGS) for Medicare Beneficiaries with Advanced Cancer (CAG-00450R) see Appendix B.