Uncovering Treatment Options for Patients with Non-Small Cell Lung Cancer (NSCLC)

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Recommend Molecular Testing for Appropriate Patients with Metastatic NSCLC, if Clinically Feasible

FOR ADENOCARCINOMA, LARGE CELL, AND NSCLC NOT OTHERWISE SPECIFIED (NOS)

1. Recommend biomarker testing for EGFR, ALK, ROS1, BRAF, NTRK, and PD-L1.

2. Strongly advise broader molecular profiling with the goal of identifying rare driver mutations for which effective drugs may already be available, or to appropriately counsel patients regarding the availability of clinical trials.

3. The use of cell-free/circulating tumor DNA can be considered in specific clinical circumstances such as a patient unfit for invasive tissue sampling or if there is insufficient material for molecular analysis following pathologic confirmation of a NSCLC diagnosis.

Expanding Therapy Options for Metastatic NSCLC patients

Our portfolio of tests analyzes all guideline recommended genes and biomarkers for relevant alterations in patients with NSCLC including EGFR, ALK, ROS1, BRAF, NTRK, and PD-L1.

Biomarkers to inform therapy selection

(Bolded therapies are FoundationOne CDx companion diagnostics for NSCLC)

- **EGFR**
  - Afatinib (Gilotrif®), Dacomitinib (Vizimpro®), Erlotinib (Tarceva®), Gefitinib (Iressa®), Osimertinib (Tagrisso®)

- **ALK**
  - Alectinib (Alecensa®), Brigatinib (Alunbrig®), Crizotinib (Zykadia®), Entrectinib (Rozlytrek™)

- **ROS1**
  - Ceritinib (Zykadia®), Crizotinib (Xalkori®), Entrectinib (Rozlytrek™)

- **BRAF**
  - Dabrafenib (Tafinlar®), Vemurafenib (Zelboraf®)

- **NTRK**
  - Entrectinib (Rozlytrek™), Larotrectinib (Vitrakvi®)

- **PD-L1**
  - Atezolizumab (Tecentriq®) in combination with chemotherapy
  - Pembrolizumab (Keytruda®) +/- chemotherapy

Single gene testing or limited panels have been shown to miss up to 35% of ALK fusions and 21% of EGFR mutations (41% of these missed EGFR mutations are common alterations targetable by an FDA-approved therapy in the applicable patient’s tumor type).

FoundationOne®Liquid is the only liquid biopsy test that has demonstrated the ability to identify patients with ALK fusions in a global prospective trial for metastatic NSCLC at similar frequencies historically published with tissue testing.

Our portfolio of tests detects additional emerging genes and biomarkers MET, RET, ERBB2 (HER2), STK11, and TMB (tumor mutational burden) and additional genes of clinical significance such as KRAS.
A portfolio of tests to help identify more treatment options:

**FOUNDATIONONE® CDx**

*FoundationOne CDx is FDA-approved with Medicare coverage for qualifying Medicare patients.*

- Analyzes 324 genes
- Reports TMB and Microsatellite Instability (MSI)

**LIQUID BIOLOGY**

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

- Analyzes 70 genes
- Reports MSI-H status

**TISSUE BIOPSY**

- FoundationOne CDx is FDA-approved with Medicare coverage for qualifying Medicare patients.
- Analyzes 324 genes
- Reports TMB and Microsatellite Instability (MSI)
- Typical turnaround time is <2 weeks from when we receive the tissue specimen
- Optional add-on with 4 additional slides
- Typical turnaround is 5 days from receipt of specimen

**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
- Typical turnaround time is <2 weeks from receipt of specimen

**Traditional testing slide requirements**

<table>
<thead>
<tr>
<th>Test</th>
<th>Slides/Blocks</th>
<th>Turnaround</th>
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</thead>
<tbody>
<tr>
<td>PD-L1 expression</td>
<td>10</td>
<td>&lt;2 weeks</td>
</tr>
<tr>
<td>EGFR mutations</td>
<td>10</td>
<td>2-4 days</td>
</tr>
<tr>
<td>ALK rearrangements</td>
<td>10</td>
<td>2-4 days</td>
</tr>
<tr>
<td>ROS1 rearrangements</td>
<td>10</td>
<td>2-4 days</td>
</tr>
<tr>
<td>IHC Testing for PD-L1</td>
<td>10</td>
<td>5 days</td>
</tr>
<tr>
<td>TMB</td>
<td>10</td>
<td>2-4 days</td>
</tr>
</tbody>
</table>

**LIQUID BIOPSY**

<table>
<thead>
<tr>
<th>Test</th>
<th>Slides/Blocks</th>
<th>Turnaround</th>
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</thead>
<tbody>
<tr>
<td>BRAF V600 mutation</td>
<td>8.5mL</td>
<td>&lt;2 weeks</td>
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<tr>
<td>KRAS mutations</td>
<td>8.5mL</td>
<td>2-4 days</td>
</tr>
<tr>
<td>MET amplification</td>
<td>8.5mL</td>
<td>2-4 days</td>
</tr>
<tr>
<td>RET rearrangements</td>
<td>8.5mL</td>
<td>2-4 days</td>
</tr>
<tr>
<td>ERBB2 (HER2) mutations</td>
<td>8.5mL</td>
<td>2-4 days</td>
</tr>
<tr>
<td>STK11 mutations and losses</td>
<td>8.5mL</td>
<td>2-4 days</td>
</tr>
<tr>
<td>NTRK fusions</td>
<td>8.5mL</td>
<td>2-4 days</td>
</tr>
<tr>
<td>Preferred testing with NGS panel</td>
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</tr>
</tbody>
</table>

**TO LEARN MORE:**

Visit [www.foundationmedicine.com](http://www.foundationmedicine.com)

**TO SIGN UP OR ORDER A TEST:**

Visit [www.foundationmedicine.com/signup](http://www.foundationmedicine.com/signup)

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**References:**

1. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for NSCLC V.1.2020. © National Comprehensive Cancer Network, Inc. 2019. All rights reserved. Accessed May 10, 2019. To view the most recent and complete version of the guideline, go online to NCCN.org.


4. LBABI_PR ‘Phase II/III blood first assay screening trial (BFAST) in patients (pts) with treatment-naive NSCLC: initial results from ALK+ cohort’ will be presented by Shirish Gadgeel during the proffered paper session on Monday, 30 September 2019, 08:30-10:00 CEST in Madrid Auditorium (Hall 2). Annals of Oncology, Volume 30, Supplement 5, October 2019.

5. 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.