Advance Beneficiary Notice Information for Foundation Medicine Tests

When patients receiving Original Medicare services do not meet coverage criteria set forth in applicable National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs), the Centers for Medicare & Medicaid Services (CMS) require that these non-covered patients complete an Advance Beneficiary Notice (ABN) prior to receiving the services.

What does this mean for my patients?
The ABN informs Medicare patients that they may have financial responsibility for services ordered by their healthcare providers. If Medicare denies a claim, patients will be billed at Foundation Medicine’s self-pay price. Medicare patients are still eligible for our financial assistance program. Foundation Medicine offers direct support and guidance during each step of the billing process for our tests, and strives to work with each patient within their ability to pay.

Are Medicare Advantage (MA) patients impacted?
Medicare Advantage patients do not need to sign an ABN and are not impacted by this change.

What else do I need to do?
- Refer to the back of this sheet to determine whether or not your patient requires an ABN for the requested test and for information on how to obtain a pre-populated ABN form
- Have patients complete a Foundation Medicine financial assistance application (when appropriate): access.foundationmedicine.com
- Submit both forms with the specimen kit
**Medicare Coverage Summary**

Foundation Medicine tests may be covered by Original Medicare\(^1\) and Medicare Advantage\(^2\).

<table>
<thead>
<tr>
<th>Test</th>
<th>Conditions for Medicare Coverage</th>
<th>Patient Coverage Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>FoundationOne®CDx</td>
<td>Covered(^3) if all patient coverage criteria are met. ABN required if patient does not meet the patient coverage criteria or if person ordering the test is not a treating physician(^4).</td>
<td>i) Patient has been diagnosed with a solid malignant neoplasm; AND ii) Patient has either recurrent, relapsed, refractory, metastatic, or advanced stages III or IV cancer (only requires one of these to be met); AND iii) Either Patient has not been previously tested using the same NGS test for the same primary diagnosis of cancer OR Patient is undergoing repeat testing using the same NGS test for a new primary cancer diagnosis made by the treating physician; AND iv) Patient has decided to seek further cancer treatment (e.g., therapeutic chemotherapy)</td>
</tr>
<tr>
<td>FoundationOne®Liquid</td>
<td>Coverage(^5) may be available if all patient coverage criteria are met. ABN required if patient does not meet the patient coverage criteria, or if person ordering the test is not a treating physician(^4).</td>
<td>N/A</td>
</tr>
<tr>
<td>FoundationOne®Heme</td>
<td>Not covered at this time. Foundation Medicine is working toward securing future coverage. ABN required for every case.</td>
<td>N/A</td>
</tr>
</tbody>
</table>

Blank ABNs can be downloaded at [www.foundationmedicine.com/genomic-testing/order](http://www.foundationmedicine.com/genomic-testing/order)

Completed ABN forms can be sent to Foundation Medicine via fax at 866.283.5838 or emailed to myABN@foundationmedicine.com.

**References**

1. Medicare administered by federal government.
2. Medicare administered by private insurers.
3. Per the "Decision for Next Generation Sequencing (NGS) for Medicare Beneficiaries with Advanced cancer - CAG-00450N
5. National Government Services, the local Medicare Administrative Contractor with jurisdiction over testing performed by Foundation Medicine at its Cambridge, MA laboratory for Original Medicare beneficiaries, does not have a Local Coverage Determination (LCD) for liquid biopsy next generation sequencing >50 genes. Coverage is determined by National Government Services on a case-by-case basis.

See full intended use for FoundationOne CDx at [www.foundationmedicine.com/genomic-testing/foundation-one-cdx](http://www.foundationmedicine.com/genomic-testing/foundation-one-cdx)