

Advanced 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 Foundation Medicine's financial assistance program. FoundationAccess™ offers direct support and guidance during each step of the billing process for our tests. Foundation Medicine 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
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Test	Conditions for Medicare Coverage	Coverage Criteria
FoundationOne CDx™	Covered if all coverage criteria are met. ABN required if patient does not meet the coverage criteria or if person ordering the test is not a treating physician ¹ .	i) Patient has been diagnosed with a solid malignant neoplasm; <i>AND</i> ii) Patient has either recurrent, relapsed, refractory, metastatic, or advanced stages III or IV cancer (only requires one of these to be met); <i>AND</i>
FoundationOne®Liquid	Covered if all coverage criteria are met. ABN required if patient does not meet the coverage criteria.	iii) Either <i>Patient has not been previously tested using the same NGS test for the same primary diagnosis of cancer</i> <i>OR</i> <i>Patient is undergoing repeat testing using the same NGS test for a new primary cancer diagnosis made by the treating physician; AND</i> iv) Patient has decided to seek further cancer treatment (e.g., therapeutic chemotherapy)
FoundationOne®Heme	Not covered at this time. Foundation Medicine is working toward future coverage. ABN required for every case.	N/A

Completed ABN forms can be sent to Foundation Medicine via fax at 866-283-5838 or emailed to billing@foundationmedicine.com.

TO LEARN MORE:

Visit www.foundationmedicine.com

TO CONTACT CLIENT SERVICES:

Call 888.988.3639 or email client.services@foundationmedicine.com

Reference

1. A "treating physician" is a physician, as defined in §1861(r) of the Social Security Act, who furnishes a consultation or treats a beneficiary for a specific medical problem, and who uses the results of a diagnostic test in the management of the beneficiary's specific medical problem. More information is available at <https://www.cms.gov/Regulationsand-Guidance/Guidance/Transmittals/downloads/R80BP.pdf>

See full intended use for FoundationOne CDx at www.foundationmedicine.com/genomic-testing/foundation-one-cdx

