

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.



FOUNDATIONONE CDx™



FOUNDATIONONE®



FOUNDATIONACT®



FOUNDATIONONE®HEME

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. The FoundationAccess™ Program 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)
<https://access.foundationmedicine.com/>
- Submit both forms with the specimen kit

Please contact your sales representative or our client services department at:

888.988.3639 or Visit www.foundationmedicine.com



**FOUNDATION
MEDICINE®**

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Summary of Medicare Beneficiary Eligibility

Summary of Medicare Beneficiary Eligibility based on the Centers for Medicare and Medicaid Services' *Decision Memo for Next Generation Sequencing (NGS) for Medicare Beneficiaries with Advanced Cancer (CAG-00450N)*

FoundationOne CDx™ is covered for Medicare and Medicare Advantage¹ beneficiaries when ordered by a **treating physician**² and when all the following clinical conditions are met:

Patient has:

1. A solid malignant neoplasm; **and**
2. Either recurrent, relapsed, refractory, metastatic, or advanced stages III or IV cancer (only requires one of these to be met); **and**
3. Either not been previously tested using the same NGS test for the same primary diagnosis of cancer or repeat testing using the same NGS test only when a new primary cancer diagnosis is made by the treating physician; **and**
4. Decided to seek further cancer treatment (e.g., therapeutic chemotherapy)

Original Advanced Beneficiary Notice (ABN) Requirements:

<https://www.cms.gov/Medicare/Medicare-General-Information/BNI/ABN.html>

Any Original Medicare patient meeting the following criteria will need to provide Foundation Medicine with a signed ABN for Foundation Medicine to perform the following requested service(s):

1. **FoundationOne CDx™** and **FoundationACT®**:
Patient does not meet the above coverage criteria
2. **FoundationOne®**: ABN required if patient does not meet the above coverage criteria and does not have a cancer diagnosis of non-small cell lung cancer (NSCLC)
3. **FoundationOne®Heme**: ABN required for all FoundationOneHeme orders

ABN forms that have been pre-populated with Foundation Medicine's tests/prices can be obtained from:

1. A Foundation Medicine Account Manager
2. Foundation Medicine's online ordering portal
3. Foundation Medicine's website:
 - a. Order a Test Page³
 - b. FoundationOne⁴, FoundationOneHeme⁵, FoundationACT⁶, and FoundationOne CDx⁷ product pages
 - c. Provider Resources and Patient Resources sites via the above referenced product pages
 - d. The FoundationACT and FoundationOneHeme specimen collection and shipping kits

Visit the CMS website⁸ and select **Download the ABN** to obtain blank ABN forms.

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

References

1. Chapter 4, § 90.1 of the Medicare Managed Care Manual
2. 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/Regulations-and-Guidance/Guidance/Transmittals/downloads/R80BP.pdf>
3. <https://www.foundationmedicine.com/genomic-testing/order>
4. <https://www.foundationmedicine.com/genomic-testing/foundation-one>
5. <https://www.foundationmedicine.com/genomic-testing/foundation-one-heme>
6. <https://www.foundationmedicine.com/genomic-testing/foundation-act>
7. <https://www.foundationmedicine.com/genomic-testing/foundation-one-cdx>
8. <https://www.cms.gov/Medicare/Medicare-General-Information/BNI/ABN.html>

