

Test Requisition Form

Please fax to: (617) 418-2290 Email: client.services@foundationmedicine.com

All fields required | For more information or to order online, visit www.foundationmedicine.com/genomic-testing/order

Patient Demographics

Last Name _____ First Name _____ MI _____ Medical Record # _____ DOB (MM/DD/YYYY) _____ Sex F M
Address _____ City/State/Postal Code _____ Country _____ Phone (primary) _____

Treating Physician Information

Facility Name _____ Treating Physician Name _____
Facility Address _____ City/State/Postal Code _____ Country _____
Phone _____ Fax _____ Email _____ Account # _____

Additional Physician to be Copied (optional) Facility Name _____ Email _____ Fax _____

Current Diagnosis/Patient History

Diagnosis: NSCLC Melanoma Colorectal Adenocarcinoma Ovarian Breast Other _____
Disease Status (select as many as apply): Metastatic Recurrent Refractory Relapse
Subtype _____ Stage _____ ICD Codes (only codes beginning C or D accepted) _____
Transplant Information _____ Targeted Therapies _____
Attachments: Copy of recent pathology/cytology reports including (if available), CBC/differential, BMA differential, FAB classification.
 Test results from all other Molecular Diagnostic Assays by FISH, IHC, or other genetic assays, e.g., ER, PR, HER2, EGFR, KRAS, etc.

Test Selection | Select one

Genomic assay	Description	Accepted Specimen Type	Genomic assay	Description	Accepted Specimen Type
<input type="radio"/> FOUNDATIONONE CDx™	FDA-approved companion.....	FFPE	<input type="radio"/> FOUNDATIONONE® HEME	For hematologic.....	Whole Blood, BMA, FFPE, sarcomas
<input type="radio"/> FOUNDATIONONE®	For all solid tumors.....	FFPE	Additional Options: -----		
<input type="checkbox"/> If tissue is insufficient, reflex to FoundationACT® liquid biopsy (option for mobile phlebotomy below).....	Whole Blood		<input type="radio"/> IHC Testing PD-L1 Dako 22C3.....		FFPE
<input type="radio"/> FOUNDATIONACT®	Liquid biopsy for all solid tumors...	Whole Blood	<input type="radio"/> IHC Testing PD-L1 Dako 22C3 (CPS Scoring.....)	for Gastric/GEJ adenocarcinoma)	FFPE

Specimen Retrieval | Only one specimen can be tested per order

Date of Collection (MM/DD/YYYY) _____ Specimen ID _____ Alternate Choice (optional) _____
 FFPE: Specimen Site _____ Let the submitting pathologist choose I will arrange for sample shipment
 Please contact the pathology lab: Submitting Pathologist Name _____ Facility Name _____ Phone _____ Fax _____
 Whole Blood (Indicate for FoundationOneHeme or FoundationACT®): Mobile Phlebotomy requested (see guidelines on website) I will arrange for sample shipment
 Bone Marrow Aspirate/Extracted Nucleic Acid: Ordering Facility responsible for shipment

Billing Information | Select one of the three payment options and complete all fields indicated

Insurance (check one): Medicare Medicare Advantage Other Health Insurance Plan Name _____
Insured Name _____ Policy # _____ Group # _____ ABN Attached Prior Authorization # _____
Patient status at time of collection (required for all Medicare patients): Office (non-hospital) Outpatient Inpatient (requires discharge date MM/DD/YYYY): _____
 Facility: _____ Address _____ Same as Ordering Physician
 Self-Pay: Contact Name _____ Phone _____ Email _____

Certificate of Medical Necessity/Consent/Test Authorization and Physician Signature

My signature constitutes a Certificate of Medical Necessity, certifies that this test information will inform the patient's ongoing treatment plan, and certifies that I am the patient's treating physician. I have explained to the patient the nature and purpose of the testing to be performed and have obtained informed consent, to the extent legally required, to permit Foundation Medicine to (a) perform the testing specified herein, (b) retain the test results for an indefinite period for internal quality assurance/operations purposes, (c) de-identify the test results and use or disclose such de-identified results for future unspecified research or other purposes, and (d) release the test results to the patient's third-party payer as needed for reimbursement purposes. My signature also authorizes Foundation Medicine to select the most appropriate test (pursuant to Foundation Medicine's Change in Test Authorization Policy) based on requisition/pathology information.

Treating Physician Signature _____ Printed Name _____ Date (MM/DD/YYYY) _____



FOUNDATIONONE CDx™

Intended Use FoundationOne CDx™ is a next-generation sequencing based *in vitro* diagnostic device for detection of substitutions, insertion and deletion alterations, and copy number alterations in 324 genes and select gene rearrangements, as well as genomic signatures including microsatellite instability (MSI) and tumor mutational burden (TMB) using DNA isolated from formalin-fixed, paraffin-embedded (FFPE) tumor tissue specimens. For the complete intended use statement, including companion diagnostic indications, please see the FoundationOne CDx Technical Information page: www.foundationmedicine.com/f1cdx.

FOUNDATIONONE®

About the Test FoundationOne® is a validated comprehensive genomic profile (CGP) for solid tumors. The test is designed to provide physicians with clinically actionable information to guide treatment decisions for patients based on the genomic profile of their disease. Test results provide information about clinically significant alterations, potential targeted therapies, available clinical trials, and quantitative markers of response for immunotherapy. FoundationOne is validated to detect all classes of genomic alterations in more than 300 cancer-related genes, including select introns from more than 25 genes often rearranged or altered in solid tumors.

FOUNDATIONONE® HEME

About the Test FoundationOne®Heme is a comprehensive genomic profiling assay for hematologic malignancies and sarcomas. The test is designed to provide physicians with clinically actionable information to help with diagnostic subclassification, prognosis assessment, and targeted therapeutic selection. Test results provide information about clinically significant alterations, potential targeted therapies, available clinical trials, and quantitative markers that may support immunotherapy clinical trial enrollment. FoundationOneHeme is validated to detect all classes of genomic alterations in more than 400 cancer-related genes. In addition to DNA sequencing, FoundationOneHeme employs RNA sequencing across more than 250 genes to capture a broad range of gene fusions, common drivers of hematologic malignancies and sarcomas.

FOUNDATIONACT®

About the Test FoundationACT® is a blood-based circulating tumor DNA (ctDNA) assay for solid tumors that identifies clinically relevant genomic alterations driving the growth of a patient's cancer. This liquid biopsy can help physicians identify treatment options by providing clinically actionable information relevant to diagnosis, risk-stratification, and prognosis. Test results provide information about potential targeted therapies and/or available clinical trials to better inform treatment decisions. FoundationACT is validated to detect all classes of genomic alterations and to analyze more than 60 of the most commonly mutated genes in solid tumors using only a blood sample.

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®**: ABN required if 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>

