Foundation Medicine Requisition Form

Our test requisition form explained

Instructions for completing the Foundation Medicine test requisition form for all assays are outlined below. These provide a general overview, but please contact Client Services at 888.988.3639 or client.services@foundationmedicine.com for questions or further detail. For more information or to order online, visit www.foundationmedicine.com.

1 Patient Demographics
Patient Last Name, First Name: Enter patient’s full legal first name (no nicknames) and full legal last name (including any hyphenations).

2 Ordering Physician Information
Account Number: If you do not know or do not have an account number, Foundation Medicine will create and/or enter it when we receive the order.

Additional Physician to be Copied: Physician indicated here will receive a copy of the report when it is available (if desired). To add more physicians, please utilize online ordering.

3 Current Diagnosis/Patient History
Accurate diagnosis information helps inform health insurance coverage and supports faster turn-around-time by preventing follow-up from our Client Services, Billing and Pathology groups.

To prevent a delay in receiving results, include:
- Stage OR Disease Status, AND
- Cancer type, ICD Code(s)

Diagnosis: Current diagnosis. Choose cancer type or fill out “other”.

Attachments: Supplementary test results may assist our pathologists in their assessment of the case. Scan and include with submission. Utilizing online ordering will make this process easier.

4 Test Selection
Select only one test. For information on what test is right for your patient, refer to our website or contact Client Services.

FACT Reflex Option: If patient tissue sample is insufficient for FoundationOne® or FoundationOne CDx™, you may preauthorize Foundation Medicine to proceed with our liquid biopsy test, FoundationACT®. We will work with you and your patient to obtain the necessary blood specimen for testing.

5 Specimen Retrieval Information
Provide information only for the specimen type that is being submitted. (If the FoundationACT reflex option has been selected, additionally provide information for Whole Blood.)

Date of Collection, Specimen ID: All orders submitted require Date of Collection and Specimen ID.

Submitting Pathologist Name, Facility Name, Phone, Fax: Foundation Medicine may need to contact your submitting pathologist to obtain the sample. Providing contact information will ensure that we can request and receive the sample in a timely manner.

6 Billing Information
READ CAREFULLY TO PREVENT A DELAY IN RECEIVING RESULTS

One of the 3 options (Insurance, Facility, Self-Pay) must be selected and all associated information must be provided.

Foundation Medicine, Inc.  |  www.foundationmedicine.com  |  Tel. 888.988.3639  |  Fax 617.418.2290  |  MKT-0192-01

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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/ftcdx.

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®HEMEn

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 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 Advantage® beneficiaries when ordered by a treating physician 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 and 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 Page
   b. FoundationOne®, FoundationOneHeme®, FoundationACT®, and FoundationOne CDx® 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 website 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, § 90.3 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