Coverage and Patient Access for Foundation Medicine Tests

FOUNDATION MEDICINE®

Insurance Coverage

- Medicare covers all Foundation Medicine tests for qualifying patients.[1]
- TRICARE covers FoundationOne CDx and FoundationOne Liquid CDx in accordance with their FDA-approved indications.[2]
- Cigna covers FoundationOne CDx and FoundationOne Liquid CDx in the cancer types where they have an FDA-approved companion diagnostic for qualifying beneficiaries.[3]
- Over 60 commercial health plans cover one or more of Foundation Medicine's comprehensive genomic profiling (CGP) tests.

The FoundationAccess™ Program

Our experience shows that:

84%
of patients have a $0 financial responsibility
for Foundation Medicine testing[4]

86%
of patients have a financial **responsibility of $100 or less**
for Foundation Medicine testing.[5]

Our FoundationAccess™ program supports providers and patients through the coverage and billing process.

- For each CGP test ordered we complete a benefits investigation and reach out to all patients who we expect may have out-of-pocket costs.
- We support providers and patients by helping obtain prior authorizations when required, billing the patient's health plan for the test and appealing denials with the patient's consent.
- The final cost for a patient's bill is determined after billing the health plan, and exhausting all available appeal efforts.

Financial Assistance Program

Financial assistance is available for qualifying patients who have out-of-pocket costs associated with Foundation Medicine testing. Financial assistance is based on need and can be applied for at any point during the testing process.*

* Foundation Medicine's Financial Assistance Program is only available to patients whose tests were ordered within the United States and U.S. territories.

Pricing for Foundation Medicine's Tests

FOUNDATION**ONE®CDx** FOUNDATION**ONE®LIQUID CDx** FOUNDATION**ONE®HEME**	**$5,800.00**
PD-L1 (Immunohistochemistry)	**$250.00**

Questions

The Foundation Medicine team is here to help. If you or your patient has an Explanation of Benefits (EOB) or bill in hand and have any questions, please contact our billing department.

Call: 877.246.9204

Email: foundationmedicine@mylabbill.com

Fax: 440.528.6010

To order a test, go to *www.foundationmedicine.com/order*

FoundationOne®Heme is a laboratory developed test that was developed and its performance characteristics determined by Foundation Medicine. FoundationOne Heme has not been cleared or approved by the U.S. Food and Drug Administration. For more information on FoundationOne Heme, please see its Technical Specifications at foundationmedicine.com/heme.

FoundationOne®CDx and FoundationOne®Liquid CDx are qualitative next-generation sequencing based in vitro diagnostic tests for advanced cancer patients with solid tumors and are for prescription use only. FoundationOne CDx utilizes FFPE tissue and analyzes 324 genes as well as genomic signatures. FoundationOne Liquid CDx analyzes 324 genes utilizing circulating cell-free DNA and is FDA-approved to report short variants in 311 genes. The tests are companion diagnostics to identify patients who may benefit from treatment with specific therapies in accordance with the therapeutic product labeling. Additional genomic findings may be reported and are not prescriptive or conclusive for labeled use of any specific therapeutic product. Use of the tests does not guarantee a patient will be matched to a treatment. A negative result does not rule out the presence of an alteration. Some patients may require a biopsy for testing with FoundationOne CDx when archival tissue is not available which may pose a risk. Patients who are tested with FoundationOne Liquid CDx and are negative for companion diagnostic mutations should be reflexed to tumor tissue testingand mutation status confirmed using an FDA-approved tumor tissue test, if feasible. For the complete label, including companion diagnostic indications and important risk information, please visit www.F1CDxLabel.com and www.F1LCDxLabel.com.

References:

1. FoundationOne®CDx and FoundationOne®Liquid CDx: "Decision Memo for Next Generation Sequencing (NGS) for Medicare Beneficiaries with Advanced Cancer – CAG-00450R." FoundationOne®Heme: Local Coverage Determination (LCD): MolDX: "Next-Generation Sequencing Lab Developed Tests for Myeloid Malignancies and Suspected Myeloid Malignancies (L38123)."
2. TRICARE Policy Manual 6010.60-M, Chapter 6, Section 3.1 Genetic Testing and Counseling, 2.2 Genetic tests that have received United States (U.S.) Food and Drug Administration (FDA) medical device 510(k) clearance or premarket approval that are medically necessary for the diagnosis and treatment of an illness or injury and have demonstrated clinical utility are a TRICARE benefit.
3. Cigna provides coverage for commercially insured beneficiaries, in accordance with the criteria within Cigna's Medical Policy 0520, titled "Molecular Diagnostic Testing for Hematology and Oncology Indications," in the cancer types where FoundationOne CDx and FoundationOne Liquid CDx are an FDA-approved companion diagnostic, and when prior authorization is obtained.
4. Data on File, Foundation Medicine, Inc., 2021. Based on settled claims from 1/1/20 to 3/31/21 for all tests offered by Foundation Medicine and reported during that time before considering any financial assistance. 58% of commercially insured and 95% of Medicare and Medicare Advantage patients paid $0 for Foundation Medicine testing.
5. Data on File, Foundation Medicine, Inc., 2021. Based on: (1) tests reported between 1/1/19 and 3/31/20; (2) patient financial responsibility before taking into account any financial assistance awarded by Foundation Medicine's need-based financial assistance program; (3) settled claims (i.e., Foundation Medicine has exhausted its appeals and reimbursement efforts); and (4) 65% of commercially insured patients and 97% of Medicare/Medicare Advantage patients having or qualifying for a payment of $100 or less. Includes FoundationOne®CDx, FoundationOne®Liquid, FoundationOne®Heme, and immunohistochemistry testing (IHC) performed at Foundation Medicine. Data current as of June 16, 2020.

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