FOUNDATION MEDICINE®

ONE PROVEN PORTFOLIO OF TESTS & SERVICES. THAT'S OUR FOUNDATION.

FOUNDATIONONE®CDx | FOUNDATIONONE®LIQUID CDx | FOUNDATIONONE®HEME

Most experience with comprehensive genomic profiling[1]

500+ Peer-reviewed publications on the current and potential utility of comprehensive genomic profiling[1]

500K+ Patients tested with comprehensive genomic profiling in a clinical setting[1]

- Tissue- AND blood-based **FDA-approved** comprehensive genomic profiling testing for all solid tumors with FoundationOne®CDx and FoundationOne®Liquid CDx
- All Foundation Medicine comprehensive genomic profiling tests are run in **CAP accredited** and **CLIA certified** labs.

Understanding Results

- Medical Case Consulting by a team of oncologists and pathologists to discuss results
- Molecular Tumor Boards are offered through our medical team for eligible institutions to educate on the actionability of comprehensive genomic profiling

Workflow Integration

- Digital Experience for ordering, tracking and reporting
- EMR interfacing

Clinical Trial Matching

- Notify physicians of enrollment opportunities for NCI-match trial arms
- Precision Enrollment program identifies patients with rare or specific biomarkers and matches them with sponsor trials using the FoundationSmartTrials™ engine

Financial Assistance and Coverage:

- Medicare covers all Foundation Medicine tests for qualifying patients who meet clinical criteria.[2]
- FoundationOne CDx and FoundationOne Liquid CDx are covered by TRICARE for qualifying patients.[3]
- Foundation Medicine's testing experience has shown that:
  - 79% of patients have $0 financial responsibility for testing[4]
  - 86% of patients have a financial responsibility of $100 or less for testing[5]
- We offer a needs-based financial assistance program for qualifying patients that may have out of pocket costs.

SEE OUR PROVEN PORTFOLIO OF TESTS ON THE BACK

Our Proven Portfolio

All Solid Tumors

Tissue Biopsy | Liquid Biopsy

Hematologic Malignancies and Sarcomas

FOUNDATIONONE®CDx

- FDA-approved companion diagnostic for 24 unique targeted therapies
- DNA (324 genes)
- Tumor mutational burden, microsatellite instability, and loss of heterozygosity*
- Option to reflex to liquid

Typical turnaround time of 10 days or less†

FOUNDATIONONE®LIQUID CDx

- FDA-approved companion diagnostic for 7 unique targeted therapies
- DNA (324 genes)‡
- Blood tumor mutational burden, microsatellite instability high, and reports tumor fraction§
- Option to reflex to tissue

Typical turnaround time of 10 days or less†

FOUNDATIONONE®HEME

- Laboratory Developed Test
- DNA (406 genes) + RNA (265 genes) for hematologic malignancies, sarcomas, or solid tumors where RNA sequencing is desired
- Tumor mutational burden and microsatellite instability
- FFPE Tissue or Bone Marrow Aspirate or Peripheral Whole Blood

Typical turnaround time of 2 weeks†

IHC
Optional Tissue add-on for PD-L1

- FDA-approved CDx for immunotherapies in specific solid tumors
- 5 day turnaround time†

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

** LOH for ovarian cancer only*
† From receipt of specimen
‡ FoundationOne®Liquid CDx is FDA-approved to report substitutions and indels in 311 genes, including rearrangements in ALK and BRCA1/2 and copy number alterations in BRCA1/2 and ERBB2 (HER2). Comprehensive results across all 324 genes are reported as a laboratory professional service which is not reviewed or approved by the FDA.
§ bTMB, MSI-H status, and tumor fraction are reported as a laboratory professional service which is not reviewed or approved by the FDA.

References

1. Data on file, Foundation Medicine, Inc, 2021
2. For FoundationOne®CDx and FoundationOne®Liquid CDx, see "Decision for Next Generation Sequencing (NGS) for Medicare Beneficiaries with Advanced cancer – CAG-00450R." (See Appendix B). For FoundationOne®Heme, see the "Local Coverage Determination (LCD): MolDX: NEXT-GENERATION Sequencing Lab-Developed Tests for Myeloid Malignancies and Suspected Myeloid Malignancies (L38047)".
3. TRICARE Policy Manual 6010.60-M, Chapter 6, Section 3.1Genetic 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.
4. Based on settled claims from 1/1/19 to 3/31/20 for all tests offered by Foundation Medicine and reported during that time before considering any financial assistance. 61% of commercially insured and 90% of Medicare and Medicare Advantage patients paid $0 for Foundation Medicine testing.
5. Based on settled claims from 1/1/19 to 3/31/20 for all tests offered by Foundation Medicine and reported during that time before considering any financial assistance. 65% of commercially insured and 97% of Medicare and Medicare Advantage patients had or qualified for a payment of $100 or less for Foundation Medicine testing.

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.*

FOUNDATION MEDICINE®

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