

FoundationOne® Heme CGP for hematologic malignancies

Comprehensive genomic profiling (CGP) with DNA and RNA provides valuable insights for diagnosis, prognosis, therapy selection, and clinical trial enrollment.

FoundationOne Heme *detects all four classes of genomic alterations* including novel fusions or complex rearrangements commonly occurring in hematologic malignancies and solid tumors.

Facilitate diagnosis based on CGP findings. In a retrospective analysis of samples from patients with hematologic malignancies analyzed with FoundationOne Heme, 50% of cases had a genomic alteration with diagnostic relevance and, in 14%, the presence of the genomic alteration led to a change or refinement of diagnosis.²

Inform patient prognosis with coverage of genomic alterations that have implications for patient risk assessment and treatment resistance.

Evaluate treatment options based on actionable genomic alterations including targeted therapy response. Across several studies, FoundationOne Heme identified potentially actionable genomic alterations in patients with hematologic malignancies in 62.5% to 100% of patients.¹⁻⁵

Identify relevant clinical trials exploring biomarker-based therapies.



Comprehensive Evaluation

Analyzes over **400 DNA and 250 RNA genes to detect all four classes of genomic alterations** (substitutions, indels, copy number alterations, SNVs and optimized for fusions).

Variant Allele Frequency (VAF%) reporting facilitates more accurate diagnoses and classification of disease, support for evaluating clonal evolution, and insights to identify and assess resistance clones.

Includes comprehensive assessment of the following biomarkers:

- Tumor Mutational Burden (TMB)
- Microsatellite Instability (MSI)

Flexibility in Sample Type

Analyzes **peripheral blood (PB), bone marrow aspirate (BMA), or formalin-fixed paraffin-embedded (FFPE) tissue**. The optimal stability window for FoundationOne Heme fresh specimens is three days or less, although samples collected after a longer time can still be processed.

Guideline Recommended

Guideline Recommended: Broad molecular testing is recommended by professional guidelines for a growing number of cancer types:

- Chronic Myeloid Leukemia (CML)⁶
- Acute Myeloid Leukemia (AML)⁷
- Acute Lymphoblastic Leukemia (ALL)^{8,12}
- Myelodysplastic Syndrome (MDS)⁹
- Myeloproliferative Neoplasms (MPN)¹⁰



For adult and pediatric patients

FoundationOne Heme identifies alterations associated with acute ALL, the most common type of cancer in children¹³. The Foundation Medicine report may identify targeted therapies or clinical trials focused on pediatric patients.



Medicare Covered

Local coverage determination for qualifying Medicare patients diagnosed with a myeloid malignancy or suspected myeloid malignancy.¹¹



On-Call Clinical Support

Discuss patient results with our Medical Affairs team. This robust **on-call program connects providers with internal experts** such as the Medical Science Liaison, oncologists or pathologists who are subject matter experts.

Order FoundationOne Heme today.

foundationmedicine.com/order

References:

1. He J, et al. Integrated genomic DNA/RNA profiling of hematologic malignancies in the clinical setting. *Blood*. 2016 Jun 16;127(24):3004-3014.
2. Pichardo JD, Feldstein JT, Arcila M, et al. A Comprehensive Clinical Next Generation Sequencing-Based Assay Can Impact Hematopathologic Diagnosis in a Significant Subset of Patients with Hematologic Malignancies. *Blood*. 2014;124(21):2984-2984.
3. Bieg-Bourne CC, Millis SZ, Piccioni DE, et al. Next-Generation Sequencing in the Clinical Setting Clarifies Patient Characteristics and Potential Actionability. *Cancer Res*. 2017;77(22):6313-6320. <https://www.ncbi.nlm.nih.gov/pubmed/28939679>.
4. Galanina N, Bejar R, Choi M, et al. Comprehensive Genomic Profiling Reveals Diverse but Actionable Molecular Portfolios across Hematologic Malignancies: Implications for Next Generation Clinical Trials. *Cancers (Basel)*. 2018;11(1). <https://www.ncbi.nlm.nih.gov/pubmed/30583461>.
5. Reitsma M, Fox J, Borre PV, et al. Effect of a Collaboration Between a Health Plan, Oncology Practice, and Comprehensive Genomic Profiling Company from the Payer Perspective. *Journal of managed care & specialty pharmacy*. 2019:1-10.
6. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Chronic Myeloid Leukemia V.2.2024. © 2024 National Comprehensive Cancer Network, Inc. All rights reserved. Accessed June 2024.
7. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Acute Myeloid Leukemia V.3.2024 © 2024 National Comprehensive Cancer Network, Inc. All rights reserved. Accessed June 2024.
8. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Acute Lymphoblastic Leukemia V.4.2023 © 2023 National Comprehensive Cancer Network, Inc. All rights reserved. Accessed June 2024.
9. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Myelodysplastic Syndromes V.2.2024. © 2024 National Comprehensive Cancer Network, Inc. All rights reserved. Accessed June 2024.
10. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Myeloproliferative Neoplasms V.1.2024. © 2024 National Comprehensive Cancer Network, Inc. All rights reserved. Accessed June 2024.
11. Qualifying Medicare and Medicare Advantage members have coverage of FoundationOne®Heme under the MoIDx Local Coverage Determination (LCD) for Next-Generation Sequencing Lab-Developed Tests for Myeloid Malignancies and Suspected Myeloid Malignancies (L38047)
12. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Pediatric Acute Lymphoblastic Leukemia V.5.2024 © 2024 National Comprehensive Cancer Network, Inc. All rights reserved. Accessed July 2024.
13. National Cancer Institute. [https://www.cancer.gov/types/leukemia/patient/child-all-treatment-pdq#:~:text=Childhood%20acute%20lymphoblastic%20leukemia%20\(also,if%20it%20is%20not%20treated.&text=Anatomy%20of%20the%20bone.,spongy%20bone%2C%20and%20bone%20marrow](https://www.cancer.gov/types/leukemia/patient/child-all-treatment-pdq#:~:text=Childhood%20acute%20lymphoblastic%20leukemia%20(also,if%20it%20is%20not%20treated.&text=Anatomy%20of%20the%20bone.,spongy%20bone%2C%20and%20bone%20marrow). Accessed July 2024.

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.