



A Patient's Guide to

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# Comprehensive Genomic Profiling



FOUNDATION  
MEDICINE®

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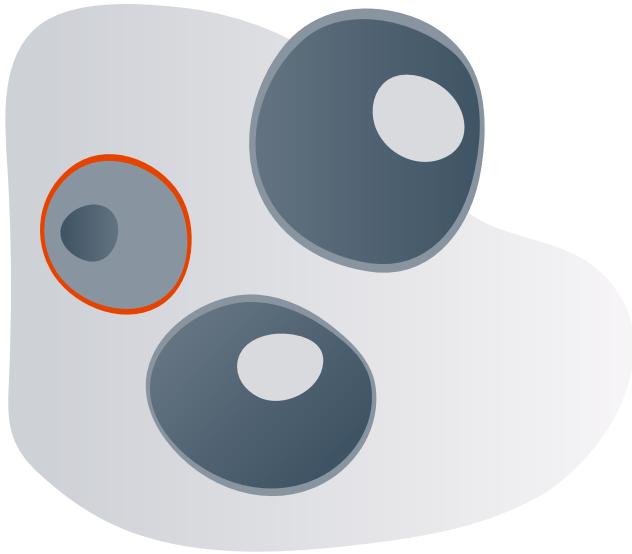
## **Contents**

01	Explore comprehensive genomic profiling and cancer treatment options.....	5
02	Treatments for cancer.....	10
03	Biomarker testing and Foundation Medicine.....	12
04	How the testing process works with Foundation Medicine.....	14
05	What the test results mean.....	17
06	Billing information.....	19
07	Medicare.....	21
08	Private insurance.....	24
09	Financial assistance.....	26
10	Questions.....	28



# **Explore comprehensive genomic profiling and cancer treatment options**

01



## Cells

Our bodies are made up of trillions of cells.

## DNA

DNA is like an instruction manual inside every cell with chapters called genes.





## Genes

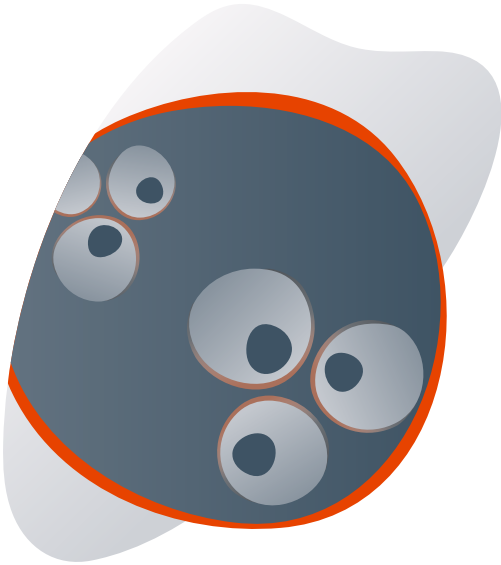
Genes tell cells what to do, including when to make new cells.

**Cancer may occur when cells are growing out of control, potentially spreading into your body's tissues.**

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This happens because the DNA that tells a cell what to do is not working as it should. This is known as a mutation. Usually, our natural immune system can stop abnormal cell growth before problems happen. But when it doesn't, cells keep growing and dividing.



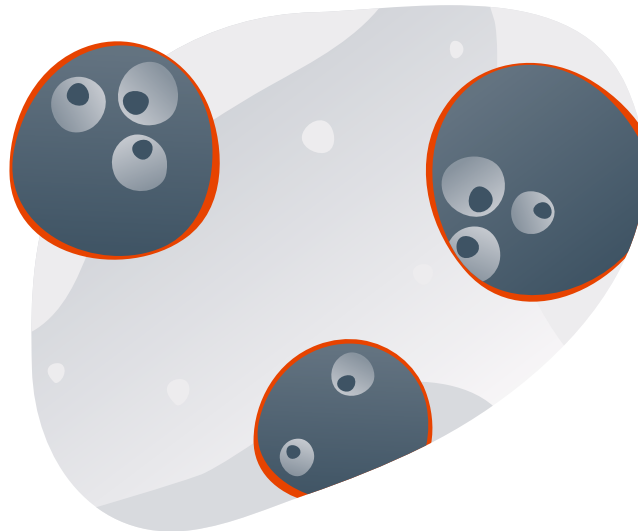


## **Localized or metastatic tumors**

In some cases, the cancer stays in one place (localized tumor). In other cases, it spreads (metastatic tumor). When tumors are metastatic, they consume the body's resources as they grow, damaging healthy tissue and organs.

## **Tumors**

When cells grow out of control, they may form a mass called a tumor. To find out if a mass is cancerous, doctors take a piece of tissue from the tumor and study it. This process is called a biopsy.





Comprehensive genomic profiling (CGP) is a method of cancer testing that can find the mutations in your DNA that may be causing your cancer to grow. The test looks at the DNA in your tumor tissue. CGP is a type of *biomarker testing* or *tumor testing*.

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**Knowing what mutations and biomarkers you have can help your doctor choose the best medicine for you.**

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This approach to treatment is called *precision medicine* or *personalized medicine*, because it is based on your own unique genomic profile and cancer type.

# Treatments for cancer

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Common cancer treatments include surgery, radiation, and chemotherapy. Your doctor may also suggest targeted therapy or immunotherapy.

02

## **Targeted therapy**

Targeted therapy may stop the growth of cancer cells by targeting certain mutations.

## **Immunotherapy**

Immunotherapy helps your body's own natural immune system find cancer cells and kill them.

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**By using comprehensive genomic profiling to identify the mutations and biomarkers in your cancer, your doctor may identify an appropriate targeted therapy or immunotherapy for you.**

# **Biomarker testing and Foundation Medicine**

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Foundation Medicine is a company comprised of a dedicated group of scientists, doctors, and other highly trained and experienced professionals, committed to making precision medicine a reality for patients like you.

03

**We work closely with your doctor in offering biomarker testing through three different CGP tests, depending on what your doctor decides is best for you.**

#### THE TESTS ARE:

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#### **FoundationOne® CDx**

- For solid tumor cancers like lung, colorectal, breast, or prostate cancer
- This test is performed on a tissue sample

#### **FoundationOne® Liquid CDx**


- Also for solid tumor cancers like lung, colorectal, breast, or prostate cancer, but performed on a blood sample
- This is called a liquid biopsy

#### **FoundationOne® Heme**

- For blood cancers like leukemia and lymphoma, and for sarcomas
- This test is performed on a blood sample, bone marrow sample, or tissue sample

# **How the testing process works with Foundation Medicine**

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**You and your doctor talk about testing options together. Your doctor orders a Foundation Medicine test for you if appropriate. Tissue or blood will be required, based on your case.**



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### **Tissue**


Foundation Medicine contacts the lab that has your tissue sample and coordinates to have it sent to our lab. The sample may be from a recent biopsy or it may be older. Your doctor may also send the sample directly.

If a tissue block was sent, we return it to the lab that sent it after testing is complete.




### **Blood**

Your doctor sends a blood sample to our lab. In certain circumstances we can arrange to have your blood drawn at your home and sent (mobile phlebotomy).








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**We study the DNA\* in your sample to find mutations and other biomarkers that may indicate if a targeted therapy or immunotherapy might work for you.**



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**We send the results to your doctor in about 2 weeks.†**



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**You and your doctor talk about the results and how they may help with your treatment plan.**

\* FoundationOne Heme also analyzes RNA. RNA contains information that has been copied from DNA.

† Typical turnaround time from receipt of specimen is <2 weeks.

# What the test results mean

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Foundation Medicine test results offer three possible options for you and your doctor to consider in your treatment.

05

## Three possible options for you and your doctor to consider in your treatment

### FDA-approved therapies

We identify approved targeted therapies or immunotherapies that may help you based on the mutations and biomarkers we found in your cancer. These therapies may have been approved for your cancer type or they may have been approved in other cancer types.

### Rule out therapies

We look at hundreds of important genes to help your doctor know which medicines may *not* work for you.

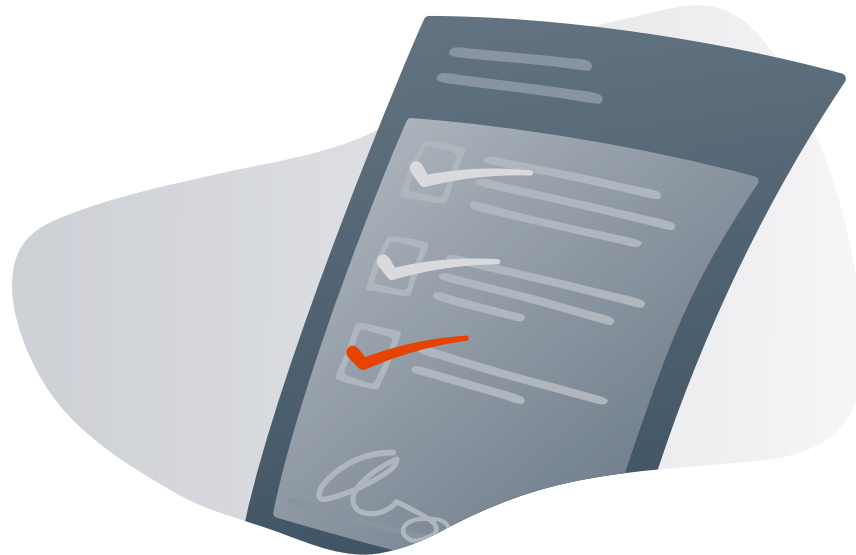
### Clinical trial options

We match your results with medicines that are currently in development through clinical trials. Talk to your doctor about which clinical trials may be available and if you might qualify.

# Billing information

06

**Your cost will depend on your insurance plan.**



# Medicare

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Medicare coverage of Foundation Medicine's tests is available for qualifying patients with advanced cancer.

07

# If you are an Original Medicare patient and you meet the following criteria, you may not have out-of-pocket expenses for your FoundationOne CDx or FoundationOne Liquid CDx testing when ordered by your treating physician:<sup>1,2,3</sup>

## One

You have been diagnosed with a solid tumor cancer.

## Two

You have either recurrent, relapsed, refractory, metastatic, or advanced stage III or IV cancer (only requires one of these to be met).

## Three

This is your first time having a FoundationOne CDx or FoundationOne Liquid CDx test OR your cancer has progressed<sup>4</sup> since your prior test.

## Four

You have decided to seek further cancer treatment (e.g. therapeutic chemotherapy).

1. In accordance with The Centers for Medicare & Medicaid Services (CMS) Decision Memo for Next Generation Sequencing (NGS) for Medicare Beneficiaries with Advanced Cancer (CAG-00450R) see Appendix B
2. Patients with Medicare Advantage Plans could have out-of-pocket expenses in the form of co-pay, co-insurance, and/or unmet deductible amounts. More information is available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R80BP.pdf>
3. 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>
4. Repeat testing (FoundationOne®CDx, FoundationOne®Liquid CDx, or FoundationOne®Heme) after disease progression (i.e., there is evidence of a new malignant growth despite response to a prior targeted therapy) may be covered under the Centers for Medicare and Medicaid Services (CMS) National Coverage Decision (NCD) for qualifying Medicare beneficiaries.

## If you are an Original Medicare patient and you meet the following criteria, you may not have out-of-pocket expenses for your FoundationOne Heme testing:<sup>1,2</sup>

### **One**

You have been diagnosed with acute myeloid leukemia (AML), myelodysplastic syndrome (MDS) or myeloproliferative neoplasms (MPN) OR You have a suspected myeloid malignancy with an undefined cytopenia for greater than 4 months, and other possible causes have been reasonably excluded.

### **Two**

You have not previously received or are not currently receiving Next Generation Sequencing (NGS)<sup>1</sup> testing on the specimen for which the test is currently being ordered.

### **Three**

This is your first time having a FoundationOne Heme test OR your cancer has progressed<sup>3</sup> since your prior test.

1. In accordance with the MoDx Local Coverage Determination (LCD): Next-Generation Sequencing Lab-Developed Tests for Myeloid Malignancies and Suspected Myeloid Malignancies (L38047)

2. Patients with Medicare Advantage Plans could have out-of-pocket expenses in the form of co-pay, co-insurance, and/or unmet deductible amounts.

3. Repeat testing (FoundationOne®CDx, FoundationOne®Liquid CDx, or FoundationOne®Heme) after disease progression (i.e., there is evidence of a new malignant growth despite response to a prior targeted therapy) may be covered under the Centers for Medicare and Medicaid Services (CMS) National Coverage Decision (NCD) for qualifying Medicare beneficiaries.



# Private insurance

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Foundation Medicine will work directly with your insurance company to try and obtain coverage.

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**Depending on the terms of your insurance plan, you may have financial responsibility for a co-pay, co-insurance, or a deductible as directed by your plan.**

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If your insurance company denies coverage, with your consent, we will attempt to obtain coverage on your behalf and will work with you and your doctor in pursuing appeals to minimize the out-of-pocket cost.

# Financial assistance

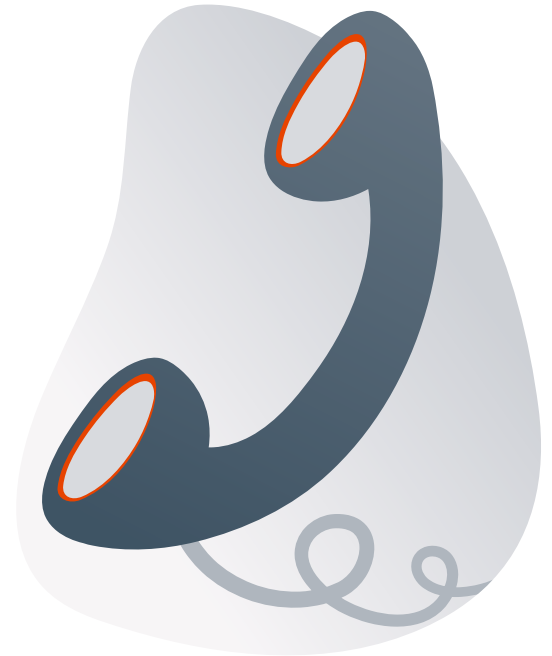
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Financial assistance is available for qualifying patients who have out-of-pocket costs associated with Foundation Medicine testing. Financial assistance is based on need and can be applied for at any point during the testing process. Payment plans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

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**To apply for financial assistance, please visit:**  
**[aid.foundationmedicine.com](https://aid.foundationmedicine.com)**

**To contact our Client Services Care Team please call**  
**888.988.3639 or email**  
**[care.team@foundationmedicine.com](mailto:care.team@foundationmedicine.com)**



# Questions

10

**We are here to help. If you have any questions about how Foundation Medicine testing could help you and your doctor, or you would like more information about the testing or billing process, please contact us.**

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**Call**

888.988.3639

**Email**

*care.team@foundationmedicine.com*

**Explore your options.  
Talk to your doctor  
about comprehensive  
genomic profiling.**



For prescription use only. FoundationOne®CDx is a qualitative genomic sequencing test for advanced cancer patients with solid tumors and analyzes 324 genes. It is intended to help doctors identify which patients may benefit from treatment with certain therapies or through clinical trials. Use of the test does not guarantee that a patient will be matched to a treatment or that all relevant genomic alterations will be detected. Some patients may require a biopsy which poses certain risks. For the full product labeling, including indications for use and risk information, visit [StartWithStepOne.com](http://StartWithStepOne.com).

FoundationOne®Liquid CDx is for prescription use only and is a next-generation sequencing based in vitro diagnostic test for advanced cancer patients with solid tumors. The test analyzes 324 genes utilizing circulating cell-free DNA, is FDA-approved to report short variants in 311 genes, and is a companion diagnostic to identify patients who may benefit from treatment with specific therapies (listed in Table 1 of the Intended Use) in accordance with the approved 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 test does not guarantee a patient will be matched to a treatment. A negative result does not rule out the presence of an alteration. Patients who are negative for companion diagnostic mutations should be reflexed to tumor tissue testing and mutation status confirmed using an FDA-approved tumor tissue test, if available. For the complete label, including companion diagnostic indications and complete risk information, please visit <http://www.FILCDxLabel.com>.

FoundationOne®Heme 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 about FoundationOne Heme, please see its Technical Specifications at [www.foundationmedicine.com](http://www.foundationmedicine.com).







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