Patient Information Guide

Frequently Asked Questions – Biomarker Testing

Test Requisition Form – FoundationOne®, FoundationOne® Heme, and FoundationACT®

Frequently Asked Questions – Billing and Reimbursement

Financial Assistance Application

Questions to Ask Your Doctor

Patient Website:
MyCancerIsUnique.com

Online Financial Assistance Application:
Access.FoundationMedicine.com
FREQUENTLY ASKED QUESTIONS – BIOMARKER TESTING

What are genomic alterations and how do they lead to cancer?

A genomic alteration (or mutation) is a change in the DNA sequence that makes up a gene and can affect the way a cell functions. These genomic changes are a normal part of life, and most won’t have a negative effect on our health. But some alterations lead to diseases, including cancer. Cancers are caused by alterations within several hundred specific genes that are found in the cells of our bodies. When changes occur in these genes, cells can grow in an abnormal fashion, causing cancerous tumors to form. These tumors may become metastatic and spread throughout the body.

What is the difference between genetic alterations and genomic alterations?

Alterations in DNA can occur in two ways: they can be inherited from our parents or acquired during a person’s lifetime. Hereditary changes are called genetic alterations and are a contributing factor in about 5-10 percent of cancers. Acquired alterations are called genomic alterations and are responsible for the majority of cancers. While some acquired alterations may be caused by environmental factors such as smoking, sun exposure and viruses like HPV, many have no known cause. There may be multiple alterations contributing to your cancer. These alterations can be detected by biomarker testing.

What are targeted therapies and immunotherapies?

Targeted therapies target specific underlying genomic alterations that are contributing to tumor growth. By attacking the cancer and sparing the surrounding tissue, targeted therapies can be more effective and have fewer and less pronounced side effects than traditional chemotherapies. Since there are hundreds of cancer genes, and many possible alterations in each gene, the number and combination of genomic alterations make each person’s cancer unique. Immunotherapies harness the body’s own immune system to attack cancer cells. Targeted therapies and immunotherapies may be available as FDA-approved therapies or they may be available as part of a clinical trial.

What is comprehensive genomic profiling?

A comprehensive genomic profiling test is a type of biomarker test that looks at all 4 types of genomic alterations in cancer-related genes in a single sample. This allows for the identification of multiple genomic alterations present in the tumor that may lead to targeted therapy or immunotherapy options that you and your doctor may consider.
How can I get a comprehensive genomic profiling test?

If you and your doctor decide to have a comprehensive genomic profiling test, you would start the process by submitting a Test Requisition Form (see next page). Foundation Medicine performs a type of biomarker testing called comprehensive genomic profiling. Once your doctor submits the Test Requisition Form to us along with the pathology report, billing information and any other attached paperwork, we will contact the hospital that has the tumor sample so it can be sent to us for testing. We will analyze the sample to identify any genomic alterations that may be driving the cancer. We will then issue a report back to your doctor that lists the genomic alterations, additional biomarkers, and the targeted therapies, immunotherapies, or clinical trials that you and your doctor may consider for the next stage in your treatment.

What type of sample should be sent?

The type of sample will depend on which test is ordered. Foundation Medicine offers a few different tests. Our FoundationOne® test for solid tumors is performed on preserved tumor tissue and follows the steps described above. Alternatively, FoundationACT® is a liquid biopsy for solid tumor patients that is performed on tumor DNA circulating in the blood. FoundationOne® Heme is performed for patients with hematologic malignancies or sarcomas, and it can be performed on blood, bone marrow, or preserved tissue (your physician will know what sample type is best). Please contact our Client Services Team at 888-988-3639 or Client.Services@FoundationMedicine.com to discuss these tests and sample types in further detail.
**Required Information**
- [ ] First Submission
- [ ] Second Submission
- [ ] Associated Requisition
- [ ] Associated Study

### Patient Information
- **Last Name***
- **First Name***
- **MI***
- **Patient Medical Record #***
- **Patient DOB***
- **Patient Gender***
  - [ ] M
  - [x] F
- **Street Address***
- **Apt. #***
- **City***
- **State***
- **Postal Code***
- **Country***
- **Patient Phone # (Primary)***
- **Patient Gender***
- **Patient Phone # (Primary)***
- **Email Address***

### Pathology Information
- **Hospital / Institution Name***
- **Submiting Pathologist Name***
- **Phone***
- **Fax***

### Ordering Physician Information
- **Office / Practice / Institution Name***
- **Ordering Physician***
- **Account #***
- **Street Address***
- **City***
- **State***
- **Postal Code***
- **Country***
- **Phone***
- **Fax***
- **Email Address***

### Additional Physician(s) to be Copied
- **Name***
- **Office/Practice/Facility Name***
- **Email***
- **Phone***
- **Fax***

### Test Ordered** (CHECK ONE BOX)
- [ ] FoundationOne® (Optimized for solid tumors)
- [ ] FoundationOne® Heme (Optimized for hematologic malignancies and sarcomas)

### Specimen Information (only one specimen can be tested per order)
- **Diagnosis***
- **Stage***
- **ICD Code(s) Listed***
- **Date of Collection***
- **Specimen Site***
- **Specimen I.D.***
- **Alternate Specimen I.D.***

### Billing Information
- **Patient Status**
  - [ ] Hospital Inpatient
  - [ ] Hospital Outpatient
  - [ ] Non-hospital patient
- **Institution Name***
- **Discharge Date***
- **Policy #***
- **Group #***
- **Insured Name***
- **Card Holder Address***
- **Patient Relationship to Insured**
  - [ ] Self
  - [ ] Spouse
  - [ ] Child
  - [ ] Other
- **Insured DOB***
- **Name on Credit Card***
- **Credit Card #***
- **Exp. Date***

### Comments, Remarks or Special Requests
- [ ] PATHOLOGIST CHOICE best specimen for testing
- [ ] Specific specimen requested
- [ ] Patient s/p TARGETED THERAPY
- [ ] Dates: ____________
- [ ] Drug:

### Physician Signature
- **Ordering Physician Signature***
- **Date (MM/DD/YYYY)***

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*Additional Test(s) (HIC):*  
- [ ] PD-1
- [ ] PD-L1

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**Test Ordered** (CHECK ONE BOX)
- [ ] FoundationOne® (Optimized for solid tumors)
- [ ] FoundationOne® Heme (Optimized for hematologic malignancies and sarcomas)

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*Additional Test(s) (IHC):*
- [ ] PD-L1

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**Additional Test(s) (IHC):**
- [ ] PD-L1

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**AUTHORITY GIVEN TO FOUNDATION MEDICINE TO CHANGE THE TEST SELECTED ABOVE BASED ON REQUISITION FORM/PATHOLOGY INFORMATION**

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**Specimen Retrieval**
- Unless otherwise specified, Foundation Medicine will contact the pathology department indicated above to request your patient’s specimen. Please indicate below if you would NOT prefer us to provide this service.
- DO NOT contact pathology regarding this case. I will arrange for the specimen to be shipped to Foundation Medicine.

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**Billing Information**
- **Patient Status**
  - [ ] Hospital Inpatient
  - [ ] Hospital Outpatient
  - [ ] Non-hospital patient
- **Institution Name***
- **Discharge Date***
- **Policy #***
- **Group #***
- **Insured Name***
- **Card Holder Address***
- **Patient Relationship to Insured**
  - [ ] Self
  - [ ] Spouse
  - [ ] Child
  - [ ] Other
- **Insured DOB***
- **Name on Credit Card***
- **Credit Card #***
- **Exp. Date***

---

**Comments, Remarks or Special Requests**
- [ ] PATHOLOGIST CHOICE best specimen for testing
- [ ] Specific specimen requested
- [ ] Patient s/p TARGETED THERAPY
- [ ] Dates: ____________
- [ ] Drug:

---

**Physician Signature**
- **Ordering Physician Signature***
- **Date (MM/DD/YYYY)***

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**Certificate of Medical Necessity/Consent**
- My signature constitutes a Certificate of Medical Necessity and certifies that I have explained to the patient the nature and purpose of the testing to be performed and have obtained informed consent, to the extent legally required, to permit FMI to (a) perform the testing specified herein, (b) retain the test results for an indefinite period for internal quality assurance/evaluation purposes, (c) de-identify the test results and use or disclose such de-identified results for future unspecified research or other purposes, and (d) release the test results to the patient’s third-party payer as needed for reimbursement purposes.
### Patient Information
- **Last Name**: 
- **First Name**: 
- **Middle Initial**: 
- **Patient Medical Record #**: 
- **Patient DOB**: 
- **Patient Gender**: [M] [F] 
- **Street Address**:  
- **City**: 
- **State**: 
- **Postal Code**: 
- **Country**: 
- **Patient Phone # (Primary)**: 
- **Has the patient had any type of transplant?**: 
- **Date of collection**: 

### Ordering Physician Information
- **Office / Practice / Institution Name**: 
- **Ordering Physician**: 
- **Account #**: 
- **Street Address**:  
- **City**: 
- **State**: 
- **Postal Code**: 
- **Country**: 
- **Email Address**: 

### Tissue diagnosis of cancer established? REQUIRED
- **YES**  
- **Tumor type/Diagnosis (provide path report)**:  
- **Stage**: 
- **Prior FMI Test? TRF#**:  
- **Prior targeted therapy?**: 

**Reason for testing (provide clinic note and/or radiology report or other documentation)**: *FoundationACT is not a cancer screening test*

- **NO**  

### Additional Physician(s) to be Copied
- **Name**:  
- **Office/Practice/Facility Name**:  
- **Phone**:  
- **Fax**: 

### Billing Information
- **Patient Status**: [ ] Hospital Inpatient  [ ] Hospital Outpatient  [ ] Non-hospital patient  [ ] **Must be filled out for Medicare** 
- **Institution Name**:  
- **Discharge Date**: 
- **Insurance**: 
- **Medicare - Part B**: 
- **Hospital/Institution**: 
- **Self-Pay**: [*credit card information required*]  

**Primary Insurance (include photocopy of card)**:  
- **Policy #**:  
- **Group #**:  
- **Insured Name**:  
- **Insured DOB**:  
- **Self**: [ ]  
- **Spouse**: [ ]  
- **Child**: [ ]  
- **Other**:  

**Patient Relationship to Insured**:  
- **Name on Credit Card**:  
- **Card Holder Address**:  
- **Credit Card #**:  
- **Exp. Date**: 

### Certificate of Medical Necessity/Consent
- **My signature constitutes a Certificate of Medical Necessity and certifies that I have explained to the patient the nature and purpose of the testing to be performed and have obtained informed consent, to the extent legally required, to permit FMI to (a) perform the testing specified herein, (b) retain the test results for an indefinite period for internal quality assurance/operations purposes, (c) de-identify the test results and use or disclose such de-identified results for future unspecified research or other purposes, and (d) release the test results to the patient’s third-party payer as needed for reimbursement purposes.**

### Comments, remarks, special requests or associated study
- **Physician Signature**:  
- **Ordering Physician Signature**:  
- **Date (MM/DD/YYYY)**: 
FREQUENTLY ASKED QUESTIONS – BILLING AND REIMBURSEMENT

How much does the test cost and do you offer financial assistance?

The list price of FoundationOne® and FoundationACT® are $5,800, and the list price of FoundationOne Heme is $7,200. These are the amounts that are billed to your insurance. If you are uninsured, or if you have insurance and cannot afford the applicable out-of-pocket cost, you have options. You can fill out a financial assistance application to determine upfront what your maximum out-of-pocket expense might be. Payment plans may also be available. Please contact our Client Services Team for more detailed information.

How does the billing process work?

You may initially receive an Explanation of Benefits – this is not a bill. Foundation Medicine® bills your insurance company after testing is completed. Depending on the terms of your health care plan, you may have financial responsibility for co-pays, coinsurance or deductibles as directed by your insurance company. Foundation Medicine will not bill you for the difference between the insurance’s allowed amount and the list price of the test. If your insurance company denies coverage, we will work on your behalf to attempt to obtain coverage and will work with you and your physician in pursuing appeals to minimize the financial burden. If you are eligible for financial assistance, this is applied to your out-of-pocket cost.

Are you contracted with my health insurance?

Foundation Medicine accepts all insurance plans; however, we are currently not in-network providers with all insurance plans.

My doctor is concerned that their practice may receive a bill. Is that the case?

Foundation Medicine will make every effort to bill your insurance directly unless specific circumstances exist that prevent the direct billing of your insurance company. Please contact our Client Services Team for more detailed information.

Is Foundation Medicine a Medicare provider?

Yes.

We’re here to help.

Our Client Services Representatives are available from 8:00 am ET – 8:00 pm ET, Monday through Friday at (888) 988-3639 or email Client.Services@FoundationMedicine.com.
FoundationACCESS: Patient Financial Assistance Application

**PATIENT INFORMATION**

<table>
<thead>
<tr>
<th>Last Name</th>
<th>First Name</th>
<th>MI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Street Address</td>
<td>Apt. #</td>
<td></td>
</tr>
<tr>
<td>City</td>
<td>State</td>
<td>Zip</td>
</tr>
<tr>
<td>Foundation Medicine Account Number</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phone Number</td>
<td>Email address</td>
<td></td>
</tr>
</tbody>
</table>

**ORDERING PHYSICIAN AND FACILITY INFORMATION**

| Office/Practice/Institution Name |
| Ordering Physician |
| Phone Number |
| Fax Number |
| Email address |

**TOTAL ANNUAL GROSS HOUSEHOLD INCOME:**

<table>
<thead>
<tr>
<th>Income Range</th>
<th># of persons:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than $20,000</td>
<td>$65,000 - $75,000</td>
</tr>
<tr>
<td>$20,000 - $30,000</td>
<td>$75,000 - $90,000</td>
</tr>
<tr>
<td>$30,000 - $40,000</td>
<td>$90,000 - $105,000</td>
</tr>
<tr>
<td>$40,000 - $50,000</td>
<td>$105,000 - $120,000</td>
</tr>
<tr>
<td>$50,000 - $60,000</td>
<td>Greater than $120,000</td>
</tr>
</tbody>
</table>

**Please advise of any extenuating circumstances that you would like us to consider:**

**Number of family members in household supported by above income:**

Who should we contact with the approval decision?  
[ ] Patient  [ ] Practice

Preferred method of contact:
[ ] Phone  [ ] Email  [ ] Mail  [ ] Fax

I HEREBY ACKNOWLEDGE THE ABOVE INFORMATION IS TRUE AND CORRECT:

Patient Name OR Personal Representative [Print]  
Signature

Date

Please, return signed form to Attn:  
Client Services  
Fax: 617-418-2290

We will automatically respond to the person who originally submitted the form within 1-2 business days. If you want us to contact anyone else, please, indicate:

Person to contact:  
Phone number:  
Best time to call:

For patients with health insurance, the insurance provider will be billed first. Your qualified amount for financial assistance will be applied to any unpaid balance left after billing Insurance.
QUESTIONS TO ASK YOUR DOCTOR

What targeted therapies or immunotherapies might be available for my cancer?

How might clinical trials be an option?

How will you use the results of a comprehensive genomic profiling test in my treatment?

What are my options if I don’t get comprehensive genomic profiling?

Do I have a tissue sample available or might I need a new biopsy?

Is a liquid biopsy (FoundationACT®) an option for me?

Can we fill out a financial assistance application for me to understand more about the financial implications?