

Checklist to Understanding Biomarker Testing

This checklist will help you understand biomarker testing, if it is appropriate for you and if your insurance will cover some of the costs of testing, how to appeal denials of coverage, and how to access financial assistance, if needed.

1. Understand the Terms

What is a biomarker?

A biomarker is a gene, protein, or other substance that is in your blood, bodily fluids, or cells. Biomarkers are also called tumor markers.

What is biomarker testing?

Biomarker testing is a way to look for those biomarkers that can provide information about your cancer. It can be confusing, because biomarker testing can be called different names, including:

- Genomic testing or profiling
- Tumor testing or subtyping
- Tumor genetic testing
- Somatic testing
- Companion diagnostic testing (when paired with a specific treatment)

Some biomarker tests can test a solid tumor, and some can test your blood and other fluids for biomarkers (i.e., liquid biopsies).

Why is biomarker testing useful?

Biomarkers may affect how certain cancer treatments will work and understanding your biomarkers can help you and your health care team make treatment decisions that are best for you. This is often called personalized or precision medicine. Biomarker testing is a key part of getting access to precision medicine. For example, some targeted therapies may only work if you have certain biomarkers.

Is biomarker testing different from genetic testing?

Genetic testing is not the same as biomarker testing. Genetic testing is a test to find out if you have an inherited genetic mutation. You inherit your genes, and sometimes genetic mutations, from your parents. You are born with those mutations. Genetic mutations may make it more likely that you will develop a specific type of cancer. For example, if you have the BRCA1 or BRCA2 mutations, you are more likely to get breast, ovarian, and other cancers. For more information about genetic testing, visit: www.cdc.gov/genomics/gtesting/genetic_testing.htm.

2. Talk to Your Health Care Team

To find out if biomarker testing is appropriate for you, it is important to talk to your health care team. Here are some potential questions that you can ask about biomarker testing:

- Is biomarker testing available for my type of cancer?
- How do I know if I need a test?
- What are the risks and benefits?
- Will you use a blood or tissue biopsy to do the testing?
- Will insurance cover the cost of testing?
- Who will help me understand the results of my testing?
- Who will see the results?
 - The results of your test become part of your medical records, which are protected by privacy laws. You are protected from discrimination by insurance companies and employers based on the results of genetic testing. For more information, about your privacy rights, read TriageCancer.org/QuickGuide-Genetics.
 - It is illegal for your health insurance company to deny you coverage or change your premium based on your test results

3. Find Out if it is Covered By Insurance

The cost of biomarker testing depends on the type of test, the type of cancer that you have, and your health insurance coverage. Some tests are covered by Medicare and Medicaid. If you are participating in a clinical trial, the trial may cover the cost of biomarker testing. Private individual or employer-sponsored health insurers will usually cover biomarker tests when they are “medically necessary.” When deciding if a test is medically necessary, insurers weigh different factors to see if the test is appropriate and necessary to treat you.

- Single gene or multigene panel tests: Tests that look at one gene are more likely to be covered by insurance. Some panel tests are covered by insurance (e.g., private insurance, Medicare, Medicaid, etc.).
- Diagnosis or indication: Some biomarker tests are only covered for certain cancer diagnoses. Others are only covered when you meet other criteria, like having a specific stage of cancer or prognosis.
- What is being tested (e.g., tissue from a tumor or liquid biopsy (usually from blood))?

Additional factors may apply:

- Is preauthorization required? About 80% of private individual and employer-sponsored insurance companies require approval from the company before you have the test.
- Some insurance policies list approved tests, while others do not. Even if a test is not named in your policy, it may be covered when medically necessary.
- Some companies require the use of specific tests, sold by specific companies.

Your state may require your health insurer to cover your biomarker test or waive preauthorization.

- AZ, IL, LA, and RI have passed laws requiring broad insurance coverage of biomarker testing. CA and WA have passed laws prohibiting insurers from requiring preauthorization for biomarker testing for individuals with advanced or metastatic stage 3 or 4 cancer. For more information about state laws, visit: [TriageCancer.org/StateLaws](https://www.triagecancer.org/state-laws).

The science of diagnostic testing is new and moves fast. Health insurance companies tend to move more slowly when deciding to cover a new test. Start the process by talking with your health care team about the cost, if your insurance will cover the cost, and if you will have any out-of-pocket costs, such as deductibles, co-payments, or cost-share payments.

4. Appeal Any Denials of Coverage

If you experience a denial of coverage from your insurance company, you can appeal that decision. Some denials of coverage can happen before you even receive the test, when you request a pre-authorization for the test. You may get a denial of coverage after you receive the test. You can appeal those denials in both cases. Your insurance company might tell you that the test is not medically necessary, or that the test is experimental or investigational.

To appeal a denial of health insurance coverage:

- Understand the appeals rules for your specific type of insurance, and gather evidence of why your test is medically necessary. Ask your health care team for help. They have a reason why they think the test is appropriate for you.
- There are two types of appeals when you have an individual policy or many types of employer-sponsored policies:
 - Internal – an appeal directly to the insurance company
 - External – an appeal to an independent medical review organization
- Medicare, Medicaid, TRICARE and VA Health have different rules to appeal denials of coverage.
- For more information about Health Insurance Appeals, visit: [CancerFinances.org](https://www.cancerfinances.org)

5. Access Financial Assistance

Financial assistance resources may be available to help cover the out-of-pocket costs that you may have to pay when you get a biomarker test. Here are some examples of assistance programs that help cover out-of-pocket costs:

- Exact Sciences: www.oncotypeiq.com/en-US or 888-662-6897
- Foundation Medicine: www.foundationmedicine.com/info/detail/for-patients#financial-support
- CancerCare: www.cancercare.org/copayfoundation
- Patient Advocate Foundation: <https://copays.org>

Visit [CancerFinances.org](https://www.cancerfinances.org) for help navigating finances and find other financial assistance resources.

This Checklist was sponsored by:

**EXACT
SCIENCES**