paf Patient Advocate Foundation

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BIOMARKER TESTS

A biomarker test analyzes tissue or blood samples for the presence of specific differences that can provide insights into diseases like cancer. Medical treatment can be guided by biomarker testing, often called precision medicine. By identifying these biomarkers, cancer patients may be able to receive treatments they might not otherwise receive.

WHY KNOWING YOUR BIOMARKER PROFILE IS IMPORTANT

Your biomarker profile is information about specific genes, including variations and gene expression, in an individual or in a certain type of tissue. A biomarker profile may be used to help diagnose a disease or learn how the disease may progress or respond to treatment with drugs or radiation. Your biomarker profile is an important piece of information for you and your medical team to have to weigh the benefits and risks of different treatment options and choose an option that is most likely to be effective for you. Personalizing treatment based on your biomarker profile may result in better clinical outcomes and reduce the possibility of trying ineffective treatments.

INSURANCE COVERAGE OF MOLECULAR GENOMIC MARKERS AND TESTING

Coverage for biomarker testing depends on many factors such as type of insurance, diagnosis, reason for testing, etc. There is no guarantee every biomarker test will be covered for every diagnosis or stage of cancer, however, insurance companies are covering more types of biomarker testing as targeted therapies become increasingly important options. Here's what we know:

Commercial insurance covers biomarker testing based on your plan but generally requires that:

- It must be an FDA-approved test
- You meet coverage guidelines based on your cancer diagnosis and stage
- The testing is supported by guidelines or evidence for molecular testing for the specific tumor type and stage
- The results of the testing should impact decisions about your treatment
- You may be responsible for out-of-pocket costs including co-pay, coinsurance, and deductible which vary by plan and where you are with meeting your out-of-pocket maximum

Medicare covers biomarker testing if the following conditions are met:

- For cancer patients with recurrent, relapsed, refractory, metastatic, and/or stages 3 or 4 of cancer
- If it is the first time having next-generation sequencing testing for a current cancer diagnosis or if a new primary cancer diagnosis has been made by the treating physician
- If the patient has decided to seek further cancer treatment (e.g., therapeutic chemotherapy)
- For patients with some germline (inherited) cancers, such as ovarian or breast cancer

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Whenever possible, contact your insurance company PRIOR to completing biomarker testing to ask about coverage requirements.

QUESTIONS TO ASK YOUR INSURANCE COMPANY ABOUT BIOMARKER TESTING

- Do you need pre-approval from your insurance company for biomarker testing to be covered?
- Is the specific biomarker test you are trying to obtain a covered benefit under your plan?
- Is there a medical coverage policy for biomarker testing or your specific test? If so, do you meet the "medical necessity" criteria under the policy?
- Is the test considered to be a companion diagnostic test? This is when a test helps match a patient to a specific drug or therapy. If so, it may be covered. If not, your diagnosis or test may be considered "experimental or investigational" and not covered under your policy.
- Do you have to use a specific testing facility for biomarker testing to be paid at an "in-network" rate?
- Are you required to provide biomarker test results to your insurance company before they approve a targeted therapy associated with a specific tumor marker for your cancer?
- Do evidence-based guidelines, such as the National Comprehensive Cancer Network (NCCN) or American Society of Clinical Oncology (ASCO) recommend biomarker testing as the standard of care for your diagnosis? Are these recommendations included in the approved guidelines?
- What can you expect your out-of-pocket expenses to be, including unmet deductible, copay, and coinsurance?

WHAT IF MY REQUEST OR CLAIM IS DENIED?

Have you received a prior authorization denial, denial letter, or explanation of benefits (EOB) indicating no insurance payment for your biomarker test?

1. Call your insurance company and ask for additional details on why your claim or request was denied.

2. Partner with your oncologist's office to appeal your denial.

3. Include any supportive evidence including approved guidelines as part of your appeal packet.

4. Deadlines are important, so make sure your appeal documents are submitted on time.

APPEALING A DENIAL OF COVERAGE

Your insurance company could deny biomarker testing, or any treatments suggested from the results. If this happens, you may have the right to ask the insurance company to reconsider their decision through a formal appeals process. For additional information on the appeals process, please refer to Patient Advocate Foundation's publication, ***Engaging with Insurers: Appealing a Denial.***

LEARN MORE

Patient Advocate Foundation can help you address financial or insurance barriers you face with gaining access. Click this link to view our full-length guide entitled ***Getting the Right Test at the Right Time: A Cancer Patient's Guide to Biomarkers.*** References for all Biomarker Tip Sheets can be found **here.**

Curious about other topics? Our newly redesigned Education Resource Library houses our resources and provides straightforward information in a variety of formats to help you make informed decisions throughout your healthcare journey. Learn about health insurance, disability, medical bill management, and more by visiting our Education Resource Library today. Call us anytime at 800-532-5274 or visit www.patientadvocate.org for help!

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