

Examining the Financial Aspects of Cancer Biomarker Testing for Prior Authorizations

Biomarker Testing and Precision Medicine

Today there are many kinds of biomarker tests that are proven to determine if a targeted therapy may be an effective treatment option for different cancer types. Effective implementation of precision medicine in oncology relies on biomarker testing. In many tumor types, biomarker testing is standard of care, however there is not always equitable access to testing and targeted therapies.

Biomarker testing may also be referred to as any of the following:

- Molecular testing or profiling
- Tumor marker or profiling
- Genomic testing or profiling
- Next-generation sequencing (NGS)
- DNA or RNA sequencing
- Panel testing

Companion Diagnostic

When targeted therapies require a specific biomarker test to provide important information related to the therapy, the test is called a **companion diagnostic**. Companion diagnostic tests are sometimes required before insurance companies will approve therapy.



TIP: Confused about these terms? Cancer care programs can follow the recommendations outlined on [commoncancertestingterms.org](https://www.commoncancertestingterms.org) when discussing biomarker testing.

TIP: Do not confuse genomic testing (tumor variant) with genetic testing (inherited mutation).

Prior Authorization

Prior authorization is often required by health insurers when ordering biomarker testing. To reduce the risk of insurance denial, prepare all the required documentation (eg, histology, clinical stage, provider documentation, etc.). In some cancer programs, a biomarker navigator (or similar role) may enter all the required prior authorization information when placing the test order.

The Basics:

- Perform a benefits investigation after the testing needs have been determined.
- Complete required prior authorizations before ordering or scheduling testing.
- Submit a new prior authorization when any change to the patient's insurance occurs and the new benefits investigation requires it.
- When a health insurer does not provide a prior authorization process, research the medical policy for requirements.
- Submit a prior authorization for surveillance testing or other post-treatment testing services, as needed.

Critical Steps for Prior Authorization

- ➔ Gather all codes (eg, CPT® and ICD-10 codes).
- ➔ Check AMP's "In My Pocket" Molecular Testing Reference Cards for biomarkers by tumor type.
- ➔ Check the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®), the Biomarker Compendia, the Library of NCCN Compendia, or other utilized pathway to ensure the treatment regimen is indicated for an FDA-approved use or considered as appropriate, and medically necessary care.
- ➔ Check your cancer program or health system's EHR for a copy of the patient's most up-to-date insurance card(s).
- ➔ Ask the health plan or company agent to search for any plan exclusions in addition to any prior authorization requirements.

Planning ahead for testing prior authorizations:

- ✓ Does the facility or rendering lab bill the insurance?
- ✓ How and where do I submit the prior authorization?
- ✓ What are the appeal options? And who will handle the appeal?
- ✓ What happens when the rendering lab is out of network?
- ✓ Consider using portal ordering.

Application of Biomarker Tests

While biomarker tests are often ordered at the time of cancer diagnosis, some patients may undergo biomarker testing to see if a new tumor mutation is causing them to be resistant to their prescribed targeted therapy. Other patients may undergo repeat testing to determine how their tumor is responding to treatment. In some cases, an oncologist may order a biomarker test on the diagnostic biopsy tissue and another biomarker test on a collected blood sample. While many insurance companies will cover the cost of one test, they may not cover multiple tests.

Other applications for biomarker testing include:

- Assessing risk of developing cancer
- Determining risk for cancer recurrence
- Predicting whether a treatment is likely to work for a specific individual
- Monitoring disease progression to determine if a treatment is working



TIP: Check to see if the reference laboratories offer financial assistance for repeat testing.

Financial Assistance Programs

In some cases, insurance companies may not cover the cost of testing (eg, the test is considered experimental or investigational, or the plan does not cover the cost of cancer treatment). Fortunately, many reference laboratories that perform biomarker testing offer patient assistance. Check vendor websites for the financial assistance program and eligibility requirements.

For more information on paying for biomarker testing, see the ACCC resource: [acccancer.org/paying-biomarker-testing](https://www.acccancer.org/paying-biomarker-testing)



TIP: Remind patients that they may receive an Explanation of Benefits (EOB), and that this is not a medical bill.

Optimizing Coordination and Communication

Biomarker tests are often ordered by medical oncologists or pathologists. Some may be ordered by surgeons or by physicians performing the initial diagnostic biopsy.

Financial advocates may be able to proactively reduce patient stress about biomarker testing by:

- Reminding providers to inform patients about financial assistance programs offered by reference laboratories
- Asking reference laboratories if they would provide regular updates on which patients have applied for financial assistance and the status of those applications
- Developing a patient education brochure that explains the clinical importance of biomarker testing and how they can apply for financial assistance
- Creating a folder of journal articles and templated appeal letters to be prepared to dispute insurance company denials
- Defining a team member who can assist patients with financial assistance needs

As more patients with cancer undergo biomarker testing, health care providers play a key role in ensuring that patients receive optimal care while minimizing the risk of experiencing financial toxicity.

Next-Generation Sequencing (NGS)

Next-generation sequencing (NGS) is a common technique used to perform cancer biomarker testing. In 2018, the Centers for Medicare and Medicaid Services (CMS) determined that **national coverage for NGS testing** will be available for patients with advanced cancers.

In 2022, the American Society of Clinical Oncology (ASCO) released a **Provisional Clinical Opinion** recommending NGS-based biomarker testing in patients with metastatic or advanced cancers to guide the use of treatments that may target specific biomarkers.



TIP: Remember that NGS is a testing technique and not a specific biomarker test. NGS allows for multiple biomarkers to be assessed as part of one test.

A Few Examples of Cancer Biomarkers and Associated Targeted Therapies:

Type of Cancer	Biomarker	Therapy
Non-small cell lung cancer (NSCLC)	EGFR	Oral EGFR inhibitor
Many solid tumors, including triple negative breast, cervical	PD-L1	Immune checkpoint inhibitor
Melanoma	BRAF	Oral BRAF inhibitor
Breast	HER2	HER2 inhibitor
Solid tumors	NTRK	Oral NTRK inhibitor
Ovarian, breast	BRCA	Oral PARP inhibitor
Solid tumors; most frequently colorectal, endometrial	MMR Deficiency (dMMR)	Immune checkpoint inhibitor

Note: Only selected tumor types and therapy may be listed for each biomarker. Please consult the current product labeling for the most up-to-date information.

Additional Resources:

- ACCC's Conversation Guide: Biomarker Testing and its Role in Cancer Care
accancer.org/biomarker-provider-guide
- Paying for Biomarker Testing
accancer.org/paying-biomarker-testing
- Learn how Precision Medicine Steward roles can help streamline biomarker workflows
accancer.org/precision-medicine-stewardship



Association of Community Cancer Centers

Learn more at accancer.org/prior-authorization.

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