

Biomarker Testing

What It Is & Why Should Employers Invest In It?

Progressive employers recognize that biomarker testing is part of precision medicine – the precise and accurate treatment of individual patients based on their unique genetic make-up. [Precision medicine](#) is an approach to medical care in which disease prevention and diagnosis and treatment are tailored to genes, proteins and other substances in a person's body. It is the act of testing and treating a patient based on their unique biomarker results.

The [Federal Drug Administration \(FDA\)](#) summarizes biomarkers and their role in disease management and drug development as “characteristics of the body that can be measured.” Biomarker testing provides a measurable way to tell how a patient is likely to respond to treatment for certain diseases based on substances found in blood, bodily fluid or tissue. By targeting the medications and therapies most likely to work, it serves as an effective tool to protect patients from exposure to potentially harmful side effects and the costs related to ineffective treatments. **Biomarker tests help employers control costs by eliminating trial-and-error prescribing**



and subsequent exposure of patients to unnecessary treatments that will not be effective and may cause harm.

Employers have a fiduciary duty to prudently utilize plan assets for the benefit of their members. One way of doing so is to **make sure that appropriate biomarker testing is a covered benefit and used before, during and after treatments.** It is not enough to simply confirm coverage by the plan. Employers must work with plan administrators (medical carriers, PBMs, etc.) to understand how and when biomarker testing is being used via prior authorizations for treatment, case management reviews and patient education.

Employers should prioritize coverage of the biomarker testing to ensure unnecessary costs are avoided by eliminating wasteful use of time, money and resources, while assisting patients to get the right care, the first time. There is ample medical evidence of the effectiveness of biomarker testing as a tool to correctly diagnose and treat a growing list of diseases.

LOOK FOR THIS ICON



This action brief is designed to help employers understand what biomarkers are and provides high level action steps around biomarker testing. As you review the action brief look for this icon which represents employer perspectives from health benefits professionals. Key elements include:

- Understanding the important role that biomarker testing can play in your health benefits strategy.
- Identifying how biomarker testing is currently being used to diagnose and treat disease.
- Determining what action steps are needed to help you optimize the use of biomarker testing in your plan design.



Biomarker tests are an important part of today's treatment to ensure patients get the medication and treatment therapy most likely to work for them, versus those they are unlikely to benefit from.





Biomarker testing is a life and cost saving tool that helps physicians take much of the guesswork out of diagnosing disease and developing treatment protocols.



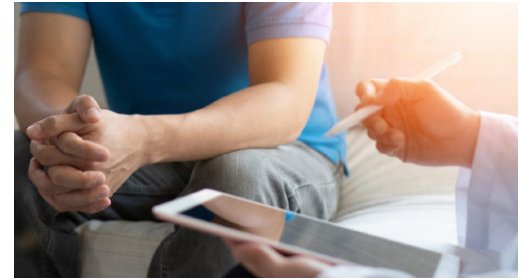
What is a Biomarker?

Biomarker testing has long been used to measure the effects of investigational drugs on patient's during clinical trials – integral to drug development. It is now used as an important part of a variety of treatments, especially cancer treatments, to ensure patients get the medications and therapies most likely to work for them, in the most timely and cost-efficient manners.

A biomarker can help determine the presence or absence of normal body processes, disease processes or bodily responses to a treatment. Many commonly used tests in clinical practice measure biomarkers and have been used in pre-clinical research and clinical diagnosis for many years. Examples of often-tested biomarkers include:

- Rheumatoid factor (RF) – proteins in the immune system that damage healthy tissue
- C-reactive protein (CRP) – protein released by the liver when there is significant inflammation of body tissue
- Prostate-Specific Antigen (PSA) – protein released by cancerous and non-cancerous cells in the prostate
- BRCA1 and BRCA2 – gene mutations linked to development of breast, ovarian, fallopian tube, prostate, and pancreatic cancer, as well as acute leukemia

Biomarkers can also be protein substances released from within cells and tissues that regulate growth and reproduction of cells and play an integral part in the body's response to infections, injuries and inflammation. For example, when a patient reports to the ER complaining of chest pain, blood samples are periodically taken over time to look for changes in the levels



of troponins I and T – proteins released when the heart muscle is damaged.

Biomarkers can also tell us whether someone has a genetic predisposition to a disease. Genetic biomarkers are like codes with characteristic biological properties that can be detected and measured in parts of the body. They can also be specific cells, molecules, genes, gene products, enzymes, or hormones with complex organ functions, or general characteristic changes in the body's cells, tissues or structures.

Measurable Medical Signs

Biomarkers may have characteristics that are:

- Physiologic – provide information about body processes, e.g., heart rate, blood pressure and body temperature.
- Histologic – reflect changes in tissues/cells; often used in determining stage of cancer.
- Molecular – check for certain genes (DNA, RNA), proteins or other molecules that can signal disease in tissue or bodily fluids.
- Radiographic – detect biomarkers using imaging such as MRI, x-ray, CT scans.



What is a Biomarker Test?

Because a biomarker test tells how the body is functioning and responding to internal and external factors, it can serve as an early warning system for an individual's health. A biomarker test:

- Can measure for a single biomarker or a panel of multiple biomarkers
- Is performed using blood, urine, saliva or tissue removal
- Can be used with other tests to more precisely diagnose diseases, determine change in the body for better or worse during treatment, and monitor for post-treatment recurrence of disease

In the new precision medicine paradigm, we will be testing before treatment to ensure the:



1. condition is properly diagnosed
2. treatment is genetically individualized
3. treatment will produce the right clinical results

We will test during treatment to make sure the right clinical outcomes are being achieved and we will test yet again after treatment to make sure disease does not recur.



The Landscape of Biomarker Testing Coverage in the U.S.

Biomarker testing is increasingly important in cancer care. Currently, 48 states have no minimum coverage requirements for biomarker testing. Consequently, gaps between current coverage and guidelines likely exist.



1.9
MILLION

PEOPLE ARE ESTIMATED TO BE DIAGNOSED WITH CANCER IN THE US IN 2022



\$500+

IN OUT-OF-POCKET COST INCURRED BY 15% OF PATIENTS RECEIVING BIOMARKER TESTING

66%



OF ONCOLOGY PROVIDERS REPORT LACK OF BIOMARKER TESTING COVERAGE AS BARRIER TO PATIENT ACCESS

Dieguez, G. & Carioto, J. (2022, Feb. 15) The landscape of biomarker testing coverage in the United States. Milliman. <https://www.milliman.com/en/insight/the-landscape-of-biomarker-testing-coverage-in-the-us>

Biomarker Testing & Cancer

Biomarker testing has become a staple of precision medicine for the diagnosis and treatment of numerous types of cancers. When a person is born with variations in their genes or mutations occur when new body cells are produced, the cycle of cancer development may begin. Each type of cancerous cell has a unique biomarker pattern and specific biomarkers can affect how well certain cancer treatments will work in preventing continued growth of mutated cells while destroying existing ones.

While biomarker testing may not yet be effective in diagnosing and treating all cancers, it has already proven to be a valuable tool in the care of patients with commonly occurring types such as breast, prostate, lung, skin and colorectal. While the body areas impacted by cancers may be similar, the gene and protein changes found in the cells of people with the same cancer areas can be very different and require highly individualized treatments. Identifying and measuring biomarker patterns found in cancerous cells are key to diagnosing the type and severity of cancers, identifying which treatments

will be most effective in eliminating and preventing regrowth of cancerous cells, monitoring for desired outcomes during treatments, and predicting/monitoring recurrence of the same or

similar cancer cells. A [2022 Milliman study](#), commissioned by the American Cancer Society Cancer Action Network, shares key information on biomarker testing coverage in the U.S.

Current Landscape of Biomarker Testing Coverage in the Large Group Commercial Market (2020)

11% of claims were for multi-gene panel tests

The average patient received **2.4** biomarker tests



The average cost per biomarker test was **\$224**.

This is about 3x the cost per test in the Medicaid market.

90% of large groups in our study provided some coverage for biomarker testing.

Half of the self-insured large groups reported between 14.4 and 32.7 biomarker tests per 1,000 members (25th to 75th percentiles, respectively), with a **median** utilization of **25.9 tests per 1,000 members**.



Dieguez, G. & Carioto, J. (2022, Feb. 15) The landscape of biomarker testing coverage in the United States. Milliman. <https://www.milliman.com/en/insight/the-landscape-of-biomarker-testing-coverage-in-the-us>

Health Equity in Biomarker Testing and Targeted Therapy



According to [The American Cancer Society](#), the use of biomarker testing and targeted therapy has been progressing rapidly and has become the standard of care for certain cancers. There are now multiple FDA-approved targeted therapies across several cancer types. Despite evidence demonstrating the effectiveness of biomarker testing and targeted therapy, not all individuals benefit equitably from these advances. There are notable racial/ethnic and socioeconomic disparities in access and utilization of these advancements in care. These disparities in access and use of guideline-indicated biomarker testing and targeted therapy can potentially widen existing disparities in cancer survival. Priorities for advancing health equity in precision medicine should include:

- Improving access to biomarker testing with special focus on ensuring that groups facing disparities have equitable access to biomarker testing and targeted therapy which can improve outcomes and quality of life. To prevent differences in outcomes due to inequalities in the use of biomarker testing and targeted therapy, health care stakeholders must dismantle barriers to access, including insurance coverage of biomarker testing.
- Differential use of guideline-indicated biomarker testing and targeted therapy which can potentially widen existing disparities in cancer outcomes. Without action – such as expanding Medicaid coverage of biomarker testing – existing disparities could be exacerbated rather than reduced as the result of the increasing use of biomarker testing and targeted therapy.
- Ensuring coverage of biomarker testing for all patients – including those insured through Medicaid – can help expand coverage and access to biomarker testing and targeted therapies for groups who are currently not benefiting.



Biomarker Testing & Rare Cancers

Biomarker testing is especially important for patients with rare cancers or those that have few treatment options, because mutations found in different cancers may overlap. If a person has a rare cancer with a mutation seen in other cancers, there may be a treatment that could potentially work in effectively treating the rare cancer as well.

According to the [Community Oncology Alliance](#), 64% of growth in oncology care spending is due to the launch of new drug treatments. They project that cancer treatment costs will reach \$240 billion in 2023. Although there are known benefits related to evidence-based biomarker testing in cancer treatment, due to associated costs, these tests continue to not be routinely used. However, as these benefits are being recognized, the tests are becoming more affordable.

The successes achieved in using biomarker testing for precise and effective treatment of cancers are leading to rapidly expanding research and development of treatments for other physically, mentally and financially debilitation diseases such as alzheimer's disease, diabetes, obesity and arthritis.

Delivering Preventive Care through Biomarker Testing

A topic of debate in employer sponsored health care is whether to proactively fund preventive biomarker testing for identification of genetically higher risks for cancers and other serious diseases. An example includes familial hypercholesterolemia, where multiple gene variants lead to markedly high cholesterol, or hemochromatosis, where too much iron is absorbed from the diet and the extra iron can harm organs like the heart and liver. While these types of conditions can be identified early in life, before extensive damage occurs, some employers don't think it makes

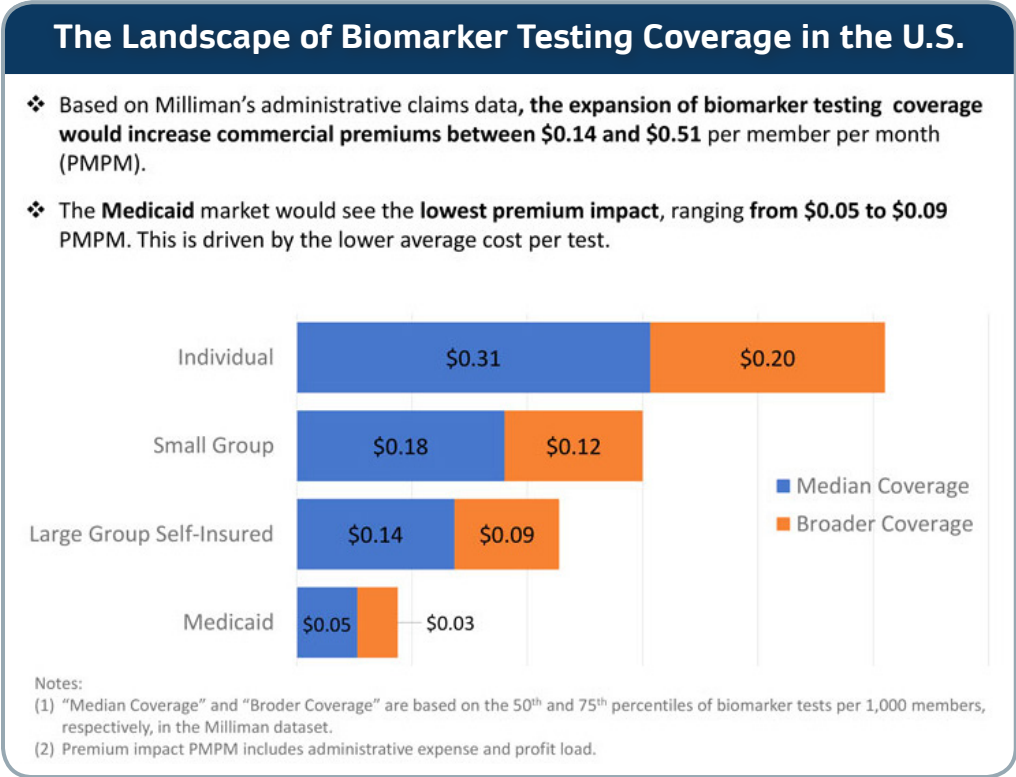
economic sense to invest in preventive biomarker testing and often do not realize they are already doing so with BRCA and PSA testing. Medical standards of care are clearly defined for these commonly used tests and the laboratories performing them can do so at reasonable costs because of economies of scale.

This has not yet occurred with most other biomarker tests, and it will take greater stakeholder promotion and support before it does.

Can Biomarker Testing Reduce Costs?

Biomarker testing quickly provides answers to medical questions that once either could not be found or were found through long and costly trial-and-error treatments. Using cancer treatment as an example, [The Economics of Comprehensive Biomarker Testing in Cancer, Scientific Magazine](#) explains that cancer treatment drugs cost on average around \$50,000 per patient. By contrast, costs for comprehensive biomarker test profiles average between \$2,000-\$4,000. Having the answers provided by biomarker testing enables the physician to precisely determine which drug or drug combination will achieve the best clinical outcomes without the patient experiencing dangerous and costly trials of multiple drugs.

The cost increment of introducing comprehensive biomarker testing into medical plan coverage for cancer for small and large employer groups is provided in the Milliman [chart](#) below and is based on median versus broader coverage.



If employers believe in prevention, early detection and the ability to monitor disease progression, biomarker testing should be a high priority.



If you’re not paying for appropriate biomarker tests, you are probably paying huge amounts for drugs that do not and never will work for many of your covered members!

Failure Rates & Preparing for the Future

According to the FDA, drug development today has many problems, and the major problem is the failure rate. Even drugs that have gone through the whole preclinical process, including animal testing and investigative procedures, have a less than a 1 in 10 chance of successfully getting through clinical trials and into the market. To improve the future success rate and efficiency of drug development, research to identify additional biomarkers needs to continue and biomarker testing should be promoted and financially supported by stakeholders. Employers, as key stakeholders in the race to develop breakthrough treatments for the many diseases impacting employee health and productivity, will not benefit by waiting to be required to add appropriate biometric testing coverage to their plans. There are multiple actions they can take now to assure employees and their families are able to reap the benefits of this life and cost saving precision medicine tool.

Biomarker testing is going to continue to grow as an accepted standard of care for the treatment of many diseases. Understanding it and working with your carriers to get in front of it now will help you avoid coverage challenges and potential complaints from your members – some of whom may be dealing with serious life-threatening diseases.

States That Require Coverage for Biomarker Testing

The states of Illinois, California, and Louisiana recently passed laws requiring fully insured employers to cover biomarker tests “for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of an enrollee’s disease or condition when the test is supported by medical and scientific evidence.” Other states are likely to follow soon.

MBGH Employer Work Group

In 2022, MBGH conducted an employer work group and a series of interviews with health benefits professionals from mid, large and jumbo public and private employers to assess their understanding and coverage of biomarker testing. This section includes important action steps, questions to ask your medical carriers and recommendations on health care benefits design and coverage.



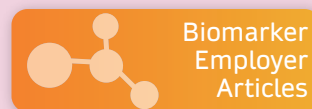
Employer Action Steps

- Confirm with your carriers that processes are in place to smoothly, efficiently and proactively evaluate appropriate use of biomarker testing for diagnosis, treatment and ongoing monitoring of an individual's condition.
- Ensure that carrier call center representatives are being provided with frequently updated lists of biomarker tests that do and do not require prior authorization reviews for coverage. To avoid delays in care make sure they understand the plan language or procedure benefits.
- Recognize that some insurance plans will not cover the costs of biomarker tests and will deem them to be “experimental and investigational.” It is important to confirm that:
 - Your plan has a strategy in place to ensure easily followed directions for appeal filing;
 - Biometric coverage appeals are processed, and decisions communicated, in a timely manner; and
 - Appropriate clinical experts are involved in appeal reviews.
- Determine whether there is a need for a narrow network of biomarker testing facilities that have the skills and resources to properly manage patient cases and control the scope and costs of these tests.
- Consider implementing a member and provider communication campaign to raise awareness of the value of biomarker testing and include plan coverage of these tests. Use approved tests, providers and labs (especially with ia growing lab cottage industry popping up).



Employee & Plan Member Communication on Biomarker Testing

Use all or parts of [these articles](#) to communicate with your employees and plan members on what biomarkers are, how and why biomarker testing is used and their role in treating certain diseases, including cancer.



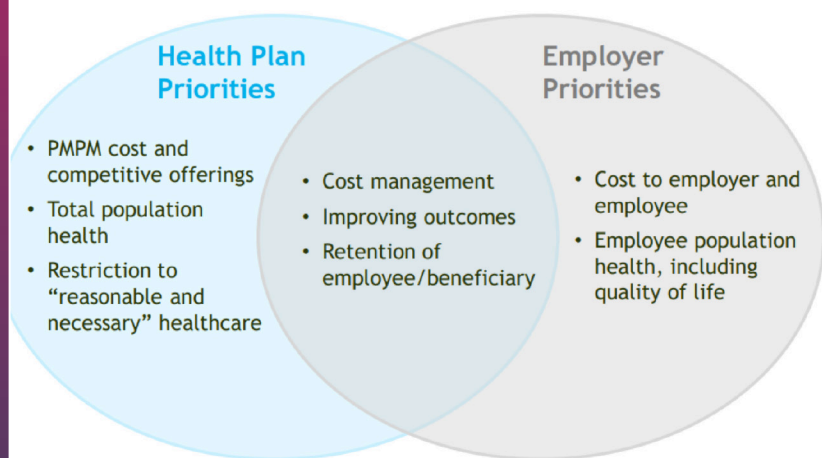
Health Care Benefits Design & Coverage

It is important for employers to determine whether their current benefit designs are impeding or supporting patient access to appropriate biomarker testing. As recommended by the [National Cancer Treatment Alliance](#), employers should ask their carriers these questions:

1. Does my plan cover all tests that are FDA-approved as a companion diagnostic to match patients to all FDA-approved targeted therapies and immunotherapies?
2. Does my plan cover tests which include all guideline-recommended genes in any given tumor type?
3. Does my plan cover tests inclusive of all genes which could indicate potential resistance to an FDA-approved therapy?
4. What is my plan doing to reduce delays for biometric testing needed to quickly get patients started on treatments?
5. Does my plan cover clinical trials?

Health Plan and Employer Priorities are Often But Not Always Aligned; Greater Employer Involvement Is Critical

Effective Application of Precision Medicine Starts with Access



PMPM: Per Member Per Month

Employers Should Talk to Their Health Plans To Understand:

- The health plan’s biomarker testing policies
- What the plan is doing to ensure coverage for comprehensive tests that comply to medical guidelines for all recommended biomarkers
- Why they are not covering certain FDA approved products
- How to improve coverage for tests that can offer eligibility to clinical trials
- Understand what the plan is doing to reduce start of treatment delays



National Cancer Treatment Alliance™

Check for Outdated Plan Design Language

Employers want to cover only medically necessary testing and broad-based plan design language can go a long way to steer proactive prior authorization reviews in this rapidly changing space of medical care. This can also help patients avoid dangerous and costly treatment failures.

It is important to check for outdated plan language to avoid overarching exclusions for “genetic testing.” Language should be modified to assure coverage for appropriate use of this evolving technology. This can be achieved through language that alerts members and call center representatives

(who answer patient/provider questions) to check for prior authorization requirements for coverage of testing. Broad-based language should include:

- For plan coverage information: “Genetic/ Biomarker Testing for diagnosis, treatment, and/or post treatment monitoring, with approval by the Plan.”
- For plan exclusion information: “Genetic/Biomarker testing, unless approved by the Plan”.

It is equally important to ensure that plan design language sections concerning prior authorizations include specifics about any requirements around genetic/biomarker testing for diagnosis, treatment, and/or post treatment monitoring.

Pharmacogenomic Biomarkers in Drug Labeling

Ask your carrier if they are using the following to develop their prior authorization protocols:

- [Drugs@FDA](#) – Offers therapeutic products with pharmacogenomic information found in the drug labeling.
- [Clinical Pharmacogenetics Implementation Consortium \(CPIC\)](#) guidelines – Helps clinicians understand how available genetic test results should be used to optimize drug therapy, rather than whether the tests should be ordered.

Resources for Employers

American Cancer Society (ACS)

[Biomarker Testing Patient Profiles: The Right Test for the Right Treatment](#)
[Biomarker Tests and Cancer Treatment](#)

Association of Community Cancer Centers (ACCC)

[State Legislation Requiring Coverage of Biomarker Testing Gains Momentum](#)

CancerCare

[Understanding the Role of Biomarkers in Treating Cancer](#)

Get the Medication Right Institute (GTMRx)

[PGx Insight for Employers: Moving from Precise to Personalized Medication Management with PGx and CMM](#)

MD Anderson

[How are biomarkers used to treat cancer?](#)

Milliman, February 2022

[The landscape of biomarker testing coverage in the United States](#)

National Cancer Institute (NCI)

[Biomarker Testing for Cancer Treatment](#)

National Cancer Treatment Alliance (NCTA)

Presentation: [What Employers Need to Know about Biomarker Testing](#)
Employer Action Brief: [Biomarker Testing in Cancer – What You Should Know](#)
Patient Journey: [Limited Panel Biomarker Testing vs. Comprehensive Genomic Profile Testing](#)

National Library of Medicine, National Center for Biotechnology Information (NIH)

[Biomarker Definitions and their Applications](#)

Testing and Treatment Guidelines

National Comprehensive Cancer Network (NCCN): [Biomarkers Compendium](#)
American Association of Clinical Oncology (ASCO): [Molecular Testing and Biomarkers](#)
College of American Pathologists (CAP) [Protocols and Guidelines](#)



Resources for Employees

U.S. Food & Drug Administration (FDA)

[What Are Biomarkers and Why Are They Important?](#)
[Video/Toolkit for patient-focused therapy development](#)

Cancer Support Community

[Biomarker Testing for Cancer](#)
[Precision Medicine](#)

About MBGH

MBGH is one of the nation's leading and largest non-profit employer coalitions. Members are represented by human resources and health benefit professionals for over 150 mid, large and jumbo self-insured public and private companies who provide health benefits for over 4 million lives. Employer members spend over \$15 billion annually on health care. Since 1980, members have used their collective voice to serve as catalysts to improve the cost, quality and safety of health care benefits.

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Click on more information about MBGH below.

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