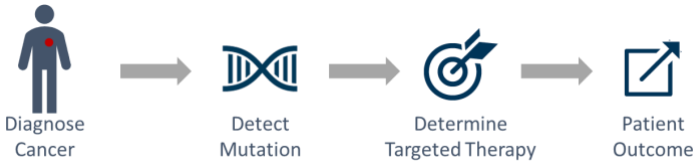
National Cancer Treatment Alliance™

Biomarker Testing in Cancer – What You Should Know

Cancer is not just tragic, it is *expensive* – the cost of cancer care could cost as much as $240,000,000,000 in the US by 2023.[i]

There are many kinds of cancer, and many more causes, but all cancers are caused by genetic mutations. Genetic mutations can cause the cells of the body to become altered, lead to tumor growth, and eventually metastatic cancer.

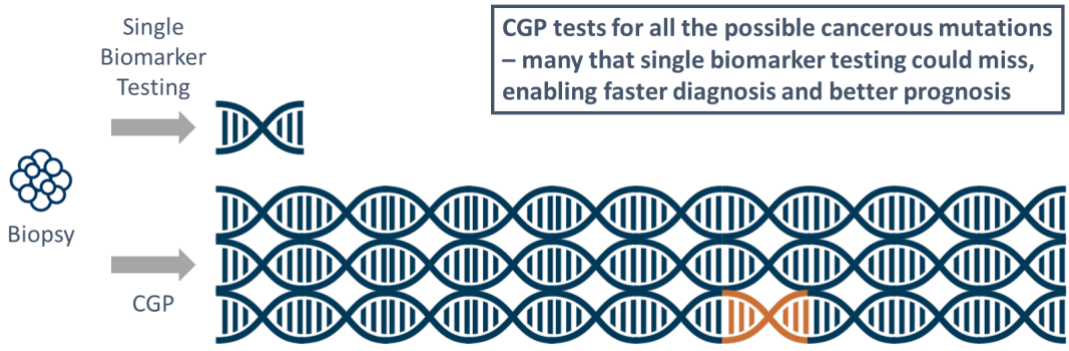
Doctors must find the gene or genes which have mutated in the patient to be able to properly treat them. **Biomarker testing** helps doctors diagnose patients faster, and more efficiently develop a treatment plan that works for them. One of the most robust and accurate forms of biomarker testing is **comprehensive genomic profiling (CGP).**



CGP Accelerates Diagnosis and Improves Outcomes

Limited panel tests, which are biomarker tests that check a single biomarker or a very small number of biomarkers, have been used for years,[ii] but may require multiple rounds of testing if they come back negative. On the other hand, CGP tests many biomarkers at once, so doctors can affirmatively diagnose their patients and quickly get them onto **targeted therapies**, if appropriate.

Targeted therapies usually have fewer toxic side effects than traditional cancer drugs, which can reduce emergency room and inpatient admissions, and workplace absenteeism. By getting on the right treatment earlier, patients may not have to undergo unnecessary procedures or consume unnecessary - or ineffective – treatments.



What is biomarker testing?

A way to look for actionable genetic mutations which can provide information about the cause of someone's cancer and develop appropriate treatment plans.

What is comprehensive genomic profiling (CGP)?

A way to, with a single blood test or biopsy, screen for hundreds of genetic mutations to quickly determine if a patient has any of those mutations driving their cancer.

What are targeted therapies?

Targeted therapies are newer medicines which can fight specific cancers but require precise diagnosis. What is highly effective for one person may not work for another.

National Cancer Treatment Alliance™

What is the role of National Comprehensive Cancer Network (NCCN) Guidelines?

The NCCN Biomarkers Compendium® contains information designed to support decision-making around the use of biomarker testing in patients with cancer.

According to a 2021 report, nearly half of all lung cancers are caused by actionable genetic mutations which have an appropriate targeted treatment.[iii] However, despite the benefits, biomarker testing – particularly CGP – is not widely performed or covered by plans. A 2017 study[iv] showed that in a group of lung cancer patients, only 8% were tested for all mutations recommended by the **National Comprehensive Cancer Network Guidelines** (NCCN).

Employers Should Work with Health Plans to Cover CGP

While initially more expensive than single biomarker testing, CGP is a better way to diagnose the mutations causing a patient's cancer and can save costs in the long run by reducing spend on inappropriate or ineffective treatments.

Greater employer involvement with health plans can help improving cancer care for their employees and covered lives. Employers and Health Plans have priorities in common that CGP can help address, including Cost Management, Improving Outcomes and Retention of Employee/Beneficiary.

Employers should consider the advantages of CGP when discussing cancer testing benefits with health plans. You have a say in how your employees and covered lives are tested if they have cancer – make your voice count!

National Cancer Treatment Alliance™

Frequently Asked Questions

What questions should I ask my health plan about CGP?

1. What are my health plan's biomarker testing policies?
2. Does my policy cover all tests that are FDA-approved as a companion diagnostic to match patients to all FDA-approved targeted therapies and immunotherapies?
3. Does my policy cover tests which include all guideline-recommended genes in any given tumor type?
4. Does my policy cover tests inclusive of all genes which could indicate potential resistance to an FDA-approved therapy?
5. Who are the providers in my network that are doing CGP testing?
6. What is my plan doing to reduce delays in getting patients started on treatments?
7. Does my policy cover clinical trials? Would the plan consider covering them?
8. What are the costs of various tests or treatments that are covered and not covered, and what are the costs for the patient?

What is a Genetic Mutation?

A genetic mutation is a permanent change in a DNA sequence which can cause genes to malfunction. Genetic mutations generally occur in two ways: they can be inherited from a parent or developed during a person's lifetime due to their environment.

What is a Genetic Profile?

Information about specific genes – including genetic mutations – in an individual or in a certain type of tissue. A genetic profile may help diagnose a disease or learn how it progresses or responds to treatment with drugs or radiation.

What is a Biopsy?

A procedure to remove a piece of tissue or a sample of cells from your body so that it can be analyzed in a laboratory, especially for genetic mutations. A biopsy is often the first step taken by an oncologist in diagnosing cancers.

What is a Liquid Biopsy?

A test done on a sample of blood to look for cancer cells or DNA from a tumor that are circulating in the blood.

What is Biomarker Testing?

A way to look for genes, proteins, and other substances (called biomarkers or tumor markers) that can provide information about cancer. Each person's cancer has a unique pattern of biomarkers. Some biomarkers affect how certain cancer treatments work. Biomarker testing may help patients and their doctors choose a cancer treatment. Limited panel tests are biomarker tests that can test for a single biomarker at a time, or a small number of biomarkers (usually less than five). Biomarker testing may also be called:

- tumor testing
- tumor genetic testing
- genomic testing
- genomic profiling
- molecular testing or molecular profiling
- companion diagnostic test

For more information, visit Biomarkers at FDA or Cancer Biomarkers at the National Cancer Institute.

National Cancer Treatment Alliance™

How has the Human Genome Project enabled Comprehensive Genomic Profiling (CGP)?

The Human Genome Project was the international research effort to determine the DNA sequence of the entire human genome. Now, next-generation sequencing (NGS) allows the sequencing of the entire genome in just a few hours to help quickly find complex or rare genetic variation associated with diseases. CGP is a method of testing tumors that uses NGS.

What is Comprehensive Genomic Profiling (CGP)?

CGP is an NGS approach that uses a single test to assess hundreds of genes at once, including relevant cancer biomarkers, and quickly get the patient on the right therapy at the right time.

What is a companion diagnostic test?

Companion diagnostic tests help doctors determine whether a particular drug will benefit their patient. For more information, visit the List of FDA Cleared or Approved Companion Diagnostics.

Why is targeted therapy important?

Targeted therapies are newer medicines which can fight specific cancers but require precise diagnosis. What is highly effective for one person may not work for another.

Can patients only get genetic testing and targeted therapies from big hospitals and teaching institutes?

No. Genetic tests can be requested by a person's genetic counselor, doctor, community oncology clinic, or other health care provider. Genetic testing is now widely available in the US, with most doctors able to request the test at the site of care or provide a referral to a nearby diagnostic center.

What is the role of American Cancer Society (ACS) Cancer Action Network (CAN)?

ACS CAN is a cancer advocacy organization that works with advocates across the country to influence public policy to make cancer issues a national priority. For more information, visit American Cancer Society Cancer Action Network.

What is the role of National Comprehensive Cancer Network (NCCN) Guidelines?

The NCCN Biomarkers Compendium® contains information designed to support decision-making around the use of biomarker testing in patients with cancer. For more information, visit NCCN Biomarkers Compendium® (subscription required).

About the Community Oncology Alliance: The Community Oncology Alliance (COA) is a non-profit organization dedicated to advocating for community oncology practices and, most importantly, the patients they serve. COA is the only organization dedicated solely to community oncology where the majority of Americans with cancer are treated. The mission of COA is to ensure that patients with cancer receive quality, affordable, and accessible cancer care in their own communities. More than 1.5 million people in the United States are diagnosed with cancer each year and deaths from the disease have been steadily declining due to earlier detection, diagnosis, and treatment. Learn more about COA at www.communityoncology.org.

[i] IQVIA, Global Oncology Trends 2019 (30 May 2019).
[ii] Genetic testing for inherited disease dates back to the late 1950s with karyotyping (counting chromosomes) for Trisomy 21, the genetic cause of Down Syndrome, while genetic testing for cancer goes back as far as the late 1990s; *see* Issacs C, Cancer.Net (ASCO), Pros and Cons of Genetic Testing and Cancer (27 September 2016).
[iii] World Economic Forum, An Economic Analysis of the Value of Genetic Testing (September 2021).
[iv] Gutierrez ME, et al, Genomic Profiling of Advanced Non-Small Cell Lung Cancer in Community Settings: Gaps and Opportunities, 17 Clinical Lung Cancer 651-59 (2017).