EXPAND ACCESS TO BIOMARKER TESTING IN NEW YORK

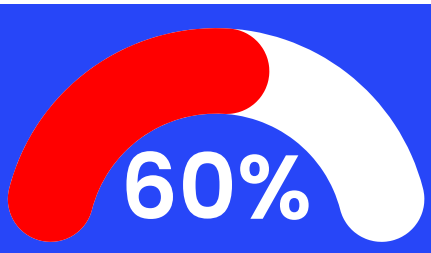
THE RIGHT TREATMENT AT THE RIGHT TIME

WHAT IS BIOMARKER TESTING?

Biomarker testing is often used to help determine the best treatment for a patient.

- It is the analysis of a patient's tissue, blood, or other biospecimen for the presence of a biomarker.
- Biomarker testing is an important step for accessing precision medicine, including targeted therapies that can lead to improved survivorship and better quality of life for cancer patients.
- While most current applications of biomarker testing are in oncology and autoimmune disease, there is research underway to benefit patients with other conditions including heart disease, neurological conditions like Alzheimer's disease, infectious disease and respiratory illness.

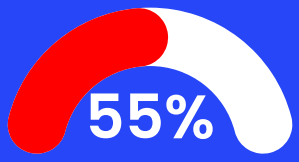
THE IMPORTANCE OF BIOMARKER TESTING



Of oncology drugs launched in the past five years require or recommend biomarker testing prior to use

In 2000:

In 2018:



Of cancer clinical trials involved biomarkers

BIOMARKER TESTING & HEALTH EQUITY

- **Not all communities in New York are benefitting from the latest advancements in biomarker testing and precision medicine.**
  - Patients who are older, Black, uninsured or Medicaid-insured, are less likely to be tested for certain guideline-indicated biomarkers.
  - There are lower rates of testing in community settings versus academic medical centers.

THE BOTTOM LINE

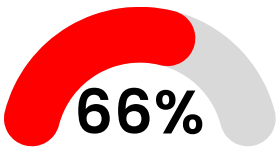
Access to appropriate biomarker testing can help to achieve:

- better health outcomes
- improved quality of life
- reduced costs

Insurance coverage for biomarker testing is failing to keep pace with innovation and advancement in treatment:

- Without action, this could increase existing disparities in cancer outcomes by race, ethnicity, income and geography.

Arizona, Illinois, Louisiana and Rhode Island have recently passed legislation to expand coverage of comprehensive biomarker testing.

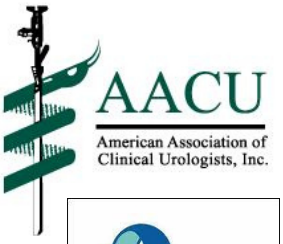


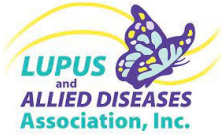
Of oncology providers reported that insurance coverage is a **significant or moderate barrier** to appropriate biomarker testing for their patients

In New York:

Of commercial insurance plans provide coverage that is more restrictive than National Comprehensive Cancer Center guidelines

SUPPORTERS OF NEW YORK BIOMARKER TESTING LEGISLATION A1673/S1196





Memorial Sloan Kettering Cancer Center

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Updated 1.17.23

BENEFITS OF BIOMARKER TESTING FOR PATIENTS

"Biomarker testing opened the door to the treatment that saved my life."

Giovanna Whitting

Memorial Sloan Kettering

My name is Giovanna Whitting, and I nearly died of thyroid cancer. Biomarker testing opened the door to the treatment that saved my life.

I found out I was sick when I was just eight years old. I was having breathing problems. And one day, my mom gave me a bowl of Cheerios and I couldn't eat it because I couldn't swallow. It turned out I had a tumor in my throat. I had an aggressive form of thyroid cancer. I had four surgeries to remove the tumor, but it was tricky because it was wrapped around my vocal cords. So, they had to leave about 5% of it because it was too dangerous to take out. My doctors told me there were no further treatments available for me at that time. So, I took medicine to regulate my thyroid function, but nothing for the cancer.

I was very much underweight and very weak. Life was very hard because I still had a lot of the cancer symptoms. I had a routine where every morning I would cough so bad I would throw up. It was heartbreaking because my mom had to hear it every single day.

When I was 15 or 16, I found out that the cancer had spread to my lungs. The doctors were very straight up with me and said, "Things are not looking good for you right now. We need to figure out an option here." But they weren't confident that anything would work. It was at that point that I decided I didn't want to fight anymore. I told my mom and said, "Look, I have been fighting my entire life and it gets to the point where you're exhausted, and you just want to die." She was very adamant. She said, "This story isn't just about you, it's about the people all around you. It's the people who love you. You need to fight. This is what you were destined to do."

Very soon after, my oncologist came to me. He said there was a clinical trial based on biomarker testing and you're a fit. This might work for you. I didn't want to get my hopes up, but of course I said, "Yes, let's do it." The trial itself was easy. Two pills in the morning and two pills at night. The morning after the first day of treatment, something was different. My cough was gone. I wasn't throwing up. My lungs didn't feel like they were going to die. I could breathe.

The instant relief I felt was indescribable. To this day, I still can't process that. Never in a million years did I think symptoms would just disappear after one dose. It felt like a miracle. And I don't even think my doctor can explain how it happened. But I do know it wouldn't have been possible without biomarker testing.

I'm 21 now, and my life is completely normal. I have amazing friends and a wonderful boyfriend. I'm studying journalism at Penn State, and it is my dream to advocate for kids with cancer because I've been doing this since I was eight years old. I know that any story I tell will include the crucial role of biomarker testing in cancer cures that seemed impossible just a few years ago.

Learn more at FightCancer.org/NYBIO For more information please contact:
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THE RIGHT TESTS FOR THE RIGHT TREATMENT:

Patient experiences with and without access to comprehensive biomarker testing

JUNE 2022

THE RIGHT TESTS FOR THE RIGHT TREATMENT:

Patient experiences with and without access to comprehensive biomarker testing

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Patient experiences with and without access to comprehensive biomarker testing

Comprehensive biomarker testing is transforming cancer treatment – allowing health care providers to understand how specific characteristics of a patient's cancer, such as gene mutations, are driving a patient's disease. This personalized information allows providers to prescribe targeted therapies that often lead to fewer side effects and longer survival for patients. It also can allow patients to avoid treatments that are likely to be ineffective. Additionally, biomarker testing can help providers determine which patients are more likely to have recurring or more aggressive disease so that patients at low risk of recurrence or progression may choose to avoid unnecessary treatment.

Despite the clear benefits of biomarker testing, many insurance plans do not cover evidence-based biomarker testing for all patients who need it. The following patient profiles highlight the potential impact of timely access to appropriate biomarker testing on treatment decisions and quality of life over the first year of treatment.

Comprehensive biomarker testing looks for all recommended biomarkers based on clinical guidelines. This is often done with a biomarker *panel test* that assesses multiple markers (e.g., genes or proteins) in one test as compared to *single marker testing* that assesses one marker per test. For some cancers, panel testing is recommended by clinical guidelines. Panel testing can limit disruptions in care, including the need for multiple biopsies to collect biospecimen samples for testing, as well as delays in initiating the most appropriate treatment. Cancer biomarkers are often noted by an abbreviation with letters and numbers (e.g., ROS1, EGFR, ALK).

Importance of Guidelines for Biomarker Testing

Oncology providers rely on clinical treatment guidelines, such as those published by the National Comprehensive Cancer Network (NCCN) and the American Society of Clinical Oncology (ASCO) to inform testing and treatment decisions. In a survey of oncology providers, 91% reported consulting clinical practice guidelines to determine when to recommend or order biomarker testing for their patients.[1] As the science of biomarker-driven treatments is quickly evolving, clinical treatment guidelines – which are developed and updated regularly based on rigorous evaluation of clinical evidence – are an essential resource to help providers offer the best care informed by the latest evidence. The comprehensive biomarker testing scenarios in this report are in line with current clinical treatment guidelines.

Because of the complexity and variation in cancer treatment, it is difficult to predict the course of treatment for any individual with cancer. The following illustrative patient profiles are hypothetical, but the treatment regimens are typical for a year of treatment for each specific cancer.

Each patient story is told with two scenarios: one with timely access to comprehensive biomarker testing (testing for all guideline-recommended markers) and another without this testing (testing for some markers and/or delayed testing). These stories illustrate the impact of timely testing and the importance of insurance coverage for comprehensive biomarker testing – not only to improve patient outcomes and quality of life but also to avoid ineffective treatments and disease progression. Each of the five patient stories starts with a simplified graphic and is followed by a more detailed narrative description of the two treatment scenarios.

[1] American Cancer Society Cancer Action Network. Survey Findings Summary: Understanding ProviderUtilization of Cancer Biomarker Testing Across Cancers. Dec. 2021. https://www.fightcancer.org/sites/default/files/national_documents/provider_utilization_of_biomarker_testing_polling_memo_dec_2021.pdf

Patient Profile Kathy, 54

Kathy is a 54-year-old white woman with no history of tobacco use. After visiting her primary care physician for persistent cough and shortness of breath, she was ultimately referred to an oncologist. Her oncologist ordered a diagnostic CT scan which revealed a large mass in the left lung with lymph node involvement. A biopsy confirmed **stage IV non-small cell lung cancer**, and her PET/CT scan was consistent with extensive bone metastases.

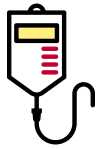
WITH COMPREHENSIVE BIOMARKER TESTING

Comprehensive biomarker testing reveals a **ROS1 mutation**. Starts targeted oral therapy. **Disease stabilizes.**

JANUARY → FEBRUARY → MARCH → APRIL → MAY → JUNE → JULY → AUGUST → SEPTEMBER → OCTOBER → NOVEMBER → DECEMBER

5 cycles of chemoimmunotherapy. Causes shortness of breath.

Insurance only covers single marker testing for ALK and EGFR. No mutations found.

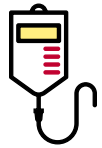


Starts combination chemotherapy. Must **stop working due to side effects.**

ER visit for shortness of breath. CT scan shows tumor continues to grow.

Rebiopsy to test for another single marker, **RET.** No mutation found.

Switches to another chemotherapy due to toxicity. **After 5 cycles, a CT scan shows the tumor continues to grow.**



Rebiopsy and single marker test for ROS1 **reveals ROS1 mutation.**

Starts targeted oral therapy. **Disease stabilizes.**

WITHOUT COMPREHENSIVE BIOMARKER TESTING

Kathy – Lung Cancer

Kathy is a 54-year-old white woman with no history of tobacco use. After visiting her primary care physician for persistent cough and shortness of breath, she was ultimately referred to an oncologist. Her oncologist ordered a diagnostic CT scan which revealed a large mass in the left lung with lymph node involvement. A biopsy confirmed stage IV non-small cell lung cancer, and her PET/CT scan was consistent with extensive bone metastases.

With comprehensive biomarker testing

Kathy's doctor recommended that she have comprehensive biomarker testing of her tumor with a panel test including all guideline-recommended markers. Through testing, Kathy's tumor was found to have a ROS1 gene rearrangement. She was placed on a targeted oral therapy, crizotinib, which is indicated for patients with ROS1 positive disease. This resulted in disease stabilization through the end of the year.

Without comprehensive biomarker testing

Kathy's doctor recommended that she have comprehensive biomarker testing of her tumor with a panel test including all guideline-recommended markers. However, Kathy's health plan will not cover panel testing, so her doctor sent a biopsy sample for biomarker testing for ALK and EGFR mutations, two of the more common mutations in non-small cell lung cancer that can be treated with targeted therapies. The test results were negative for ALK and EGFR mutations. The oncologist discussed drug therapy options with Kathy, and she started chemoimmunotherapy (pembrolizumab + platinum-based chemotherapy). She continued drug therapy for five cycles but had shortness of breath. She went to the ER and was admitted to the hospital for shortness of breath, and a CT scan revealed the tumor had progressed. She was discharged and followed up with her oncologist who rebiopsied her tumor. The sample was sent for biomarker testing to look for a RET gene rearrangement. The test was negative. Her oncologist started Kathy on a combination chemotherapy, gemcitabine and docetaxel, but she went to the emergency room for hemoptysis (coughing up blood) after just two cycles. The side effects of the chemotherapy severely impacted Kathy's day-to-day life and she had to stop working. Due to the toxic side effects, Kathy's oncologist switched her to another chemotherapy, albumin-bound paclitaxel, but after five cycles, her PET/CT scans showed disease progression. Finally, her oncologist rebiopsied her tumor and sent the sample for biomarker testing to look for a ROS1 gene rearrangement, a more rare mutation. The test was positive. Kathy was then placed on a targeted oral therapy crizotinib, which is indicated for patients with ROS1 positive disease. This resulted in disease stabilization through the end of the year.

Patient Profile Mary, 40

Mary is a 40-year-old white woman who noticed a lump in her left breast during a self-exam. Her doctor ordered a diagnostic mammogram which showed a large mass in her left breast with lymph node involvement. A biopsy confirmed invasive breast cancer, and her PET/CT scans were consistent with extensive bone metastases. Her tumor sample was tested for ER, PR, HER2 status; her cancer was classified as triple-negative breast cancer.

WITH COMPREHENSIVE BIOMARKER TESTING

Comprehensive biomarker testing reveals high levels of **microsatellite instability (MSI-H).**

Starts chemotherapy. After four cycles, PET/CT scans show disease progression.

Starts immunotherapy recommended for MSI-H. **Disease stabilizes.**

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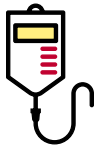
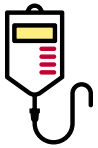


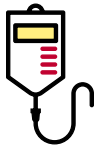
Starts chemotherapy. After four cycles, PET/CT scans show disease progression.

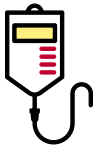


Starts another chemotherapy.

PET/CT scans show further disease progression.

Doctor recommends comprehensive biomarker testing, but insurance will not cover it. **Starts another chemotherapy.**





After four cycles of chemotherapy, PET/CT scans show the cancer is continuing to grow.

Tries another **chemotherapy** but has signs of toxicity.

Mary has to stop treatment and wait for symptoms to resolve before trying any other options. Her cancer continues to grow.

WITHOUT COMPREHENSIVE BIOMARKER TESTING

Mary – Breast Cancer

Mary is a 40-year-old white woman who noticed a lump in her left breast during a self-exam. Her doctor ordered a diagnostic mammogram, which showed a large mass in her left breast with lymph node involvement. A biopsy confirmed invasive breast cancer, and her PET/CT scans were consistent with extensive bone metastases. PR, ER, and HER2 results indicated triple-negative breast cancer.

With comprehensive biomarker testing

Mary's doctor recommended that she have comprehensive biomarker testing of her tumor, which was found to have high levels of microsatellite instability (MSI-H). She started chemotherapy, liposomal doxorubicin, for four cycles but had disease progression upon evaluation by PET/CT scans. She was then placed on an immunotherapy, pembrolizumab, which is indicated as a second-line therapy for MSI-H tumors which have progressed following prior treatment. This resulted in disease stabilization until the end of the year.

Without comprehensive biomarker testing

Mary started chemotherapy, liposomal doxorubicin, for four cycles, but PET/CT scans show disease progression. She then started a second chemotherapy, paclitaxel, but after four cycles, her PET/CT scan again showed disease progression. Her doctor wanted to rebiopsy her tumor and recommended comprehensive biomarker testing to identify other treatment options, however, her health insurance did not cover the testing. Mary's oncologist then started her on another chemotherapy, gemcitabine. After four cycles, her PET/CT scans again showed disease progression. Mary's oncologist then switched her to another chemotherapy, eribulin. After one cycle of eribulin, Mary showed signs of drug toxicity (dizziness, tinnitus, and lack of coordination). Her oncologist decided to delay her next cycle of eribulin until her symptoms resolved.

Patient Profile Robert, 61

Robert is a 61-year-old Black man who has Type 2 diabetes. After visiting his doctor for abdominal pain, fatigue, loss of appetite, weight loss, and yellowing of the eyes, his doctor ordered diagnostic CT evaluation, which revealed a large mass in the pancreas with lymph node involvement. A biopsy confirmed pancreatic cancer, and his PET/CT was consistent with metastatic disease to the liver.

WITH COMPREHENSIVE BIOMARKER TESTING

Comprehensive biomarker testing reveals **NTRK mutation.**

4 cycles of chemotherapy.

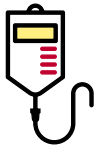
CT scans show disease progression.

Starts targeted oral therapy. **Disease stabilizes.**

JANUARY → FEBRUARY → MARCH → APRIL → MAY → JUNE

4 cycles of chemotherapy.

CT scans show disease progression. Starts another chemotherapy.



Discontinues chemotherapy after 2 cycles when CT scans show continued disease progression. Rebiopsy shows liver metastases still present.

Comprehensive biomarker testing reveals **NTRK mutation.**

Starts targeted oral therapy. **Disease stabilizes.**

WITHOUT TIMELY COMPREHENSIVE BIOMARKER TESTING

Robert – Pancreatic Cancer

Robert is a 61-year-old Black man who has Type 2 diabetes. After visiting his doctor for abdominal pain, fatigue, loss of appetite, weight loss, and yellowing of the eyes, his doctor ordered a diagnostic CT evaluation. This revealed a large mass in the pancreas with lymph node involvement. A biopsy confirmed pancreatic cancer, and his PET/CT was consistent with metastatic disease to the liver.

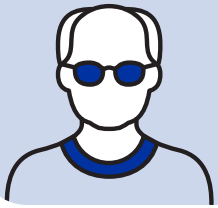
With comprehensive biomarker testing

Robert's oncologist recommended he have comprehensive biomarker testing of his tumor. Through testing, Robert's tumor was found to be positive for a NTRK gene fusion. Robert was placed on chemotherapy, FOLFIRINOX, for four cycles but had progressive disease upon CT scan evaluation. He was then placed on larotrectinib targeted oral therapy, which is indicated as a second-line therapy for NTRK positive tumors which have progressed following prior treatment. This resulted in disease stabilization through the end of the year.

With delayed comprehensive biomarker testing

Robert was placed on chemotherapy, FOLFIRINOX, for four cycles but had progressive disease upon CT scan evaluation. He then started another chemotherapy, gemcitabine, but his disease progressed again after only two cycles of this therapy. A rebiopsy showed liver metastases were still present. His physician then recommended comprehensive biomarker testing to identify other treatment options. His tumor was found to be positive for NTRK gene fusion. He then started larotrectinib targeted oral therapy. This resulted in disease stabilization through the end of the year.

Patient Profile Samuel, 54

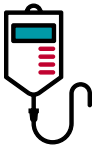


Samuel is a 54-year-old Asian man with a history of tobacco use. He visited his primary doctor with complaints of chest pain, shortness of breath, persistent cough and hemoptysis (coughing up blood). His doctor ordered a diagnostic CT scan which revealed a large mass on his left lung with lymph node involvement. He is diagnosed with stage IV non-small cell lung cancer after a biopsy of the lung, and his PET/CT was consistent with extensive bone metastases.

WITH COMPREHENSIVE BIOMARKER TESTING

Comprehensive biomarker testing reveals **KRAS G12C mutation.**

Starts chemoimmunotherapy. Discontinues after 4 cycles due to shortness of breath.

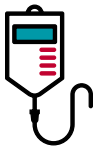


CT scan shows disease progression.

Starts targeted oral therapy. **Disease stabilizes.**

JANUARY → FEBRUARY → MARCH → APRIL → MAY → JUNE → JULY

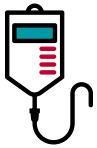
Single marker testing for ALK and EGFR shows no mutations.



Starts chemoimmunotherapy.

Discontinues after 4 cycles due to shortness of breath.

CT scan shows disease progression.



Starts another **chemoimmunotherapy.**

CT scan shows disease progression.

Comprehensive biomarker testing reveals **KRAS G12C mutation.**

Starts targeted oral therapy. **Disease stabilizes.**

WITHOUT TIMELY COMPREHENSIVE BIOMARKER TESTING

Samuel – Lung Cancer

Samuel is a 54-year-old Asian man with a history of tobacco use. He visited his primary doctor with complaints of chest pain, shortness of breath, persistent cough and hemoptysis (coughing up blood). His doctor ordered a diagnostic CT scan which revealed a large mass on his left lung with lymph node involvement. A biopsy confirmed stage IV non-small cell lung cancer, and his PET/CT was consistent with extensive bone metastases.

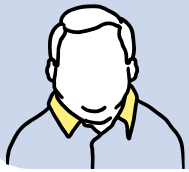
With comprehensive biomarker testing

Samuel's doctor recommended he have comprehensive biomarker testing of his tumor. The testing showed the mass was positive for a KRAS G12C gene mutation. Samuel started chemoimmunotherapy (pembrolizumab + pemetrexed + carboplatin). He continued this treatment for four cycles but he experienced shortness of breath. A CT scan confirmed disease progression. He was then placed on sotorasib, which is indicated as a second-line therapy for KRAS G12C positive tumors. This resulted in disease stabilization through the end of the year.

With delayed comprehensive biomarker testing

Samuel's tumor sample was sent for single marker testing for ALK and EGFR mutations only. ALK and EGFR results came back negative. The oncologist discussed drug therapy options with Samuel, and he started chemoimmunotherapy (pembrolizumab + pemetrexed + carboplatin). Samuel continued drug therapy for four cycles, but he experienced shortness of breath. A CT scan showed disease progression. He was then placed on a second chemoimmunotherapy (ramucirumab + docetaxel). After two cycles, his CT scan still showed disease progression. The oncologist performed comprehensive biomarker testing, which revealed a positive KRAS G12C mutation. He was placed on a targeted oral therapy, sotorasib, which is indicated as a second-line therapy for KRAS G12C positive tumors. This resulted in disease stabilization through the end of the year.

Patient Profile Brian, 57



Brian is a 57-year-old white man who was referred to urology due to an elevated blood prostate-specific antigen (PSA) level. He had no prostate-related symptoms or family history of prostate or breast cancer. An MRI revealed a tumor on the right base of the prostate. Brian underwent a biopsy and the pathology report confirmed prostate cancer.

WITH COMPREHENSIVE BIOMARKER TESTING

A prognostic biomarker test shows low risk of disease progression. **He receives no additional treatment and is monitored (active surveillance).**

No evidence of disease progression.

JANUARY → FEBRUARY → MARCH → APRIL → MAY → JUNE → JULY → AUGUST → SEPTEMBER → OCTOBER → NOVEMBER → DECEMBER

Develops post-prostatectomy **urinary incontinence** and **erectile dysfunction.**

His incontinence and erectile dysfunction persist.

He receives an **implanted artificial urinary sphincter** to treat incontinence. He receives a **penile prosthesis** to treat erectile dysfunction.

Undergoes a **radical prostectomy.**

WITHOUT COMPREHENSIVE BIOMARKER TESTING

Brian – Prostate Cancer

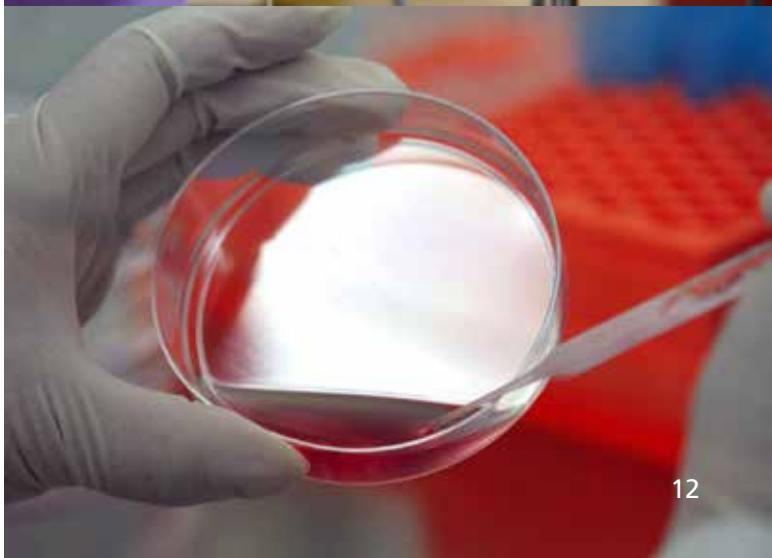
Brian is a 57-year-old white man who was referred to urology due to an elevated blood prostate-specific antigen (PSA) level. He had no prostate-related symptoms or family history of prostate or breast cancer. An MRI revealed a tumor on the right base of the prostate. Brian underwent a biopsy and the pathology report confirmed prostate cancer. The risk of his cancer returning was uncertain based on his biopsy results.

With comprehensive biomarker testing

Brian's urologist recommended he have his prostate tumor sample tested with a prognostic biomarker test, which is a type of test that can be used to determine the likelihood of disease progression. The test revealed his cancer was low risk (3% chance of metastasis in the next 10 years and a less than 1% chance of prostate cancer death in the next 10 years). Given these test results and clinical features, he chose active surveillance (no further treatment, but regular checkups). After one year of follow-up, Brian remains on active surveillance with no evidence of disease progression.

Without comprehensive biomarker testing

Brian's urologist explained he had localized prostate cancer and recommended radical prostatectomy or radiotherapy. Brian decided to undergo radical prostatectomy. He was discharged two days after his surgery and the urinary catheter was removed one week later. His postoperative PSA was undetectable at the first follow-up office visit. Although Brian was cancer-free, he developed post-prostatectomy urinary incontinence and erectile dysfunction. The urinary incontinence did not improve with treatment; the erectile dysfunction did not improve with oral medications and intracavernosal injection. Both conditions negatively impacted Brian's quality of life. One year after his radical prostatectomy, Brian continues to suffer from urinary incontinence and erectile dysfunction. His urologist recommended the implantation of an artificial urinary sphincter to treat the urinary incontinence and penile prosthesis to address erectile dysfunction.



About ACS CAN

The American Cancer Society Cancer Action Network (ACS CAN) makes cancer a top priority for policymakers at every level of government. ACS CAN empowers volunteers across the country to make their voices heard to influence evidence-based public policy change that saves lives. We believe everyone should have a fair and just opportunity to prevent, find, treat, and survive cancer. Since 2001, as the American Cancer Society's nonprofit, nonpartisan advocacy affiliate, ACS CAN has successfully advocated for billions of dollars in cancer research funding, expanded access to quality affordable health care, and made workplaces, including restaurants and bars, smoke-free. As we mark our 20th anniversary, we're more determined than ever to stand together with our volunteers and save more lives from cancer. Join the fight by visiting **www.fightcancer.org**.

Health Equity in Biomarker Testing and Targeted Therapy

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Targeted therapy can improve survival and quality of life by connecting patients to the most beneficial treatment for their disease.

Advancements in cancer treatment are saving more lives – leading to declines in cancer deaths in recent years.[1] This important progress is driven by developments in *targeted therapy* which identifies and attacks certain types of cancer cells with specific *biomarkers* – molecules like proteins or genetic alterations such as mutations, rearrangements, or fusions.

- Treatment with targeted therapy often requires diagnostic testing to identify biomarkers which can inform targeted therapy options for cancer patients.

- 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, currently 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.

For example, studies have shown:

- Patients with advanced non-small cell lung cancer who were Black, older, or Medicaid-insured had lower odds of next-generation sequencing biomarker testing compared to patients who were White, younger, or commercially insured, respectively.[2]

- Patients who are older, Black, uninsured, or Medicaid-insured, are less likely to be tested for certain guideline indicated biomarkers for colorectal cancer.[3]

- There are socioeconomic inequalities in biomarker testing and targeted therapy utilization across cancer types.[4]

- Racial and socioeconomic disparities in the uptake of testing of Medicare enrollees with stage IV lung adenocarcinoma.[5]

- There are lower rates of testing in community oncology settings versus academic medical centers.[6,7]

Priorities for Advancing Health Equity in Precision Medicine

- Improving access to biomarker testing is important for advancing health equity. Special focus should be placed 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 utilization biomarker testing and targeted therapy we must dismantle access barriers, including insurance coverage of biomarker testing.

- Differential use of guideline-indicated biomarker testing and targeted therapy 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 benefitting.

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Biomarker Testing in Clinical Trials

Biomarker testing is the analysis of a patient's tissue, blood, or other biospecimen for the presence of a biomarker that can provide insight into diseases like cancer[1]. Information gained from biomarker testing can then be used to help guide medical treatment, often called precision medicine. By identifying biomarkers, patients can receive treatments that may not otherwise be considered for their disease or cancer.

Importance of biomarker testing:

- Recent studies show that biomarker testing may improve outcomes for patients with hard-to-treat cancer types such as digestive cancers, lung, and breast.[2]
- Nearly 60% of all cancer drugs approved in the last 5 years require or recommend biomarker testing before use.[3]
- Biomarkers may guide doctors' treatment decisions by providing clues about whether patients will respond to standard treatment options.[4]

The number of targeted therapies that require biomarker testing is increasing rapidly and cancer clinical trials are increasingly driven by biomarkers and the development of targeted therapies.

What are clinical trials?

Clinical trials are a key step in advancing potential new cancer treatments from the research setting to the cancer care clinic and give patients the opportunity to access the latest developments in treatment and access to care that is equivalent to treatment outside of a trial. Patient participation in trials is crucial to their success.

Cancer clinical trials are increasingly driven by biomarkers and the development of targeted therapies. Biomarker testing can identify patients who are eligible for these trials. For example, after biomarker testing, a patient may find that their cancer has biomarkers that are not well understood or lack a corresponding targeted therapy. However, they may find that their test results make them eligible for a clinical trial of an investigational targeted therapy.

How has biomarker testing impacted clinical trials?

- The number and percentage of cancer clinical trials that involve biomarkers has grown significantly, from 15 percent in 2000 to 55 percent in 2018.[5]
- In clinical trials, patients whose cancer care was based on biomarker testing had a better response to treatments than those without biomarker testing.[6,7]
- In a study on pancreatic cancer, patients receiving targeted therapies following biomarker testing lasted twice as long on treatments without disease progression.[8]

Biomarker testing is becoming increasingly important for new targeted therapies. However, access to appropriate biomarker testing can still be a challenge for patients. By working to remove these barriers, we can ensure more patients receive the best care for their specific cancer.

Learn more at www.fightcancer.org/biomarkers.

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Biomarker Testing: Advancing Precision Medicine

Precision medicine uses ***biomarker testing*** to gather information about a person's own body to prevent, diagnose, or treat disease.[1] This information is found by testing a patient's tissue, blood, or other biospecimen for the presence of a ***biomarker*** (e.g., genetic alterations, molecular signatures). The results of biomarker testing can help determine the medication(s) or treatment(s) that will work best for a specific patient.

In certain areas of medicine, like cancer care, advances in precision medicine have been progressing rapidly in recent years and have led to targeted cancer therapies that work by interfering with specific cellular processes involved in the growth, spread, and progression of cancer. In other words, effective treatments can be selected based on the tumor itself, rather than just its location in the body.

Research shows that targeted therapy can improve health outcomes, increase quality of life, and prolong patient survival.

Using the traditional trial and error method, identifying an effective treatment for a particular patient can take months — even years. **In chronic, degenerative diseases like rheumatoid arthritis, any length of time spent trying (and failing) ineffective treatments allows the disease to continue causing irreversible damage to the joints, increasing health care consumption and costs**. In cancer care and some autoimmune conditions, the length of time it takes to identify an effective treatment can be a matter of life or death. **In all cases, ineffective treatments exacerbate the physical, emotional, and economic burdens of disease, and the price is paid by both the patient and the insurer.**

Despite evidence pointing to the clinical benefits associated with biomarker testing, routine clinical use does not always follow, and testing rates lag behind clinical guideline recommendations. In a 2021 survey, 66% of oncology providers reported that insurance coverage for biomarker testing is a significant or moderate barrier to appropriate biomarker testing.[2]

Expand Access to Biomarker Testing and Precision Medicine

Insurance coverage for biomarker testing is failing to keep pace with innovations and advancements in treatment. We must work to remove barriers to biomarker testing to ensure that patients can unlock the value and cost-savings potential of precision medicine. [Our groups] support expanding appropriate coverage of biomarker testing for public and private insurance plans. Without action to expand coverage and access to biomarker testing, advances in precision medicine could exacerbate existing disparities in access to care and, consequently, health outcomes associated with race, ethnicity, income, and geography.

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Biomarker Testing and Cost Savings

Timely access to guideline-indicated comprehensive biomarker testing can help achieve the triple aim of health care including better health outcomes, improved quality of life, and reduced costs. Comprehensive biomarker testing looks for all recommended biomarkers based on clinical guidelines. This testing can lead to treatments with fewer side effects, longer survival and allow patients to avoid treatments that are likely to be ineffective or unnecessary. Exposure to these ineffective treatments can exacerbate the physical, emotional, and economic burdens of disease.

Spending on Biomarker Testing Can Yield Savings on Treatment Costs

There are several studies looking at the cost effectiveness of *single marker testing*, which are most likely to be covered by insurance plans currently, to more comprehensive testing, which isn't always covered. Comprehensive biomarker testing is often done with a *panel test* that assesses multiple biomarkers (e.g., genes or proteins) in one test as compared to single marker testing that assesses one marker per test. For many patients, panel testing is most appropriate. Examples include when there is limited tissue available for testing or as recommended by clinical practice guidelines to gain sufficient information to appropriately guide treatment decisions.

Often paying more upfront for comprehensive testing can result in overall savings in treatment costs.

- In a study sponsored by CVS Health looking at total cost of care for non-small cell lung cancer patients who received broad panel biomarker testing in comparison to narrow panel biomarker testing; broad panel testing had an average additional up-front cost increase of approximately $1,200 in comparison to narrow panel biomarker testing. However, those patients who underwent broad panel biomarker testing experienced a savings of approximately $8,500 per member per month in total cost of care, as a result of more optimal treatment.[i]
- Other studies have found upfront broader biomarker testing results in substantial cost savings for commercial payers ($3,809; $127,402; and $250,842 less than exclusionary, sequential testing, and hotspot panels, respectively)[ii] and decreased expected testing procedure costs to the health plan by $24,651.[iii]
- Some studies have found minimal cost increases as a result of the costs of more effective treatment and prolonged patient survival.[iv, v]

Costs to Insurers

According to a 2022 analysis of biomarker testing coverage by Milliman, the average allowed unit cost to insurers per biomarker test ranges from $78.71 (Medicaid) to $224.40 (large group self-insured).[vi] When biomarker testing is not covered by insurance, patients can be on the hook for hundreds or even thousands of dollars in out-of-pocket costs.[vii]

This study also projected the impact of legislation requiring robust coverage of biomarker testing, projecting an impact of $0.08-$0.51 per member per month. This does not account for any potential cost savings from avoiding ineffective treatments.[viii]

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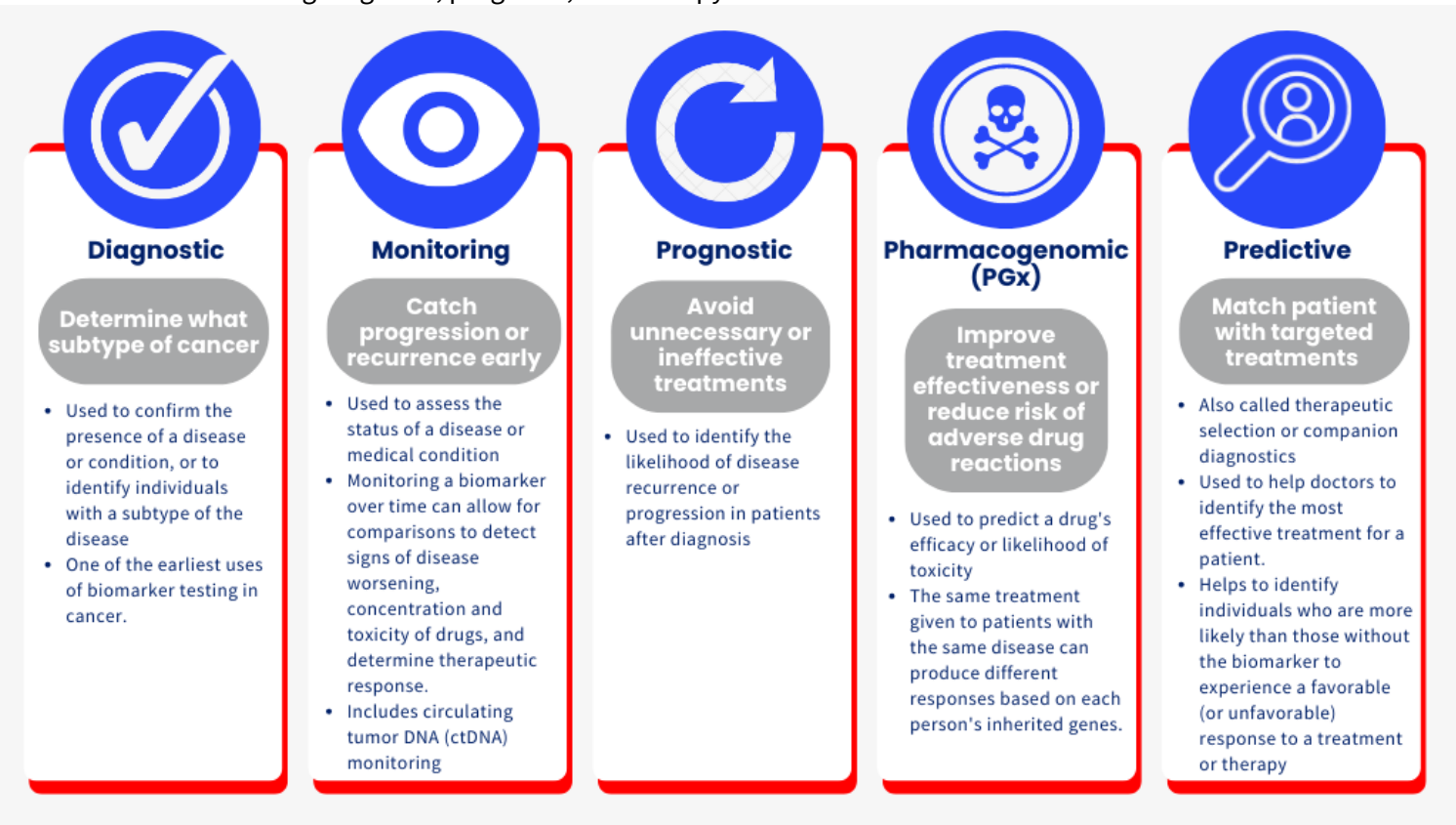
Biomarker Testing: Breaking Down the Terminology

Categories of Biomarkers

There are a variety of clinical uses for **biomarker testing**. Distinct categories of biomarkers can reveal information that is critical to informing diagnosis, prognosis, and therapy selection.



Single Marker vs. Panel Testing

There are many different types of biomarker tests and different tests are appropriate for different patients and circumstances. Oncology providers rely on clinical practice guidelines, such as those published by the National Comprehensive Cancer Network (NCCN) and the American Society of Clinical Oncology (ASCO) to inform testing and treatment decisions. In a survey of oncology providers, 91% reported consulting clinical practice guidelines to determine when to recommend or order biomarker testing for their patients.[i] As the science of biomarker-driven care is quickly evolving, clinical practice guidelines – which are developed and updated regularly based on rigorous evaluation of clinical evidence – are an essential resource to help providers offer the best care informed by the latest evidence.

Single marker tests identify or measure one marker (e.g., gene or molecule). For example, a single-gene biomarker test.

Panel tests identify or measure multiple markers (ranging from a few to several hundred) in the same test.

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Comprehensive biomarker testing looks for all recommended biomarkers based on clinical guidelines. This is often done with a panel test. For some cancers, panel testing is recommended by clinical guidelines. Panel testing can limit disruptions in care, including the need for multiple biopsies to collect biospecimen samples for testing, as well as delays in initiating the most appropriate treatment.

Broad panel testing minimizes tissue use, enables personalized treatment, and can decrease the use of ineffective treatments and unwarranted side effects, in addition to opening pathways to early clinical trials. However, many payors do not reimburse for broad panel testing, despite strong evidence that panel tests lead to overall cost savings for testing and treatment.[ii,iii,iv]

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