

THE RIGHT TESTS FOR THE RIGHT TREATMENT:

Patient experiences with and without access to comprehensive biomarker testing

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TABLE OF CONTENTS

Introduction 2

Kathy, Lung Cancer **Timeline** 3
 **Profile** 4

Mary, Breast Cancer **Timeline** 5
 **Profile** 6

Robert, Pancreatic Cancer **Timeline** 7
 **Profile** 8

Samuel, Lung Cancer **Timeline** 9
 **Profile** 10

Brian, Prostate Cancer **Timeline** 11
 **Profile** 12

About ACS CAN 13

THE RIGHT TESTS FOR THE RIGHT TREATMENT:

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

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.

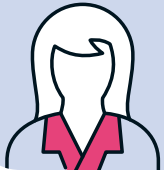
to collect biospecimen samples for testing, as well as delays in initiating the most appropriate treatment. Cancer biomarkers are often noted by an abbreviation with letters and numbers (e.g., ROS1, EGFR, ALK).

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.

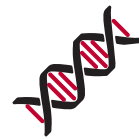
Patient Profile Kathy, 54



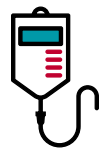
Kathy is a 54-year-old white woman with no history of tobacco use. After visiting her primary care physician for persistent cough and shortness of breath, she was ultimately referred to an oncologist. Her oncologist ordered a diagnostic CT scan which revealed a large mass in the left lung with lymph 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.**

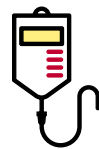


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5 cycles of chemoimmunotherapy.
Causes shortness of breath.

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



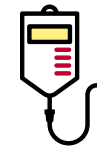
Starts combination chemotherapy. Must **stop working due to side effects.**

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

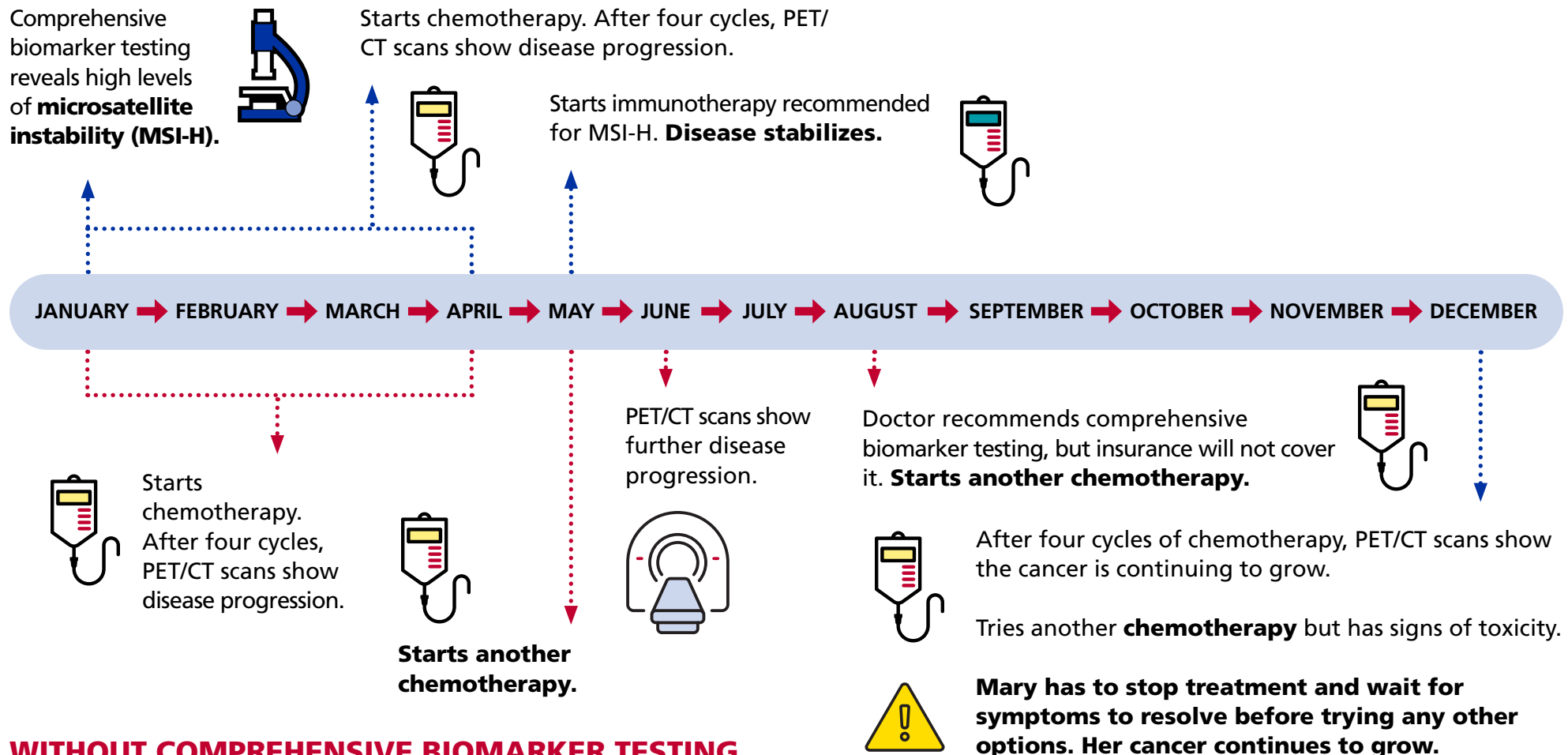
Kathy's doctor recommended that she have comprehensive biomarker testing of her tumor with a panel test including all guideline-recommended markers. However, Kathy's health plan will not cover panel testing, so her doctor sent a biopsy sample for biomarker testing for ALK and EGFR mutations, two of the 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



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

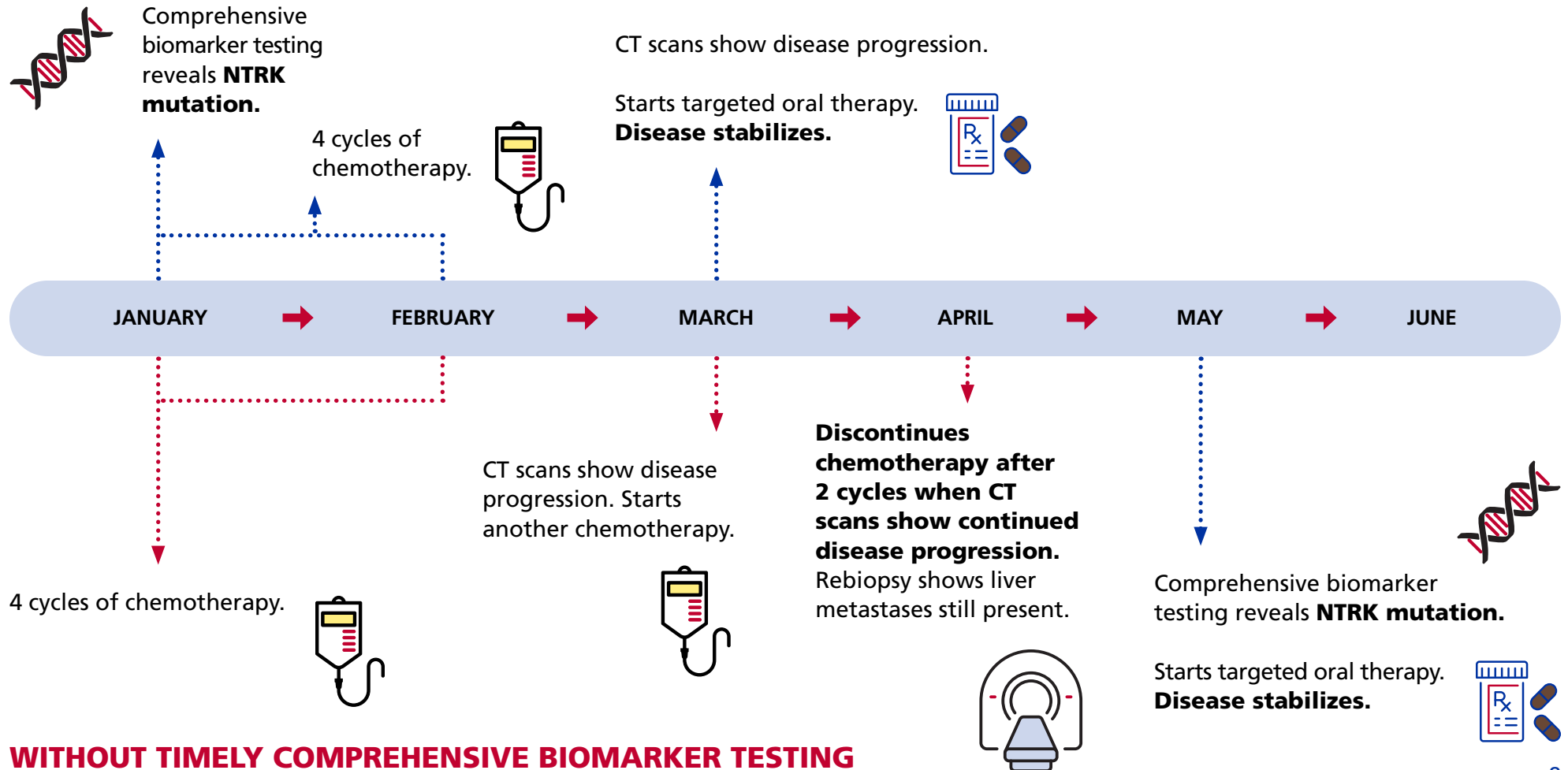
Mary started chemotherapy, liposomal doxorubicin, for four cycles, but PET/CT scans show disease progression. She then started a second chemotherapy, paclitaxel, but after four cycles, her PET/CT scan again showed disease progression. Her doctor wanted to rebiopsy her tumor and recommended comprehensive 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



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

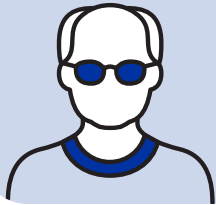
Robert's oncologist recommended he have comprehensive biomarker testing of his tumor. Through testing, Robert's tumor was found to be positive for a NTRK gene fusion. Robert was placed on chemotherapy, FOLFIRINOX, for four cycles but had progressive disease upon CT scan evaluation. He was then placed on entrectinib 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 entrectinib targeted oral therapy. This resulted in disease stabilization through the end of the year.

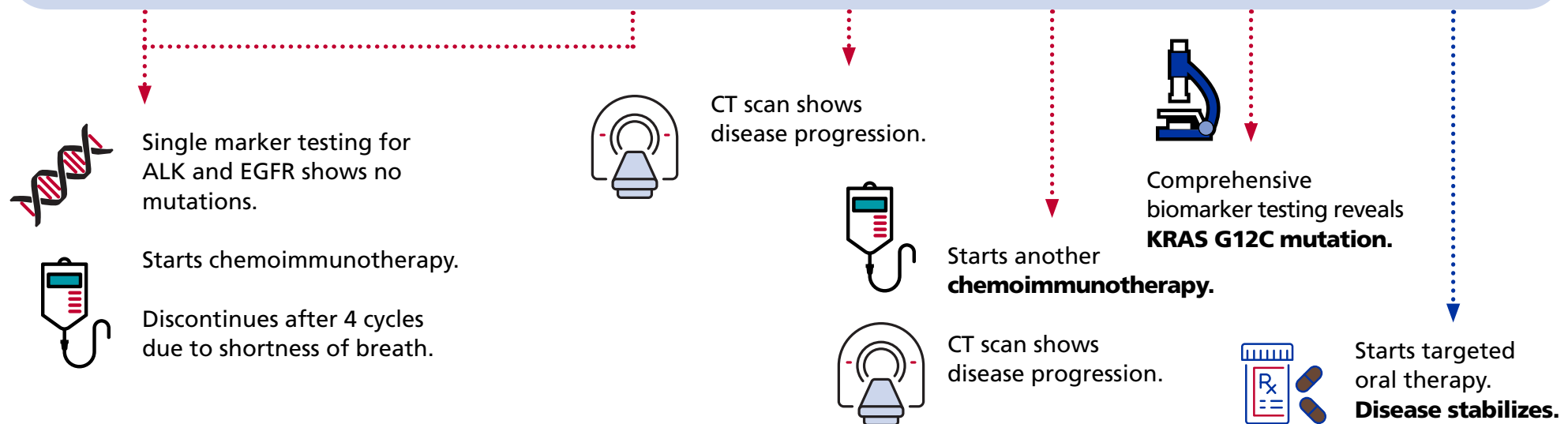
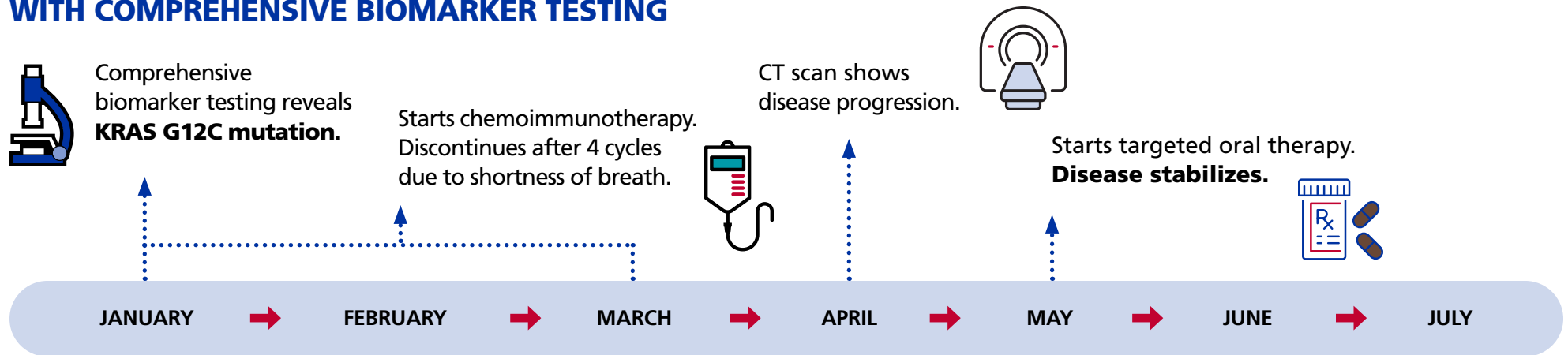


Patient Profile Samuel, 54



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



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

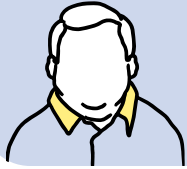
Samuel's doctor recommended he have comprehensive biomarker testing of his tumor. The testing showed the mass was positive for a KRAS G12C gene mutation. Samuel started chemoimmunotherapy (pembrolizumab + pemetrexed + carboplatin). He continued this treatment for four cycles but he experienced shortness 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.

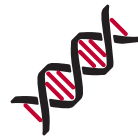
Patient Profile Brian, 57



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.

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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 prostatectomy**.



WITHOUT COMPREHENSIVE BIOMARKER TESTING

Brian – Prostate Cancer

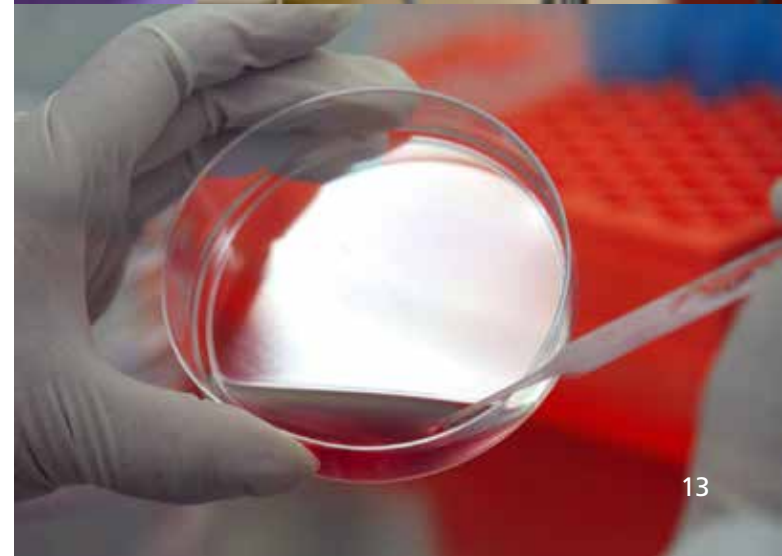
Brian is a 57-year-old white man who was referred to urology due to an elevated blood prostate-specific antigen (PSA) level. He had no prostate-related symptoms or family history of prostate or breast cancer. An MRI revealed a tumor on the right base of the prostate. Brian underwent a biopsy and the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

