



National
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Biomarker Testing: What Employers and Insurers Need to Know

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THE CASE FOR BIOMARKER TESTING

Biomarkers & Biomarker Testing



Biomarker tests are recommended for many cancer drugs introduced since 2017.



Access to biomarker testing can help physicians and patients select the best treatment and ensure the patient receives the right drug at the right time.

- Although many employers provide some coverage, policy terms vary since there are no consistent minimum coverage requirements for biomarker testing.
- This may result in sub-optimal treatment and patient outcomes and additional costs to the employer and patient.

Precision Medicine & Biomarker Testing



Precision medicine targets cancers based on specific biomarkers rather than the tumor's location in the body.



By targeting these specific biomarkers, oncologists are able to provide more effective cancer treatments with fewer side effects for their patients.



In 2001, there was 1 biomarker-directed therapy for 1 cancer type.



As of 2022, there are over 55 biomarker-directed therapies for 24 types of cancer, including many common cancers like lung cancer, breast cancer, melanoma, and colorectal cancer.



Choosing The Right Test for the Right Patient

- Next Generation Sequencing (NGS) looks at all the DNA (within and outside of genes) in the cancer.
- Many biomarker tests are performed by evaluating a tissue sample from a biopsy.
- Liquid biopsies are a newer class of biomarker tests that are designed to evaluate a patient's blood to identify certain biomarkers.

Some tests check for a single biomarker (single analyte tests), while others look for multiple biomarkers at once (panel tests).

Some tests focus on a particular cancer (e.g., lung cancer), while others focus on individual biomarkers that may be found in multiple cancers (e.g., BRAF mutations).



Case Study

The Power of Science

- 55-year-old female on routine mammogram revealed a breast mass
 - Biopsy showed invasive ductal breast carcinoma grade 3
 - Similar tumors were found in her lung and kidney
 - Treatment for mBC was initiated with 1st line SOC cytotoxic chemotherapy with no response
 - 2nd line SOC cytotoxic chemotherapy was started with no response
 - A new adrenal tumor appeared, and 3rd line was initiated
 - At the time, no BC data on genomic testing was available
 - She was tested and found to have a genetic mutation found in lung CA and that was responsive to immunotherapy
 - Nivolumab compassionate use was provided by the manufacturer
 - Six years and 75 doses later she is thriving, working, and has no side effects
 - Tumors have all shrunk and are continuing to shrink with no new metastases



The Coverage Conundrum: How Employers May Help



THE NATIONAL COMPREHENSIVE CANCER NETWORK (NCCN), THE AMERICAN ASSOCIATION OF CLINICAL ONCOLOGY (ASCO), & THE COLLEGE OF AMERICAN PATHOLOGISTS (CAP) HAVE DEVELOPED BIOMARKER TESTING AND TREATMENT GUIDELINES.



EMPLOYERS SHOULD MANDATE THE REFERENCE OF THESE ORGANIZATIONS IN THEIR POLICIES TO ENSURE THAT WHAT IS RECOMMENDED IN THEIR GUIDELINES IS COVERED AND CAN BE ACCESSED IN A **TIMELY AND COST-EFFECTIVE** MANNER BY COVERED CANCER PATIENTS.



THIS IS NOT ALWAYS THE CASE



Coverage & Reimbursement Gaps for Biomarker Testing



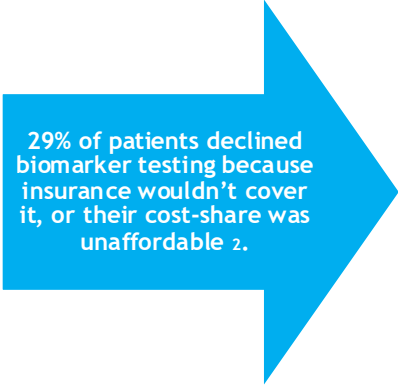
Despite the potential for significantly improved outcomes when using biomarker-directed treatments, many cancer patients are still not receiving this testing. WHY???



A 2020 review of health insurance guidelines by the American Cancer Society found lack of consistent coverage for guideline-recommended tests since payers use different approaches in making coverage decisions, including which tests from which vendors will be covered and at what cost-share to the patient 1.



And The Survey Says.....Results from ACS & JCO



29% of patients declined biomarker testing because insurance wouldn't cover it, or their cost-share was unaffordable ².



The % increased among racial and ethnic minorities and socioeconomically disadvantaged patients³.

- In Non-Small Cell Lung Cancer patients, the most common lung cancer, almost one-fourth of these patients didn't receive biomarker testing to determine whether a specific available treatment may work for them ⁴.



What Do The Oncologists Say? More ACS Survey Results



66% of oncologists report moderate to significant insurance barriers in accessing biomarker testing for their patients.



48% of the HCPs reported needing to “often” or “always” seek PAs from insurers.

- Even when insurance coverage exists for recommended biomarker testing, health plans often require higher patient cost-sharing and longer prior authorization times, resulting in delays in a patient’s access to care.



Making The Case: Biomarker Testing Can Reduce Costs

- A 2015 study by the Journal of Thoracic Oncology found that treatment based on testing for key biomarkers in NSCLC patients was more cost-effective than failing to use biomarker testing and treating these patients with chemotherapy ⁵.
- A 2020 study evaluating the use of biomarkers to direct targeted maintenance therapy for certain ovarian cancer patients found it to yield significant savings ⁶.



Continuing To Make The Case



- A 2012 study by the National Cancer Institute of colorectal cancer patients found that using identified biomarkers to direct treatment decisions helped ensure that only patients who may benefit from a treatment receive it. The study also reported an increase of overall survival while saving \$7500 per patient when compared to using non-biomarker directed treatment⁷.



Impact Of Coverage Expansion of Biomarker Testing on Member Premiums



- Published in 2022, Milliman studied the potential cost for expanding coverage of biomarker testing among various types of insurance and determined that it would have a very small per-member/per-month impact.
- Based on Milliman’s administrative claims data, the expansion of biomarker testing coverage would increase commercial premiums between \$0.14 and \$0.51 per member per month (PMPM)⁸.



Recommendations For Biomarkers Testing Coverage in Your Plan Benefit Design



- Coverage should follow guideline recommendations and FDA-approved uses
- Coverage should include as wide a range of tests as possible, including biomarkers tests, next generation sequencing, companion diagnostics, and lab-developed tests, as directed by guidelines and FDA-approvals.
- Coverage should be extended to testing that may be used to inform clinicians and patients of potential clinical trials.
- Coverage should be updated as new tests are approved by the FDA or added to expert guidelines (NCCN, ASCO, CAP). Any waiting period should be predetermined between the payer and employer.



Recommendations (continued)

- Coverage should be comprehensive
- Coverage should extend to genetic testing for inherited risk and genetic counseling.

Coverage should ensure access to biomarker testing at time of diagnosis and/or recurrence

Coverage of biomarker testing should not be restricted to a single time. It should allow for additional testing to identify changes in the genetics of a patient's cancer or to monitor disease progression.



Questions To Ask Your Benefit Consultant and Insurance Provider



- **Coverage Tied to Guidelines**
 - Does the plan include coverage for all expert guideline recommended cancer biomarker testing (NCCN, ASCO, CAP)?
 - Does the plan have a waiting period before newly FDA-approved biomarker tests are covered?
 - Are coverage guidelines regularly updated as new guidelines and FDA-approved biomarker tests are available?
 - If so, does this happen in real-time or periodically?
 - If periodically, how often?



Which Tests Will Be Covered?

Does the plan include coverage for:

- * all FDA-approved biomarker tests?
- * lab-developed tests (LDTs)?
- * NGS biomarker tests?
- * companion diagnostic tests?

Does the plan cover biomarker testing to determine a patient's potential clinical trial eligibility?

Does the plan specify in-network test providers for biomarker testing?

Are there limitations on types or providers of covered tests?

What are the associated OOP costs to patients?

Test Timing & Utilization Review

Does the plan cover biomarker testing at the time of cancer diagnosis?
Recurrence?

Does the plan cover biomarker testing during transitions in treatment plans and when other testing shows significant changes in the cancer?

Does the plan have limitations or restriction on the timing of biomarker tests covered? If so, request an explanation on the limitations and their rationale, including whether the restrictions are consistent with current expert guidance from NCCN, ASCO, and CAP.



Test Timing & Utilization Review (continued)

Does the plan require prior authorization or limitations on referrals for biomarker testing? If so, ask the plan to provide details on the time limits for decisions and requests for additional information from the provider.

What is the approval rate and timing on appeals when the authorization is denied?



Coverage Limitations



Does the plan restrict biomarker testing coverage depending on the type or stage of cancer?



Does the plan place restrictions on how many times a patient may receive biomarker testing?



Does the plan include prior authorizations or restrictions for biomarker testing services (including biopsy procedures, blood draws, etc.)? What is the patient's cost-share for these services?



If the plan says “yes” to any of the 3 above questions, ask them to explain the restrictions and provide their rationale, including whether the restrictions are consistent with current NCCN, ASCO, and CAP guidelines.



Interpreting Results & Coverage of Ancillary Services

Does the plan cover pathology and physician billing for interpretation of biomarker results? If so, what is the patient's cost-share requirement?

Does the plan cover genetic testing for inherited risk?

Does the plan cover genetic counseling?

If the plans answers “yes” to the last 2 questions, ask them to provide details on coverage, prior authorization requirements, and patient cost-sharing requirements.



Resources

- [NCTA Biomarker Resources and Toolkit](#)

- Visit our website at www.NCTAcancer.com





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