Biomarker Testing and Targeted Therapies

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The Growing Importance of Biomarker Testing in Cancer Treatment

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Trends in Biomarker Usage

BRINGING SCIENTIFIC ADVANCES TO CANCER PATIENTS

Nearly 80 oncology medicines are used after a predictive biomarker test up from 20 in 2011

Exhibit 38: Number of U.S. Oncology Medicines with Required or Recommended Predictive Biomarker Testing

Source: IQVIA Institute, May 2021
What is Biomarker Testing?

- Biomarker Testing - the analysis of a patient’s tissue, blood, or fluid biospecimen for the presence of a biomarker

- Biomarker Testing in People with Cancer
  - Looks for the presence of molecules like proteins or gene mutations found only in cancer cells
  - Can be used to inform therapy selection
  - Example: EGFR-positive non-small cell lung cancer > several EGFR inhibitors

- Differs from genetic testing for an inherited mutation or genetic testing for inherited cancer risk

- Being explored in a variety of disease areas (e.g., cardiology, rheumatology, neurology, infectious diseases, respiratory, autoimmune)

Biomarker Testing and Clinical Trials

• Biomarker testing provides value beyond therapy selection, and results from testing can be utilized to inform patients of relevant clinical trial opportunities

• Cancer clinical trials are increasingly driven by biomarkers and the development of targeted therapies
  – From 15% in 2000 to 55% in 2018

• Today, nearly 80 oncology medicines have required or recommended predictive biomarker testing, up from 20 in 2011

Barriers to Cancer Biomarker Testing

Steps to Biomarker-Driven Targeted Cancer Therapy to Improve Patient Outcomes

- Development of reliable, valid, and relevant biomarker tests
- Patient is diagnosed with cancer and a biopsy is performed
- Provider orders appropriate test and the clinical facility is equipped with testing infrastructure
- Patient's insurance provides test coverage
- Test is performed, interpreted, and identifies a therapeutic selection biomarker
- Patient receives a targeted therapy
Barriers to Cancer Biomarker Testing

- Coverage of tests differs greatly across payers (e.g., Medicare, Medicaid, commercial) and cancer types
  - Different approaches in making coverage decisions

- Coverage policies generally more common for single-gene tests vs. multi-gene panel tests
  - Panel tests can make more efficient use of a tissue sample compared to multiple single-gene tests

- Medicaid patients less likely to be tested for some biomarkers compared to patients with private coverage and Medicare\(^1,2\)

- Biomarker testing should be covered and reimbursed by public and private payers when supported by clinical guidelines or peer-reviewed scientific evidence

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\(^2\) Lamba, N., et al. (2020). Disparities in microsatellite instability/mismatch repair biomarker testing for patients with advanced colorectal cancer.
Legislation to Address Coverage

• Requires *state-regulated insurance plans including Medicaid* to cover comprehensive biomarker testing when supported by medical and scientific evidence*

• Disease and stage agnostic
Legislation to Address Coverage

Biomarker testing must be covered 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, including, but not limited to:

1. Labeled indications for an FDA-approved or -cleared test or indicated tests for an FDA-approved drug;
2. Centers for Medicare and Medicaid Services (CMS) National Coverage Determinations and Medicare Administrative Contractor (MAC) Local Coverage Determinations; or
State Activities

• 2021 legislative wins in Illinois and Louisiana

• Educational events and coalition engagement in: California, Colorado, Florida, Illinois, Iowa, Maryland, Massachusetts, Michigan, Minnesota, New York, Ohio, Tennessee, Texas, and Washington
State Principles to Support Biomarker Testing
Questions?

Learn more at:
fightcancer.org/biomarkers