

Welcome to ACS CAN Lawmaker Meeting Training

Cancer Action Day at the New York State Capitol.



April 25, 2023

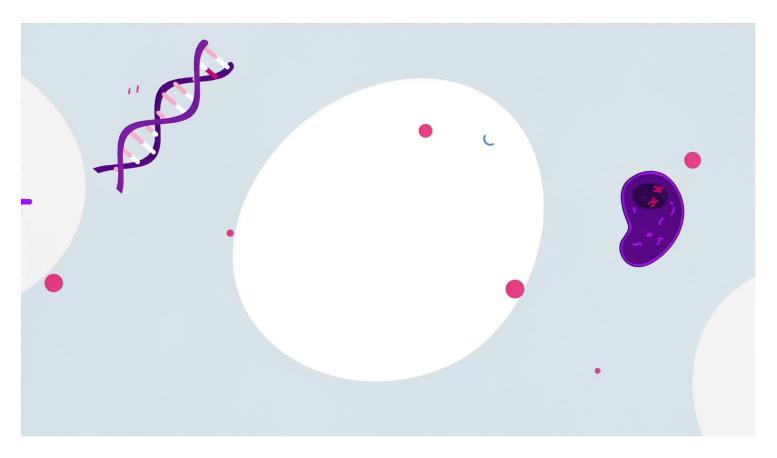


Agenda for Today

The Asks
Deeper Dive into the Asks
Flow of the Meeting
Hook, Line, Sinker
Example of Meeting
Schedule of Events for the day
Social Media
Event Reminders
Questions?



Biomarkers and Precision Medicine



Biomarker Testing and Precision Medicine

Biomarkers: a characteristic that is objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes, or pharmacologic responses to a specific therapeutic intervention. Includes *gene mutations* or *protein expression*.

The right treatment, at the right time

- An essential component of precision medicine
- Targeted cancer therapy
- Avoidance of therapies unlikely to provide clinical benefit

Not just about cancer:

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

Screening vs. Genetic testing vs. Biomarker testing

Screening tests – like MCED, mammograms, PSA testing

Looking for signs of cancer in general population

Genetic testing

Testing for <u>inherited risk</u> to determine risk for developing certain cancers or passing risk onto children

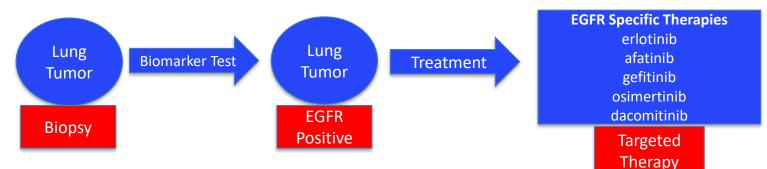
Biomarker testing

Used in people who <u>already have cancer</u> to determine best treatment options, how aggressive the disease is, monitor for recurrence

What is biomarker testing?

Biomarker testing in people with cancer

- Looks for the presence of molecules like proteins or gene mutations found in cancer cells
- Can be used to inform therapy selection and treatment decisions
- Example: EGFR-positive non-small cell lung cancer --> several EGFR inhibitors



Biomarker testing can also be used to:

- Identify the likeliness of disease recurrence or progression
- Predict a drug's efficacy or likelihood of toxicity

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• Identify signs of disease recurrence before it is visible on imaging

Trends in biomarker testing

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

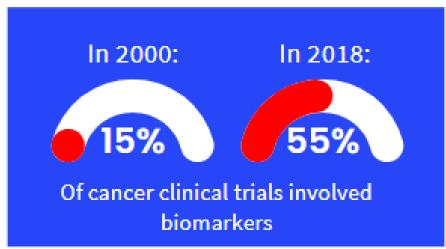


Exhibit 38: Number of U.S. Oncology Medicines with Required or Recommended Predictive Biomarker Testing

Source: IQVIA Institute, May 2021

Biomarker testing and clinical trials

Cancer clinical trials are increasingly driven by biomarkers and the development of targeted therapies



Increasing access to biomarker testing key to supporting access to clinical trials

[1] The Evolution of Biomarker Use in Clinical Trials for Cancer Treatment Key Findings and Implications. Personalized Medicine Coalition 2019.

What does this look like for a patient?



Barriers to Cancer Biomarker Testing

Coverage of tests differs greatly across payers

Coverage policies generally more common for single-gene tests vs. multi-gene panel tests

Plans aren't necessarily following the evidence

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- A recent paper in *Personalized Medicine* highlights gaps between insurance coverage and clinical practice guidelines.
 - Although 91% of plans evaluated reference NCCN treatment guidelines in their biomarker testing policies, **71% are "more restrictive" than these guidelines** for biomarker testing in breast, non-small cell lung cancer, melanoma and/or prostate cancer patients.
- In New York State, 33% are more restrictive. This shows that several million patients in our state could be missing out on needed testing that could connect them with a targeted therapy.

Wong, W., et al. (2022) Alignment of health plan coverage policies for somatic multigene panel testing with clinical guidelines in select solid tumors.

Health Equity in Biomarker Testing and Targeted Therapy

For example, studies have shown:

- Patients who are older, Black, uninsured, or Medicaid-insured, are less likely to be tested for certain guideline indicated biomarkers for colorectal cancer.
- There are socioeconomic inequalities in biomarker testing and targeted therapy utilization across cancer types.
- Racial and socioeconomic disparities in the uptake of testing of Medicare enrollees with stage IV lung adenocarcinoma.
- There are lower rates of testing in community oncology settings versus academic medical centers.

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..
- 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.

Legislation to Address Coverage Gaps

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

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 FDAapproved drug;
- 2. Centers for Medicare and Medicaid Services (CMS) National Coverage Determinations and Medicare Administrative Contractor (MAC) Local Coverage Determinations; or
- 3. Nationally recognized clinical practice guidelines and consensus statements.

Disease and stage agnostic

Why Disease Agnostic?

Biomarker testing applications extend beyond oncology

- Biomarker testing is increasingly important for the treatment of diseases including:
 - Arthritis and other autoimmune conditions
 - Rare diseases

Research is happening in many other areas including Alzheimer's, other neurological conditions, and cardiology.

Cancer patients and survivors have high rates of comorbidities

- Substantial progress has been made in the fight against cancer in recent decades, resulting in a 33% reduction in the cancer death rate since its peak in 1991.
- As patients are living longer, and some cancers become more of a chronic condition, cancer patients are often living with one or more comorbidities.
 - Most common comorbidities include diabetes, cardiac conditions (COPD, congestive heart failure, cerebrovascular disease, peripheral vascular disease), renal failure, and rheumatological conditions.
 - A recent study found that nearly two-thirds of patients diagnosed with colorectal cancer, lung cancer, or Hodgkin's lymphoma had at least one comorbidity at the time of their diagnosis, and about half of patients had multiple comorbidities.

How will A1673/S1196 help?

 Biomarker testing helps connect patients with the most effective treatment for their cancer and avoid treatments that will be ineffective.

> Currently, most plans cover some biomarker testing for some patients.

Without action to improve access to biomarker testing, some patients will be left behind from the latest advancements in treatment.

 Personalized treatments are helping cancer patients live longer and better.

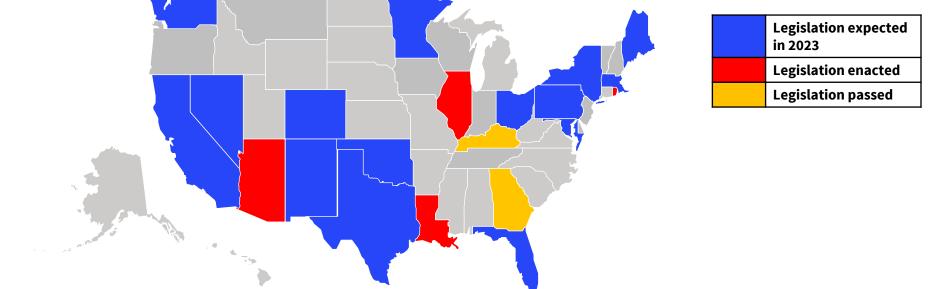
- Legislation applies to state-regulated insurance plans, including Medicaid
- Disease & stage agnostic

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

Broad Support From Public Health Community



Legislation to Expand Access to Biomarker Testing



Legislation enacted: AZ, IL, LA, RI Legislation passed (2023 session): GA, KY Legislation expected in 2023: CA*, CO, FL, MA, ME, MD, MN, NV, NM, NY, OH, OK, PA, TX, WA

Legislative Ask

Will you support and cosponsor A1673 / S1196 which will ensure New Yorkers covered by state-regulated insurance plans, including Medicaid, have coverage for biomarker testing when medically appropriate.



Ask Pt 2



All state legislators, policymakers and staff are invited to join Assemblymember Pamela Hunter, Senator Roxanne Persaud, and ACS CAN for **Legislative Breakfast** on **Wednesday, April 26 from 8:30am-10am in LOB Room 711A** to learn about biomarker testing from a panel of experts and discuss the proposed legislation.

While every lawmaker has already been invited, please remind them and encourage them and their staff to attend.

Flow of the Meeting

HOOK - Meeting leader introduces the group (name + geography). I am here as a volunteer for ACS CAN. We are meeting with Members of the New York Legislature.

LINE - Explain the need.

Why this is needed/impact on state/why important for cancer etc. Tell your personal story: Connect your personal story to the importance of the ask/issue.

SINKER - Make the ask.

- 1. Will you support and cosponsor A1673 / S1196 which will ensure New Yorkers covered by stateregulated insurance plans, including Medicaid, have coverage for biomarker testing when medically appropriate.
- 2. Will you attend the Legislative Breakfast on April 26 from 8:30-10am?







Breaking it down: The Hook

Introductions
Who you are, where you're from
Who else is in

your group



Breaking it down: The Line



Craft your story:

- You know your passion
- You know your cancer connection
- You know the asks
- You have your talking points

Tell your personal story:

• Connect your story to the importance of the asks



Breaking it down: The Sinker



Make the asks:

- 1. Will you support and cosponsor A1673 / S1196 which will ensure New Yorkers covered by stateregulated insurance plans, including Medicaid, have coverage for biomarker testing when medically appropriate.
- 2. Will you attend the Legislative Breakfast on April 26 from 8:30-10am?

Example of a Legislative Meeting

Listen for:

- Introductions (Hook)
- Personal connection to cancer (Line)
- A request for support (Sinker)



Breaking It Down



Telling Your Story

- Your story will be different.
- You don't have to be perfect.
- If your story doesn't align to the asks, you can say:

I know what it's like to hear the words "you have cancer" or I know the impact that a cancer diagnosis can have on a family. Let me tell you about my friend/relative/coworker....



Social Media f Y O in



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- Follow ACS CAN NY and share/retweet our posts.
- Our handles: Facebook: @acscanofNY
 Instagram: @acscan_NY Twitter:@acscan_NY
- Follow your state Assembly member and Senator's social media pages
- Post tagging your lawmakers, use #BiomarkerTestingNY and #FightCancerNY
- Post selfies or videos
- Take group pictures with permission from legislator or staff member





6:00 AM -10:00 AM - Travel

10:00 AM - 10:30 AM - Check in - The Well, LOB

10:45 AM - 11:50 AM - Event Kick-off and Speaker Program

12:00 PM – 4:00 PM – Meetings with Elected Officials

4:00-4:30 PM – Cancer Action Day Debrief

4:30-5:00 PM – Departure

American Cancer Society Cancer Action Network

- Buses will drop off in front of the NYS Museum on Madison Avenue. There will be greeters along the concourse to direct you.
- We will be gathering in the Well of the Legislative Office Building (LOB).
- You will need to go through security, be sure you have your ID with you. If parked underneath the Empire Plaza, enter security from the concourse, go to your left to the LOB and The Well is the entry level floor.
- Coffee, tea, water and grab and go snacks will be available upon your arrival.
- Boxed lunches will be available from 11-1:30 PM, stop by and grab them when your schedule allows.
- We will hand out t-shirts, volunteer packets and leave behind packets to you when you arrive.

Want to practice or have questions?

Join us for Virtual Open Office Hours on Friday, April 21, 5-6:30 PM

Click here to join the meeting

Questions?





Thank You