2023 Cancer Action Day

REMOVE BARRIERS TO BIOMARKER TESTING

SUPPORT A1673 / S1196

Biomarker testing helps get the right treatment to the right patient at the right time. Progress in improving health outcomes increasingly involves the use of precision medicine, which uses information about a person's own genes or proteins to prevent, diagnose or treat various diseases and chronic illnesses like cancer. Biomarker testing is an important step to accessing precision medicine which includes targeted therapies that can lead to improved survivorship and better quality of life for patients battling diseases and chronic illnesses like cancer.

Biomarker testing is increasingly important for cancer care – and for the treatment of other diseases. Thirty-seven of the 62 oncology drugs launched in the past five years require or recommend biomarker testing prior to use.

Despite the growing importance of biomarker testing in personalized medicine, significant barriers to biomarker testing persist. A significant percentage of cancer patients and survivors do not receive biomarker testing because it is not covered by their insurer, or the out-of-pocket costs would be too high.

A1673 / S1196 requires all state-regulated insurance plans, including Medicaid, to cover comprehensive biomarker testing when medically appropriate.

REQUEST: Will you support and cosponsor **A1673 / S1196**

Additionally, 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 and discuss the proposed legislation.

For more information, contact: Michael Davoli, Senior Government Relations Director – New York, ACS CAN
Michael.Davoli@cancer.org (646) 502-9145

ACS CAN is making cancer a top priority for public officials and candidates at the federal, state, and local levels. ACS CAN empowers advocates across the country to make their voices heard and influence evidence-based public policy change as well as legislative and regulatory solutions that will reduce the cancer burden. As the American Cancer Society's nonprofit, nonpartisan advocacy affiliate, ACS CAN is critical to the fight for a world without cancer. For more information, please visit www.fightcancer.org.

EXPAND ACCESS TO BIOMARKER TESTING IN NEW YORK-PASS A1673/S1196

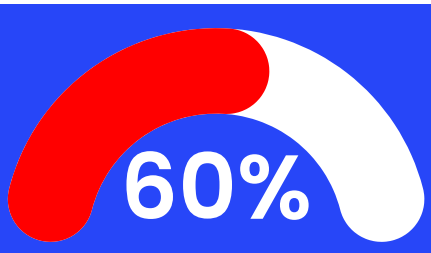
Biomarker testing is the key to unlocking access to precision medicine and saving lives

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.

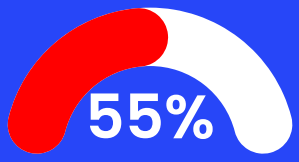
THE IMPORTANCE OF BIOMARKER TESTING



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

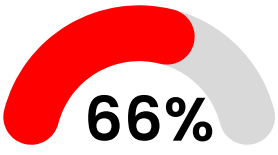
Access to appropriate biomarker testing can help to achieve:

- 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

Biomarker testing is the key to unlocking access to precision medicine and saving lives

American Cancer Society Cancer Action Network
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#BiomarkerTestingNY

For more information please contact: Michael Davoli, ACS CAN Senior Government Relations Director
michael.davoli@cancer.org 646.502.9145

Updated 4.19.23

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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[1] NCI Dictionary of Terms. https://www.cancer.gov/about-cancer/treatment/types/biomarker-testing-cancer-treatmen. Accessed August 16, 2021.
[2] Massard C, Michiels S, Ferté C, et al. High-Throughput Genomics and Clinical Outcome in Hard-to-Treat Advanced Cancers: Results of the MOSCATO 01 Trial. Cancer Discovery. 2017;7(6):586-595.
[3] Global Oncology Trends 2021. IQVIA Institute; June 2021.
[4] Devarakonda S, Govindan R. Biomarker-Driven Staging—Are We There Yet? JAMA Network Open. 2019;2(12):e1917052-e1917052.
[5] https://www.personalizedmedicinecoalition.org/Userfiles/PMC-Corporate/file/The_Evolution_of_Biomarker_Use_in_Clinical_Trials_for_Cancer_Treatments.pdf
[6] Massard C, Michiels S, Ferté C, et al. High-Throughput Genomics and Clinical Outcome in Hard-to-Treat Advanced Cancers: Results of the MOSCATO 01 Trial. Cancer Discovery. 2017;7(6):586-595.
[7] Schwaederle M, Zhao M, Lee JJ, et al. Association of Biomarker-Based Treatment Strategies With Response Rates and Progression-Free Survival in Refractory Malignant Neoplasms: A Meta-analysis. JAMA Oncology. 2016;2(11):1452-1459.
[8] Pishvaian MJ, Blais EM, Brody JR, et al. Overall survival in patients with pancreatic cancer receiving matched therapies following molecular profiling: a retrospective analysis of the Know Your Tumor registry trial. The Lancet Oncology. 2020;21(4):508-518.

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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[i] Brito RA, Cullum B, Hastings K, et al. Total cost of lung cancer care associated with broad panel versus narrow panel sequencing. Journal of Clinical Oncology 2020; 38, no. 15_suppl; 7077. https://ascopubs.org/doi/abs/10.1200/JCO.2020.38.15_suppl.7077

[ii] Economic Impact of Next-Generation Sequencing Versus Single-Gene Testing to Detect Genomic Alterations in Metastatic Non–Small-Cell Lung Cancer Using a Decision Analytic Model
DOI: 10.1200/PO.18.00356 JCO Precision Oncology - published online May 16, 2019.

[iii] Budget Impact of Next-Generation Sequencing for Molecular Assessment of Advanced Non–Small Cell Lung Cancer https://doi.org/10.1016/j.jval.2018.04.1372

[iv] Budget Impact of Next-Generation Sequencing for Molecular Assessment of Advanced Non–Small Cell Lung Cancer https://doi.org/10.1016/j.jval.2018.04.1372

[v] Budget impact analysis of comprehensive genomic profiling in patients with advanced non-small cell lung cancer
Source: James Signorovitch, Zhou Zhou, Jason Ryan, Rachel Anhorn & Anita Chawla (2019) Budget impact analysis of comprehensive genomic profiling in patients with advanced non-small cell lung cancer, Journal of Medical Economics, 22:2, 140-150, DOI: 10.1080/13696998.2018.1549056

[vi] The landscape of biomarker testing coverage in the United States: Quantifying the impact of expanding biomarker testing coverage in the commercial and Medicaid markets. https://www.milliman.com/-/media/milliman/pdfs/2022-articles/2-16-22_the_landscape_of_biomarker_testing_coverage_in_the_us.ashx

[vii] Survivor Views: Biomarker Testing. ACS CAN. Sept. 2020. https://www.fightcancer.org/sites/default/files/Survivor%20Views%20Biomarker%20Testing%20Polling%20Memo.pdf

[viii] The landscape of biomarker testing coverage in the United States: Quantifying the impact of expanding biomarker testing coverage in the commercial and Medicaid markets. https://www.milliman.com/-/media/milliman/pdfs/2022-articles/2-16-22_the_landscape_of_biomarker_testing_coverage_in_the_us.ashx

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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[1] NCI Dictionary of Cancer Terms. https://www.cancer.gov/publications/dictionaries/cancer-terms/def/precision-medicine. Accessed September 7, 2020.
[2] ACS CAN. "Survey Findings Summary: Understanding Provider Utilization of Cancer Biomarker Testing Across Cancers." December 2021. https://www.fightcancer.org/sites/default/files/national_documents/provider_utilization_of_biomarker_testing_polling_memo_dec_2021.pdf

Health Equity in Biomarker Testing and Targeted Therapy

American Cancer Society Cancer Action Network
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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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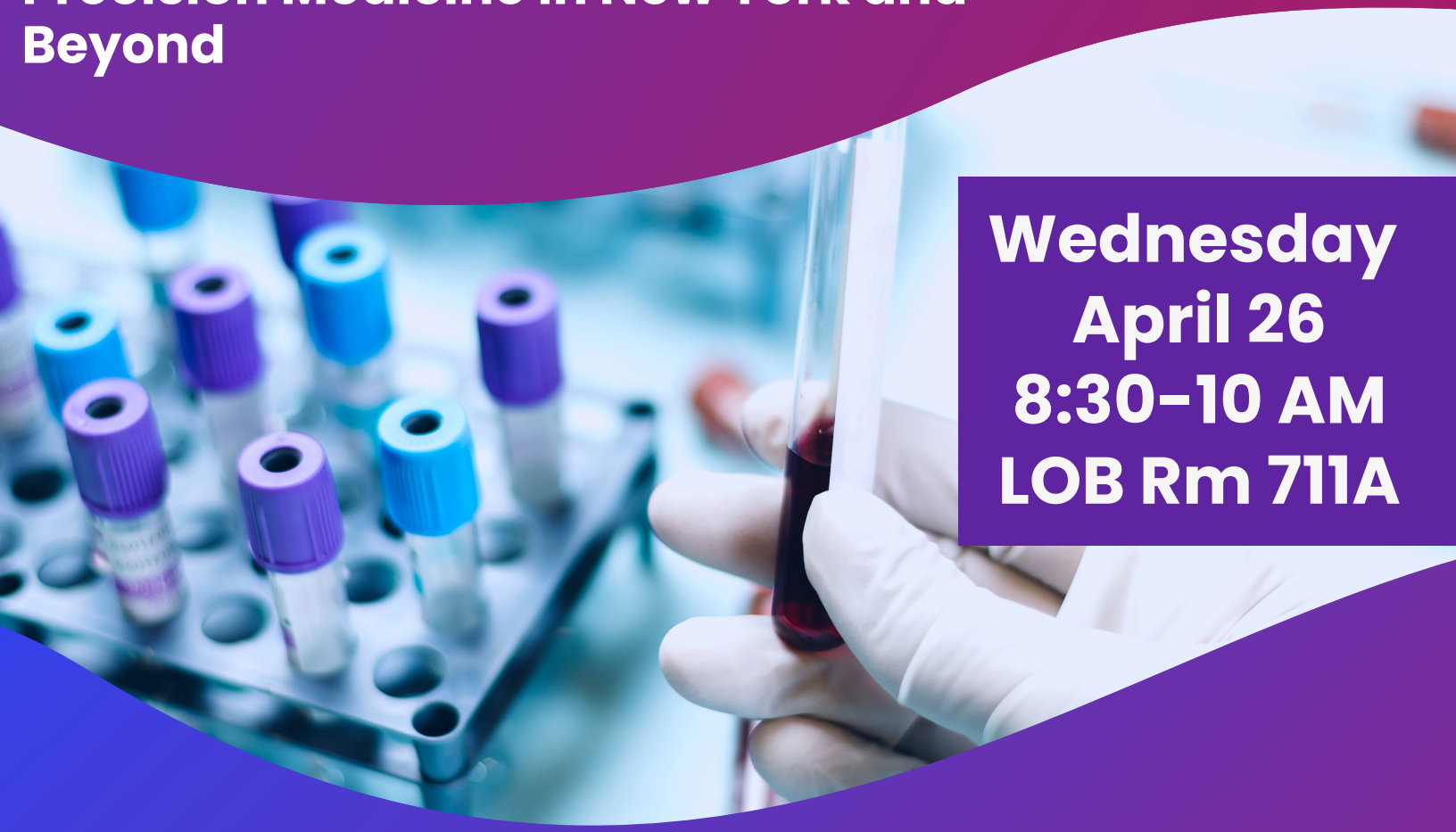
[1] American Cancer Society. Cancer Facts & Figures 2022. Atlanta: American Cancer Society; 2022.
[2] Presley, C., Soulos, P., Chiang, A., Longtine, J., Adelson, K., Herbst, R., Nussbaum, N., Sorg, R., Abernethy, A., Agarwala, V., & Gross, C. (2017). Disparities in next generation sequencing in a population-based community cohort of patients with advanced non-small cell lung cancer. Journal of Clinical Oncology. 35. 6563-6563. 10.1200/JCO.2017.35.15_suppl.6563.
[3] Lamba, N., & Iorgulescu, B. (2020). Disparities in microsatellite instability/mismatch repair biomarker testing for patients with advanced colorectal cancer. Cancer Epidemiol Biomarkers Prev December 1 2020 (29) (12 Supplement) PO-091; DOI: 10.1158/1538-7755.DISP20-PO-091.
[4] Norris, R. P., Dew, R., Sharp, L., Greystoke, A., Rice, S., Johnell, K., & Todd, A. (2020). Are there socio-economic inequalities in utilization of predictive biomarker tests and biological and precision therapies for cancer? A systematic review and meta-analysis. BMC medicine, 18(1), 282. https://doi.org/10.1186/s12916-020-01753-0.
[5] Kehl, K. L., Lathan, C. S., Johnson, B. E., & Schrag, D. (2019). Race, Poverty, and Initial Implementation of Precision Medicine for Lung Cancer. Journal of the National Cancer Institute, 111(4), 431–434. https://doi.org/10.1093/jnci/djy202.
[6] Kim, E. S., Roy, U. B., Ersek, J. L., King, J., Smith, R. A., Martin, N., Martins, R., Moore, A., Silvestri, G. A., & Jett, J. (2019). Updates Regarding Biomarker Testing for Non-Small Cell Lung Cancer: Considerations from the National Lung Cancer Roundtable. Journal of thoracic oncology : official publication of the International Association for the Study of Lung Cancer, 14(3), 338–342. https://doi.org/10.1016/j.jtho.2019.01.002
[7] F. R., Kerr, K. M., Bunn, P. A., Jr, Kim, E. S., Obasaju, C., Pérol, M., Bonomi, P., Bradley, J. D., Gandara, D., Jett, J. R., Langer, C. J., Natale, R. B., Novello, S., Paz-Ares, L., Ramalingam, S. S., Reck, M., Reynolds, C. H., Smit, E. F., Socinski, M. A., Spigel, D. R., … Thatcher, N. (2018). Molecular and Immune Biomarker Testing in SquamousCell Lung Cancer: Effect of Current and Future Therapies and Technologies. Clinical lung cancer, 19(4), 331–339. https://doi.org/10.1016/j.cllc.2018.03.014

You're Invited To A Legislative Breakfast On Biomarker Testing: The Key to Unlocking Precision Medicine in New York and Beyond



Wednesday
April 26
8:30-10 AM
LOB Rm 711A

Legislators, staff and the general public are invited to come and learn about biomarker testing and discuss A1673/S1196.

Initial Speakers Include:

Andrea Cercek, MD
Section Head, Colorectal Cancer, Memorial Sloan Kettering

Giovanna Whitting
Thyroid Cancer Survivor

Michael Davoli
American Cancer Society Cancer Action Network

Hosted By

Assemblymember Pamela Jo Hunter

and

Senator Roxanne J. Persaud

American Cancer Society Cancer Action Network℠

For more information contact: Michael.Davoli@cancer.org
RSVP at https://act.fightcancer.org/a/ny-biomarker-leg-briefing

SUPPORTERS OF NEW YORK BIOMARKER TESTING LEGISLATION A1673/S1196

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For more information please contact: Michael Davoli, ACS CAN Senior Government Relations Director
michael.davoli@cancer.org 646.502.9145

Updated 4.19.23

STATE OF NEW YORK

1196

2023-2024 Regular Sessions

IN SENATE

January 10, 2023

Introduced by Sens. PERSAUD, BROUK, CLEARE, GOUNARDES, HOYLMAN-SIGAL, MANNION, MAY, MYRIE, THOMAS -- read twice and ordered printed, and when printed to be committed to the Committee on Insurance

AN ACT to amend the insurance law and the social services law, in relation to requiring health insurance policies and medicaid to cover biomarker testing for certain purposes

The People of the State of New York, represented in Senate and Assembly, do enact as follows:

Section 1. Subsection (i) of section 3216 of the insurance law is amended by adding a new paragraph 11-c to read as follows:

(11-c) (A) Every policy which provides medical, major medical, or similar comprehensive-type coverage shall provide coverage for biomarker testing for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a covered person's disease or condition when the test is supported by medical and scientific evidence, including, but not limited to:

(i) labeled indications for a test approved or cleared by the food and drug administration of the United States government or indicated tests for a food and drug administration approved drug;

(ii) centers for medicare and medicaid services national coverage determinations and medicare administrative contractor local coverage determinations; or

(iii) nationally recognized clinical practice guidelines and consensus statements.

(B) Such coverage shall be provided in a manner that shall limit disruptions in care including the need for multiple biopsies or biospecimen samples.

(C) The covered person and prescribing practitioner shall have access to a clear, readily accessible, and convenient process to request an exception to a coverage policy provided pursuant to the provisions of

EXPLANATION--Matter in *italics* (underscored) is new; matter in brackets [-] is old law to be omitted.

LBD02625-01-3

this paragraph. Such process shall be made readily accessible on the website of the insurer.

(D) As used in this paragraph, the following terms shall have the following meanings:

(i) "Biomarker" means 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. Biomarkers include but are not limited to gene mutations or protein expression.

(ii) "Biomarker testing" means the analysis of a patient's tissue, blood, or other biospecimen for the presence of a biomarker. Biomarker testing includes but is not limited to single-analyte tests, multi-plex panel tests, and whole genome sequencing.

(iii) "Consensus statements" means statements developed by an independent, multidisciplinary panel of experts utilizing a transparent methodology and reporting structure and with a conflict of interest policy. Such statements are aimed at specific clinical circumstances and base the statements on the best available evidence for the purpose of optimizing the outcomes of clinical care.

(iv) "Nationally recognized clinical practice guidelines" means evidence-based clinical practice guidelines developed by independent organizations or medical professional societies utilizing a transparent methodology and reporting structure and with a conflict of interest policy. Clinical practice guidelines establish standards of care informed by a systematic review of evidence and an assessment of the benefits and costs of alternative care options and include recommendations intended to optimize patient care.

§ 2. Subsection (l) of section 3221 of the insurance law is amended by adding a new paragraph 11-c to read as follows:

(11-c) (A) Every insurer delivering a group or blanket policy or issuing a group or blanket policy for delivery in this state that provides coverage for medical, major medical, or similar comprehensive-type coverage shall provide coverage for biomarker testing for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a covered person's disease or condition when the test is supported by medical and scientific evidence, including, but not limited to:

(i) labeled indications for a test approved or cleared by the food and drug administration of the United States government or indicated tests for a food and drug administration approved drug;

(ii) centers for medicare and medicaid services national coverage determinations and medicare administrative contractor local coverage determinations; or

(iii) nationally recognized clinical practice guidelines and consensus statements.

(B) Such coverage shall be provided in a manner that shall limit disruptions in care including the need for multiple biopsies or biospecimen samples.

(C) The covered person and prescribing practitioner shall have access to a clear, readily accessible, and convenient process to request an exception to a coverage policy provided pursuant to the provisions of this paragraph. Such process shall be made readily accessible on the website of the insurer.

(D) As used in this paragraph, the following terms shall have the following meanings:

(i) "Biomarker" means 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. Biomarkers include but are not limited to gene mutations or protein expression.

(ii) "Biomarker testing" means the analysis of a patient's tissue, blood, or other biospecimen for the presence of a biomarker. Biomarker testing includes but is not limited to single-analyte tests, multi-plex panel tests, and whole genome sequencing.

(iii) "Consensus statements" means statements developed by an independent, multidisciplinary panel of experts utilizing a transparent methodology and reporting structure and with a conflict of interest policy. Such statements are aimed at specific clinical circumstances and base the statements on the best available evidence for the purpose of optimizing the outcomes of clinical care.

(iv) "Nationally recognized clinical practice guidelines" means evidence-based clinical practice guidelines developed by independent organizations or medical professional societies utilizing a transparent methodology and reporting structure and with a conflict of interest policy. Clinical practice guidelines establish standards of care informed by a systematic review of evidence and an assessment of the benefits and costs of alternative care options and include recommendations intended to optimize patient care.

§ 3. Section 4303 of the insurance law is amended by adding a new subsection (p-1) to read as follows:

(p-1) (1) A medical expense indemnity corporation, a hospital service corporation or a health service corporation that provides coverage for medical, major medical, or similar comprehensive-type coverage shall provide coverage for biomarker testing for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a covered person's disease or condition when the test is supported by medical and scientific evidence, including, but not limited to:

(A) labeled indications for a test approved or cleared by the food and drug administration of the United States government or indicated tests for a food and drug administration approved drug;

(B) centers for medicare and medicaid services national coverage determinations and medicare administrative contractor local coverage determinations; or

(C) nationally recognized clinical practice guidelines and consensus statements.

(2) Such coverage shall be provided in a manner that shall limit disruptions in care including the need for multiple biopsies or biospecimen samples.

(3) The covered person and prescribing practitioner shall have access to a clear, readily accessible, and convenient process to request an exception to a coverage policy provided pursuant to the provisions of this subsection. Such process shall be made readily accessible on the website of the insurer.

(4) As used in this subsection, the following terms shall have the following meanings:

(A) "Biomarker" means 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. Biomarkers include but are not limited to gene mutations or protein expression.

(B) "Biomarker testing" means the analysis of a patient's tissue, blood, or other biospecimen for the presence of a biomarker. Biomarker

testing includes but is not limited to single-analyte tests, multi-plex panel tests, and whole genome sequencing.

(C) "Consensus statements" means statements developed by an independent, multidisciplinary panel of experts utilizing a transparent methodology and reporting structure and with a conflict of interest policy. Such statements are aimed at specific clinical circumstances and base the statements on the best available evidence for the purpose of optimizing the outcomes of clinical care.

(D) "Nationally recognized clinical practice guidelines" means evidence-based clinical practice guidelines developed by independent organizations or medical professional societies utilizing a transparent methodology and reporting structure and with a conflict of interest policy. Clinical practice guidelines establish standards of care informed by a systematic review of evidence and an assessment of the benefits and costs of alternative care options and include recommendations intended to optimize patient care.

§ 4. Subdivision 2 of section 365-a of the social services law is amended by adding a new paragraph (kk) to read as follows:

(kk) (i) biomarker testing for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a recipient's disease or condition when the test is supported by medical and scientific evidence, including, but not limited to:

(1) labeled indications for a test approved or cleared by the food and drug administration of the United States government or indicated tests for a food and drug administration approved drug;

(2) centers for medicare and medicaid services national coverage determinations and medicare administrative contractor local coverage determinations; or

(3) nationally recognized clinical practice guidelines and consensus statements.

(ii) Risk-bearing entities contracted to the medicaid program to deliver services to recipients shall provide biomarker testing at the same scope, duration and frequency as the medicaid program otherwise provides to enrollees.

(iii) The recipient and participating provider shall have access to a clear, readily accessible, and convenient process to request an exception to a coverage policy of the medicaid program or by risk-bearing entities contracted to the medicaid program. Such process shall be made readily accessible to all participating providers and enrollees online.

(iv) As used in this paragraph, the following terms shall have the following meanings:

(1) "Biomarker" means 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. Biomarkers include but are not limited to gene mutations or protein expression.

(2) "Biomarker testing" means the analysis of a patient's tissue, blood, or other biospecimen for the presence of a biomarker. Biomarker testing includes but is not limited to single-analyte tests, multi-plex panel tests, and whole genome sequencing.

(3) "Consensus statements" means statements developed by an independent, multidisciplinary panel of experts utilizing a transparent methodology and reporting structure and with a conflict of interest policy. Such statements are aimed at specific clinical circumstances and base the statements on the best available evidence for the purpose of optimizing the outcomes of clinical care.

(4) "Nationally recognized clinical practice guidelines" means evidence-based clinical practice guidelines developed by independent organizations or medical professional societies utilizing a transparent methodology and reporting structure and with a conflict of interest policy. Clinical practice guidelines establish standards of care informed by a systematic review of evidence and an assessment of the benefits and costs of alternative care options and include recommendations intended to optimize patient care.

§ 5. This act shall take effect January 1, 2024 and shall apply to all policies and contracts issued, renewed, modified, altered or amended on or after such date.

BILL NUMBER: S1196

SPONSOR: PERSAUD

TITLE OF BILL:

An act to amend the insurance law and the social services law, in relation to requiring health insurance policies and medicaid to cover biomarker testing for certain purposes

PURPOSE OR GENERAL IDEA OF BILL:

This legislation will require that every state-regulated insurance plan, including Medicaid, provides coverage for biomarker testing when medically appropriate.

SUMMARY OF PROVISIONS:

Section 1 requires every individual accident and health insurance policy that provides coverage for medical, major medical, or similar comprehensive-type coverage shall provide coverage for biomarker testing for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a covered person's disease or condition. Defines criteria for what types of medical and scientific evidence qualify as sufficient medical and scientific evidence for biomarker testing.

Section 2 applies these same provisions to group or blanket accident and health insurance policies

Section 3 applies these same provisions to all hospital service corporation or health service corporation

Section 4 applies these same provisions to Medicaid

Section 5 provides for the effective date

JUSTIFICATION:

In cancer care, biomarkers are often used to help determine the best treatment for a patient. A "biomarker" is a sign of disease or abnormal function that can be measured in blood, tissue, or bodily fluid. Biomarker testing is the analysis of a patient's tissue, blood or fluid biospecimen for the presence of a biomarker.

Progress in improving cancer outconkies increasingly involves the use of precision medicihe. Biomarker testing is an important step for accessing precision medicine, including targeted therapies that can improve survivorship and better cancer patients' quality of life. Biomarker testing is increasingly important for cancer care and for the treatment of other diseases. Thirty- seven of the 62 oncology drugs launched in the past five years require or recommend biomarker testing before use.

This legislation will ensure New Yorkers covered by state-regulated insurance plans, including Medicaid, have coverage for biomarker testing when medically appropriate.

Improving access to biomarker testing and thereby access to targeted therapies is a strategy to reduce health disparities and improve outcomes for cancer patients.

Ensuring equitable access to biomarker testing by improving coverage for and access to testing across insurance types is key to reducing health disparities. Indeed, without action like this to expand coverage for

biomarker testing - including Medicaid - advances in precision oncology could increase existing health disparities.

Legislation to expand coverage of biomarker testing in New York would make it possible for more patients to get the proper treatment at the right time.

PRIOR LEGISLATIVE HISTORY:

2022: S8147 Referred to Insurance

FISCAL IMPLICATIONS:

Any cost of enacting this legislation is far overshadowed by ensuring that the course of treatment used in treating an individual patient's cancer is the most effective and cost-effective treatment.

EFFECTIVE DATE:
First of January, succeeding the date on which it shall become a law.