Washington State Mandated Benefits Reviews
Statutory Review Criteria (RCW 48.47.030)

Applicants

This Mandated Benefits Review Application is submitted by:
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Based on the availability of relevant information, the following criteria shall be used to assess the impact of proposed mandated benefits:

1. The social impact:
(i) To what extent is the benefit generally utilized by a significant portion of the population?
This legislation will help provide more equitable access to critical biomarker testing for Washington residents covered by state regulated commercial health plans and AppleCare by ensuring coverage is and remains consistent with scientific and clinical evidence.

Biomarker testing is not currently indicated or necessary for all cancer patients, and many plans currently cover some of this testing for some patients. In addition to cancer applications, biomarker testing is increasingly important to the treatment of other diseases including arthritis, other autoimmune diseases and rare diseases. Research is also happening in many other areas including Alzheimer's, Parkinson's, and other neurological diseases, cardiology, and more.

The proposed legislation requires coverage for testing in line with medical and scientific evidence, such as FDA indications and the clinical practice guidelines that providers rely on to determine when biomarker testing is appropriate. This legislation also limits to the *circumstances* when biomarker testing should be covered (diagnosis, treatment, ongoing monitoring or appropriate management of a disease or condition) and specifies the *evidence* that must be met in order for testing to qualify for coverage.

This legislation is not intended to require coverage of biomarker testing for screening purposes and does not require coverage of "experimental" or "investigational" biomarker testing.[1] We would support amendments to this effect. Nothing in the proposed legislation prohibits the use of utilization management or cost sharing on biomarker testing.

Similar legislation has been signed into law in 17 states as of 5/31/2024.[2] In states where this policy is currently in effect, none have reported challenges with costs for implementation, including for Medicaid populations. Within the Medicaid program, biomarker testing is an allowable service and would be subject to the same cost sharing provisions as other services.

Targeted therapy can improve survival and quality of life by connecting patients to the most beneficial treatment for their disease. Treatment with targeted therapy often requires testing to

[1] "Investigatory biomarker tests" means biomarker tests that are subject to the United States Food and Drug Administration's investigational device exemption (21 CFR 812).
[2] AZ, AR, CA, CT, GA, IL, IN, IA, KY, LA, MD, MN, NM, NY, OK, RI, TX
CO, FL have passed similar bills that are awaiting governors' signatures as of 5/31/2024.

identify biomarkers like gene mutations and protein expression which can inform targeted therapy options. 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. According to a recent national survey of oncology providers, concerns about patients' costs and coverage are key barriers to needed biomarker testing. Two-thirds report that patient insurer coverage for a desired biomarker test is a significant or moderate barrier.[3]

Not all patients representing diverse communities are benefiting from the latest advancements in biomarker testing. Improving coverage for and access to biomarker testing across all payers is key to reducing health disparities. Insurer coverage is important for provider uptake and patient access.

For example, studies have shown:

- In metastatic non-small cell lung cancer (NSCLC), **eligible Black patients are less likely to receive biomarker testing compared to white patients**.[4]
- Medicaid enrollees with NSCLC are 19% **less likely to receive biomarker testing**, 30% **less likely to receive first line targeted treatment** and face a 23% **higher risk of death** compared to patients with commercial insurance. Medicaid enrollees who were not tested had a 27% **higher risk of death** than those who were tested.[5]
- Patients with advanced NSCLC who were **Black or older had lower odds of next-generation sequencing biomarker testing compared to patients who were white or younger** respectively.[6]
- Patients who are **older or Black are less likely to be tested for certain guideline-indicated biomarkers** for colorectal cancer.[7]
- Patients **with fully-insured (state regulated) plans had a 10% lower likelihood of receiving upfront biomarker testing and a 44% lower chance of receiving upfront multi-gene panel testing** compared to self-funded plans (ERISA regulated).[8]

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[3] Understanding Provider Utilization of Cancer Biomarker Testing Across Cancers, December 2021, American Cancer Society Cancer Action Network. https://www.fightcancer.org/sites/default/files/national_documents/provider_utilization_of_biomarker_testing_polling_memo_dec_2021.pdf

[4] 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

[5] Gross CP, Meyer CS, Ogale S, Kent M, Wong WB. Associations Between Medicaid Insurance, Biomarker Testing, and Outcomes in Patients With Advanced NSCLC. J Natl Compr Canc Netw. 2022;20(5):479-487.e2. doi:10.6004/jnccn.2021.7083

[6] 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.

[7] 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.

[8] Wong WB, To TM. State-level opportunities for advancing biomarker testing in advanced non-small cell lung cancer (aNSCLC) patients with fully-insured commercial health plans

- There are **socioeconomic inequalities in biomarker testing and targeted therapy utilization across cancer types**.[9]
- There are lower rates of testing in **community oncology settings versus academic medical centers**.[10,11]

Studies have shown significant health benefits of clinical guideline-indicated biomarker testing and biomarker-driven treatments. For example, looking at clinical outcomes of non-small cell lung cancer (NSCLC) patients who received biomarker testing compared with those that did not receive testing in a real-world setting, advanced NSCLC patients who received biomarker testing showed better survival than patients who did not receive biomarker testing.[12,13]

One study found the use of targeted therapy, enabled by biomarker testing, has been associated with a more favorable outcome in advanced NSCLC, with a 31 percent reduction in risk of death and improved survival duration that was about 1.5-fold longer compared to patients with an identified mutational driver who did not receive targeted therapy.[14]

In another real-world study, patients who did not receive any biomarker test had a 50% higher risk of death than patients who had a positive biomarker test and received appropriate targeted treatment as an initial treatment in the metastatic setting.[15]

Additionally, patients who received treatments informed by biomarker testing results had lower risk of discontinuation than patients who were not tested or did not receive appropriate biomarker-informed treatment.[16]

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[9] 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

[10] 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

[11] 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 Squamous-Cell 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

[12] John A, Shah R, Wong WB, et al. Value of precision medicine in advanced NSCLC: Real-world outcomes associated with the use of companion diagnostics. Journal of Clinical Oncology 2019; 37, no. 15_suppl. https://ascopubs.org/doi/abs/10.1200/JCO.2019.37.15_suppl.e20015

[13] John A, Yang B, and Shah R, et al. Clinical Impact of Adherence to NCCN Guidelines for Biomarker Testing and First-Line Treatment in Advanced Non-Small Cell Lung Cancer (aNSCLC) Using Real-World Electronic Health Record Data. Adv Ther. 2021;38:1552-1566. https://pubmed.ncbi.nlm.nih.gov/33537872/

[14] Kris MG, et al. JAMA. 2014;311:1998-2006. https://pubmed.ncbi.nlm.nih.gov/24846037/

[15] John A, Yang B, and Shah R, et al. Clinical Impact of Adherence to NCCN Guidelines for Biomarker Testing and First-Line Treatment in Advanced Non-Small Cell Lung Cancer (aNSCLC) Using Real-World Electronic Health Record Data. Adv Ther. 2021;38:1552-1566. https://pubmed.ncbi.nlm.nih.gov/33537872/

[16] John A, Shah R, Wong WB, et al. Value of precision medicine in advanced NSCLC: Real-world

Pharmacogenomic (PGx) testing (also known as pharmacogenomic biomarker testing) is a component of precision medicine that involves examining a patient's inherited genes to detect variations that may impact the way a drug is broken down, absorbed and used within the body. Sometimes these variations can impact the safety and effectiveness of treatment. The same treatment given to patients with the same disease can produce different responses based on each person's inherited genes. There are a significant number of drug-gene pairs that can impact a patient's response to a medication, thus making PGx testing beneficial. These interactions are most common in oncology, neurology, cardiology and infectious disease. PGx biomarker testing can be used to inform the selection of prescription drugs to treat patients. This type of testing can help a provider to understand the way a patient's genomic make up may affect an individual's response to certain psychiatric drugs – including those used to treat depression. Selective serotonin reuptake inhibitors (SSRIs) are the most commonly used drugs to treat depression in adults. There are several genetic variants that may impact the effectiveness or safety of SSRIs.[17]

Biomarker testing is increasingly important to enrolling patients in clinical trials as the number and percentage of available clinical trials that involve biomarkers has grown significantly. The percentage of cancer clinical trials that involve biomarkers has grown significantly, from 15 percent in 2000 to 55 percent in 2018.[18]

(ii) To what extent is the benefit already generally available?
Samples for biomarker testing can be collected in most hospitals and medical facilities. Testing is conducted in commercial labs or sometimes in on-site labs at hospitals, depending on the particular test and facility.

Currently insurers cover some biomarker tests for some patients, but coverage policies are not always consistent with medical and scientific evidence or across different insurance plans. For example, a recent peer reviewed study in *Personalized Medicine* found that 55% of Washingtonians are covered by plans that have more restrictive biomarker testing coverage policies than what is indicated by National Comprehensive Cancer Network (NCCN) clinical practice guidelines for advanced breast, lung, melanoma, and prostate cancers.[19]

(iii) If the benefit is not generally available, to what extent has its unavailability resulted in persons not receiving needed services?
Without the appropriate biomarker testing for their disease, some patients will receive ineffective or unnecessary treatments. In turn, this is a missed opportunity to save lives as targeted therapies

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outcomes associated with the use of companion diagnostics. Journal of Clinical Oncology 2019; 37, no. 15_suppl. https://ascopubs.org/doi/abs/10.1200/JCO.2019.37.15_suppl.e20015

[17] ACS CAN, ALS Association, The Michael J Fox Foundation, The National Marrow Donor Program, The National Organization for Rare Diseases, AiArthritis, Lupus and Allied Diseases, End Preeclampsia. Biomarker Testing: Beyond Oncology.

[18] The Evolution of Biomarker Use in Clinical Trials for Cancer Treatments: Key Findings and Implications. https://www.personalizedmedicinecoalition.org/Userfiles/PMC-Corporate/file/The_Evolution_of_Biomarker_Use_in_Clinical_Trials_for_Cancer_Treatments.pdf

[19] Alignment of health plan coverage policies for somatic multigene panel testing with clinical guidelines in select solid tumors. https://www.futuremedicine.com/doi/10.2217/pme-2021-0174

can be more effective and have fewer side effects.[20] Providers and patients cite lack of insurance coverage for appropriate testing as a reason for not getting biomarker testing.[21,22]

In a study of Medicaid enrollees with advanced NSCLC, those who were not tested had a 27% higher risk of death than those who were tested.[23] Medicaid enrollees are less likely to get tested or treated with targeted therapy and have worse survival, and this is likely true in Washington where targeted therapy utilization is lower than expected for Medicaid enrollees.[24]

Among Washington state patients diagnosed between 2018 and 2022 with advanced NSCLC or metastatic colorectal cancer, less than 5% with fully-insured plans (state regulated) had evidence of multi-gene panel testing reimbursement codes.[25]

(iv) If the benefit is not generally available, to what extent has its unavailability resulted in unreasonable financial hardship?

Some patients who receive biomarker testing that is not covered by their insurance may be billed thousands of dollars.[26] Patients who do not receive recommended biomarker testing may receive less effective therapies with greater toxicity leading to increased hospitalization and associated costs.

(v) What is the level of public demand for the benefit?

Eighty two percent of oncology providers report that biomarker testing helps them make more informed treatment recommendations for their patients.[27]In 2024 alone, more than 44,000 Washingtonians are expected to be diagnosed with cancer.[28] The use of biomarker testing has become the standard of care for certain cancers. It opens the door to precision medicine and the use of many FDA-approved targeted therapies across many cancer types, including some of the

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[20] Improving Access to Biomarker Testing: Advancing Precision Medicine in Cancer Care. https://www.fightcancer.org/sites/default/files/Improving%20Access%20to%20Biomarker%20Testing.pdf

[21] Yabroff et al. Importance of Patient Health Insurance Coverage and Out-of-Pocket Costs for Genomic Testing in Oncologists' Treatment Decisions. https://ascopubs.org/doi/full/10.1200/OP.23.00153#figA1

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

[23] Gross CP, Meyer CS, Ogale S, Kent M, Wong WB. Associations Between Medicaid Insurance, Biomarker Testing, and Outcomes in Patients With Advanced NSCLC. J Natl Compr Canc Netw. 2022;20(5):479-487.e2. doi:10.6004/jnccn.2021.7083

[24] Roberts TJ, Kesselheim AS, Avorn J. Variation in Use of Lung Cancer Targeted Therapies Across State Medicaid Programs, 2020-2021. JAMA Netw Open. 2023;6(1):e2252562. Published 2023 Jan 3. doi:10.1001/jamanetworkopen.2022.52562

[25] Wong WB, To TM. State-level opportunities for advancing biomarker testing in advanced non-small cell lung cancer (aNSCLC) patients with fully-insured commercial health plans.

[26] Gelareh Sadigh MD, Hilary Gee Goeckner MSW, Ella A. Kazerooni MD, Bruce E. Johnson MD, Robert A. Smith PhD, Devon V. Adams RN, MPH, Ruth C. Carlos MD. State legislative trends related to biomarker testing. 24 May 2022 https://doi.org/10.1002/cncr.34271

[27] Survey Findings Summary: Understanding Provider Utilization of Cancer Biomarker Testing Across Cancers. https://www.fightcancer.org/sites/default/files/national_documents/provider_utilization_of_biomarker_testing_polling_memo_dec_2021.pdf

[28] American Cancer Society. Cancer Facts & Figures 2024. Atlanta: American Cancer Society; 2024.

most common and deadly cancers like lung, breast, prostate, and melanoma. In addition to cancer, biomarker testing is increasingly important to the treatment of other diseases including arthritis, other autoimmune diseases and rare diseases. Research is also happening in many other areas including Alzheimer's, Parkinson's, and other neurological diseases, cardiology, and more.

(vi) What is the level of interest of collective bargaining agents in negotiating privately for inclusion of this benefit in group contracts?
n/a

2. The financial impact:
(i) To what extent will the benefit increase or decrease the cost of treatment or service?
Appropriate use of biomarker testing can allow some patients to avoid unnecessary or ineffective treatments that would otherwise be covered by plans, resulting in lower overall treatment costs. Biomarker testing can also be used to understand a patient's prognosis and adjust treatment plans accordingly.

For many patients, comprehensive biomarker panel testing is most appropriate and recommended by clinical practice guidelines. Further, comprehensive biomarker panel testing is particularly important when there is limited tissue available for testing. In this case, providers do not have the time or resources to perform sequential testing for providers to have sufficient information to appropriately guide treatment decisions, and thus risk delaying access to the most effective treatment.

For example, in NSCLC, clinical practice guidelines recommend testing for nine biomarkers but large tissue samples sufficient for single gene tests of all biomarkers are hard to obtain.
There are several studies looking at the cost effectiveness of *single biomarker testing*, which are most likely to be covered by insurance plans currently, to more comprehensive biomarker panel testing, which isn't always covered.

Comprehensive biomarker testing is often done as a *panel test* that assesses multiple biomarkers (e.g., genes or proteins) in one test as compared to single biomarker testing that assesses one marker per test. Often paying more upfront for comprehensive biomarker panel 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 (NSCLC) patients who received comprehensive biomarker panel testing (broad) in comparison to single biomarker testing (narrow); 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.[29]

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,

[29] 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

and hotspot panels, respectively)[30] and decreased expected testing procedure costs to the health plan by $24,651.[31]

Some studies have found minimal cost increases as a result of the costs of more effective treatment and prolonged patient survival.[32,33]

(ii) To what extent will the coverage increase the appropriate use of the benefit?
Aligning coverage of biomarker testing with medical and scientific evidence would allow more appropriate and equitable use of biomarker testing across populations. Nothing in the proposed legislation prohibits the use of utilization management or cost sharing on biomarker testing.

Patients and health care providers cite lack of insurance coverage as a barrier to appropriate uses of biomarker testing;[34,35] aligning insurance coverage of biomarker testing with clinical practice guidelines and the evidence providers rely on should increase appropriate use of biomarker testing.

(iii) To what extent will the benefit be a substitute for a more expensive benefit?
Better coverage of biomarker testing – consistent with medical and scientific evidence such as clinical practice guidelines – will allow patients to avoid ineffective or harmful treatments, allowing for more efficient care delivery and often lower overall treatment costs.

(iv) To what extent will the benefit increase or decrease the administrative expenses of health carriers and the premium and administrative expenses of policyholders?
See below (v). Milliman study includes estimated administrative expenses and profits for insurers.

(v) What will be the impact of this benefit on the total cost of health care services and on premiums for health coverage?
A recent study by Milliman looking at the cost implications of legislation to improve coverage estimates that robust coverage of biomarker testing would result in premium impact of $0.14-$0.51 per member per month (PMPM) in the private market. This does not account for any potential cost savings or cost avoidance from avoiding ineffective treatments, disease progression or

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[30] 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
[31] 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
[32] 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
[33] 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
[34] Survivor Views: Biomarker Testing. ACS CAN. Sept. 2020.
https://www.fightcancer.org/sites/default/files/Survivor%20Views%20Biomarker%20Testing%20Polling%20Memo.pdf
[35] Understanding Provider Utilization of Cancer Biomarker Testing Across Cancers, December 2021, American Cancer Society Cancer Action Network.
https://www.fightcancer.org/sites/default/files/national_documents/provider_utilization_of_biomarker_testing_polling_memo_dec_2021.pdf

complications. It does include additional profit and administrative costs insurers would build into the benefit costs. The estimated impact on Medicaid would be $0.05-$0.09 PMPM. The average cost per biomarker test in the private market was $224, average cost in the Medicaid market was $78.71.[36] Another study found that coverage of multi-gene panel testing is expected to have minimal impact on premiums, of $0.04 per enrollee per month.[37]

Coverage is only required for tests that are appropriate for individual patients. This legislation establishes clear guardrails to align coverage of biomarker testing with robust and reputable sources of evidence. Tests will not meet the criteria spelled out without having clear benefit of informing treatment options, and physicians will not order tests that won't provide useful information.

(vi) What will be the impact of this benefit on costs for state purchased health care?
According to a Milliman analysis, the estimated impact on Medicaid is $0.05-$0.09 PMPM. The average cost per biomarker test in the private market was $224, average cost in the Medicaid market was $78.71.[38]

(vii) What will be the impact of this benefit on affordability and access to coverage?
Appropriate biomarker testing can allow for more efficient care delivery, allowing some patients to bypass ineffective treatments and require less trial and error to determine the best treatment for individual patients.

3. Evidence of health care service efficacy:
(i) If a mandatory benefit of a specific service is sought, to what extent has there been conducted professionally accepted controlled trials demonstrating the health consequences of that service compared to no service or an alternative service?
Biomarkers are discovered through various research methods and undergo rigorous testing to confirm their association with a given condition and their usefulness in diagnosis, prognosis, or treatment. Biomarker testing in and of itself does not result in changes in health status, changes result due to the actions taken once biomarker testing results are received. If certain biomarkers are identified health care providers can proceed with specific treatment plans, such as targeted therapy, that can result in improved health outcomes compared to treatment that are not informed by biomarker testing. These treatment plans are informed by controlled clinical trials.

One notable clinical trial demonstrating the benefits of biomarker testing in on treatment and outcomes is the TAILORx trial. TAILORx (Trial Assigning Individualized Options for Treatment) was a landmark study in breast cancer treatment. It investigated the use of a genomic assay called

[36] The Landscape of Biomarker Testing Coverage in the US: Quantifying the impact of expanding coverage in the commercial and Medicaid markets. https://www.milliman.com/en/insight/the-landscape-of-biomarker-testing-coverage-in-the-US
[37] Wong W, Sheinson D, Liu Y, To TM. Costs associated with the use of multigene panel tests in three solid tumor types and the impact on insurance premiums. Future Oncol. 2023;19(10):705-714. doi:10.2217/fon-2023-0094
[38] The Landscape of Biomarker Testing Coverage in the US: Quantifying the impact of expanding coverage in the commercial and Medicaid markets. https://www.milliman.com/en/insight/the-landscape-of-biomarker-testing-coverage-in-the-US

Oncotype DX to guide decisions about chemotherapy in early-stage, hormone receptor-positive, HER2-negative breast cancer.

The trial enrolled over 10,000 women with early-stage breast cancer and utilized the Oncotype DX test to analyze the expression of 21 genes in tumor tissue. Based on the test results, patients were categorized into three risk groups: low risk, intermediate risk, and high risk. Patients in the low-risk group received hormone therapy alone, while those in the high-risk group received hormone therapy plus chemotherapy. The intermediate-risk group was randomly assigned to receive hormone therapy alone or hormone therapy plus chemotherapy.

The results of TAILORx showed that women in the low-risk group, as identified by the Oncotype DX test, derived no additional benefit from adding chemotherapy to hormone therapy. This finding spared thousands of women from unnecessary chemotherapy and its associated side effects. On the other hand, women in the high-risk group benefited significantly from the addition of chemotherapy.[39]

The TAILORx trial provided robust evidence supporting the use of biomarker testing, such as Oncotype DX, to personalize treatment decisions in early-stage breast cancer. It highlighted the importance of precision medicine in optimizing cancer care and avoiding overtreatment.

(ii) If a mandated benefit of a category of health care provider is sought, to what extent has there been conducted professionally accepted controlled trials demonstrating the health consequences achieved by the mandated benefit of this category of health care provider?
n/a

(iii) To what extent will the mandated benefit enhance the general health status of the state residents?
Targeted therapy can improve survival and quality of life by connecting patients to the most beneficial treatment for their disease. Treatment with targeted therapy often requires testing to identify biomarkers like gene mutations and protein expression 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.

According to a recent national survey of oncology providers, patient concerns about cost and coverage are key barriers to needed biomarker testing. Two-thirds report that patient insurer coverage for a desired biomarker test is a significant or moderate barrier.[40]

Studies have shown significant health benefits of guideline-indicated biomarker testing and biomarker-driven treatments. For example, looking at clinical outcomes of non-small cell lung

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[39] Joseph A. Sparano et al. Adjuvant Chemotherapy Guided by a 21-Gene Expression Assay in Breast Cancer. 2018. New England Journal of Medicine. P 111-121. V 379: 2. doi:10.1056/NEJMoa1804710 https://www.nejm.org/doi/full/10.1056/NEJMoa1804710

[40] Understanding Provider Utilization of Cancer Biomarker Testing Across Cancers, December 2021, American Cancer Society Cancer Action Network. https://www.fightcancer.org/sites/default/files/national_documents/provider_utilization_of_biomarker_testing_polling_memo_dec_2021.pdf

cancer (NSCL) patients who received biomarker testing compared with those that did not receive testing in a real-world setting, advanced NSCLC patients who received biomarker testing showed better survival than patients who did not receive biomarker testing.[41,42]

One study found the use of targeted therapy, enabled by biomarker testing, has been associated with a more favorable outcome in advanced NSCLC, with a 31 percent reduction in risk of death and improved survival duration that was about 1.5-fold longer compared to patients with an identified mutational driver who did not receive targeted therapy.[43] Another study found population-level mortality from NSCLC in the United States fell sharply from 2013 to 2016, and survival after diagnosis improved substantially, most likely attributable to use of targeted therapy.[44]

Additionally, patients who received treatments informed by biomarker testing results had lower risk of discontinuation than patients who were not tested or did not receive appropriate biomarker-informed treatment.[45]

In another real-world study, patients who did not receive any biomarker test had a 50% higher risk of death than patients who had a positive biomarker test and received appropriate targeted treatment as an initial treatment in the metastatic setting.[46]

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[41] John A, Shah R, Wong WB, et al. Value of precision medicine in advanced NSCLC: Real-world outcomes associated with the use of companion diagnostics. Journal of Clinical Oncology 2019; 37, no. 15_suppl. https://ascopubs.org/doi/abs/10.1200/JCO.2019.37.15_suppl.e20015

[42] John A, Yang B, and Shah R, et al. Clinical Impact of Adherence to NCCN Guidelines for Biomarker Testing and First-Line Treatment in Advanced Non-Small Cell Lung Cancer (aNSCLC) Using Real-World Electronic Health Record Data. Adv Ther. 2021;38:1552-1566. https://pubmed.ncbi.nlm.nih.gov/33537872/

[43] Kris MG, et al. JAMA. 2014;311:1998-2006. https://pubmed.ncbi.nlm.nih.gov/24846037/

[44] Howlader N, Forjaz G, Mooradian MJ, et al. The Effect of Advances in Lung-Cancer Treatment on Population Mortality. N Engl J Med. 2020;383(7):640-649. doi:10.1056/NEJMoa1916623

[45] John A, Shah R, Wong WB, et al. Value of precision medicine in advanced NSCLC: Real-world outcomes associated with the use of companion diagnostics. Journal of Clinical Oncology 2019; 37, no. 15_suppl. https://ascopubs.org/doi/abs/10.1200/JCO.2019.37.15_suppl.e20015

[46] John A, Yang B, and Shah R, et al. Clinical Impact of Adherence to NCCN Guidelines for Biomarker Testing and First-Line Treatment in Advanced Non-Small Cell Lung Cancer (aNSCLC) Using Real-World Electronic Health Record Data. Adv Ther. 2021;38:1552-1566. https://pubmed.ncbi.nlm.nih.gov/33537872/