MANDATED BENEFIT REVIEW OF HOUSE BILL 1074 AND SENATE BILL 689

SUBMITTED TO THE 193rd GENERAL COURT:

AN ACT RELATIVE TO PATIENT ACCESS TO BIOMARKER TESTING TO PROVIDE APPROPRIATE THERAPY

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CHIA

Mandated Benefit Review of House Bill (H.B.) 1074 and Senate Bill (S.B.) 689 Submitted to the 193rd General Court

An Act Relative to Patient Access to Biomarker Testing to Provide Appropriate Therapy

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1.0 Executive Summary: H.B. 1074 and S.B.689; "An Act relative to patient access to biomarker testing to provide appropriate therapy"

The Massachusetts Legislature's Committee on Financial Services referred House Bill (H.B.) 1074, titled "An Act relative to cancer patient access to biomarker testing to provide appropriate therapy"[i] and Senate Bill (S.B.) 689, titled, "An Act Relative to patient access to biomarker testing to provide appropriate therapy"[1,2] to the Massachusetts Center for Health Information and Analysis (CHIA) for review. This report references H.B.1074 and S.B. 689 together and hereafter as "the bill."

As submitted to the 193rd General Court of the Commonwealth of Massachusetts (the Commonwealth), the bill requires health insurers[ii] to provide coverage for biomarker testing for diagnosis, treatment, appropriate management, or ongoing monitoring of a member's disease or condition when the test is supported by medical and scientific evidence that includes, but is not limited to:

1) "Labeled indications for an FDA[iii] approved or -cleared test or indicated tests for an FDA approved drug;
2) Centers for Medicare and Medicaid Services (CMS) National Coverage Determinations [NCDs] or Medicare Administrative Contractor (MAC) Local Coverage Determinations [LCDs]; or
3) Nationally recognized clinical practice guidelines and consensus statements."

This bill also prescribes time frames for prior authorization approvals or denials (72 hours) and expedited approvals or denials (24 hours) if a delay would risk a member's health. The bill does not include direct-to-consumer screening tests or provider-ordered screening tests for asymptomatic members.[3]

1.1 What is Biomarker Testing?

A biomarker is a biological molecule found in blood, body fluids, or tissues that can reflect normal or abnormal processes, conditions, or diseases. Biomarker testing, performed on samples like tissue or blood, evaluates the presence and status of specific genes, proteins, or molecules that can signal diseases, including cancer, autoimmune diseases, and rare diseases.[iv]

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[i] The legislative sponsors indicated that the bill is intended to be disease-agnostic—not specific to members with cancer.
[ii] The bill amends statutes that regulate health insurance carriers in the Commonwealth. It includes Chapter 32A (GIC), Chapter 175 (Commercial Health Insurance Companies), Chapter 176A (Hospital Service Corporations), Chapter 176B (Medical Service Corporations), and Chapter 176G (HMOs).
[iii] United States (U.S.) Food and Drug Administration.
[iv] "Biomarker testing" can also broadly include imaging studies, such as computerized tomography (CT) scans, and magnetic resonance imaging (MRI), as well blood pressure readings and pulse rates (heart rates).

Biomarker tests aid in diagnosis, risk assessment, treatment planning, monitoring treatment effectiveness, prognosis, and predicting disease recurrence or spread. Biomarker testing can also be referred to as "molecular profiling" or "molecular testing."[4,5] Biomarkers can be divided into several categories based on their function and relevance:

- **Diagnostic Biomarkers** are used to identify the presence or absence of a disease. For instance, elevated levels of prostate-specific antigen (PSA) can indicate prostate cancer.
- **Prognostic Biomarkers** help predict the likely outcome of a disease. They provide insights into the disease's progression and severity. An example is human epidermal growth factor receptor 2 (HER2) status in breast cancer, which helps determine the aggressiveness of the cancer.
- **Predictive Biomarkers** indicate how well a patient is likely to respond to a specific treatment. Genetic mutations affecting drug metabolism enzymes are examples of predictive biomarkers.
- **Surrogate Biomarkers** are used as substitutes for clinical endpoints in drug development. They help determine the effectiveness of a treatment by measuring a response that is correlated with the desired clinical outcome.
- **Monitoring Biomarkers** are used to track disease progression or treatment response over time. Blood glucose levels in diabetes patients are an example of monitoring biomarkers.[6,7]

1.2 Current Coverage

There are many common biomarkers that are used routinely in patient care to monitor and track an individual's health status. Common blood biomarker tests (e.g., complete blood count [CBC]) are often ordered by primary care physicians and specialists. Biomarker tests that are conducted as a component of routine patient care are included in the Commonwealth's Essential Health Benefit (EHB) benchmark plan and are already broadly covered.[v] The Affordable Care Act (ACA) requires coverage, without cost-sharing, of biomarker tests that receive a grade A or B by the United States Preventive Services Task Force (USPSTF).

While the Commonwealth does not currently mandate broad coverage of biomarker testing, human leukocyte antigen (HLA) testing, conducted for transplant recipients and/or transplant donors, is a state-required benefit.[vi,8]

Beyond broad coverage of common biomarker tests routinely used in patient care, coverage of other biomarker testing (e.g., liquid biomarker testing) varies by carrier. Carriers indicate that most genetic biomarker tests, including blood tests, are subject to prior authorization and medical guidelines.[vii]

[v] Blue Cross Blue Shield of MA-HMO Blue.
[vi] M.G.L. c. 175 § 47V M.G.L. c. 176A § 8V M.G.L. c. 176B § 4V M.G.L. c. 176G § 4N.
[vii] BerryDunn surveyed 10 insurance carriers in the Commonwealth (although Tufts Health Plan and Harvard Pilgrim Health Care recently merged, they are accounted for separately); responses represent five carriers and 79.9% coverage of members.

1.3 Analysis Overview

The bill's language is broad—including the definitions of "biomarker" and "biomarker testing,[viii]" as well as the types of supporting medical and scientific evidence (including, but "not limited to" three types of evidence) that would require carriers to cover biomarker tests. Using the bill's definition of biomarker testing, there are estimated to be over 27,000 biomarker tests as of 2021, with the number of tests continuously increasing due to novel advancements in biomarker testing.[9]

During research for this report, carriers indicated the bill's language would potentially require carriers to cover biomarker tests with low clinical utility, or large, multi-panel biomarker tests that could result in false positives or unactionable results. Carriers note different standards used by CMS (e.g., regarding coverage of investigational and experimental services). Supporters of the bill report current inconsistent coverage for biomarker tests (e.g., liquid biopsies), biomarker tests' potential to prevent the need for multiple blood draws and/or tissue samples, and indicate that efficiencies can be gained through large, multi-panel testing.

In a response to a subsequent inquiry, the legislative sponsors indicated the intent of the bill is to require coverage for diagnosis, treatment, and ongoing monitoring when the evidentiary standards stated in the bill are met. Sponsors noted that while carriers may require utilization management, such as prior authorization to review patient specifics and determine if the testing fits the stated criteria, the bill's intent is to prevent carriers from establishing their own medical necessity criteria, with the goal to align coverage policies across all carriers. This analysis is based on this interpretation and the legislative sponsors' stated intent.

1.4 Estimated Cost of Enactment

The discovery and use of biomarker tests have increased dramatically over the last decade.[10] Tests discovered over the last few years are not yet reflected in the Massachusetts All-Payer Claims Database (APCD) used for this report.[ix] Furthermore, some of the most recently discovered tests do not have procedure codes. Because carriers broadly cover common biomarker testing[x] and report coverage of medically necessary biomarker testing, it is likely that carriers would voluntarily cover many currently uncovered biomarker tests in the future—after additional evidence of their efficacy—absent the mandate.

Requiring coverage for this benefit by fully insured health plans would result in an average annual increase to the typical member's health insurance premium of between $0.45 to $1.32 per member per month (PMPM) or between 0.072% to 0.211% of premium, over a projection period of five years.

[viii] The bills define biomarker and biomarker testing as follows. "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. "Biomarker testing" is 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.

[ix] The APCD version used for this report included claims incurred between January 1, 2017 and December 31, 2021, with paid claims through June 30, 2022.

[x] Common biomarkers are used routinely in patient care to monitor and track an individual's health status. Common blood biomarker tests (e.g., complete blood count [CBC]) are often ordered by primary care physicians and specialists and are part of routine patient care.

1.5 Efficacy Impact

Biomarker tests have varying accuracy, for example, while some biomarker tests may confirm certain conditions, they may not be able to provide a definitive diagnosis.[11] Research emphasizes the importance of biomarkers in guiding treatment decisions, such as in cancer therapy, in which genetic testing can identify optimal treatment strategies.[12] Additionally, biomarker testing can aid in predicting and mitigating risks associated with complex therapies.[13] Family history often prompts genetic testing, especially for cancer, though access and coverage for these tests can vary and may require out-of-pocket expenses or enrollment in research studies in order to receive testing.[14] Biomarkers have implications for diagnosing rare diseases, developing appropriate therapeutic agents and doses, and monitoring disease progression.[15,16] The National Organization of Rare Disorders estimates that approximately 10% of individuals have a rare disease diagnosis, which in MA would equate to a prevalence of nearly 700,000 people.[17]

1.6 Equity Impact

Research suggests that biomarker testing, including genome sequencing, is often conducted on white populations, potentially leading to lower diagnostic accuracy for underrepresented minorities.[18] Socio-economic status influences the utilization of predictive biomarker tests and precision therapies for cancer, with disparities more pronounced in lung cancer studies.[19] Disparities also exist in biomarker testing rates for advanced colorectal cancer, with individuals identifying as Black non-Hispanic, patients who were uninsured or patients insured via Medicaid, and individuals diagnosed at community health care centers all being less likely to receive testing.[20] Demographic disparities persist in genetic testing, with females, individuals with higher education levels, and those with higher incomes more likely to receive genetic tests.[21]

Endnotes

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AN ACT RELATIVE TO PATIENT ACCESS TO BIOMARKER TESTING TO PROVIDE APPROPRIATE THERAPY

MEDICAL EFFICACY ASSESMENT

2.0 Medical Efficacy Assessment

House Bill (H.B.) 1074 and Senate Bill (S.B.) 689 (collectively, "the bill"), as submitted to the 193rd General Court would require health insurers to provide coverage for biomarker testing for diagnosis, treatment, appropriate management, or ongoing monitoring of a member's disease or condition when the test is supported by medical and scientific evidence that includes but is 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 or Medicare Administrative Contractor (MAC) Local Coverage Determinations; or
3) Nationally recognized clinical practice guidelines and consensus statements."

This bill indicates that requiring coverage for biomarker testing should minimize care disruptions such as the need for multiple biopsies or biospecimen samples.

For coverage requiring prior authorization, the bill requires a carrier or utilization review organization to approve or deny a prior authorization request or appeal and inform the member and healthcare provider within 72 hours. If further delay risks the member's health, the carrier or organization must decide within 24 hours. If no response is received within this time, the bill would require the request or appeal to be considered granted.[xi,1]

The bill also states that patients and prescribing practitioners should have accessible, clear, and convenient exception request processes for coverage policy or utilization review challenges. This process should be easily available on the carrier's website.

In response to a request for clarification, the bill sponsor indicated the bill's intent is to:

- Align coverage of biomarker testing with reputable sources of medical evidence to enable patients to obtain medically appropriate biomarker testing to guide their treatment.
- Exclude testing for screening purposes, even for patients who are considered high-risk because of a family history of a condition.[xii]
- Allow utilization management to determine whether testing is appropriate.
- Prohibit establishment of carrier-specific medical necessity criteria.[2]

M.G.L. Chapter 3 §38C charges CHIA with reviewing the medical efficacy of proposed mandated health insurance benefits. Medical efficacy reviews summarize current literature on the effectiveness and use of the treatment or service and describe the potential impact of a mandated benefit on the quality of patient care and health status of the population.

[xi] Chapter 254, An Act relative to step therapy and patient safety, contains the amended language "three business days" in lieu of "72 hours," however the sponsoring legislators intend the required timeframe to remain "72 hours" in the current bill as "72 hours" is more advantageous for the patient.
[xii] Some screening tests, as noted below, are required to be covered by the Affordable Care Act.

Due to the extensive number of biomarker tests available, conducting a comprehensive efficacy review is not feasible for this report. Hence, the subsequent medical efficacy assessment offers insights into the descriptions, indications, and applications of biomarker tests, along with study findings on outcomes for select common biomarker tests designed for specific objectives. The clinical efficacy of biomarker testing fluctuates based on factors such as patient status, testing type, and other variables.

This report proceeds in the following sections:

2.1 Biomarker Types and Applications

A biomarker is a biological molecule found in blood, body fluids, or tissues that can reflect normal or abnormal processes, conditions, or diseases. Biomarker testing, performed on samples like tissue or blood, evaluates the presence and status of specific genes, proteins, or molecules that can signal diseases, including cancer, autoimmune diseases, and rare diseases. Broadly defined, biomarker testing can also include imaging studies, such as computerized tomography (CT) scans, and magnetic resonance imaging (MRI), as well as blood pressure readings and pulse rates (heart rates). These tests aid in diagnosis, risk assessment, treatment planning, monitoring treatment effectiveness, prognosis, and predicting disease recurrence or spread. Biomarker testing can also be referred to as "molecular profiling" or "molecular testing."[3,4] For the purposes of this report, "biomarker testing" includes laboratory testing and analysis of biological samples such as tissue or blood. This testing includes but is not limited to single-analyte tests, multi-plex panel tests, and whole-genome sequencing.[xiii] Biomarkers can be divided into several categories based on their function and relevance:

- **Diagnostic Biomarkers** are used to identify the presence or absence of a disease. For instance, elevated levels of PSA can indicate prostate cancer.
- **Prognostic Biomarkers** help predict the likely outcome of a disease. They provide insights into the disease's progression and severity. An example is HER2 status in breast cancer, which helps determine the aggressiveness of the cancer.
- **Predictive Biomarkers** indicate how well a patient is likely to respond to a specific treatment. Genetic mutations affecting drug metabolism enzymes are examples of predictive biomarkers.

[xiii] The bills define biomarker and biomarker testing as follows. "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. "Biomarker testing" is 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.

- **Surrogate Biomarkers** are used as substitutes for clinical endpoints in drug development. They help determine the effectiveness of a treatment by measuring a response that is correlated with the desired clinical outcome.
- **Monitoring Biomarkers** are used to track disease progression or treatment response over time. Blood glucose levels in diabetes patients are an example of monitoring biomarkers.[5, 6]

These types of biomarkers have numerous applications in medicine and research:

Disease Diagnosis: Biomarkers aid in early detection and accurate diagnosis of diseases, which can lead to better treatment outcomes. These types of biomarkers not only identify people with a disease but can also redefine the classification of the disease. Susceptibility/risk biomarkers are often considered with regard to diagnosis and are used to determine the potential for the eventual development of a disease or medical condition in an individual who does not currently have the disease or medical condition.

Monitoring Progression: Biomarkers are used to monitor disease progression, relapse, or remission over time, guiding treatment adjustments. Monitoring biomarkers can measure pharmacodynamic effects to assess therapeutic response and detect potential complications of diseases and/or therapies. These types of biomarkers are also considered to provide the best metric of the likely outcome for an individual patient or a population.

Drug Development: Pharmacodynamic/response biomarkers are used to identify responses to exposures to medical products or environmental agents, as well as to assess drug safety, and evaluate treatment effectiveness during clinical trials. Safety biomarkers are used to identify patients who might experience adverse effects from a treatment, and consideration is given to the balance of patient safety and the potential therapeutic benefit.

Personalized Medicine: Biomarkers can help tailor treatment plans to individual patients based on their genetic makeup and disease characteristics, optimizing therapy, and minimizing side effects.

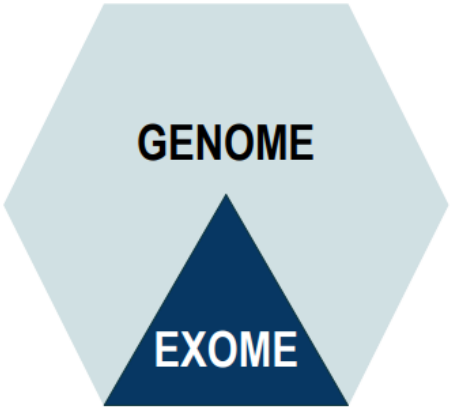
Research: Biomarkers are essential tools in understanding disease mechanisms, identifying risk factors, and uncovering potential therapeutic interventions. [7,8,9]

The FDA's Biomarkers, Endpoints, and other Tools (BEST) glossary categorizes biomarkers into seven groups: susceptibility/risk, diagnostic, monitoring, prognostic, predictive, pharmacodynamic/response, and safety.[10] Biomarkers can also be categorized into single-gene tests, multigene/broad panel gene testing that tests multiple genes, whole-genome sequencing (WGS)/whole-exome sequencing (WES) that analyzes the bulk of an individual's DNA to find genetic variations, and next-generation sequencing that enables rapid sequencing of DNA or RNA and allows the analysis of entire genomes, transcriptomes, or targeted regions.[11,12]

Newer genetic tests, such as next-generation sequencing, are blood biomarker tests that are being used more frequently as diagnostic tests. Next-generation sequencing is an advanced technique that analyzes an individual's DNA and includes WES and WGS (see Figure 1). WES examines the exome, which is the part of DNA that contains instructions for making proteins that have crucial roles in the body's structure and function. Many genetic conditions and diseases are caused by changes in the protein-coding regions of DNA. WES helps identify these changes, allowing researchers to understand the genetic basis of various conditions. WGS, examines the entire genome, the complete set of DNA, including both protein-coding and non-coding regions. WGS provides a complete view of DNA,

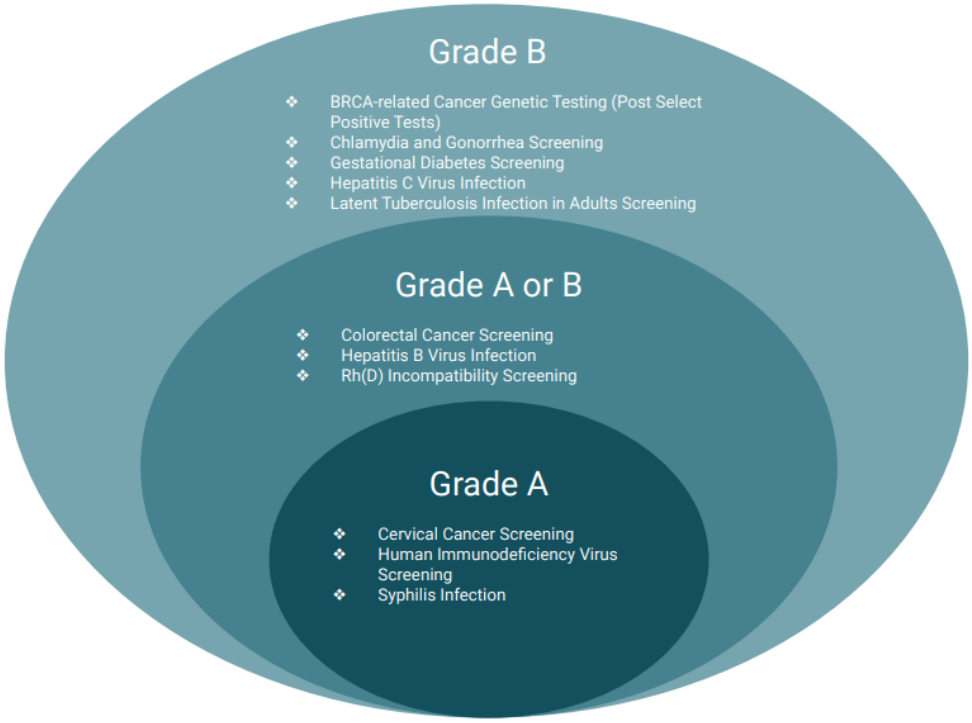
offering insights not only into protein-coding genes but also into regulatory regions and non-coding DNA. This can be valuable for understanding a wide range of genetic factors, from disease risk to ancestry.[13,14]

Figure 1. Next-Generation Sequencing: Genome vs. Exome



There are many common biomarkers that are used routinely in patient care to monitor and track an individual's health status (e.g., CBC).[15] Biomarker testing that is conducted as a component of routine patient care is already covered by commercial health insurance carriers in the Commonwealth, and thus the focus of this review is on biomarker tests that might be newly covered by some carriers, should the bill become enacted. USPSTF grade A and B screening tests (see Figure 2) have been shown to have a high or moderate net benefit for patients as part of routine patient care and are already required to be covered under the ACA.

Figure 2. United States Preventive Services Taskforce Grade A and B Screening Tests[16]



Certain biomarker tests can have multiple usages, such as liquid biopsies which can be utilized as diagnostic, prognostic, and pharmacogenomic biomarkers for targeted therapy (treatment that targets genetic changes or mutations that transform normal cells into cancerous ones).[17] When tumors grow, portions can separate and circulate in the bloodstream, and liquid biopsies test for evidence of tumors in the bloodstream. Liquid biopsies can also provide genetic information about the specific cancer that is present, are minimally invasive, and require a single blood test. However, traditional biopsies are still considered the "gold standard" for cancer diagnosis, as with liquid biopsies, even if an individual has a tumor, it may be undetectable in their bloodstream.[18] The FDA has approved certain liquid biopsy tests for advanced cancer, predicting prognosis, and treatment decision-making, as well as situations in which individuals may not be candidates for traditional biopsies. In Massachusetts, coverage for liquid biopsies varies depending on the carrier and on the type of cancer.[19,20]

A predictive biomarker is characterized by its ability to indicate whether the presence or alteration of the biomarker predicts a higher likelihood of individuals, or a group of individuals, to experience either favorable or unfavorable effects in response to exposure to a medical product or environmental agent. A prognostic biomarker is characterized by its ability to identify the likelihood of a clinical event, disease recurrence, or disease progression in patients with an established disease or condition. The key difference between prognostic and predictive biomarkers is that prognostic

biomarkers result in differential disease outcomes, while predictive biomarkers can identify individuals who will or will not respond to therapy.[21]

2.2 Efficacy of Biomarkers

The ability of a biomarker test to accurately identify whether a patient has a disease, or marker, of interest varies considerably depending on the test. High-sensitivity biomarker tests are more able to correctly identify individuals who have a specific condition (true positives), while high-specificity biomarker tests are more able to correctly identify individuals who do not have a specific condition (true negatives).[22] Some biomarker tests utilized to identify patients with chronic health conditions are not recommended for diagnostic tests but could be utilized for confirmatory tests.

2.2.1 Cancer-Related Biomarkers

Genetic testing via the usage of multigene or single-gene biomarker tests is commonly recommended for individuals who have a family history of cancer diagnoses. These tests are typically blood tests but can also involve saliva and/or cell sampling and are often conducted with the guidance of a genetic counselor.[23]

The value of BReast CAncer gene (BRCA) testing for breast and ovarian cancer diagnosis and treatment has been established for decades, with its efficacy and significance becoming increasingly recognized. USPSTF, as well as Healthy People 2030, a set of goals established by the U.S. Department of Health and Human Services, have acknowledged the value of biomarkers, reflecting its established role in healthcare guidelines.[24] In a study conducted in 2017, a growing trend was observed in BRCA genetic testing among individuals with a family history of cancer. Between 2003 and 2013, BRCA testing was predominantly performed on women with diagnosis codes reflecting a personal history of breast or ovarian cancer. However, starting in 2007, an increasing number of women with a family history diagnosis began undergoing testing, surpassing those with a personal history diagnosis. Notably, BRCA testing for individuals with a family history diagnosis constituted 47.9% of all BRCA tests administered. Individuals with a family history of breast or ovarian cancer experienced greater decreases in out-of-pocket expenses for BRCA testing compared to those with a personal history.[25] Testing for BRCA1 and BRCA2 is covered federally and was first recommended by the USPSTF in 2013 for individuals with family histories of breast, ovarian, tubal, or peritoneal cancer, and in 2019 the USPSTF expanded these recommendations to include recommendations for BRCA1 and BRCA2 based on individuals' ethnicity and ancestry associated with these gene variants.[26] In a 2019 study of women in California and Georgia aged 20 and older who had received breast or ovarian cancer diagnoses between 2013 and 2014, 24.1% of individuals with breast cancer and 30.9% of individuals with ovarian cancer had received a genetic test.[27] One of the objectives of Healthy People 2030 is to increase the number of women with a family history of breast and/or ovarian cancer who undergo genetic counseling.[28]

Biomarker testing can guide treatment decisions as it enables providers to identify specific genetic mutations associated with certain diseases. The presence of specific BRCA mutations in breast or ovarian cancer can enhance or compromise the response of cancer cells to specific types of treatment. By ascertaining whether an individual has a BRCA mutation, the optimal treatment can be determined. Biomarker tests can also be used to monitor patients' progress and assess the stage of the disease.[29]

In the first real-world study assessing biomarker test utilization and subsequent treatment of patients with early-stage non-small cell lung cancer (eNSCLC), the results indicated that the trend of biomarker testing was increasing over the past decade, and leading toward the personalization of treatment decisions that help to ensure patients receive

the appropriate treatment at the right time in their disease progression. The proportion of patients who received biomarker testing in 2011 was 55.3% and rose to 88.1% in 2021. The majority of patients (74.1%) received at least one biomarker test within the first six months of their eNSCLC diagnosis, and almost all of the patients who received the five most common biomarker tests in the study, received at least one test before starting a systemic treatment.[30]

Biomarker testing can result in improved clinical outcomes, and longer lifespans among patients diagnosed with cancer. A 2021 study explored the link between adherence to National Comprehensive Cancer Network (NCCN) guidelines and clinical outcomes in adult patients with advanced non-small-cell lung cancer (aNSCLC) using a real-world database. Of the 28,784 aNSCLC patients included, two-thirds (n = 19,787) had biomarker testing and these patients had a significantly lower mortality risk and slightly longer median overall survival (15.4 vs. 14.2 months). Adherence to NCCN guidelines for biomarker testing was found to correlate with improved clinical outcomes in aNSCLC patients.[31]

To help ensure and advance cancer treatment effectively, monitoring a patient's disease should be efficient and repeatable. Biomarker research endeavors to monitor diseases noninvasively, using, for example, liquid biopsy samples from urine, saliva, or blood. The markers should exhibit sufficiently high sensitivity and specificity to predict the development of specific diseases.[32]

Biomarker testing can also determine the safety and necessity of pursuing costly and invasive treatments, as well as identify interventions to mitigate risks associated with complex therapies. For example, a 2023 study examined the usage of risk biomarkers for sinusoidal obstruction syndrome (SOS), a deadly side effect that can occur in patients who receive stem cell transplants (most often used for treatment of blood cancers) and is more likely to occur in pediatric patients. By measuring biomarkers like L-ficolin, hyaluronic acid, and stimulation 2 three days post-transplant, the study identified patients at high-risk of SOS. This allowed physicians to implement preemptive measures, such as administering defibrotide, reducing the risk of SOS.[33]

In a 2022 trial exploring the role of adjuvant chemotherapy in stage II colon cancer, patients were randomly assigned treatment decisions based on circulating tumor DNA (ctDNA) results or standard clinicopathological features. The ctDNA-guided approach significantly reduced adjuvant chemotherapy use (15% vs. 28%) without compromising recurrence-free survival, showcasing ctDNA's potential in personalized treatment decisions for stage II colon cancer.[34]

2.2.2 Biomarkers Related to Other Conditions

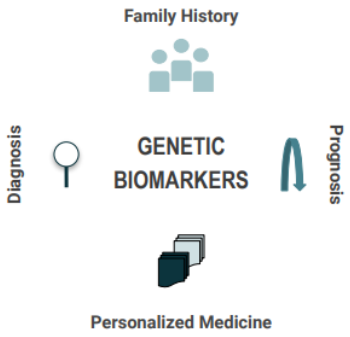
Multigene panel testing, including WES and WGS, has been demonstrated to be an effective tool for personalized medicine for patients with neuromuscular diseases, such as amyotrophic lateral sclerosis (ALS). For individuals with genetically caused ALS, early genetic testing is recommended to facilitate access to novel drug developments and help to ensure prompt availability of therapeutic interventions.[35]

Genetic testing for other heritable diseases can also be appropriate, particularly within the cardiology specialty.[36] Many individuals with cardiovascular disease (CVD) want to know the cause of their disease. Genetic testing for individuals with CVD can also provide specific diagnostic information and prognostic information. For example, genetic tests can examine the presence of inherited genetic changes in three genes (LDLR, APOB, and PCSK9) known to lead to the development of familial hypercholesterolemia (FH). Tests for mutations in these genes can

identify the mutation that causes FH in approximately 60% – 80% of people who were suspected to have FH (some individuals will have a mutation that is not discovered via genetic testing).[37] Additionally, among individuals who have the same low-density lipoprotein cholesterol-level, individuals who have confirmed FH are three times more likely to experience a cardiac event than individuals who do not have FH. This can impact preventive treatment options that doctors may recommend.[38] It can also be appropriate to conduct genetic tests for individuals with a family history of myocarditis and sudden cardiac death.[39]

Genetic diseases are primary contributors to childhood mortality. Chromosomal microarrays, which can detect genetic abnormalities in DNA associated with various medical conditions,[40] are commonly employed as diagnostic tools, while WGS and WES are newer tests that are increasingly gaining usage. A 2018 systematic review and meta-analysis comparing the diagnostic and clinical utility of these three tests in children with suspected genetic diseases found that in 37 studies encompassing 20,068 children, both whole-genome sequencing and WES exhibited qualitatively higher diagnostic utility than chromosomal microarrays.[41] Figure 3 demonstrates the informational facets that genetic biomarkers can provide.

Figure 3. Genetic Biomarkers



2.2.3 Rare Disease-Related Biomarkers

Biomarkers have implications for diagnosing rare diseases, developing appropriate therapeutic agents and doses, and monitoring disease progression. Currently there is no universal definition of rare disease; in the U.S., a rare disease is a disease that impacts fewer than 200,000 people among the population. Rare diseases collectively are estimated to impact approximately 400 million people globally, and 30 million people in the U.S.[42,43] Many rare diseases do not have International Classification of Disease (ICD-10) codes associated with them. There are estimated to be 6,000 to 8,000 rare diseases identified as of 2021, with additional conditions regularly detailed in medical literature.[44] The majority of rare diseases, estimated at 80%, are genetic in origin.[45] There are technical, financial, and policy challenges for accurately diagnosing patients who have rare diseases, and on average, it can take 6.3 years for individuals to receive a confirmed rare disease diagnosis.[46, 47]

The Massachusetts Rare Disease Advisory Council (RDAC) September 2023 report, using rare disease datasets from Orphanet and extrapolating from the total population based on 2022 MA Census data, estimates that in MA there is a minimum of 244,369 to 432,882 people (between 3,500 and 6,200 per 100,000 people) who have a rare

disease. The RDAC acknowledges that these figures might underestimate the actual number of people in MA with a rare diagnosis, as Orphanet data excludes certain disease categories like rare cancers, and does not consider underdiagnosis, misdiagnosis, and the discovery of new diseases. The National Organization of Rare Disorders estimates in accordance with these additional factors, that approximately 10% of individuals have a rare disease diagnosis, which in Massachusetts would equate to a prevalence of nearly 700,000 people.[48] Biomarker tests such as gene panels, WES, and WGS, have facilitated diagnoses for approximately 25% – 35% of previously undiagnosed patients. These diagnoses are actionable, enabling patients to receive targeted treatment for their symptoms.[49]

A 2020 study found that plasma biomarker distribution testing could aid in early diagnosis of Gaucher disease (GD), a rare autosomal recessive multisystemic lysosomal storage disorder[xiv,50] with variability in clinical presentation. The findings also suggest that this panel could assist with monitoring of GD disease progression.[51] The usage of biomarkers is not universally recommended for all rare diseases. A 2020 literature review of 73 Hemophilia B and B congenital bleeding disorder biomarker testing studies found that when these disorders are in the preclinical or asymptomatic phase and are potentially reversible, the usage of biomarkers is challenging. According to this review, the clinical utility of these biomarkers is hindered by a lack of standardization and the reviewers hold that standardizing biomarkers in association with clinical and radiological parameters holds promise for improving clinical practice.[52]

2.3 Access and Health Equity

Research on biomarker testing, including genome sequencing, is frequently carried out on a homogeneous population, primarily white populations. Thus, for underrepresented minorities, these tests may exhibit lower diagnostic accuracy.[53]

A 2020 systematic review and meta-analysis examined whether there are socio-economic inequalities in the utilization of predictive biomarker tests, as well as biological and precision therapies for cancer. The results showed that low socio-economic status was associated with slightly lower predictive biomarker test utilization, and significantly lower biological and precision therapy utilization. These associations were stronger in lung cancer studies than in breast cancer studies.[54] A 2020 study of microsatellite instability/mismatch repair biomarker testing for patients with advanced colorectal cancer found that while overall testing rates increased from 14.4% in 2010 to 41.1% in 2016 in the 45,326 patient population, disparities existed across all study years. Individuals older in age, males, individuals identifying as Black non-Hispanic, individuals who were uninsured or patients insured via Medicaid, and individuals diagnosed at community health care centers were all less likely to undergo testing.[55]

A 2023 study using data from the 2020 Health Information National Trends Survey (HINTS) found demographic disparities among those who receive genetic tests. Respondents identifying as female had a higher likelihood of having received any genetic tests, while respondents identifying as Hispanic had a lower likelihood. Individuals with bachelor's degrees or graduate degrees were more likely to have received a genetic test than individuals with only high school education or some college education. Those in the highest income category of greater than $75,000

[xiv] Gaucher disease occurs from a build of fatty substances around organs, adversely affecting their function. Fatty substances can also build up around bone tissue, leading to fractures. Mayo Clinic. Diseases and Conditions. Gaucher Disease. Updated April 30, 2022. https://www.mayoclinic.org/diseases-conditions/gauchers-disease/symptoms-causes/syc-20355546.

annually were more likely to have had a genetic test than those in the lower income categories. When accounting for personal history cancer, these differences were still present.[56]

2.4 Biomarker Testing Advancements

Research is continually underway to discover new biomarker tests that can enhance diagnosis and facilitate targeted treatment. Multi-cancer early detection (MCED) tests (also referred to as "Multi-Cancer Detection tests" by the National Cancer Institute)[57] are novel biomarker tests that can potentially identify more than one type of cancer from a single blood sample. These tests evaluate the presence of certain DNA or proteins that originates from cancer cells. MCED tests can identify whether a person has cancer, and some tests can also identify the organ in which the cancer started. Additional testing may be required after MCED tests, particularly if the test did not identify the originating organ. The advent of MCED tests may lead to reducing cancer deaths, as approximately 70% of cancer deaths are due to cancers with no FDA-approved screening tests, leading the cancer to be diagnosed at a more advanced and difficult to treat stage.[58] It is possible that MCED tests could identify cancers before individuals demonstrate symptoms, but currently these tests are more accurate when detecting cancer in later stages than in pre-disease or early-stage disease.[59] MCED tests are not yet FDA approved, but some tests may be classified as lab-developed tests based on the Clinical Laboratory Improvement Act (CLIA), which enables them to be prescribed and used. Many companies who are developing MCEDs are in the data-gathering phase and will eventually seek FDA approval. Individuals who receive MCED testing will likely have to pay for the test out-of-pocket, either in full, or in part, unless they are enrolled in clinical trials.[60]

Tumor-normal sequencing, also referred to as paired testing or matched testing, is another newer biomarker test, and is currently being used in cancer research and diagnostics. Tumor-normal sequencing compares the DNA from a sample of tumor with a sample of corresponding normal tissue from the same individual. The normal tissue sample acts as a baseline or reference for the individual's genetic makeup, enabling identification of specific genetic alternations that are present in the tumor sample. This testing can be conducted simultaneously in a single test, rendering it an efficient test. Tumor-normal sequencing can detect an individual's hereditary cancer risk, as well as genetic mutations that can guide targeted treatment.[61]

3.0 Conclusion

Biomarkers, which are biological indicators found in blood, body fluids, or tissues, play a crucial role in diagnosing diseases, guiding treatment decisions, and monitoring disease progression.[62,63] They encompass various types, including diagnostic, prognostic, predictive, and monitoring biomarkers, each serving distinct functions in health care and research.[64, 65] These biomarkers aid in disease diagnosis, personalized medicine, drug development, and understanding disease mechanisms.[66,67,68] The FDA categorizes biomarkers into seven groups: susceptibility/risk, diagnostic, monitoring, prognostic, predictive, pharmacodynamic/response, and safety.[69] Emerging genetic tests, like next-generation sequencing, offer advanced diagnostic capabilities by analyzing an individual's DNA comprehensively, enabling precise diagnosis and personalized treatment strategies.[70,71] While it is not feasible to review all biomarkers for purposes of this report, the bill's intent to enhance access to scientifically validated testing reflects the expanding utility and significance of biomarkers in health care.

Biomarker tests vary in sensitivity and specificity, influencing their diagnostic utility; for instance, while some biomarker tests may confirm certain conditions, they may not suffice as initial diagnostic tools.[72] Research supports the value of biomarkers in guiding many treatment decisions, such as in cancer therapy, where genetic testing plays a pivotal role in identifying optimal treatment strategies.[73] Additionally, biomarker testing can aid in predicting and mitigating risks associated with complex therapies.[74] Family history often prompts genetic testing, especially for cancer, though access and coverage for these tests remain variable and may require out-of-pocket expenses or enrollment in research studies.[75] The bill's proposed expansion of access to biomarker testing could contribute to fostering equity by potentially broadening the availability of advanced diagnostic and treatment resources. This may have the effect of helping to mitigate and reduce disparities in health care access and outcomes.

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AN ACT RELATIVE TO PATIENT ACCESS TO BIOMARKER TESTING TO PROVIDE APPROPRIATE THERAPY

ACTUARIAL ASSESSMENT

4.0 Actuarial Assessment

4.1 Background

H.B. 1074 and S.B. 689 ("the bill") mandates health insurers to cover biomarker testing for diagnosis, treatment, and monitoring of diseases or conditions supported by medical and scientific evidence. Coverage criteria includes but is not limited to FDA-approved tests, CMS determinations, and clinical practice guidelines. The bill aims to reduce care disruptions and help ensure timely prior authorization decisions that align with existing legislation.[1,2] The sponsors clarified that the bill does not cover screening tests; the bill aims to provide patients with medically appropriate biomarker testing for treatment guidance.[3]

4.2 Plans Affected by the Proposed Mandate

The bill amends statutes that regulate commercial healthcare carriers in the Commonwealth. It includes the following sections, each of which addresses statutes dealing with a particular type of health insurance policy when issued or renewed in the Commonwealth:[4]

- Chapter 32A – Plans Operated by the Group Insurance Commission (GIC) for the Benefit of Public Employees
- Chapter 175 – Commercial Health Insurance Companies
- Chapter 176A – Hospital Service Corporations
- Chapter 176B – Medical Service Corporations
- Chapter 176G – Health Maintenance Organizations (HMOs)

This analysis includes members under 65 years of age who have fully insured commercial plans.

Plans Not Affected by the Proposed Benefit Mandate

Self-insured plans (i.e., where the employer or policyholder retains the risk for medical expenses and uses a third-party administrator or insurer to provide only administrative functions), except for those provided by the GIC, are not subject to state-level health insurance mandates. State mandates do not apply to Medicare, Medicare Advantage plans, or other federally funded plans, including TRICARE (covering military personnel and dependents), the Veterans Administration, and the Federal Employees Health Benefit Plan, the benefits for which are determined by, or under the rules set by, the federal government. Although the bill includes Chapter 118, this analysis does not estimate the bill's impact to MassHealth, nor does it address any potential effect on Medicare supplement plans—even to the extent they are regulated by state law.

This report is not intended to determine whether the bill would constitute a health insurance benefit mandate for purposes of Commonwealth defrayal under the ACA, nor is it intended to assist with Commonwealth defrayal calculations if it is determined to be a health insurance mandate requiring Commonwealth defrayal.

4.3 Existing Laws Affecting the Cost of the Bill

Under the ACA, preventive services with a USPSTF grade A or B must be covered by commercial health insurers without member cost-sharing. Therefore, many preventive biomarkers are already covered (see Figure 2 on pg. 12).

The Commonwealth benchmark plan, Blue Cross Blue Shield of MA-HMO Blue, covers common blood biomarker tests used in routine patient care and HLA testing, or histocompatibility locus antigen, testing that is necessary to establish stem cell transplant donor compatibility (HLA testing is a Commonwealth state-mandated benefit enacted prior to December 31, 2011).

Commonwealth law requires coverage of services for patients enrolled in a qualified clinical trial to the same extent that the services would be covered if the patients were not receiving care in a qualified clinical trial.[5] In order to be qualified, the trial must intend to treat cancer and meet criteria provided in the law (e.g., patient meets the selection criteria and has provided informed consent). Commonwealth carriers already cover these services; according to 2021 Comprehensive Mandated Benefit Review carrier survey findings, carriers consistently noted they would cover these services if the current mandate were not enacted.

4.4 Current Coverage

BerryDunn surveyed 10 insurance carriers in the Commonwealth, and five responded.[xv] Beyond broad coverage of common biomarker tests, coverage of other biomarker testing (e.g., liquid biomarker testing) varies by carrier. The responses indicated that most genetic biomarker tests, including blood tests, are subject to prior authorization and medical guidelines. Carrier responses regarding how costs would be impacted if 72-hour and 24-hour prior authorization-imposed time frames were implemented varied by carrier. Some carriers anticipated these time frames would not impact cost. However, others stated the denial rate would likely increase due to the shortened time frame for gathering necessary information, which would result in increased costs for the carrier to process appeals for these denials and for patients who may choose to pay out of pocket rather than undergoing the appeal process. Carriers also noted that if prior authorization forms are submitted on a Friday, there would be insufficient time to consider the forms due to the shortened time frame.

5.0 Methodology

5.1 Overview

Coverage for biomarker testing varies among carriers, with some offering broader coverage for a range of tests compared to others. Some carriers impose prior authorization requirements for specific biomarker tests, although these requirements are not uniform across carriers and tests. Additionally, some carriers may require detailed medically necessary criteria be met for certain biomarker tests (e.g., a different test must be performed first), while others may cover the same tests without such requirements. The extent of coverage (e.g., for liquid biopsy testing) can also be influenced by the individual's diagnosis.

The analysis considered prior reports conducted for other states with similar legislation. Other reviews identified the complexities of measuring the impact of this type of legislation, and cost estimates varied widely; one review

[xv] BerryDunn surveyed 10 insurance carriers in the Commonwealth (although Tufts Health Plan and Harvard Pilgrim Health Care recently merged, they are accounted for separately); responses represent five carriers and 79.9% coverage of members.

determined that estimated costs were immeasurable. Given the complexities, BerryDunn developed a tailored approach to estimate financial impact.[6,7,8,9,10,11]

To estimate the impact of increased coverage of biomarker testing, BerryDunn considered the differences in utilization patterns among carriers to inform whether there were meaningful coverage and utilization management differences for a given biomarker test.

5.2 Data Sources

The primary data sources used in the analysis are as follows:

- Input from legislative sponsors regarding the intended effect of the bill
- Survey of commercial carriers in the Commonwealth regarding descriptions of current coverage
- Interviews with medical experts, including a genetic counselor
- Massachusetts APCD
- Published scholarly literature, reports, and population data, cited as appropriate
- Benefit policies from other states

5.3 Steps in the Analysis

This section summarizes the analytic steps used to estimate the bill's impact on premiums.

1. **Estimated the marginal costs for insurers for expanded coverage of biomarker tests.**
   - **A.** Compiled an extensive list of biomarker procedure codes from carrier policies and literature research.
   - **B.** Used APCD data to calculate utilization per 1,000 members and unit cost by procedure code and by carrier.
   - **C.** Ranked carrier utilization per 1,000 by procedure code for each year from 2019 to 2021.
   - **D.** Averaged the carrier-specific ranking from 2019 to 2021 and determined the difference of the minimum and maximum of the average carrier ranks.
   - **E.** Removed procedure codes with a rank measure of less than three from Step 1 D.
   - **F.** Calculated average utilization per 1,000 over the three-year period (2019 to 2021) for the remaining procedure codes.
   - **G.** Constructed a coefficient of variation (CV) measure for all procedure codes remaining from Step E.
   - **H.** Determined the procedure codes that met a 25% CV threshold and a 75% CV threshold.
   - **I.** Calculated the impact of the potential increased utilization per 1,000 for each carrier for each set of procedure codes in Step H by taking the difference between the carrier's (lower) utilization per 1,000 for each procedure code and the 75th percentile (or second highest) utilization per 1,000 among all carriers for each procedure code.
   - **J.** Multiplied carrier-specific unit costs by procedure code from Step B with the corresponding utilization per 1,000 increases calculated in Step I and by 1,000 to derive the marginal cost for each set of procedure codes in Step H. (Used average unit cost across carriers when carrier-specific unit cost was unavailable.)
   - **K.** Calculated the PMPM impact for each set of procedure codes by dividing the marginal cost in Step J by carrier member months.

L. Developed a range of marginal cost PMPMs by setting the impact of the procedure codes for the 25% CV threshold as the high end of the range and the impact of the procedure codes for the 75% CV threshold as the low end of the range.
M. Calculated the best estimate mid scenario as the average of the low end and high end of the range from Step L.

2. **Calculated the impact of the projected claim costs on insurance premiums.**

A. Estimated the fully insured Commonwealth population under age 65 for the next five years (2025 – 2029).
B. Multiplied the PMPM incremental net cost of the mandate by the projected population estimate to calculate the total estimated marginal claims cost of the bill.
C. Estimated insurer retention (administrative costs, taxes, and profit) and applied the estimate to the final incremental claims cost calculated in Step 2B.

5.4 Assumptions and Limitations

Analytic Approach Considerations

Certain biomarker tests may enable health care providers to determine optimal or personalized treatments or could help avoid treatment options less likely to be effective. In such cases, these biomarker tests could reduce long-term medical costs, which could offset the costs associated with increased utilization of these biomarker tests. Consideration of such offsets is outside the scope of this analysis. Potential new tests and therapies—as well as future changes in clinical guidelines and practices regarding biomarker test usage—were not considered given the likelihood that carriers would update their biomarker tests' medical policies at a varying pace regardless of legislation. Given the large volume of biomarker tests and the volatility of costs for tests with low utilization rates, it is not feasible to tailor the analysis to individual biomarker tests. Instead, a broad, simplified measurement approach is necessary.

The analysis encompasses claims data from 2019 to 2021. It also considers biomarker tests that may have transitioned from investigational status to established clinical use during this period. The analysis integrated carriers' procedure codes with literature review and expert interview findings. The combined list of codes, while thorough, may have not included every potential applicable code. The impact of COVID-19 on utilization in 2020 and 2021 was not considered, as determining that impact is outside the scope of this analysis.

BerryDunn reviewed carriers' online benefits policies and procedures from other states to assess their coverage revisions following similar legislative language. Because policy and procedure revisions were inconsistent across carriers, it was not possible to definitively predict how Massachusetts carriers would respond if the legislation passed. Additionally, data to measure how changes in benefits policies and procedures impacted utilization in those states was unavailable.

The cost estimate did not incorporate any potential administrative impacts associated with the bill's requirement for shortened prior authorization time frames. The cost impact depends on carriers' current coverage status for each procedure code and potential coverage gaps across carriers and procedure codes. The claims data does not contain

sufficient clinical details to conduct such an analysis. It is also impractical to perform such analysis given the broad range of tests included in this mandate.

Coding Practices

Providers might initially order single- or double-gene tests but later update them to multigene panel tests once they reach the lab. This adjustment enables the lab to receive payment for the single- or double-gene tests, avoiding a situation in which no payment is received if the test was originally ordered as a multigene panel test. Consequently, the actual claims for multigene tests may be understated when queried from the APCD. However, given the pricing for multigene panel testing tends to be relatively comparable to that of single or limited gene testing,[12] the impact of this practice may be minimal, and even if the bill were to pass, the practice may still occur.

Procedure code modifiers provide supplementary information for carrier-instituted policy requirements and could, in some cases, reflect whether a test was conducted for screening or diagnostic purposes. However, modifiers may be used inconsistently in coding practices, and thus—due to variation of modifier usage across tests and medical coders—were not considered in this analysis.[13,14]

Insights From Carriers and Experts

BerryDunn's research revealed carrier concerns related to the "including, but not limited to [the three types of medical evidence]" language in the bill. BerryDunn's assumption was that providers would adhere to reputable sources of medical evidence when ordering medically appropriate biomarker testing, aligned with the legislative sponsors' intended purpose of the bill. This analysis is based on this interpretation and the legislative sponsors' stated intent.

Experts consulted for this review highlighted that obtaining a diagnosis for a rare disease can take more than six years, and genetic testing has the potential to significantly reduce this time frame. However, this review does not factor in any potential cost savings resulting from obtaining an earlier definitive diagnosis. Experts also noted that some individuals may opt to pay for biomarker tests out of pocket, and certain facilities may absorb the cost for biomarker testing without billing for them; both situations would not be captured in the claims data.

6.0 Analysis

This section describes the calculations outlined in the previous section in more detail. The analysis includes a best estimate middle-cost scenario, a low-cost scenario, and a high-cost scenario using more conservative assumptions. The analysis section proceeds as follows: Section 6.1 describes the steps used to calculate the incremental cost of the bill. Section 6.2 projects the fully insured population age 0 to 64 in the Commonwealth over the years 2025 – 2029. Section 6.3 calculates the total marginal medical expense. Section 6.4 adjusts these projections for carrier retention to arrive at an estimate of the bill's effect on premiums for fully insured plans.

6.1 Incremental Cost of Expanded Coverage of Biomarker Tests

To estimate the impact of increased coverage of biomarker testing, BerryDunn considered the differences in utilization patterns among carriers to inform whether there were meaningful coverage and utilization management differences for a given biomarker test.

Due to the broad coverage of this mandate, BerryDunn started with an extensive list of approximately 3,000 procedure codes that includes a wide range of biomarker tests, such as genetic tests, whole-genome sequencing, and molecular or non-molecular biomarker tests. BerryDunn then reviewed these procedure code descriptions and excluded codes associated with preventive services, codes already covered by existing legislation, and codes that reflect consistently covered common biomarker tests (e.g., complete blood count [CBC]), bringing the total procedure codes to approximately 2,000. BerryDunn then removed procedure codes with extremely low utilization, representing 0.1% of the total biomarker test spending,[xvi] resulting in a final list of approximately 1,300 procedure codes. Given cost differences between carriers due to contracting, BerryDunn looked at utilization per 1,000 metric by procedure code and carrier over a three-year period (2019 – 2021).

BerryDunn made a conservative assumption that, under the influence of this mandate, carriers with more limited coverage or more restrictive utilization management practices would expand their coverage or modify their utilization management to the extent that they would match the 75th percentile level of utilization among their peer carriers. BerryDunn used a ranking method to identify procedure codes with consistent year-over-year utilization patterns by carrier, as utilization differences in these codes are more likely to be driven by differences in coverage between carriers, not random volatility. However, consistent year-over-year utilization patterns between carriers could be due to other forces, such as demographic or morbidity differences in carrier populations.

BerryDunn used a CV measure to identify procedure codes with a significant variance in utilization between carriers, making it more likely the difference was driven by carrier coverage and utilization management practices. The financial impact was calculated by applying a carrier-specific unit cost to the anticipated increase in carrier utilization by procedure code to align with the 75th percentile level of utilization for that procedure code. BerryDunn then calculated the range of the financial impact of this mandate by selecting a 25% CV measure as the upper bound threshold and a 75% CV measure as the lower bound threshold.

BerryDunn estimated the low scenario and high scenario PMPM impact of expanded biomarker test coverage with methodologies described in Section 5.3. The percentage of procedure codes included in each scenario—together with the percentage of total CY21 spending for the procedure codes included—are listed in Table 1. Certain high-volume procedure codes did not demonstrate meaningful variance in utilization, and accordingly they were excluded in the impact calculation. As a result, the selected codes represented a lower percentage in total spending in each scenario. BerryDunn created the mid scenario (shown in Table 2) by taking the average PMPM impacts of the high and low scenarios.

[xvi] For the majority of these procedure codes, respondent carriers did not explicitly state there is no coverage.

Table 1. Marginal Costs for Insurers for Expanded Coverage of Biomarker Tests

	PMPM IMPACT	% OF PROCEDURE CODES INCLUDED	% OF SPENDING FOR PROCEDURE CODES INCLUDED
Low Scenario	$0.29	13%	3%
High Scenario	$0.85	43%	15%

BerryDunn trended the PMPM impact from Table 1 from CY21 to CY24 and forward using the long-term average national projection for cost increases to physician and clinical services (calculated at 5.0%[15]).

Table 2. Projected PMPM

	2024	2025	2026	2027	2028	2029
Low Scenario	$0.34	$0.35	$0.37	$0.39	$0.41	$0.43
Mid Scenario	$0.66	$0.69	$0.73	$0.76	$0.80	$0.84
High Scenario	$0.98	$1.03	$1.08	$1.14	$1.20	$1.26

6.2 Projected Fully Insured Population in the Commonwealth

Table 3 shows the Commonwealth's fully insured population (ages 0 to 64) projected for the next five years. Appendix A describes the sources of these values.

Table 3. Projected Fully Insured Population in the Commonwealth, Ages 0 – 64

YEAR	2025	2026	2027	2028	2029
Total (0 – 64)	2,163,026	2,240,830	2,275,249	2,273,358	2,271,701

6.3 Total Marginal Medical Expense

The analysis assumes the mandate would be effective for policies issued and renewed on or after January 1, 2025. Based on an assumed renewal distribution by month, by market segment, and by the Commonwealth market segment composition, 72.1% of the member months exposed in 2025 will have the proposed mandate coverage in effect during calendar year 2025. The annual dollar impact of the mandate in 2025 was estimated using the estimated PMPM and applying it to 72.1% of the member months exposed.

Multiplying the total estimated PMPM cost by the projected fully insured membership over the analysis period results in the total cost (medical expense) associated with the proposed requirement, shown in Table 4.

Table 4. Estimated Marginal Claims Cost

	2025	2026	2027	2028	2029
Low Scenario	$6,613,469	$9,980,868	$10,644,263	$11,170,730	$11,724,442
Mid Scenario	$12,970,970	$19,575,436	$20,876,551	$21,909,108	$22,995,101
High Scenario	$19,328,471	$29,170,004	$31,108,839	$32,647,486	$34,265,759

6.4 Carrier Retention and Increase in Premium

Assuming an average retention rate of 13.1%—based on CHIA's analysis of administrative costs and profit in the Commonwealth[16]—the increase in medical expense was adjusted upward to approximate the total impact on premiums. Table 5 displays the result.

Table 5. Estimate of Increase in Carrier Premium Expense

	2025	2026	2027	2028	2029
Low Scenario	$7,607,266	$11,480,680	$12,243,764	$12,849,342	$13,486,259
Mid Scenario	$14,920,101	$22,517,013	$24,013,644	$25,201,363	$26,450,546
High Scenario	$22,232,936	$33,553,345	$35,783,525	$37,553,384	$39,414,832

7.0 Results

7.1 Five-Year Estimated Impact

For each year in the five-year analysis period, Table 6 displays the projected net impact of the proposed language on medical expenses and premiums using a projection of the Commonwealth's fully insured membership. Note that the relevant provisions are assumed effective January 1, 2025.[17]

Table 6 displays projected membership based on a population projection. A 72.1% adjustment factor to the first year (2025) implementation is also applied to account for ramp up in implementation.

Finally, the impact of the proposed law on any one individual, employer group, or carrier may vary from the overall results, depending on the current level of benefits each receives or provides, and on how the benefits will change under the proposed language.

Table 6. Summary Results

	2025	2026	2027	2028	2029	WEIGHTED AVERAGE	FIVE-YEAR TOTAL
Average Members (000s)	2,163	2,241	2,275	2,273	2,272		
Medical Expense Low ($000s)	$6,613	$9,981	$10,644	$11,171	$11,724	$10,596	$50,134
Medical Expense Mid ($000s)	$12,971	$19,575	$20,877	$21,909	$22,995	$20,783	$98,327
Medical Expense High ($000s)	$19,328	$29,170	$31,109	$32,647	$34,266	$30,969	$146,521
Premium Low ($000s)	$7,607	$11,481	$12,244	$12,849	$13,486	$12,189	$57,667
Premium Mid ($000s)	$14,920	$22,517	$24,014	$25,201	$26,451	$23,906	$113,103
Premium High ($000s)	$22,233	$33,553	$35,784	$37,553	$39,415	$35,623	$168,538
PMPM Low	$0.41	$0.43	$0.45	$0.47	$0.49	$0.45	$0.45
PMPM Mid	$0.80	$0.84	$0.88	$0.92	$0.97	$0.89	$0.89
PMPM High	$1.19	$1.25	$1.31	$1.38	$1.45	$1.32	$1.32
Estimated Monthly Premium	$593	$609	$625	$642	$660	$626	$626
Premium % Rise Low	0.069%	0.070%	0.072%	0.073%	0.075%	0.072%	0.072%
Premium % Rise Mid	0.134%	0.138%	0.141%	0.144%	0.147%	0.142%	0.142%
Premium % Rise High	0.200%	0.205%	0.210%	0.214%	0.219%	0.211%	0.211%

7.2 Impact on GIC

The proposed mandate would apply to self-insured plans operating for state and local employees by the GIC. The benefit offerings of GIC plans are similar to most other commercial plans in Massachusetts. This section describes the results for the GIC.

Findings from BerryDunn's carrier survey indicate that benefit offerings for GIC and other commercial plans in the Commonwealth are similar. For this reason, the cost of the bill for GIC will likely be similar to the cost for other fully insured plans in the Commonwealth.

BerryDunn assumed the proposed legislative change will apply to self-insured plans that the GIC operates for state and local employees, with an effective date of July 1, 2025. Because of the July effective date, the results in 2025 are approximately one-half of an annual value. Table 7 breaks out the GIC's self-insured membership, as well as the corresponding incremental medical expense.

Table 7. GIC Summary Results

	2025	2026	2027	2028	2029	WEIGHTED AVERAGE	FIVE-YEAR TOTAL
GIC Self-Insured							
Members (000s)	312	312	311	310	310		
Medical Expense Low ($000s)	$662	$1,388	$1,455	$1,525	$1,600	$1,474	$6,629
Medical Expense Mid ($000s)	$1,298	$2,721	$2,853	$2,992	$3,138	$2,891	$13,002
Medical Expense High ($000s)	$1,934	$4,055	$4,252	$4,458	$4,676	$4,307	$19,375

Endnotes

[1] H.B. 1074. An Act relative to cancer patient access to biomarker testing to provide appropriate therapy. Accessed November 29, 2023. **https://malegislature.gov/Bills/193/H1074.**

[2] S.B. 689. An Act relative to patient access to biomarker testing to provide appropriate therapy. Accessed November 29, 2023. **https://malegislature.gov/Bills/193/S689.**

[3] Senator Susan Moran and Representative Meghan Kilcoyne. Sponsor Questions Responses. December 26, 2023.
[4] The bill, as currently written, does not include Chapter 176A. However, the Sponsors confirmed that the bill's intent is to include Chapter 176A.

[5] M.G.L. c.175 §110L, c.176A §8X, c.176B §4X, c.176G §4P.

[6] Rocha, A. Cadwell, R., Novak, D., Hooper, M. A Report to the Joint Standing Committee on Health Coverage, Insurance and Financial Services of the 131st Maine Legislature Review and Evaluation of LD 1577. An Act to Require Health Insurance Coverage for Biomarker Testing. January 2024. Accessed March 20, 2024. **https://www.maine.gov/pfr/sites/maine.gov.pfr/files/inline-files/LD-1577-Biomarker-Report_0.pdf.**

[7] California Health Benefits Review Program. Key Findings Analysis of California Senate Bill 535 Biomarker Testing. Summary to the 2021–2022 California State Legislature, April 20, 2021. Accessed March 20, 2024. **https://www.chbrp.org/sites/default/files/bill-documents/SB535/sb535-KeyFindings.pdf.**

[8] Dieguez, G. Carioto, J. The landscape of biomarker testing coverage in the United States. February 15, 2022. Accessed March 20, 2024. **https://www.milliman.com/-/media/milliman/pdfs/2022-articles/2-16-22_the_landscape_of_biomarker_testing_coverage_in_the_us.ashx.**

[9] Louisiana Legislative Fiscal Office. Fiscal Note. S.B. 104. Mandates Coverage of Biomarker Testing. May 18, 2023. **https://www.legis.la.gov/legis/ViewDocument.aspx?d=1323594.**

[10] Legislative Services Agency, Serving the Iowa Legislature. Fiscal Note, Fiscal Services Division. HF 2492 – Biomarker Testing, Health Insurance (LSB6095HV). February 21, 2024. **https://www.legis.iowa.gov/docs/publications/FN/1447125.pdf.**

[11] Evaluation of HF 4899: Requirement for Health Plans to Provide Coverage for Biomarker Testing Report to the Minnesota Legislature Pursuant to Minn. Stat. § 62J.26. Minnesota Department of Commerce. January 2023. Accessed March 21, 2024. **https://mn.gov/commerce-stat/pdfs/Comm-AIR-HF4899-EvalRprt-508.pdf.**

[12] Lynce, F., & Isaacs, C. (2016). How Far Do We Go With Genetic Evaluation? Gene, Panel, and Tumor Testing. American Society of Clinical Oncology educational book. American Society of Clinical Oncology. Annual Meeting, 35, e72–e78. Accessed February 21, 2024. **https://doi.org/10.1200/EDBK_160391.**

[13] Robeznieks, A. American Medical Association. Setting the record straight on proper use of modifier 25. August 17, 2023. Accessed February 29, 2024. **https://www.ama-assn.org/practice-management/cpt/setting-record-straight-proper-use-modifier-25.**

[14]Should You Modify Your Use of Modifiers? Family Practice Management 1999. Accessed February 29, 2024. **https://www.aafp.org/pubs/fpm/issues/1999/0500/p18.html.**

[15] U.S. Centers for Medicare & Medicaid Services, Office of the Actuary. National Health Expenditure Projections. "Table 7, Physician and Clinical Services Expenditures; Aggregate and per Capita Amounts, Percent Distribution and Annual Percent Change by Source of Funds: Calendar Years 2015-2031; Private Insurance." Accessed March 28, 2024. **https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected.html**

[16] Massachusetts Center for Health Information and Analysis. Annual Report on the Massachusetts Health Care System, March 2024. Accessed March 25, 2024. **https://www.chiamass.gov/assets/2024-annual-report/2024-Annual-Report.pdf.**

[17] With an assumed start date of January 1, 2025, dollars were estimated at 72.1% of the annual cost, based upon an assumed renewal distribution by month (Jan through Dec) by market segment and the Massachusetts market segment composition.

Appendix A: Membership Affected by the Proposed Language

Membership potentially affected by proposed mandated change criteria includes Commonwealth residents with fully insured, employer-sponsored health insurance (ESI) issued by a Commonwealth-licensed company (including through the GIC); nonresidents with fully insured, ESI issued in the Commonwealth; Commonwealth residents with individual (direct) health insurance coverage; and lives covered by GIC self-insured coverage. Other populations within the self-insured commercial sector are excluded from the state coverage mandate due to federal Employee Retirement Income Security Act (ERISA) protections of self-insured plans.

The unprecedented economic circumstances due to COVID-19 add particular challenges to the estimation of health plan membership. The membership projections are used to determine the total dollar impact of the proposed mandate in question; however, variations in the membership forecast will not affect the general magnitude of the dollar estimates. Given the uncertainty, BerryDunn took a simplified approach to membership projections. These membership projections are not intended for any purpose other than producing the total dollar range in this study. Further, to assess how recent volatility in commercial enrollment levels might affect these cost estimates, please note that the PMPM and percentage of premium estimates are unaffected because they are per-person estimates, and the total dollar estimates will vary by the same percentage as any percentage change in enrollment levels.

CHIA publishes monthly enrollment summaries in addition to its biannual enrollment trends report and supporting databook (enrollment-trends-Data Through September 2023 databook[1] and Monthly Enrollment Summary – June 2021),[2] which provide enrollment data for Commonwealth residents by insurance carrier for most carriers, excluding some small carriers. CHIA uses supplemental information beyond the data in the Massachusetts APCD to develop its enrollment trends report and adjust the resident totals from the Massachusetts APCD. CHIA-reported enrollment data formed the base for membership projections. For the base year 2019 in the membership projection, the 2019 Massachusetts APCD and published 2019 membership reports available from the Massachusetts Division of Insurance (DOI) [3,4] were used to develop a factor to adjust the CHIA enrollment data for the few small carriers not present in the enrollment report. The adjustment was trended forward to 2022 and applied to CHIA enrollment data.

In 2021, commercial, fully insured membership was 5.6% less than in 2019, with a shift to both uninsured and MassHealth coverage. As part of the public health emergency (PHE), members were not disenrolled from MassHealth coverage even when they no longer passed eligibility criteria. Shortly before the PHE ended, redetermination efforts began in April 2023 and are anticipated to occur over a 12-month period. Many of the individuals subject to redetermination will no longer be eligible for MassHealth coverage. It is anticipated that a portion of individuals losing coverage will be eligible for coverage in individual ACA plans and ESI. The impact of COVID-19 on the fully insured market over the five-year projected period (2025 – 2029) is uncertain. It is not anticipated that enrollment levels in commercial insurance will immediately return to 2019 levels.

The number of MassHealth members moving to commercially insured plans after the unwinding of the PHE was estimated by a study performed by the National Opinion Research Center (NORC) at the University of Chicago.[5] BerryDunn used these results and assumed MassHealth disenrollment occurs uniformly from April 2023 to March 2024. BerryDunn further assumed that the commercial market will return to pre-pandemic enrollment levels by the end of the projection period in December 2027.

The distribution of members by age and gender was estimated using Massachusetts APCD population distribution ratios and was checked for reasonableness and validated against U.S. Census Bureau data.[6] Membership was projected from 2025 to 2029 using Massachusetts Department of Transportation population growth rate estimates by age and gender.[7]

Projections for the GIC self-insured lives were developed using the GIC base data for 2018 and 2019, which BerryDunn received directly from the GIC, as well as the same projected growth rates from the Census Bureau used for the Commonwealth population. Breakdowns of the GIC self-insured lives by gender and age were based on Census Bureau distributions.

Endnotes

[1] Center for Health Information and Analysis. Estimates of fully insured and self-insured membership by insurance carrier. Accessed March 19, 2024. **https://www.chiamass.gov/enrollment-in-health-insurance/.**

[2] Ibid.

[3] Massachusetts Department of Insurance. HMO Group Membership and HMO Individual Membership Accessed March 21, 2023. **https://www.mass.gov/info-details/hmo-membership-reports#2019-hmo-membership-reports-.**

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