MILLIMAN REPORT

Biomarker Testing Coverage Analysis

Prepared for the Colorado Division of Insurance

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Introduction

Under Colo. Rev. Stat. § 10-16-155, the Colorado Division of Insurance (DOI) under the Colorado Department of Regulatory Agencies (DORA) has retained Milliman, Inc. ("Milliman"), a global actuarial consulting firm, to perform actuarial reviews of legislative proposals that may impose a new health benefit coverage requirement on health benefit plans or reduce or eliminate coverage required under health benefit plans. The legislative requirements impact the individual, small group, and large group plans regulated by the Colorado Department of Insurance. The actuarial review must consider the predicted effects of the legislative proposal on the affected markets during the one, five, and ten years immediately following the effective date of the legislative proposal, or during another time period following the effective date of the legislative proposal if such consideration is more actuarially feasible, including:

- An estimate of the number of Colorado residents who will be directly affected by the legislative proposal;
- Estimates of changes in the rates of utilization of specific health-care services that may result from the legislative proposal;
- Estimates of changes in consumer cost sharing that would result from the legislative proposal;
- Estimates of changes in health benefit plan premiums charged to covered persons or employers, in individual, small group, and large group markets, that would result from the legislative proposal;
- An estimate of the out-of-pocket health-care cost changes associated with the legislative proposal;
- An estimate of the potential long-term health-care cost changes associated with the legislative proposal;
- Identification of any potential health benefits for individuals or communities that would result from the legislative proposal;
- Information concerning who would benefit from any cost changes and benefit expansions and any disproportionate effects it may have on protected classes, as available; and
- To the extent practicable, the social and economic impacts of the legislative proposal, including information concerning who would benefit from cost changes, and any disproportion effects and a qualitative analysis of the impacts of the legislative proposal.

At the request of the DOI, Milliman was asked to provide an analysis of a legislative proposal regarding the coverage of various biomarker testing requirements, House Bill 23-1110. The proposed legislation requires all individual and group health benefit plans to provide coverage for biomarker testing for diagnosis, treatment, appropriate management, or ongoing monitoring of a covered person's disease or condition when the testing is supported by medical and scientific evidence.

The proposed legislation defines biomarker testing as an analysis of a patient's tissue, blood, or other biospecimen for the presence of an indicator of normal biological processes, pathogenic processes, or pharmacologic responses to a specific therapeutic intervention. It includes but is not limited to single-analyte tests, multi-plex panel tests, protein expression, and whole exome, whole genome, and whole transcriptome sequencing.

Executive Summary

Biomarker testing has wide ranging applications and spans a large number of specific services, including the screening, diagnosis, treatment, appropriate management, and ongoing monitoring across many different conditions. The use of biomarker testing for the screening, diagnosis, treatment, and monitoring of various cancers has been integrated into clinical guidelines and shown to shorten time to appropriate treatment (Lim et al. 2015**;** Bergman et al. 2020). Pharmacogenetics have also been shown to reduce the time it takes for the patient to get appropriate treatment (Bergman et al 2020).

There are current gaps in the evidence base on the application and efficacy of biomarker testing for racial and ethnic minorities due to underrepresentation in clinical trials and genomic databases and disproportionate utilization of genomic testing across underrepresented groups (Jooma et al 2019). Limited participation in clinical trials will continue to limit the generalizability of research, leading to the data on the benefits and treatment decisions related to genetic testing being applied unequally across these populations, further exacerbating disparities. Studies have also found there are existing disparities in the demand, utilization and availability of biomarker testing by race, ethnicity, age, socio-economic status, and geographic location (McAlarnen et al. 2021; Khoury et al. 2022; Shaaban and Yi 2023; Williams et al. 2018; Norris et al 2020; Johnson et. al. 2014; Mileham et al. 2022; Berninger et al. 2021).

The medical and scientific evidence standard to be used as the basis of coverage policies is not defined in the proposed legislation. This allows carriers to select which nationally recognized clinical practice guidelines will be used as the basis of their coverage determinations. This is aligned with how carriers currently determine their coverage policies. A December 2023 coverage survey of fully-insured individual, small group, and large group carriers in Colorado indicated that carriers cover 100% of biomarker tests impacted by the proposed legislation. This suggests the proposed legislation will not increase utilization through coverage expansion, resulting in no financial impact of expansion of coverage.

Though the survey responses indicate near complete coverage for biomarker tests available at the time of this report for which coverage would be required under the proposed legislation, carriers may review the body of evidence and update coverage policies more frequently as a result of this legislation, resulting in an increase in the utilization of biomarker tests. In addition, the legislation may lead to increased awareness and consideration of biomarker testing by patients and providers. To account for these factors, we performed a financial analysis assuming a 1% increase in current utilization. The results of the financial analysis are dependent on this utilization impact assumption. We also assumed the average cost of the additional utilization is the same as the average cost of currently covered biomarker tests.

The estimated 2025 average allowed cost for a biomarker test is between $175 and $390 and the average patient cost sharing for a biomarker test is between $60 and $160. The estimated 1 year, 5 year cumulative, and 10 year cumulative premium impacts for the fully-insured commercial market are $245,000, $1,707,000, and $5,400,000 respectively, or $0.02, $0.03, and $0.04 per member per month (PMPM) respectively. This is a 0.004%, 0.005%, and 0.006% change to premium. Due to the breadth and complexity of the topic, financial impacts associated with treatment decisions based on the results of the assumed increase in utilization of biomarker tests were not quantified. The resulting financial impacts only include the cost of the biomarker tests resulting from the assumed increase in utilization of biomarker tests at the trended average cost of biomarker tests available at the time of this report.

	1 YEAR IMPACT	5 YEAR CUMULATIVE IMPACT	10 YEAR CUMULATIVE IMPACT
All Commercial - Total Dollars	**$245,000**	**$1,707,000**	**$5,400,000**
All Commercial - PMPM	**$0.02**	**$0.03**	**$0.04**
All Commercial – Percent Change	**0.004%**	**0.005%**	**0.006%**

Background

BIOMARKER TESTING

Biomarker testing, as defined by the proposed coverage requirement, is an analysis of a patient's tissue, blood, or other biospecimen for the presence of an indicator of normal biological processes, pathogenic processes, or pharmacologic responses to a specific therapeutic intervention. Biomarker testing includes but is not limited to single-analyte tests, multi-plex panel tests, protein expression, and whole exome, whole genome, and whole transcriptome sequencing.

Biomarker testing has wide ranging applications and spans a large number of specific services, including the screening, diagnosis, treatment, appropriate management, and ongoing monitoring across many different conditions. The proposed coverage requirement does not include required coverage of screening tests, genetic testing for inherited risk or over-the-counter genetic tests; these tests are excluded from consideration in this analysis. Screening or genetic tests for inherited risk in the context of pregnancy are also excluded.

Once the exclusions are applied, there are over 700 biomarker test billing codes considered for this analysis. The biomarker tests reported by these billing codes can be classified into one or more of the three clinical use categories listed below.

- Oncology Testing – Can be used to identify certain types of cancer, how likely a cancer may spread, what courses of treatment may be appropriate, and to what degree a cancer treatment is working.
- Pharmacogenomic testing - An approach to drug prescribing using genetic information to determine whether certain drugs will be safe or effective for an individual based on their genetic profile, including minimizing side effects and adverse drug reactions.
- Testing not related to pharmacogenomics or oncology – This category includes biomarker testing to diagnose, monitor, and evaluate the response to treatment for conditions other than cancer.

In our review of the literature, we found that evidence for biomarker testing is most mature for cancer screening, diagnostics and treatment. Evidence exists for other applications of biomarker testing, but for many non-cancer conditions and pharmacogenomic uses it is still emerging. Therefore, literature cited throughout the report predominantly relies on cancer related studies.

POTENTIAL HEALTH BENEFITS

As mentioned previously, cancer is the most studied application for biomarker testing. The use of biomarker testing for the screening, diagnosis, treatment, and monitoring of various cancers has been integrated into clinical guidelines and shown to shorten time to appropriate treatment (Lim et al. 2015**;** Bergman et al. 2020), have higher response rates and improve progression-free survival times (Schwaederle et al. 2016). Pharmacogenetics have also shown to reduce time to appropriate treatment (Bergman et al. 2020).

There are gaps in the current evidence base on the application and efficacy of biomarker testing for racial and ethnic minorities due to underrepresentation in clinical trials and genomic databases. In a summary of the state of health equity in genomic medicine, Jooma et al. (2019) cite multiple studies with study samples comprised of mainly people with European ancestry. The biased sample in these studies led to lower predictive power for other populations or resulted in missing critical genomic variants only found in populations with non-European ancestry. The authors recommend improving clinical trial recruitment to include a more diverse population. Pharmacogenetics have been used to determine the appropriate dosage of the anti-coagulation drug, Warfarin, based on genetic variation in study samples; proper dosing for African American and Hispanic populations has been a challenge due to the limited representation of these populations in studies on dosing (Bress et al. 2012; Duconge et al. 2015).

McAlarnen et al. (2021) notes that the disproportionate utilization of genomic testing across underrepresented groups and limited participation in clinical trials will continue to limit the generalizability of research, leading to the data on the benefits and treatment decisions related to genetic testing being applied unequally across these populations, further exacerbating disparities.

INSURANCE COVERAGE AND UTILIZATION OF BIOMARKER TESTING

In December 2023, insurance carriers in Colorado with individual, small group, or large group enrollment were surveyed by the Colorado DOI about their coverage of biomarker testing for the diagnosis, treatment, appropriate management, or ongoing monitoring of a covered person's disease or condition when the testing is supported by medical and scientific evidence.

Biomarker testing is a complex topic. To perform a thorough review, the survey would have needed to ask for the coverage policy for each of the 700 biomarker tests considered for this study. Each test would require a detailed response as coverage is dependent on other conditions being met. A study of this magnitude could not be performed given the time and budget constraints.

Instead, carriers were asked to respond if they covered no, some, or all biomarker testing for diagnosis, treatment, appropriate management, or ongoing monitoring of a covered person's disease or condition when the testing is supported by medical and scientific evidence or as having coverage when medically necessary. If they responded that they covered some biomarker testing, they were asked to estimate the percentage of tests that are covered by various sources of medical and scientific evidence categories. The survey can be found in Appendix A.

We received responses from nine carriers comprising approximately 70% of fully insured individual, small group, and large group enrollment in Colorado. Some carriers reported that they cover all biomarker tests. All other carriers reported covering some biomarker tests but indicated that enrollees have 100% coverage under each medical and scientific evidence category. The survey results suggest that biomarker tests are widely covered, however there may be some biomarker tests not covered as defined by the proposed legislation.

Panel tests are biomarker tests that test more than one biomarker from a sample at a time. Some carriers noted that panel tests are not covered if some of the biomarkers included on the panel are not supported by medical or scientific evidence to evaluate or treat the enrollee. The panel would not be covered because these additional biomarker tests are not considered medically necessary. The individual biomarker tests that are supported by medical or scientific evidence to treat the enrollee are covered. Exhibit 1 shows the number of biomarker tests performed in 2022 for every 1,000 enrollees as summarized from the Colorado All Payer Claims Database.

EXHIBIT 1: BIOMARKER TESTING UTILIZATION PER 1,000, 2022

	INDIVIDUAL	SMALL GROUP	LARGE GROUP
Oncology biomarker test	35.4	25.7	27.9
Pharmacogenomic biomarker test	6.4	4.8	6.6
Non-oncology, non-pharmacogenomic biomarker test	55.1	53.8	70.8

PUBLIC DEMAND, DISPARITY, & AVAILABILITY OF SERVICES

Though survey responses described above indicate near complete coverage of biomarker tests for which coverage would likely be required under the proposed legislation, there are existing disparities in the demand, utilization and availability of biomarker testing by race, ethnicity, age, socio-economic status, and geographic location. These disparities may persist without efforts to comprehensively address additional barriers to adequate prevention, diagnostics, treatment, and monitoring of cancer risks.

There are well-documented disparities in the incidence and health outcomes of conditions that utilize biomarker testing for prevention, diagnostics, treatment, or monitoring. For example, compared to the white population within the US, the American Indian/Alaska native population has an 80% higher incidence rate of kidney cancer (AACR 2022), the Hispanic population's mortality rate from liver cancer is 50% higher (AACR 2022) and despite incidence rates of breast cancer being approximately equal between Black and white women (126.9 per 100,000 versus 133.3 per 100,000) Black women die at a much higher rate than white women (27.6 deaths per 100,000 versus 19.7 deaths per

100,000) (National Cancer Institute, 2024). When looking at all cancer in aggregate, males in the US have a higher overall incidence and mortality rate as compared to females (Siegel et al. 2022).

Exhibit 2 describes the aggregate cancer incidence and mortality rates by race/ethnicity, sex and age for Colorado and Colorado demographic population characteristics There is variation in cancer incidence and mortality rates by age, sex, and race/ethnicity. Colorado males have higher overall cancer incidence than females. White Coloradans have the highest incidence rate of cancer, but Black Coloradans have the highest mortality rate. Asian/Pacific Islander Coloradans have the lowest incidence and mortality rates. Results are for the total cancer rates, variation in rates among demographic groups will vary by specific cancer diagnoses.

EXHIBIT 2: COLORADO CANCER INCIDENCE AND MORTALITY RATE (CASES PER 100,000) BY DEMOGRAPHIC CATEGORY

	INCIDENCE RATE	MORTALITY RATE	COUNT (%)
Sex			
Male	410.8	152.8	2,960,896 (50.7%)
Female	381.8	113.1	2,879,030 (49.3%)
Race/Ethnicity			
White Alone	397.2	130.4	3,793,270 (65%)
Black Alone	382.2	154.4	220,756 (3.8%)
American Indian/Alaska Native Alone	362.6	106.4	23,389 (0.4%)
Asian/Pacific Islander Alone	259.7	88.1	188,997 (3.2%)
Hispanic or Latino (any race)	350.1	127.8	1,314,962 (22.5%)
Some Other Race Alone			29,798 (0.5%)
Two or More Races			268,754 (4.6%)
Age (years)			
<50	94.4	11.4	3,884,429 (66.5%)
50+	1173.8	440.4	1,955,497 (33.5%)
<65	194.4	35.7	4,924,265 (84.3%)
65+	1755.8	781.7	915,661 (15.7%)
Total Colorado Population	**391.7**	**130.0**	**5,839,926**

Notes:

Source: State Cancer Profiles. January 2024. Accessed February 23, 2024. https://statecancerprofiles.cancer.gov/.

Source: "ACS Demographic and Housing Estimates." American Community Survey, 2022 ACS 1-Year Estimates Data Profiles. U.S. Census Bureau. Accessed February 23, 2024. https://data.census.gov

Race / Ethnicity

Studies have reported racial and ethnic disparities in the utilization of cancer related screening and immunotherapy. For example, a retrospective study on disparities in biomarker testing and clinical trial enrollment found next generation sequencing testing before first line treatment differed significantly between white and Black patients with non-small-cell lung cancer (36.6% *v* 29.7%, $P < .0001$) or metastatic colorectal cancer (white 51.6%; Black 41.8%, $P < .0001$) (Bruno et al. 2022). In another review on health equity in genomics and precision medicine, authors note that patients of racial and ethnic minorities with breast cancer, colorectal cancer and familial hypercholesterolemia are less likely to receive referrals to genetic specialists or receive genetic testing as compared to white patients (Khoury et al. 2022). Similar disparities in access and utilization have been reported for pharmacogenomics testing (Shaaban and Yi 2023).

Studies have also found lower awareness of biomarker testing among racial and ethnic minorities, which may drive some of the disparities in utilization (Williams et al. 2018; Rosas et al. 2020; Saulsberry and Terry 2013). For example, in a qualitative study of the awareness of genetic testing for breast cancer, authors found African American, Latina and Asian women had lower awareness of genetic testing as compared to white women (Williams et al 2018). In another qualitative study of the perception of precision medicine, authors found that African American and American Indian patients had mistrust in genetic testing and precision health research (Rosas et al. 2020). In a review of biomarker testing challenges in breast and ovarian cancers, (McAlarnen et al. 2021) summarized results across studies that found white study participants had higher awareness than Hispanic, African American or Asian participants and that distrust related the use of genomic information was higher among racial and ethnic minorities.

Age

Studies have reported differences in biomarker testing by age. Younger patients have higher rates of utilization of biomarker testing in cancer treatment than older patients in studies of utilization of biomarker testing and precision medicine in colorectal cancer (Papke et al. 2022; Greenbaum et al. 2017). In a study of a biomarker test that detects a mutation and informs treatment for colorectal cancer, patients older than age 65 years were much less likely to be tested for a genetic mutation (odds ratio = 0.22) as compared to 40-64 year olds (odds ratio = 0.62) or 22-39 year olds (odds ratio= 1.0, reference group) (Greenbaum 2017). Authors note that the disparity might be due to patient comorbidities, poor performance status and shorter life-expectancy, or a patient's refusal of treatment.

Socio-economic status

Differences in biomarker utilization across income status have also been reported. In a 2020 meta-analysis and systematic literature review that pooled 27 studies on socio-economic inequalities in biomarker and precision medicine utilization, authors found that patients with lower socio-economic status were less likely to receive predictive biomarker testing for cancers (odds ratio = 0.86) and to receive biological and precision therapies (odds ratio = 0.82) relative to those with higher socio-economic status (Norris et al. 2020). Insurance coverage type was not addressed in this meta-analysis, but many studies included were of Medicare populations or from disease registries that did not note coverage type only employment and income levels (Norris et al. 2020). Similar results were found in a study of biomarker testing for advanced colorectal cancer (Papke et al. 2022) and pharmacogenomics (Shaaban and Yi 2023). Papke et al. (2022) did not find an association between testing rates and insurance coverage type, but did find a relationship between income level and testing rates.

Geography

Geographic differences in the incidence of conditions for which biomarker tests are supported by evidence and proximity to appropriate healthcare resources can also influence the availability and use of biomarker tests.

Rates of biomarker testing have also been found to be lower in rural areas as compared to urban settings. In one retrospective study of non-small cell lung cancer from the Georgia comprehensive Cancer registry, people living in rural and suburban areas were less likely to receive guideline recommended treatment for lung cancer as compared to people living in urban areas (Johnson et. al 2014). Similar disparities have been reported in colorectal cancer (Noll et al. 2018), breast cancer (Kolor et al. 2017) and other lung cancer studies (Mileham et al. 2022). Utilization of pharmacogenomics testing has also found to be limited in rural settings (Shaaban and Ji 2023). In Colorado, 12.5% of residents live in rural areas according to 2020 US American Community Survey (ACS) estimates (https://www.ruralhealthinfo.org/states/colorado).

Shortages of genetic counselors are predicted nationally (Jooma et al. 2019; Hoskovec et al. 2018), but are more pronounced in rural areas (Villegas et al. 2019, Berninger et al. 2021).

Clinical barriers

Biomarker testing and precision medicine are rapidly evolving clinical practices. Low genomic literacy, including the familiarity of guidelines and protocols and ability to interpret and communicate test results, have been cited in studies as a barrier to accessing appropriate and timely care (Boehmer et al. 2021; Duarte et al. 2021; Wilson et al. 2018).

Differences in rates of biomarker testing have been observed across care settings. Biomarker testing for advanced colorectal cancer at community programs (46.6% probability) is generally lower than at academic medical centers or

NCI designated cancer centers (62.8% probability) (Papke et al. 2022). In a 2018 survey of oncology pulmonologists, 48% of community clinicians reported using biomarker testing as compared to 73% of academic clinicians (Boehmer et al. 2021).

As noted above, a workforce shortage of genetic counselors is reported nationally (Jooma et al. 2019; Hoskovec et al. 2018) and is most acute in rural areas (Villegas et al. 2019 , Berninger et al., 2021), meaning patients living in rural areas have lower access to services.

Financial Analysis

The proposed legislation would require all individual and group health benefit plans to provide coverage for biomarker testing for diagnosis, treatment, appropriate management, or ongoing monitoring of a covered person's disease or condition when the testing is supported by medical and scientific evidence.

Our evaluation projects the population, cost of benefits, premium and enrollee cost sharing for calendar year 2025, calendar years 2025 through 2029, and calendar years 2025 through 2034 under the following two scenarios:

1. Baseline – Proposed legislation **does not** go into effect.
2. Post benefit requirement – Proposed legislation **does** go into effect.

The difference between the baseline and post benefit requirement values is the impact of the proposed legislation.

The medical and scientific evidence standard to be used as the basis of coverage policies is not defined in the proposed legislation. This allows carriers to select which nationally recognized clinical practice guidelines will be used as the basis of their coverage determinations. This is aligned with how carriers currently determine their coverage policies. As discussed in the "Insurance Coverage and Utilization of Biomarker Testing" section above, carriers currently cover all biomarker tests that meet the requirements outlined in the proposed legislation. This results in no financial impact of expansion of coverage.

However, biomarker testing is a growing area of research with rapidly changing scientific and medical evidence. There may be new biomarker tests not yet covered by carriers for diagnosis, treatment, appropriate management, or ongoing monitoring of a covered person's disease or condition that are required to be covered if the proposed legislation is passed. This may apply pressure to carriers to review the body of evidence and update coverage policies more frequently, resulting in an increase in the coverage of biomarker tests. We are unable to quantify how this will expand the coverage, if at all. Additionally, the passage of the proposed legislation may lead to increased awareness of biomarker testing coverage among patients and providers, which may lead to increased utilization. To account for these factors, we assumed a 1% increase in the utilization of biomarker testing for which coverage would be required under the proposed legislation.

Because carriers indicated all biomarker tests as defined by the proposed legislation are covered, we did not assume enrollees are utilizing biomarker tests outside of insurance at baseline. It is possible that enrollees are paying out-of-pocket for tests that are considered experimental by the body of medical and scientific evidence the carrier uses to determine their coverage policy. However, these tests would not become covered as a result of the proposed legislation and were not considered in this analysis.

For this analysis, biomarker testing is split into three clinical use categories: oncology testing, pharmacogenomics testing, and testing not related to pharmacogenomics or oncology. Oncology testing will determine appropriate treatment or management of cancers. To determine the financial impact of an increase in the utilization of biomarker tests, we would need to investigate what the standard course of treatment for an enrollee would be if the biomarker test was not performed and compare that to the revised course of treatment for an enrollee who had a biomarker test performed. For some enrollees using oncology biomarker testing, this may increase costs in the short term as the biomarker testing may indicate an appropriate course of care that includes additional therapies or more expensive therapies compared to a standard course of treatment. For other patients, biomarker testing may reduce costs by securing patients appropriate care in a timelier manner such that the cancer does not progress into a more advanced stage. Similarly, enrollees using pharmacogenomic biomarker testing may receive a more or less expensive

treatment than they otherwise would have received. The financial impact on related services will vary on a patient by patient basis.

Biomarker tests not related to pharmacogenomics or oncology are primarily used for diagnostic purposes after symptoms have presented. Typically, enrollees receive treatment once they have a diagnosis. An increase in the utilization of biomarker tests for diagnostic purposes would increase the number of enrollees with a diagnosis, thereby increasing treatment costs. These treatment costs would need to be compared to the alternative tests and treatments an individual would receive without the proper diagnosis.

There are over 700 biomarker testing procedures considered for this analysis. Due to the breadth of this proposed legislation, we are unable to quantify the resulting change in utilization or cost of treatments for these enrollees as a result of biomarker testing.

ENROLLEE UTILIZATION

Biomarker tests were split into oncology tests, pharmacogenomics tests, and tests not related to pharmacogenomics or oncology. If a test could be used for two or all three categories, its utilization was equally distributed among the relevant categories. Baseline biomarker utilization for the three categories is shown in Exhibit 3. In baseline 2025 individual, small group, and large group plans: oncology biomarker tests are 47.1, 34.2, and 37.1 utilizations per 1,000 respectively; pharmacogenomic biomarker tests are 8.5, 6.4, and 8.8 utilizations per 1,000 respectively, and non-oncology, non-pharmacogenomic biomarker tests are 73.3, 71.6, and 94.2 utilizations per 1,000 respectively.

EXHIBIT 3: BASELINE BIOMARKER TEST UTILIZATION PER 1,000, 2025

	INDIVIDUAL	SMALL GROUP	LARGE GROUP
Oncology biomarker test	47.1	34.2	37.1
Pharmacogenomic biomarker test	8.5	6.4	8.8
Non-oncology, non-pharmacogenomic biomarker test	73.3	71.6	94.2

The marginal post benefit requirement biomarker test utilization, assuming a 1% increase in the number of biomarker tests at baseline, is shown in Exhibit 4. In 2025 the estimated marginal utilization increase in biomarker tests for individual, small group, and large group plans: oncology biomarker tests are 0.5, 0.3, and 0.4 tests per 1,000 respectively; pharmacogenomic biomarker tests are 0.1, 0.1, and 0.1 tests per 1,000 respectively, and non-oncology, non-pharmacogenomic biomarker tests are 0.7, 0.7, and 0.9 tests per 1,000 respectively.

EXHIBIT 4: MARGINAL BIOMARKER TEST UTILIZATION PER 1,000 POST BENEFIT REQUIREMENT, 2025

	INDIVIDUAL	SMALL GROUP	LARGE GROUP
Oncology biomarker test	0.5	0.3	0.4
Pharmacogenomic biomarker test	0.1	0.1	0.1
Non-oncology, non-pharmacogenomic biomarker test	0.7	0.7	0.9

COST PER SERVICE AND ENROLLEE COST SHARING

We do not expect the average cost of biomarker testing or enrollee cost sharing to change post benefit requirement. The estimated 2025 cost for biomarker tests is shown in Exhibit 5. In 2025, the estimated average cost of a biomarker test for individual, small group, and large group plans are: $380, $385, and $390 for oncology tests respectively, $320, $285, and $305 for pharmacogenomics tests respectively, and $205, $200, and $175 for non-oncology, non-pharmacogenomic biomarker tests respectively. The cost per service varies by line of business due to demographic and geographic variations by line of business.

EXHIBIT 5: AVERAGE BIOMARKER TEST COST, 2025

	INDIVIDUAL	SMALL GROUP	LARGE GROUP
Oncology biomarker test	$380	$385	$390
Pharmacogenomic biomarker test	$320	$285	$305
Non-oncology, non-pharmacogenomic biomarker test	$205	$200	$175

The 2025 estimated average cost sharing for biomarker tests is shown in Exhibit 6. In 2025, the estimated average cost-sharing of a biomarker test for individual, small group, and large group plans are: $140, $145, and $160 for oncology tests respectively, $125, $135, and $155 for pharmacogenomics tests respectively, and $70, $60, and $60 for non-oncology, non-pharmacogenomic biomarker test respectively.

EXHIBIT 6: AVERAGE BIOMARKER TEST COST-SHARING, 2025

	INDIVIDUAL	SMALL GROUP	LARGE GROUP
Oncology biomarker test	$140	$145	$160
Pharmacogenomic biomarker test	$125	$135	$155
Non-oncology, non-pharmacogenomic biomarker test	$70	$60	$60

PREMIUM IMPACT

The estimated premium impact from passing the proposed legislation is in Exhibit 7 below.

- For individual insurance, we estimate a 1 year premium impact of $70,000, a 5 year cumulative premium impact of $486,000, and a 10 year cumulative premium impact of $1,540,000, or $0.02, $0.03, and $0.05 per member per month respectively. Or 0.004%, 0.005%, and 0.006% percent change over baseline premium respectively.
- For small group insurance, we estimate a 1 year premium impact of $57,000, a 5 year cumulative premium impact of $398,000, and a 10 year cumulative premium impact of $1,258,000, or $0.02, $0.03, and $0.04 per member per month respectively, or 0.003%, 0.004%, and 0.005% percent change over baseline premium respectively.
- For large group insurance, we estimate a 1 year premium impact of $118,000, a 5 year cumulative premium impact of $823,000, and a 10 year cumulative premium impact of $2,602,000, or $0.02, $0.03, and $0.04 per member per month respectively, or 0.004%, 0.005%, and 0.006% percent change over baseline premium respectively.

EXHIBIT 7: ESTIMATED PREMIUM IMPACT OF THE PROPOSED LEGISLATION

	1 YEAR IMPACT	5 YEAR CUMULATIVE IMPACT	10 YEAR CUMULATIVE IMPACT
Individual – Total Dollars	$70,000	$486,000	$1,540,000
Individual – PMPM	$0.02	$0.03	$0.05
Individual – Percent Change	0.004%	0.005%	0.006%
Small Group – Total Dollars	$57,000	$398,000	$1,258,000
Small Group – PMPM	$0.02	$0.03	$0.04
Small Group – Percent Change	0.003%	0.004%	0.005%
Large Group – Total Dollars	$118,000	$823,000	$2,602,000
Large Group – PMPM	$0.02	$0.03	$0.04
Large Group – Percent Change	0.004%	0.005%	0.006%

All Commercial – Total Dollars	**$245,000**	**$1,707,000**	**$5,400,000**
All Commercial – PMPM	**$0.02**	**$0.03**	**$0.04**
All Commercial – Percentage Change	**0.004%**	**0.005%**	**0.006%**

ENROLLEE OUT-OF-POCKET IMPACT

The estimated enrollee out-of-pocket cost impact is in Exhibit 8 below. As previously mentioned, we are not considering biomarker tests denied by an insurance company due to it being considered an experimental or not medically necessary treatment because those biomarker tests would remain not covered even with the passage of the proposed legislation. The out-of-pocket presented below only includes cost sharing for covered benefits.

- For individual insurance, we estimate a 1 year enrollee out-of-pocket impact of $32,000, a 5 year cumulative enrollee out-of-pocket impact of $225,000, and a 10 year cumulative enrollee out-of-pocket impact of $711,000 or $0.01, $0.01, and $0.02 per member per month respectively
- For small group insurance, we estimate a 1 year enrollee out-of-pocket impact of $25,000, a 5 year cumulative enrollee out-of-pocket impact of $172,000, and a 10 year cumulative enrollee out-of-pocket impact of $546,000 or $0.01, $0.01, and $0.02 per member per month respectively
- For large group insurance, we estimate a 1 year enrollee out-of-pocket impact of $65,000, a 5 year cumulative enrollee out-of-pocket impact of $458,000, and a 10 year cumulative enrollee out-of-pocket impact of $1,448,000 or $0.01, $0.01, and $0.02 per member per month respectively

EXHIBIT 8: ESTIMATED ENROLLEE OUT-OF-POCKET IMPACT OF THE PROPOSED LEGISLATION

	1 YEAR IMPACT	5 YEAR CUMULATIVE IMPACT	10 YEAR CUMULATIVE IMPACT
Individual – Total Dollars	$32,000	$225,000	$711,000
Individual – PMPM	$0.01	$0.01	$0.02
Small Group – Total Dollars	$25,000	$172,000	$546,000
Small Group – PMPM	$0.01	$0.01	$0.02
Large Group – Total Dollars	$65,000	$458,000	$1,448,000
Large Group – PMPM	$0.01	$0.01	$0.02
All Commercial – Total Dollars	**$122,000**	**$855,000**	**$2,705,000**
All Commercial – PMPM	**$0.01**	**$0.01**	**$0.02**

TOTAL EXPENDITURE IMPACT

The total estimated expenditure impact, including premium and enrollee out-of-pocket costs, from passing the proposed legislation is in Exhibit 9 below.

- For individual insurance, we estimate a 1 year total cost of care impact of $102,000, a 5 year cumulative total cost of care impact of $711,000, and a 10 year cumulative total cost of care impact of $2,251,000 or $0.03, $0.05, and $0.07 per member per month respectively
- For small group insurance, we estimate a 1 year total cost of care impact of $82,000, a 5 year cumulative total cost of care impact of $570,000, and a 10 year cumulative total cost of care impact of $1,804,000 or $0.03, $0.04, and $0.06 per member per month respectively
- For large group insurance, we estimate a 1 year total cost of care impact of $183,000, a 5 year cumulative total cost of care impact of $1,281,000, and a 10 year cumulative total cost of care impact of $4,050,000 or $0.03, $0.04, and $0.06 per member per month respectively

EXHIBIT 9: ESTIMATED TOTAL COST OF CARE IMPACT OF THE PROPOSED LEGISLATION

	1 YEAR IMPACT	5 YEAR CUMULATIVE IMPACT	10 YEAR CUMULATIVE IMPACT
Individual – Total Dollars	$102,000	$711,000	$2,251,000
Individual – PMPM	$0.03	$0.05	$0.07
Small Group – Total Dollars	$82,000	$570,000	$1,804,000
Small Group – PMPM	$0.03	$0.04	$0.06
Large Group – Total Dollars	$183,000	$1,281,000	$4,050,000
Large Group – PMPM	$0.03	$0.04	$0.06
All Commercial – Total Dollars	**$367,000**	**$2,562,000**	**$8,105,000**
All Commercial – PMPM	**$0.03**	**$0.04**	**$0.06**

See Appendices B through J for more detailed information on PMPM and Total Cost of Care.

LONG TERM HEALTH CARE COST IMPACT

Post benefit requirement, full coverage for biomarker testing will likely lead to quicker access to appropriate treatment (Pennell et al. 2023; Lim et al. 2015**;** Bergman et al. 2020) and less wasted health care spending. Biomarker testing is a rapidly growing field and as more testing is done, the better health outcomes from appropriate treatment may dampen future health care cost increases.

Long term cost impacts will depend on the specific condition and test, but small net savings have been observed in some cases. For example, the use of biomarker testing to identify rheumatoid arthritis patients who were unlikely to respond to biologic pharmacy treatment resulted in a 5% decrease in overall healthcare costs and a 22% decrease in costs attributed to ineffective treatment (Bergman et al. 2020). A different study confirmed that using biomarker testing to determine treatments for nonmetastatic colorectal cancer reduced costs for some patients (Seo et al. 2018).

Given the rapidly changing field, it is possible that healthcare costs may increase as biomarker tests pave the way for novel and more personal specialized treatment.

As previously noted, there are racial, ethnic, socio-economic, age and geographic disparities in the utilization of biomarker testing. If the root causes are not addressed, these disparities are anticipated to continue.

STATE DEFRAYAL OF MANDATED BENEFITS IN EXCESS OF ESSENTIAL HEALTH BENEFITS

Carriers offering individual and small group health benefit plans in Colorado are currently required to cover laboratory services that are substantially equal to Colorado's EHB-benchmark plan. If the proposed legislation is written in a manner to be clear that the coverage is not in excess of EHBs, it does not appear that the legislative proposal would be a new coverage that exceeds EHBs. Ultimately, if it were determined to be in excess of EHB coverage, the state could be required to defray the costs of mandating coverage for this benefit. The Colorado DOI believes that if the ultimate conclusion is that this coverage creates a new mandate that must be defrayed, regardless of whether it is currently covered as part of EHB, the defrayal costs could increase.

Social and Economic Impact

Given that carrier responses indicate near complete coverage of biomarker testing, we conclude that the passage of the proposed legislation would have minimal social or economic impact on Coloradans. As indicated throughout the report, there are barriers to accessing biomarker testing beyond health care coverage that disproportionately affect certain populations, including racial and ethnic minorities, low-income individuals and rural communities. The passage of the proposed legislation would not address these barriers. Out-of-pocket costs and co-insurance may continue to be a barrier for low-income beneficiaries. As described in Exhibit 6, average out of pocket costs of biomarker testing in Colorado in 2025 ranges from $60 to $160 per test.

In 2022, 9.2% of Coloradans live under 100% of the federal poverty limit and impact racial and ethnic minorities at higher rates than white Coloradans (American Community Survey 2022 data sourced from KFF). As previously noted in “Socio-economic status” section low-income beneficiaries are less likely to receive biomarker testing (Norris et al. 2020).

Methodology and Assumptions

As noted in the prior section, the financial evaluation projects the population, cost of benefits, premium and enrollee cost sharing for calendar year 2025, calendar years 2025 through 2029, and calendar years 2025 through 2034 under the following two scenarios:

1. Baseline – Proposed legislation **does not** go into effect.
2. Post benefit requirement – Proposed legislation **does** go into effect.

The difference between the baseline and post benefit requirement values is the impact of the proposed legislation.

To perform the financial evaluation, we made the following key assumptions:

- Carriers indicated there is 100% coverage of the biomarker tests required to be covered by the proposed legislation at baseline.
- As a result of the proposed legislation, carriers may review the body of evidence and update coverage policies more frequently, resulting in an increase in the coverage of biomarker tests. Increased awareness among patients and providers may also lead to an increase in the use of these tests. We assumed a 1% increase in baseline biomarker test utilization.
- Because biomarker tests are covered at baseline, enrollees are not paying out of pocket for non-covered biomarker testing at baseline. They are paying cost-sharing in the form of copayments, deductibles and coinsurances.
- Due to the breadth and complexity of the topic, utilization and financial impacts related to treatments resulting from an increase in the utilization of biomarker tests was not quantified.

COLORADO POPULATION

We used 2022 enrollment data from the Colorado All Payer Claims Database (APCD) to identify fully-insured commercial enrollment in preferred provider organization plans (PPO), point of service plans (POS), exclusive provider organization plans (EPO), and health maintenance organization plans (HMO). We limited the data to enrollment months with both medical and pharmacy coverage and placed each enrollment month into individual, small group, or large group based on their plan size. We then used Colorado population projections from the Department of Local Affairs to trend the 2022 enrollment data to 2025 through 2034.

COLORADO CLAIMS AND PREMIUM

Using the data provided in the Colorado APCD, we summarized paid medical and pharmacy claims by individual, small group, and large group incurred during calendar year 2022 and paid through July 2023. Claims were adjusted to account for claims incurred but not paid using completion factors calculated using the development method. The resulting completion factors are in Exhibit 10. The medical factors range from 0.967 to 0.980 and the pharmacy completion factors range from 0.997 to 1.000.

EXHIBIT 10: 2022 COMPLETION FACTORS

	INDIVIDUAL	SMALL GROUP	LARGE GROUP
Medical Completion Factor	0.980	0.973	0.967
Pharmacy Completion Factor	0.998	1.000	0.997

The 2022 estimated incurred medical and pharmacy claims were projected to 2025 through 2034 claims using a 6.5% annual claims trend with an additional 0.5% leveraging factor. Claims trend was developed by reviewing historical

individual, small group, and large group trend in Colorado and nationwide, as well as reviewing Colorado filing documents and unified rate review templates submitted by various insurance carriers to the DOI.

We applied administration expense ratios by individual, small group, and large group from the 2020 and 2021 Colorado Department of Regulatory Agencies Health Insurance Cost Reports to the projected claims to develop premiums for 2025 through 2034. Administration expenses include 2% assumed profit. Exhibit 11 shows the assumed administration expenses as a percentage of total premium.

EXHIBIT 11: ADMINISTRATION EXPENSES AS A PERCENTAGE OF TOTAL PREMIUM INCLUDING PROFIT

	INDIVIDUAL	SMALL GROUP	LARGE GROUP
Administration Ratio	16.8%	16.1%	10.0%

BENEFIT COVERAGE

We surveyed insurance carriers in Colorado about current coverage of biomarker testing for the diagnosis, treatment, appropriate management, or ongoing monitoring of a covered person's disease or condition when the testing is supported by medical and scientific evidence. The survey is in Appendix A. We received responses from nine carriers with fully-insured commercial enrollees.

Carriers indicated there is 100% coverage of the biomarker tests required to be covered by the proposed legislation at baseline. As a result of the proposed legislation, carriers may review the body of evidence and update coverage policies more frequently, resulting in an increase in the number of biomarker tests that are covered. In the post benefit coverage requirement scenario, we assume a 1% increase in utilization of biomarker tests compared to baseline scenario.

BIOMARKER UTILIZATION AND COST

We identified and summarized biomarker tests from the 2022 incurred claims data in Colorado APCD by commercial line of business. Biomarker tests were split into pharmacogenomics tests, oncology tests, and tests not related to pharmacogenomics or oncology. If a test could be used for two or all three categories, its utilization was uniformly assigned to the categories. Biomarker tests with pregnancy diagnosis codes were excluded from the analysis. The methodology used to generate the list of CPT/HCPCS procedure codes used in the analysis can be found in Appendix K.[1]

Due to the rapid growth of research in the field of biomarker testing, we applied a 10% annual utilization trend to the 2022 data to project 2025 through 2034. As more research is done in the field of biomarkers and providers incorporate testing into diagnosis and treatment, we expect the utilization of biomarker tests to trend higher than typical medical services. For example, a study of new U.S. Food and Drug Administration (FDA) approved drugs from 2000 to 2020 shows that the annual proportion of drug approvals with pharmacogenomic biomarkers mentioned in the label has grown from 10.3% in 2000 to 33.9% in 2019 with greater emphasis on the latter half of the study period (Kim et al 2021).

We assumed a 5% annual trend to project 2025 through 2034 average allowed cost. Patient cost sharing is calculated by applying the ratio of 2022 insurer paid amount per biomarker test to 2022 average cost per biomarker test to the 2025 through 2034 projected average allowed cost.

BIOMARKER OFFSETS

Additional coverage of biomarker testing may increase the utilization of treatments that depend on biomarker testing and decrease the utilization of alternate treatments. Improvements to treatment patterns, such as quicker access to care or better treatment trajectory, as a result of increased biomarker testing was not modeled. Due to the breadth of conditions and treatments related to biomarker testing, we did not model offsets.

ADMINISTRATIVE COSTS

We assumed no additional administrative costs due to this requirement beyond the typical proportional increase in retention costs when applied to increases in medical cost.

CONSIDERATIONS AND LIMITATIONS

Carriers reported covering 100% of the biomarker tests subject to the proposed legislation at baseline. However, if the legislation passes, carriers may review research on this topic more often and expand the biomarker tests included in their coverage policies. To account for this, we assumed a 1% increase in utilization of biomarker tests in the post benefit requirement scenario compared to baseline. We assumed the additional biomarker tests were the same average cost as currently available biomarker tests. Our analysis may overstate or understate the impact of this legislation to the extent that biomarker tests are covered at baseline and how it compares to our assumed increase in utilization.

Biomarker tests intended only for screening, such as during pregnancy, were excluded from this analysis. However, some biomarker tests included in the analysis may be used for screening, diagnosis, or treatment. The biomarker test utilization in our analysis may be overstated as screening uses of these biomarker tests could not be easily identified and excluded from the analysis. The baseline biomarker utilization and the post benefit requirement increase in utilization will be overstated to the extent that the biomarker tests we have included are used from screening instead of diagnosis, treatment, appropriate management, or ongoing monitoring.

Results from biomarker testing may cause significant cost increases or decreases from diagnosing conditions or changing treatment courses. As mentioned above, the changes in the courses of treatment as a result of newly covered biomarker tests were not modeled. Due to the breadth of services impacted by this legislation and the complexity of the changing treatment patterns, we were not able to quantify the financial impact of the treatments resulting from increases in biomarker testing.

Variability of Results

Differences between our estimates and actual amounts depend on the extent to which future experience conforms to the assumptions made in this model. It is almost certain that actual experience will not conform exactly to the assumptions used in this model. Actual amounts will differ from projected amounts to the extent that actual experience is better or worse than expected.

Model and Data Reliance

Milliman has developed certain models to estimate the values included in this report. The intent of the models was to estimate the impact of bill House Bill 23-1110. We have reviewed this model, including its inputs, calculations, and outputs for consistency, reasonableness, and appropriateness to the intended purpose and in compliance with generally accepted actuarial practice and relevant actuarial standards of practice (ASOP).

The models rely on data and information as input to the models. We have relied upon certain data and information for this purpose and accepted it without audit. To the extent that the data and information provided is not accurate, or is not complete, the values provided in this report may likewise be inaccurate or incomplete.

Milliman's data and information reliance includes:

- Data from Colorado's All Payer Claims Database
- Colorado census data and projections
- FDA's list of therapeutic products with pharmacogenomic information found in the drug labeling (FDA, 2024) and list of cleared or approved companion diagnostic devices (FDA, 2023)
- Clinical Pharmacogenetics Implementation Consortium's (CPIC) gene-drug level assignments and guidelines (CPIC, 2024)
- Published papers, reports, and articles listed in the references section
- All other sources mentioned inline and in references, including survey and studies.

The models, including all input, calculations, and output may not be appropriate for any other purpose.

We have performed a limited review of the data used directly in our analysis for reasonableness and consistency and have not found material defects in the data. If there are material defects in the data, it is possible that they would be uncovered by a detailed, systematic review and comparison of the data to search for data values that are questionable or for relationships that are materially inconsistent. Such a review was beyond the scope of our investigation.

Distribution and Usage

We understand that the DOI intends to distribute this report to legislators and it may be published on their website. We consent to this distribution as long as the work is distributed in its entirety. Milliman does not intend to benefit any third-party recipient of its work product, even if Milliman consents to the release of its work product to such third party.

Qualifications to Perform Analysis

Guidelines issued by the American Academy of Actuaries require actuaries to include their professional qualifications in all actuarial communications. Casey Hammer and Norman Yu are members of the American Academy of Actuaries and meet the qualification standards for performing the analyses supported by this model.

Appendix A: Carrier Coverage Survey

COLORADO
Department of Regulatory Agencies

COVERAGE SURVEY FOR BIOMARKER TESTING

Biomarker testing is defined as an analysis of a patient's tissue, blood, or other biospecimen for the presence of an indicator of normal biological processes, pathogenic processes, or pharmacologic responses to a specific therapeutic intervention.

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

For the purposes of this survey, do NOT include coverage for screening tests, genetic testing for inherited risk, or over the counter genetic tests.

Please return this survey via email to Tara Smith (tara.smith@state.co.us) and Debra Judy (debra.judy@state.co.us) by December 27, 2023.

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1) What is the name of the insurance carrier?

2) Please complete the following table with how many people are enrolled in the following lines of business as of October 31, 2023? Please exclude all self-insured or administrative services only plans in your responses.

Individual Market	Small Group Market	Large Group Market
#	#	#

3) Please complete the following table with the % of members that do not have any coverage for biomarker tests as defined above, the % of members have some coverage for biomarker tests as defined above, and the % of members that have coverage for biomarker tests as defined above.

	Individual Market	Small Group Market	Large Group Market
% of members that **do not have any** coverage for biomarker tests as defined above	%	%	%
% of members that **have some** coverage for biomarker tests as defined above	%	%	%
% of members that **have** coverage for **all** biomarker tests as defined above	%	%	%

4) What **percentage** of biomarker tests are covered for enrollees who currently **have some** coverage of biomarker testing as defined above.

Source of Medical and Scientific Evidence	Individual Market	Small Group Market	Large Group Market
Labeled indications for an FDA-approved or FDA-cleared test	%	%	%
Indicated tests for an FDA-approved drug	%	%	%
Warnings and precautions on FDA-approved drug labels	%	%	%
Centers for Medicare and Medicaid Services (CMS) National Coverage Determinations or Medicare Administrative Contractor (MAC) Local Coverage Determinations	%	%	%
Nationally recognized clinical practice guidelines and consensus statements	%	%	%

5) If only a portion of biomarkers on a panel test are supported by scientific and medical evidence, is the full panel test covered?

6) Is there any additional information you would like to share about coverage for biomarker tests as defined above?

Appendix B: Individual Enrollees Impacted by Benefit Requirement

Individual Market	1-Year	5-year cumulative	10-year cumulative
Total enrollment subject to state benefit requirements	252,347	1,286,557	2,641,694
Total population affected	252,347	1,286,557	2,641,694
Baseline Utilization per 1,000			
Oncology biomarker test	47.1	57.6	75.7
Pharmacogenomic biomarker test	8.5	10.5	13.7
Non-oncology, non-pharmacogenomic biomarker test	73.3	89.7	117.8
Baseline Cost per procedure			
Oncology biomarker test	$380	$425	$495
Pharmacogenomic biomarker test	$320	$355	$420
Non-oncology, non-pharmacogenomic biomarker test	$205	$230	$270
Baseline Patient Cost-sharing per procedure			
Oncology biomarker test	$140	$155	$180
Pharmacogenomic biomarker test	$125	$140	$165
Non-oncology, non-pharmacogenomic biomarker test	$70	$80	$90
Post-benefit requirement Utilization per 1,000			
Oncology biomarker test	47.6	58.2	76.4
Pharmacogenomic biomarker test	8.6	10.6	13.9
Non-oncology, non-pharmacogenomic biomarker test	74.0	90.6	118.9
Post-benefit requirement Cost per procedure			
Oncology biomarker test	$380	$425	$495
Pharmacogenomic biomarker test	$320	$355	$420
Non-oncology, non-pharmacogenomic biomarker test	$205	$230	$270
Post-benefit requirement Patient Cost-sharing per procedure			
Oncology biomarker test	$140	$155	$180
Pharmacogenomic biomarker test	$125	$140	$165
Non-oncology, non-pharmacogenomic biomarker test	$70	$80	$90

Appendix C: Individual Enrollee PMPM

Individual Market	1-Year	5-year cumulative	10-year cumulative
Total enrollment subject to state benefit requirements	252,347	1,286,557	2,641,694
Total population affected	252,347	1,286,557	2,641,694
Baseline PMPM			
Insurer premium	$590.06	$680.85	$822.66
Patient out-of-pocket	$1.06	$1.45	$2.24
Patient non-covered	$0.00	$0.00	$0.00
Total Baseline PMPM	**$591.12**	**$682.30**	**$824.90**
Post benefit requirement PMPM			
Insurer premium	$590.08	$680.88	$822.70
Patient out-of-pocket	$1.07	$1.47	$2.26
Patient non-covered	$0.00	$0.00	$0.00
Total Post benefit requirement PMPM	**$591.15**	**$682.35**	**$824.97**
Change attributable to proposed benefits			
Insurer premium	$0.02	$0.03	$0.05
Patient out-of-pocket	$0.01	$0.01	$0.02
Patient non-covered	$0.00	$0.00	$0.00
Total change PMPM	**$0.03**	**$0.05**	**$0.07**
Percent change attributable to proposed benefits			
Insurer premium	0.004%	0.005%	0.006%
Patient out-of-pocket	1.000%	1.000%	1.000%
Patient non-covered	0.000%	0.000%	0.000%
Total percent change	**0.006%**	**0.007%**	**0.009%**

Appendix D: Individual Enrollee Total Dollars

Individual Market	1-Year	5-year cumulative	10-year cumulative
Total enrollment subject to state benefit requirements	252,347	1,286,557	2,641,694
Total population affected	252,347	1,286,557	2,641,694
Baseline total dollars			
Insurer premium	$1,786,785,000	$10,511,432,000	$26,078,438,000
Patient out-of-pocket	$3,223,000	$22,440,000	$71,027,000
Patient non-covered	$0	$0	$0
Total Baseline dollars	**$1,790,008,000**	**$10,533,872,000**	**$26,149,465,000**
Post benefit requirement total dollars			
Insurer premium	$1,786,855,000	$10,511,918,000	$26,079,978,000
Patient out-of-pocket	$3,255,000	$22,665,000	$71,738,000
Patient non-covered	$0	$0	$0
Total Post benefit requirement dollars	**$1,790,110,000**	**$10,534,583,000**	**$26,151,716,000**
Change attributable to proposed benefits			
Insurer premium	$70,000	$486,000	$1,540,000
Patient out-of-pocket	$32,000	$225,000	$711,000
Patient non-covered	$0	$0	$0
Total change	**$102,000**	**$711,000**	**$2,251,000**
Percent change attributable to proposed benefits			
Insurer premium	0.004%	0.005%	0.006%
Patient out-of-pocket	1.000%	1.000%	1.000%
Patient non-covered	0.000%	0.000%	0.000%
Total percent change	**0.006%**	**0.007%**	**0.009%**

Appendix E: Small Group Enrollees Impacted by Benefit Requirement

Small Group Market	1-Year	5-year cumulative	10-year cumulative
Total enrollment subject to state benefit requirements	248,814	1,266,864	2,598,754
Total population affected	248,814	1,266,864	2,598,754
Baseline Utilization per 1,000			
Oncology biomarker test	34.2	41.8	54.9
Pharmacogenomic biomarker test	6.4	7.8	10.3
Non-oncology, non-pharmacogenomic biomarker test	71.6	87.5	114.9
Baseline Cost per procedure			
Oncology biomarker test	$385	$430	$510
Pharmacogenomic biomarker test	$285	$320	$375
Non-oncology, non-pharmacogenomic biomarker test	$200	$220	$260
Baseline Patient Cost-sharing per procedure			
Oncology biomarker test	$145	$160	$190
Pharmacogenomic biomarker test	$135	$150	$180
Non-oncology, non-pharmacogenomic biomarker test	$60	$65	$75
Post-benefit requirement Utilization per 1,000			
Oncology biomarker test	34.5	42.2	55.4
Pharmacogenomic biomarker test	6.5	7.9	10.4
Non-oncology, non-pharmacogenomic biomarker test	72.3	88.4	116.1
Post-benefit requirement Cost per procedure			
Oncology biomarker test	$385	$430	$510
Pharmacogenomic biomarker test	$285	$320	$375
Non-oncology, non-pharmacogenomic biomarker test	$200	$220	$260
Post-benefit requirement Patient Cost-sharing per procedure			
Oncology biomarker test	$145	$160	$190
Pharmacogenomic biomarker test	$135	$150	$180
Non-oncology, non-pharmacogenomic biomarker test	$60	$65	$75

Appendix F: Small Group Enrollee PMPM

Small Group Market	1-Year	5-year cumulative	10-year cumulative
Total enrollment subject to state benefit requirements	248,814	1,266,864	2,598,754
Total population affected	248,814	1,266,864	2,598,754
Baseline PMPM			
Insurer premium	$554.27	$639.54	$772.70
Patient out-of-pocket	$0.83	$1.14	$1.75
Patient non-covered	$0.00	$0.00	$0.00
Total Baseline PMPM	**$555.11**	**$640.68**	**$774.45**
Post benefit requirement PMPM			
Insurer premium	$554.29	$639.57	$772.74
Patient out-of-pocket	$0.84	$1.15	$1.77
Patient non-covered	$0.00	$0.00	$0.00
Total Post benefit requirement PMPM	**$555.13**	**$640.72**	**$774.50**
Change attributable to proposed benefits			
Insurer premium	$0.02	$0.03	$0.04
Patient out-of-pocket	$0.01	$0.01	$0.02
Patient non-covered	$0.00	$0.00	$0.00
Total change PMPM	**$0.03**	**$0.04**	**$0.06**
Percent change attributable to proposed benefits			
Insurer premium	0.003%	0.004%	0.005%
Patient out-of-pocket	1.000%	1.000%	1.000%
Patient non-covered	0.000%	0.000%	0.000%
Total percent change	**0.005%**	**0.006%**	**0.007%**

Appendix G: Small Group Enrollee Total Dollars

Small Group Market	1-Year	5-year cumulative	10-year cumulative
Total enrollment subject to state benefit requirements	248,814	1,266,864	2,598,754
Total population affected	248,814	1,266,864	2,598,754
Baseline total dollars			
Insurer premium	$1,654,933,000	$9,722,572,000	$24,096,555,000
Patient out-of-pocket	$2,482,000	$17,258,000	$54,557,000
Patient non-covered	$0	$0	$0
Total Baseline dollars	**$1,657,415,000**	**$9,739,830,000**	**$24,151,112,000**
Post benefit requirement total dollars			
Insurer premium	$1,654,990,000	$9,722,970,000	$24,097,813,000
Patient out-of-pocket	$2,507,000	$17,430,000	$55,103,000
Patient non-covered	$0	$0	$0
Total Post benefit requirement dollars	**$1,657,497,000**	**$9,740,400,000**	**$24,152,916,000**
Change attributable to proposed benefits			
Insurer premium	$57,000	$398,000	$1,258,000
Patient out-of-pocket	$25,000	$172,000	$546,000
Patient non-covered	$0	$0	$0
Total change	**$82,000**	**$570,000**	**$1,804,000**
Percent change attributable to proposed benefits			
Insurer premium	0.003%	0.004%	0.005%
Patient out-of-pocket	1.000%	1.000%	1.000%
Patient non-covered	0.000%	0.000%	0.000%
Total percent change	**0.005%**	**0.006%**	**0.007%**

Appendix H: Large Group Enrollees Impacted by Benefit Requirement

Large Group Market	1-Year	5-year cumulative	10-year cumulative
Total enrollment subject to state benefit requirements	512,833	2,611,186	5,356,563
Total population affected	512,833	2,611,186	5,356,563
Baseline Utilization per 1,000			
Oncology biomarker test	37.1	45.4	59.6
Pharmacogenomic biomarker test	8.8	10.8	14.1
Non-oncology, non-pharmacogenomic biomarker test	94.2	115.2	151.3
Baseline Cost per procedure			
Oncology biomarker test	$390	$435	$510
Pharmacogenomic biomarker test	$305	$340	$400
Non-oncology, non-pharmacogenomic biomarker test	$175	$195	$230
Baseline Patient Cost-sharing per procedure			
Oncology biomarker test	$160	$175	$210
Pharmacogenomic biomarker test	$155	$175	$205
Non-oncology, non-pharmacogenomic biomarker test	$60	$65	$80
Post-benefit requirement Utilization per 1,000			
Oncology biomarker test	37.5	45.9	60.2
Pharmacogenomic biomarker test	8.9	10.9	14.3
Non-oncology, non-pharmacogenomic biomarker test	95.1	116.4	152.8
Post-benefit requirement Cost per procedure			
Oncology biomarker test	$390	$435	$510
Pharmacogenomic biomarker test	$305	$340	$400
Non-oncology, non-pharmacogenomic biomarker test	$175	$195	$230
Post-benefit requirement Patient Cost-sharing per procedure			
Oncology biomarker test	$160	$175	$210
Pharmacogenomic biomarker test	$155	$175	$205
Non-oncology, non-pharmacogenomic biomarker test	$60	$65	$80

Appendix I: Large Group Enrollee PMPM

Large Group Market	1-Year	5-year cumulative	10-year cumulative
Total enrollment subject to state benefit requirements	512,833	2,611,186	5,356,563
Total population affected	512,833	2,611,186	5,356,563
Baseline PMPM			
Insurer premium	$482.42	$557.08	$673.50
Patient out-of-pocket	$1.07	$1.46	$2.25
Patient non-covered	$0.00	$0.00	$0.00
Total Baseline PMPM	**$483.49**	**$558.54**	**$675.75**
Post benefit requirement PMPM			
Insurer premium	$482.43	$557.11	$673.54
Patient out-of-pocket	$1.08	$1.48	$2.27
Patient non-covered	$0.00	$0.00	$0.00
Total Post benefit requirement PMPM	**$483.52**	**$558.58**	**$675.81**
Change attributable to proposed benefits			
Insurer premium	$0.02	$0.03	$0.04
Patient out-of-pocket	$0.01	$0.01	$0.02
Patient non-covered	$0.00	$0.00	$0.00
Total change PMPM	**$0.03**	**$0.04**	**$0.06**
Percent change attributable to proposed benefits			
Insurer premium	0.004%	0.005%	0.006%
Patient out-of-pocket	1.000%	1.000%	1.000%
Patient non-covered	0.000%	0.000%	0.000%
Total percent change	**0.006%**	**0.007%**	**0.009%**

Appendix J: Large Group Enrollee Total Dollars

Large Group Market	1-Year	5-year cumulative	10-year cumulative
Total enrollment subject to state benefit requirements	512,833	2,611,186	5,356,563
Total population affected	512,833	2,611,186	5,356,563
Baseline total dollars			
Insurer premium	$2,968,782,000	$17,455,695,000	$43,291,598,000
Patient out-of-pocket	$6,586,000	$45,791,000	$144,765,000
Patient non-covered	$0	$0	$0
Total Baseline dollars	**$2,975,368,000**	**$17,501,486,000**	**$43,436,363,000**
Post benefit requirement total dollars			
Insurer premium	$2,968,900,000	$17,456,518,000	$43,294,200,000
Patient out-of-pocket	$6,651,000	$46,249,000	$146,213,000
Patient non-covered	$0	$0	$0
Total Post benefit requirement dollars	**$2,975,551,000**	**$17,502,767,000**	**$43,440,413,000**
Change attributable to proposed benefits			
Insurer premium	$118,000	$823,000	$2,602,000
Patient out-of-pocket	$65,000	$458,000	$1,448,000
Patient non-covered	$0	$0	$0
Total change	**$183,000**	**$1,281,000**	**$4,050,000**
Percent change attributable to proposed benefits			
Insurer premium	0.004%	0.005%	0.006%
Patient out-of-pocket	1.000%	1.000%	1.000%
Patient non-covered	0.000%	0.000%	0.000%
Total percent change	**0.006%**	**0.007%**	**0.009%**

Appendix K: Biomarker Test Code Identification

CPT/HCPCS codes for biomarker tests effective through 2023 were identified by Milliman clinicians, and those codes exclusively used to report screening tests or genetic tests for inherited risk, including in the context of pregnancy, were excluded from further consideration. The remaining codes represented biomarker tests for the diagnosis, treatment, appropriate management, or ongoing monitoring of a disease or condition, consistent with the coverage required by the legislation. The biomarker test codes were categorized using publicly available documentation from the U.S. Food and Drug Administration (FDA) (FDA, 2024; FDA, 2023) and Clinical Pharmacogenetics Implementation Consortium (CPIC) (CPIC, 2024), as well as FDA drug labels as applicable. Expert clinical judgement was used to identify and categorize biomarker test codes that were not included in the documentation, resolve conflicts between sources, and adjudicate information in the source documentation about clinical significance in the context of the coverage required by the legislation.

Over 700 CPT/HCPCS codes were identified and classified into one or more of three testing categories based on their expected clinical use - Oncology Testing, Pharmacogenomic Testing, and Testing Not Related to Pharmacogenomics or Oncology. The categorization of each code was not mutually exclusive as some codes can be used report biomarker tests in more than one category. The categories were assigned by identifying the biomarker, or combination of biomarkers in the case of panel tests, included in the CPT/HCPCS code description and comparing them to reference tables about biomarkers provided by the FDA (FDA, 2024; FDA, 2023) and CPIC (CPIC, 2024). Milliman clinicians also assessed the FDA labels for drugs included in the source documentation and excluded biomarker CPT/HCPCS codes that did not have clinically significant impacts on the indications, dosage, or therapeutic monitoring of these drugs. CPT/HCPCS codes used to report biomarker tests with more than one clinical use category, such as biomarkers tests that could be used for oncology as well as for conditions other than cancer, were flagged under multiple categories.

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