

# The landscape of biomarker testing coverage in the United States

Quantifying the impact of expanding biomarker testing coverage in the commercial and Medicaid markets

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In 2022, 1.9 million patients are estimated to be diagnosed with cancer in the United States.<sup>1</sup> Biomarker testing is becoming increasingly important to cancer care because it helps providers tailor cancer treatment when actionable biomarkers are present.<sup>2</sup> While clinical guidelines exist for use of biomarker testing,<sup>3</sup> insurance coverage of biomarker testing varies widely. Two states recently passed laws expanding their coverage of biomarker testing,<sup>4 5</sup> and lawmakers in several states are considering similar legislation.<sup>6</sup> We examined administrative claims data to understand the premium impact of expanding biomarker testing coverage in four markets: commercial self-insured large group, small group, individual, and Medicaid.

## Executive Summary

Milliman's analysis of healthcare claims data showed that over 90% of self-insured large groups paid for at least some biomarker testing in 2020; although, the level of coverage varied by group. Differences in biomarker testing coverage in self-insured large groups ranged from 14.4 and 32.7 tests per 1,000 for the 25<sup>th</sup> to 75<sup>th</sup> percentiles. Among the four market segments we studied, we observed the highest utilization of biomarker testing in the individual market and lowest utilization in the Medicaid market.

To estimate the impact of expanding coverage for biomarker testing in the commercial and Medicaid markets, we segmented large groups in our study into quartiles according to their level of biomarker testing utilization, measured as the demographically adjusted tests per 1,000 members. We used this metric as a proxy for coverage richness.

Because claims data lacks clinical granularity to assess coverage according to clinical guidelines, we assumed that, under the legislations' new coverage requirement, plans will have to expand coverage to a level that is at least as good as either ½ of the groups in our study (median) or ¾ of the groups in our study (75<sup>th</sup> percentile). These two benchmarks were chosen to illustrate a range of results.

As shown in the Figure 1, the impact on premiums of expanding coverage for biomarker testing from current levels to the median ranges from \$0.05 to \$0.31 per member per month (PMPM). Under this scenario, we assumed that 50% of plans do not currently provide coverage according to guidelines. If the benchmark for biomarker testing coverage is set at the 75<sup>th</sup> percentile, the impact on premiums ranges from \$0.09 to \$0.51 PMPM. As expected, this scenario produces a higher premium impact estimate because it assumes that 75% of plans would be required to improve coverage from current levels.

**FIGURE 1: PREMIUM PER MEMBER PER MONTH IMPACT OF EXPANDING COMMERCIAL AND MEDICAID BIOMARKER TESTING COVERAGE (2022)**

COVERAGE REQUIREMENT	PREMIUM IMPACT PER MEMBER PER MONTH (PMPM) <sup>a</sup>			
	COMMERCIAL			MEDICAID
	LARGE GROUP SELF-INSURED	SMALL GROUP	INDIVIDUAL	
Median Coverage <sup>b</sup>	\$0.14	\$0.18	\$0.31	\$0.05
Broader Coverage <sup>b</sup>	\$0.23	\$0.30	\$0.51	\$0.09

(a) Premium impact PMPM includes administrative expense and profit load

(b) Median and broader coverage benchmarks were based on the 50<sup>th</sup> and 75<sup>th</sup> percentiles of biomarker tests per 1,000 members, respectively, for groups with over 10,000 members.

FIGURE 2: CURRENT BIOMARKER TESTING COVERAGE AVERAGES BY MARKET, 2020

AVERAGE BIOMARKER TESTING COVERAGE	COMMERCIAL			MEDICAID
	LARGE GROUP SELF-INSURED	SMALL GROUP	INDIVIDUAL	
PATIENTS RECEIVING A TEST PER 1,000 MEMBERS	9.2	9.3	12.9	5.9
TESTS PER 1,000 MEMBERS	22.1	26.5	48.1	19.2
TESTS PER PATIENT	2.4	2.9	3.7	3.3
ALLOWED UNIT COST PER TEST	\$224.40	\$221.92	\$221.84	\$78.71
ACTUARIAL VALUE (PLAN PAID / ALLOWED SPENDING)	87.7%	82.6%	77.6%	100.0%
PERCENTAGE OF MUTLI-GENE PANEL TESTS	11.2%	11.3%	7.7%	5.6%

## Background

Biomarker testing is an increasingly important part of cancer care.<sup>7</sup> Biomarker testing is a procedure that provides specific information on cancer by looking for gene mutations, protein expression, and other markers (or biomarkers) in a patient's biospecimen by collecting a patient's blood, saliva, or small piece of skin.

One advantage of biomarker testing is it helps providers decide what treatment is best for cancer patients, as certain treatments are only effective for those with certain cancers or patients who have certain biomarkers. However, lack of coverage, whether related to frequency of testing or type of tests covered, may be a barrier for cancer patients to obtain these tests. According to a survey, some patients report paying \$500 or more out-of-pocket for biomarker testing.<sup>8</sup> Another survey found that 66% of oncology providers report that the lack of insurance coverage for desired biomarker test is a moderate or significant barrier to patient access.<sup>9</sup>

Effective January 1, 2022, Illinois<sup>10</sup> and Louisiana<sup>11</sup> require health plans to cover biomarker testing. Lawmakers in several states are considering similar policies that would require state-regulated health plans, including Medicaid, to provide coverage for biomarker testing when the testing is supported by medical and scientific evidence such as:

- Labeled indications for an FDA-approved or -cleared test, or indicated tests for an FDA-approved drug
- Centers for Medicare and Medicaid Services (CMS) National Coverage Determinations or Medicare Administrative Contractor (MAC) Local Coverage Determinations, or
- Nationally recognized clinical practice guidelines and consensus statements.

<sup>1</sup> Allowed amount is the negotiated rate between providers and payers before member cost sharing.

## Results

### CURRENT LANDSCAPE OF BIOMARKER TESTING COVERAGE

Figure 2 presents key utilization and cost metrics in the commercial and Medicaid markets for biomarker testing.

In the commercial market, patients using biomarker testing obtain, on average, 2.4 to 3.7 tests annually, with more utilization in the individual market. Higher utilization in the individual market is driven by demographics, with more members aged 55 to 64 (who have a higher incidence of cancer and therefore higher utilization of biomarker testing) and, possibly, anti-selection (where sicker patients are more likely to buy and use coverage).

The average allowed<sup>1</sup> unit cost per test was consistent across the commercial markets at about \$225, suggesting the variation across commercially insured markets is driven principally by utilization differences rather than unit cost differences. As expected, we also found the actuarial value<sup>2</sup> decreases from large groups to small groups to the individual market, reflecting leaner benefits as group size decreases.

Average biomarker tests per patient in Medicaid were similar to the commercial market at 3.3 tests annually, but the average allowed unit cost per test of about \$80 was almost one third of the unit cost in the commercial market. Therefore, the financial impact of expanding coverage of biomarker testing in Medicaid is expected to be lower than in the commercial market.

### DEVELOPMENT OF BENCHMARKS FOR BIOMARKER TESTING COVERAGE

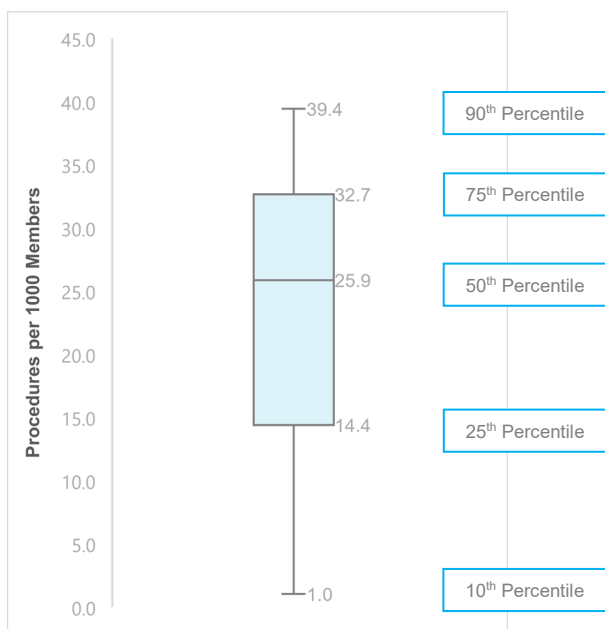
We segmented self-insured large groups in our dataset into quartiles, based on their utilization of biomarker testing, to understand the variation in biomarker testing coverage. We measured tests per 1,000 members as a proxy for coverage

<sup>2</sup> Actuarial value is the portion of allowed spending covered by the plan.

richness. We demographically-adjusted the data to normalize for differences in age and gender.

Our analysis of administrative claims data found that, among self-insured large groups, 90% provided at least some coverage for biomarker testing in 2020; the other 10% of groups had no biomarker tests in the claims data we reviewed. Among self-insured large groups, there were considerable differences in biomarker testing, with half of the groups reporting between 14.4 and 32.7 tests per 1,000 members (25<sup>th</sup> to 75<sup>th</sup> percentiles, respectively), with a median of 25.9 tests per 1,000 members. (Figure 3).

**FIGURE 3: DISPERSION IN BIOMARKER TESTING UTILIZATION IN THE LARGE GROUP MARKET (2020)**



We assumed that, under the new legislations' requirements, plans would have to provide coverage that is at least as good as:

- Median Coverage: the 50<sup>th</sup> percentile representing coverage that is better than ½ of the groups, and
- Broader Coverage: the 75<sup>th</sup> percentile, representing coverage that is better than ¾ of the groups

These two benchmarks were chosen to illustrate a range of coverage levels for biomarker testing assumed to be consistent with the legislations' requirements. We developed median and broader coverage benchmarks within each market to estimate the impact on member premiums.

**IMPACT ON MEMBER PREMIUMS**

The expected premium impact of expanding biomarker testing coverage, given our coverage assumptions, varies by market segment, ranging from \$0.05 up to \$0.51 PMPM (Figure 4). As expected, the Medicaid market saw the lowest premium impact,

ranging from \$0.05 to \$0.09 PMPM. This is driven by the lower average cost per test. In the commercial market, individual plans will observe the largest premium impact, ranging from \$0.31 to \$0.51 PMPM, as biomarker testing utilization is highest in that market segment.

**FIGURE 4: DEVELOPMENT OF THE PREMIUM PMPM IMPACT (2022)**

PMPM	COMMERCIAL			MEDICAID
	LARGE GROUP SELF-INSURED	SMALL GROUP	INDIVIDUAL	
<b>Median Coverage Premium Impact</b>				
Current Plan Paid <sup>a</sup>	\$0.11	\$0.12	\$0.20	\$0.04
Median Coverage <sup>b</sup>	\$0.23	\$0.25	\$0.43	\$0.08
Change in Coverage	\$0.12	\$0.13	\$0.23	\$0.04
Trend, Admin Expense and Profit Load <sup>c</sup>	\$0.01	\$0.05	\$0.08	\$0.01
<b>Median Coverage Premium PMPM Impact</b>	<b>\$0.14</b>	<b>\$0.18</b>	<b>\$0.31</b>	<b>\$0.05</b>
<b>Broader Coverage Premium Impact</b>				
Current Plan Paid <sup>a</sup>	\$0.25	\$0.27	\$0.46	\$0.08
Broader Coverage <sup>b</sup>	\$0.46	\$0.50	\$0.84	\$0.15
Change in Coverage	\$0.20	\$0.22	\$0.38	\$0.07
Trend, Admin Expense and Profit Load <sup>c</sup>	\$0.02	\$0.08	\$0.13	\$0.02
<b>Broader Coverage Premium PMPM Impact</b>	<b>\$0.23</b>	<b>\$0.30</b>	<b>\$0.51</b>	<b>\$0.09</b>

(a) 'Current Plan Paid' represents the utilization below the 50<sup>th</sup> and 75<sup>th</sup> percentiles.

(b) Median and Broader Coverage: Based on the 50<sup>th</sup> and 75<sup>th</sup> percentiles of biomarker tests per 1,000 members, respectively, for each market.

(c) Trend = 4% per year; Admin Expense and Profit Load = 20% Small Group and Individual, 15% Medicaid, 3% Large Group Self-insured.

**Methodology and Data Sources**

We used 2020 data from the Milliman's Consolidated Health Cost Guidelines Source Databases ("CHSD") to characterize the current coverage landscape of biomarker testing in the commercial and Medicaid markets. This data source contains proprietary historical claims experience from several of Milliman's Health Cost Guideline (HCG) data contributors. We used Current Procedural Terminology (CPT) codes to identify predictive and prognostic<sup>12</sup> biomarker claims, in line with clinical treatment guidelines.

We segmented large groups into demographically adjusted percentiles based on their biomarker testing utilization per 1,000 members. For our large group study cohort, we limited groups to those with over 10,000 members to limit statistical fluctuation in

biomarker testing. For the small group, individual and Medicaid markets, where utilization of biomarker testing is subject to statistical fluctuation, we assumed a distribution of quartiles, representing levels of coverage, similar to that of large groups. We adjusted quartiles to reflect the average utilization level in the entire small group, individual, and Medicaid dataset to develop median and broader coverage utilization benchmarks within each market. These levels of coverage implicitly reflect the demographics and cost sharing levels within each market.

We developed two benchmarks for modeling the new legislations' biomarker testing coverage requirements, to provide ranges of results. The median and broader coverage benchmarks represent the 50<sup>th</sup> and 75<sup>th</sup> percentiles, respectively, of biomarker testing utilization in each market. To determine the premium impact by market, we calculated the difference in current coverage for each quartile and the median or 75<sup>th</sup> percentile benchmarks.

We trended our 2020 data at 4% per year to reflect expected 2022 levels. Lastly, we added an administrative expense and profit load to the premium to reflect minimum loss ratio requirements in each market (except the self-insured large group market where we assumed a 3% profit load). The minimum loss ratio assumed was 80% for small group and individual markets, and 85% in the Medicaid market.

## Conclusions

Biomarker testing is an increasingly important part of cancer care and ongoing research could lead to applications in other disease areas.<sup>13 14</sup> Currently, there are no minimum coverage requirements for health plans, except in Illinois<sup>15</sup> and Louisiana<sup>16</sup>, for biomarker testing. Consequently, gaps between current coverage and guidelines likely exist today. If state or federal legislation were implemented in the commercial and Medicaid markets to expand biomarker testing to align with a median level of coverage, premiums would be expected to increase from \$0.05 to \$0.31 PMPM. An expansion in coverage to match the current 75<sup>th</sup> percentile levels would increase premiums from \$0.09 to \$0.51 PMPM.

## Caveats and Limitations

This report was commissioned by American Cancer Society Cancer Action Network. The findings reflect the research of the authors. Milliman does not endorse any product or organization. American Cancer Society Cancer Action Network did not author this paper or influence the findings.

This study has several limitations. First, this study was performed using data from the commercially insured and Medicaid populations. Biomarker testing may vary significantly among patients with cancer in other contexts where demography and prices differ. It is also important to note that we examined data from 2020 and did not consider the historical impact of the COVID-19 pandemic or the potential impact of future therapies or medical technologies on our results nor did we account for longitudinal changes in the costs of care evaluated in this study. As such, the costs presented here may under- or overestimate the future financial impact of biomarker testing.

Our analysis provides the average premium impact by market to expand coverage to the median and broader coverage levels. However, this impact will vary by health plan depending on the current coverage provided today. While the benchmarks used to determine the premium impact rely on utilization as a proxy for biomarker testing coverage, we are unable to determine whether these are consistent with guidelines due to limitations in administrative claims data.

Guidelines issued by the American Academy of Actuaries require actuaries to include their professional qualifications in all actuarial communications. Gabriela Dieguez and Jennifer Carioto are members of the American Academy of Actuaries and meet the qualification standards for performing the analyses in this report and rendering the actuarial opinions contained herein.



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## ENDNOTES

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