MeAHP
MAINE ASSOCIATION OF HEALTH PLANS

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Testimony In Opposition to LD 107
An Act to Require Health Insurance Coverage for Biomarker Testing
January 28, 2025

Senator Bailey, Representative Mathieson, and Members of the Joint Standing Committee on Health Coverage, Insurance, and Financial Services:

My name is Dan Demeritt, the Executive Director of the Maine Association of Health Plans. Policies offered or administered by our member plans provide access to care and better outcomes for many of the Mainers who receive coverage through an employer plan or the individual market. Our mission as an association is to improve the health of Maine people by promoting affordable, safe, and coordinated health care.

Maine's health plans provide members with covered access to biomarker testing proven through peer-reviewed medical research to advance care and improve outcomes.

If LD 107 advances as drafted it will drive up premiums and utilization for health care that may not have the clinical utility needed to meet Maine's standards for medical necessity. The bill will also create a defrayal obligation for Maine.

We urge the Committee and stakeholders to instead advance the conversation about coverage for biomarker testing through the on-going, stakeholder-engaged Essential Health Benefit Benchmark Plan Update led by the Maine Bureau of Insurance.[1]

Coverage Exists for Evidenced-Based Biomarker Testing

While commercial insurance plans vary, biomarking testing coverage through commercial health plans is widespread and increasing as new tests are accepted as a standard of care.

Biomarker testing is typically covered when it is supported by peer-reviewed medical research and proven to improve outcomes. Covered testing is also known to directly impact clinical decision-making and can be linked directly to a course of therapy or treatment for a covered medical condition.

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[1] https://www.maine.gov/pfr/insurance/sites/maine.gov.pfr.insurance/files/inline-files/EHB%20Benchmark%20Plan%20Initiative%20HCIS%202025_0.pdf

LD 107 Creates an Imprecise Path to Medical Necessity

Maine law defines "medically necessary health care" as health care services or products provided to an enrollee for the purpose of preventing, diagnosing or treating an illness, injury or disease or the symptoms of an illness, injury or disease in a manner that is:

A. Consistent with generally accepted standards of medical practice;

B. Clinically appropriate in terms of type, frequency, extent, site and duration;

C. Demonstrated through scientific evidence to be effective in improving health outcomes;

D. Representative of "best practices" in the medical profession; and

E. Not primarily for the convenience of the enrollee or physician or other health care practitioner.[2]

However, as drafted, the bill would require health plans to cover tests with no clinical utility including asymptomatic testing, testing without treatment options, and larger multi-panel tests that could lead to false positives and unnecessary treatments which is inconsistent with the requirements outlined above.

The bill also includes overly broad and imprecise paths to mandated coverage using nationally recognized clinical practice guidelines and consensus statements. These two provisions will require coverage of tests with little evidence to support their value or impact on patient outcomes.

The bill will also mandate coverage in Maine for any biomarker testing that receives a Local Coverage Determination (LCD) from any of the Medicare Administrative Contractors operating anywhere in the United States.

LCDs can be requested by email, fax, or written letter from Medicare beneficiaries, health care professionals, and any interested party doing business in a contractor's jurisdiction.[3]

The LCD process has led to concerns about coverage consistency and equity.[4]

If the Committee advances this bill, we urge it to maintain consistency with Maine's definition of medical necessity. Please consider emphasizing that mandated tests have clear clinical utility and striking the use of nationally recognized clinical practices, consensus statements, and local coverage determinations as paths to mandated coverage and instead require that statutorily required coverage be supported by peer reviewed medical literature.

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[2] https://legislature.maine.gov/statutes/24-A/title24-Asec4301-A.html

[3] https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/pim83c13.pdf

[4] https://oig.hhs.gov/oei/reports/oei-01-11-00500.pdf

Modifying the bill in this manner may also reduce the fiscal note accompanying the bill.

The Scale of Biomarker Innovation

According to a biomarker online database there are 34,483 biomarkers – a 24.6% increase over the last three years. The number of pre-clinical or investigational biomarkers have increased from 1,550 to 7,879 – a 408% increase – in the same three years.[5]

The U.S biomarker market was $32 billion in 2023 and is projected to grow at a 12.9% compounded annual growth rate to $75 billion in 2030.[6]

Biomarker Testing Subject to Defrayal

A similar bill was considered by the Legislature last session and guidance from the Bureau of Insurance indicated that a biomarker testing mandate requires defrayal and referenced a precedent set by the State of Kentucky's similar mandate.

The Bureau warned that federal pass-through funding provided for the Maine Guaranteed Access Reinsurance Association (MGARA) could be reduced if CMS became aware that Maine is not providing required defrayal payments.[7]

GAO Recommends CMS Conduct Risk Assessment of Non-EHB Mandated Benefits

The states should expect greater scrutiny when they expand coverage mandates.

Last week this Committee participated in a joint public hearing on the FY25 Supplemental Budget proposal with the Appropriations Committee. That conversation included a discussion of November 2024 Report from the U.S. Government Accountability Office involving federal oversight of the costs of non-EHB mandated benefits.

GAO found that U.S. Centers for Medicare and Medicaid Services (CMS) does not collect information on states that have identified non-EHB mandated benefits. The report notes at least six states, including Maine with its fertility care mandate, have reported the establishment of a non-EHB mandated benefit.

CMS agreed with GAO's recommendation that it conduct a risk assessment to determine if its oversight approach to non-EHB mandated benefits is sufficient or whether additional oversight is needed.[8]

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[5] https://markerdb.ca/statistics

[6] https://www.grandviewresearch.com/horizon/outlook/biomarkers-market/united-states

[7] ME BOI Memo to 131st Legislature, 5/9/24: https://bit.ly/DefrayalMemo

[8] https://www.gao.gov/products/gao-25-107220#summary_recommend

EHB Benchmark Plan Update

It has been a decade since Maine conducted a comprehensive assessment of its Essential Health Benefits benchmarks. We have confidence in the process the Bureau of Insurance has established to lead this important conversation.

We urge a vote of ought-not-to-pass on LD 107 and ask the Committee and advocates to work through the EHB update initiative to determine Maine's standards for biomarker testing coverage.

About Maine's Health Insurance Carriers

Health insurance carriers are providing coverage for more than 50% of insured Mainers through either an employment-based plan or insurance purchased through the individual market. Carriers operating in Maine support more than 6,000 jobs in direct and insurance related employment.

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

LOCAL COVERAGE DETERMINATIONS CREATE INCONSISTENCY IN MEDICARE COVERAGE

https://oig.hhs.gov/oei/reports/oei-01-11-00500.pdf

Daniel R. Levinson
Inspector General

January 2014
OEI-01-11-00500

EXECUTIVE SUMMARY: Local Coverage Determinations Create Inconsistency in Medicare Coverage
OEI-01-11-00500

WHY WE DID THIS STUDY

Medicare administrative contractors (MACs) and the Centers for Medicare & Medicaid Services (CMS) sometimes develop policies to limit Medicare coverage of specific items and services. MACs issue local coverage determinations (LCDs) that limit coverage for a particular item or service in their jurisdictions only. This can lead to State-by-State variation in Medicare coverage for similar items and services. Section 731 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) calls for a plan to evaluate new LCDs to determine which should be adopted nationally and to what extent greater consistency can be achieved among LCDs. This study determined the variation in coverage of Part B items and services as a result of LCDs and assessed CMS's efforts to evaluate LCDs for national coverage as required by the MMA.

HOW WE DID THIS STUDY

We analyzed a 1-week period within the Medicare Coverage Database to determine the LCD-caused variation in coverage of Part B items and services. We also used data from the National Claims History and the Enrollment Database to test for relationships between cost and utilization of items and services and presence or absence of an LCD. From CMS, we requested documents created by its 731 Advisory Group and LCD Writers' Group. Finally, we interviewed CMS staff and MAC staff to further our understanding of actions CMS has taken in response to Section 731 of the MMA.

WHAT WE FOUND

In October 2011, over half of Part B procedure codes were subject to an LCD in one or more States. The presence of these LCDs was unrelated to the cost and utilization of items and services. Furthermore, LCDs limited coverage for these items and services differently across States. LCDs also defined similar clinical topics inconsistently. Finally, CMS has taken steps to increase consistency among LCDs, but it lacks a plan to evaluate new LCDs for national coverage as called for by the MMA.

WHAT WE RECOMMEND

We recommend that CMS establish a plan to evaluate new LCD topics for national coverage consistent with MMA requirements. We also recommend that CMS continue efforts to increase consistency among existing LCDs. Finally, we recommend that CMS consider requiring MACs to jointly develop a single set of coverage policies. CMS concurred with all of our recommendations.

Version 1.0 vs Version 2.0

This section provides an overview of the biomarker data available in MarkerDB 1.0 and MarkerDB 2.0 as of 2024. **MarkerDB 1.0 database contained a total of 27686** biomarkers, including **26434** clinically approved biomarkers and **1550** pre-clinical or investigatio biomarkers. Whereas, new MarkerDB 2.0 contains a total of **34483** biomarkers with **27128** clinically approved biomarkers and **7879** pre-clinical or investigational biomarkers. This dataset offers valuable insights into the scope and scale of biomarkers tracked wit MarkerDB, providing a foundation for comparison with the latest data from 2024.

Link to MarkerDB 1.0

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	2021	2025		
Biomarker data in MarkerDB	**Version 1.0**	**Version 2.0**	**Value Change**	**Percent Change**
Total number of biomarkers	27686	34483	6797	24.6%
Number of pre-clinical or investigational biomarkers	1550	7879	6329	408.3%
Number of clinically approved biomarkers	26434	27128	694	2.6%
Number of chemical biomarkers	1090	1664	574	52.7%
Number of protein biomarkers	142	218	76	53.5%
Number of genetic biomarkers	26300	32447	6147	23.4%
Number of karyotype biomarkers	154	154	-	-
Number of genes	930	3212	2282	245.4%
Number of conditions	667	992	325	48.7%
Number of chemicals with structures	1089	1661	572	52.5%
Number of proteins with 3D structures	50	218	168	336.0%
Average number of words in descriptions	153.4	214.5	61.1	39.8%
Number of diagnostic biomarkers	25535	25760	225	0.9%
Number of prognostic biomarkers	13	13	-	-
Number of risk biomarkers	0	12674	12674	>12674%
Number of safety biomarkers	0	45	45	>45%
Number of monitoring biomarkers	0	636	636	>636%
Number of response biomarkers	0	25	25	>25%
Number of diet-related biomarkers	21	117	96	457.1%

https://markerdb.ca/statistics