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## Health Care & Wellness Committee

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### HB 1062

**Brief Description:** Providing coverage for biomarker testing.

**Sponsors:** Representatives Stonier, Corry, Parshley, Thai, Macri, Ryu, Leavitt, Berry, Reed, Alvarado, Callan, Tharinger, Fosse, Simmons, Davis, Ormsby, Reeves, Bernbaum, Donaghy and Hill.

<p><b>Brief Summary of Bill</b></p> <ul style="list-style-type: none"><li>• Requires coverage for biomarker testing under certain circumstances.</li></ul>
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**Hearing Date:** 1/21/25

**Staff:** Jim Morishima (786-7191).

**Background:**

A biomarker is generally a measurable substance, the presence of which may indicate a disease, infection, or environmental exposure. While there is no specific requirement for insurers or Medicaid to cover biomarker testing, some biomarker testing is included under general coverage requirements such as laboratory services and preventive care. This coverage is, however, limited by medical necessity requirements and prohibitions against investigational services.

In 2024 the Department of Health (DOH) conducted a Sunrise Review of a proposal to specifically require coverage for biomarker testing. The DOH concluded that the proposal did not meaningfully contribute to the goals of: (1) increasing access to medically and scientifically supported health care; and (2) reducing inequities and disparities in access to care. The DOH therefore did not recommend adoption of the proposed benefit.

**Summary of Bill:**

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*This analysis was prepared by non-partisan legislative staff for the use of legislative members in their deliberations. This analysis is not part of the legislation nor does it constitute a statement of legislative intent.*

Health plans (including health plans offered to public employees) and the state's Medicaid program must include coverage for biomarker testing. This coverage is for purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of an enrollee's disease or condition. The test must be supported by medical and scientific evidence, including:

- labeled indications for tests approved or cleared by the United States Food and Drug Administration (FDA) or indicated tests for a drug approved by the FDA;
- Centers for Medicare and Medicaid Services national coverage determinations or Medicare administrative contractor local coverage determinations;
- nationally recognized clinical practice guidelines; or
- consensus statements.

The biomarker testing requirements apply beginning January 1, 2026. The coverage must be provided in a manner that limits disruptions in care, including the need for multiple biopsies or biospecimen samples. When administering the benefit for purposes of Medicaid, the Health Care Authority must seek any available federal financial participation under the Medical Assistance Program or any other federal funding sources that are available or may become available.

"Biomarker testing" is defined as a characteristic that is objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes, or pharmacological responses to a specific therapeutic intervention, including gene mutations or protein expressions.

"Biomarker testing" is defined as the analysis of a patient's tissue, blood, or other biospecimen for the presence of a biomarker, including single-analyte tests, multiplex panel tests, and whole genome sequencing.

**Appropriation:** None.

**Fiscal Note:** Requested on January 14, 2025.

**Effective Date:** The bill takes effect 90 days after adjournment of the session in which the bill is passed.