Senate

General Assembly

File No. 317

February Session, 2024

Substitute Senate Bill No. 307

Senate, April 8, 2024

The Committee on Human Services reported through SEN. LESSER of the 9th Dist., Chairperson of the Committee on the part of the Senate, that the substitute bill ought to pass.

AN ACT CONCERNING MEDICAID COVERAGE OF BIOMARKER TESTING.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

Section 1. (NEW) (*Effective July 1, 2024*) (a) As used in this section:

(1) "Biomarker" means a characteristic, including, but not limited to, a gene mutation or protein expression that can be objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes or pharmacologic responses to a specific therapeutic intervention for a disease or condition.

(2) "Biomarker testing" means the analysis of a patient's tissue, blood or other biospecimen for the presence of a biomarker, including, but not limited to, tests for a single substance, tests for multiple substances, diseases or conditions, and whole genome sequencing.

(3) "Consensus statements" means statements developed by an independent, multidisciplinary panel of experts utilizing a transparent

methodology and reporting structure and with a conflict-of-interest policy that are (A) aimed at specific clinical circumstances, and (B) based on the best available evidence for the purpose of optimizing clinical care outcomes.

(4) "Nationally recognized clinical practice guidelines" means evidence-based guidelines developed by independent organizations or medical professional societies utilizing transparent methodologies and reporting structures and conflict-of-interest policies that (A) establish standards of care informed by a systematic review of evidence and assessments of the benefits and costs of alternative care options, and (B) include recommendations intended to optimize patient care.

(b) The Commissioner of Social Services, to the extent permissible under federal law, shall provide coverage for biomarker testing for the purpose of diagnosis, treatment, appropriate management or ongoing monitoring of a Medicaid enrollee's disease or condition. The commissioner shall condition such coverage on medical and scientific evidence supporting such testing, including, but not limited to, (1) (A) approval of such testing by the federal Food and Drug Administration, or (B) recommendations provided on the labels of certain drugs approved by the federal Food and Drug Administration that such testing should be conducted prior to the use of such drugs, (2) national coverage determinations or local coverage determinations for Medicare Administrative Contractors by the Centers for Medicare and Medicaid Services, (3) nationally recognized clinical practice guidelines and consensus statements, or (4) any other sources for establishing medical necessity in accordance with section 17b-259b of the general statutes.

(c) Nothing in this section shall be construed to limit the ability of the Department of Social Services to require prior authorization to ensure that a request for biomarker testing meets the standards under this section.

This act shall take effect as follows and shall amend the following sections:

Section 1	*July 1, 2024*	New section

Statement of Legislative Commissioners:
In Subsec. (b), "test" was changed to "testing" for consistency, Subsec. (b)(1) was redrafted for clarity, and in Subsec. (c), "testing" was changed to "biomarker testing" for consistency.

HS *Joint Favorable Subst.*

The following Fiscal Impact Statement and Bill Analysis are prepared for the benefit of the members of the General Assembly, solely for purposes of information, summarization and explanation and do not represent the intent of the General Assembly or either chamber thereof for any purpose. In general, fiscal impacts are based upon a variety of informational sources, including the analyst's professional knowledge. Whenever applicable, agency data is consulted as part of the analysis, however final products do not necessarily reflect an assessment from any specific department.

OFA Fiscal Note

State Impact: See Below

Municipal Impact: None

Explanation

The bill requires Medicaid coverage of biomarker testing and conditions such as coverage on certain medical and scientific evidence. As such testing is currently covered, and the bill maintains prior authorization and medical necessity as a potential condition, the bill is not anticipated to result in a fiscal impact to the Department of Social Services (DSS). However, to the extent DSS conditions coverage on a more expansive basis, beyond the current definition of medical necessity, the state would incur increased Medicaid costs.

The Out Years

The annualized ongoing fiscal impact identified above would continue into the future subject to the conditions on which biomarking testing is covered.

OLR Bill Analysis

sSB 307

AN ACT CONCERNING MEDICAID COVERAGE OF BIOMARKER TESTING.

SUMMARY

This bill requires the Department of Social Services (DSS), to the extent federal law allows, to provide coverage for biomarker testing to diagnose, treat, manage, or monitor a Medicaid enrollee's disease or condition. The bill requires DSS to condition coverage on medical and scientific evidence supporting the test, including the following:

1. FDA approval or FDA-approved drug label recommendations;

2. national or local coverage determinations for Medicare Administrative Contractors by the federal Centers for Medicare and Medicaid Services;

3. nationally recognized clinical practice guidelines, which are evidence-based guidelines that set standards of care informed by a systemic evidence review and cost-benefit analysis of alternative care options, and are developed by independent organizations or medical professional societies;

4. consensus statements, which are statements developed by an independent, multidisciplinary expert panel, aimed at specific clinical circumstances and based on the best available evidence to optimize clinical care outcomes; or

5. any other sources for establishing medical necessity as defined in existing state law (see BACKGROUND).

Both the clinical practice guidelines and the consensus statements

described above must be developed using transparent methodologies, reporting structures, and conflict of interest policies.

The bill specifies that its provisions do not limit DSS's ability to require prior authorization to ensure that requested testing meets the standards described above.

EFFECTIVE DATE: July 1, 2024

BIOMARKER TESTING

The bill's coverage requirements apply to biomarker testing, which is the analysis of a patient's tissue, blood, or other biospecimen for biomarkers, which are characteristics, like a gene mutation or protein expression, that can be objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes, or pharmacologic responses to a specific therapeutic intervention for a disease or condition. The testing includes tests for single or multiple substances, diseases or conditions, and whole genome sequencing.

BACKGROUND

Related Bill

sHB 5367, favorably reported by the Human Services Committee, requires DSS to provide medically necessary Medicaid coverage for rapid whole genome sequencing for critically ill infants.

Medical Necessity

By law, for DSS's medical assistance programs (e.g., Medicaid), "medically necessary" means health services required to prevent, identify, diagnose, treat, rehabilitate, or ameliorate a person's medical condition, or its effects, to attain or maintain achievable health and independent functioning. Medically necessary services must be

1. consistent with generally accepted medical practice standards;

2. clinically appropriate in terms of type, frequency, timing, site, extent, and duration and considered effective for the person's illness, injury, or disease;

3. not primarily for the person's or the health care provider's convenience;

4. not more costly than an alternative service that is at least as likely to produce equivalent therapeutic or diagnostic results for the person's illness, injury, or disease; and

5. based on an assessment of the person and their medical condition (CGS § 17b-259b).

COMMITTEE ACTION

Human Services Committee

Joint Favorable Substitute
Yea 22 Nay 0 (03/19/2024)