**OLR Bill Analysis**

**sSB 307 (File 317, as amended by Senate "A")**

***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 the DSS commissioner to ensure this coverage is medically necessary under existing state law applicable to Medicaid services (see BACKGROUND).

The bill requires the commissioner to analyze relevant information and use applicable clinical guidelines to inform her medical necessity determination for the testing, including medical and scientific evidence that demonstrates that a test provides clinical utility (e.g., FDA approval or recommendations or other coverage determinations).

Under existing law, clinical policies, medical policies, clinical criteria, and any other generally accepted clinical practice guidelines that DSS uses to evaluate a service's medical necessity are only used as guidelines and are not the basis for DSS's final determination. The bill specifies that its provisions do not change these medical necessity provisions in existing law. The bill further specifies that its provisions do not limit DSS's ability to require prior authorization to ensure that requested testing meets the standards described above.

The bill requires the DSS commissioner to ensure that Medicaid coverage of biomarker testing is provided in a way that limits disruptions in care. The bill allows anyone adversely affected by DSS's decisions on this testing to request a fair hearing from the department under a process established in existing law (CGS § 17b-60).

*Senate Amendment "A" (1) requires DSS to ensure coverage is

medically necessary under existing law rather than conditioning coverage on certain evidence to determine medical necessity, (2) requires evidence to demonstrate clinical utility and defines this term, and (3) adds provisions on limiting disruptions in care and fair hearings.

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.

## MEDICAL AND SCIENTIFIC EVIDENCE TO SUPPORT TEST COVERAGE

Under the bill, DSS must use applicable clinical guidelines to inform its medical necessity determination for biomarker testing, including medical and scientific evidence that demonstrates that a test provides clinical utility. Under the bill, a test result has "clinical utility" if it provides information used to make a treatment or monitoring strategy that informs a patient's outcome and impacts the clinical decision, and it may include both information that is actionable and information that cannot be immediately used to make a clinical decision.

Under the bill, this medical and scientific evidence may include one or more of the following:

1. FDA approval of the test or FDA drug label recommendations to conduct the test;

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

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

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.

Both the clinical practice guidelines and the consensus statements described above must be developed using transparent methodologies, reporting structures, and conflict of interest policies.

## BACKGROUND

### *Related Bill*

sHB 5367 (File 282), favorably reported by the Appropriations and Human Services committees, 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)