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)