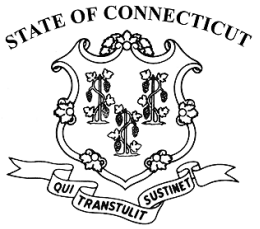

Substitute Senate Bill No. 307

Public Act No. 24-50

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) "Clinical utility" means the test result provides information that is used in the formulation of a treatment or monitoring strategy that informs a patient's outcome and impacts the clinical decision. The most appropriate test may include both information that is actionable and some information that cannot be immediately used in the formulation of a clinical decision.

(4) "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.

(5) "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 ensure that such coverage is medically necessary pursuant to section 17b-259b of the general statutes and, to assist in such determination of medical necessity, shall analyze relevant information and use applicable clinical guidelines to help inform such determination, including medical and scientific evidence supporting such test when the test provides clinical utility as demonstrated by medical and scientific evidence, including, but not limited to, one or more of the following: (1) Approval of such test by the federal Food and Drug Administration or recommendations on labels of drugs approved by the federal Food and Drug Administration to conduct such test, (2) national coverage determinations or local coverage determinations for Medicare Administrative Contractors by the Centers for Medicare and Medicaid Services, or (3) nationally recognized clinical practice guidelines and consensus statements. Nothing in this section shall

change the requirement in section 17b-259b of the general statutes that policies, guidelines and similar information shall be used solely as guidelines and shall not be the basis for a final determination of medical necessity.

(c) Nothing herein shall restrict the ability of the Department of Social Services to require prior authorization to assure that a request for testing meets the standards under this section.

(d) Any Medicaid enrollee who is adversely affected by a decision of the department under this section may request a hearing in accordance with section 17b-60 of the general statutes.

(e) The Commissioner of Social Services shall ensure that the coverage as defined in subsection (b) of this section is provided in a manner that is designed to limit disruptions in care.

Approved May 28, 2024