

General Assembly

Raised Bill No. 307

February Session, 2024

LCO No. 1433



Referred to Committee on HUMAN SERVICES

Introduced by: (HS)

AN ACT CONCERNING MEDICAID COVERAGE OF BIOMARKER TESTING.

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

- 1 Section 1. (NEW) (*Effective July 1, 2024*) (a) As used in this section:
- 2 (1) "Biomarker" means a characteristic, including, but not limited to,
- a gene mutation or protein expression that can be objectively measured
- 4 and evaluated as an indicator of normal biological processes, pathogenic
- 5 processes or pharmacologic responses to a specific therapeutic
- 6 intervention for a disease or condition.
- 7 (2) "Biomarker testing" means the analysis of a patient's tissue, blood
- 8 or other biospecimen for the presence of a biomarker, including, but not
- 9 limited to, tests for a single substance, tests for multiple substances,
- 10 diseases or conditions, and whole genome sequencing.
- 11 (3) "Consensus statements" means statements developed by an
- 12 independent, multidisciplinary panel of experts utilizing a transparent
- 13 methodology and reporting structure and with a conflict-of-interest
- 14 policy that are (A) aimed at specific clinical circumstances, and (B) based

LCO No. 1433 1 of 3

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 test, including, but not limited to, (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.
- (c) The Commissioner of Social Services shall provide online access to a Medicaid enrollee and a Medicaid provider to a clear, readily accessible and convenient process to request an exception to a prior authorization requirement or other coverage policy provision for biomarker testing.

LCO No. 1433 2 of 3

307

Statement of Purpose:

To improve outcomes for Medicaid enrollees afflicted with cancer and other diseases by utilizing biomarker testing to help guide treatment.

[Proposed deletions are enclosed in brackets. Proposed additions are indicated by underline, except that when the entire text of a bill or resolution or a section of a bill or resolution is new, it is not underlined.]

LCO No. 1433 3 of 3