



General Assembly

Substitute Bill No. 307

February Session, 2024



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,
3 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
15 on the best available evidence for the purpose of optimizing clinical care
16 outcomes.
- 17 (4) "Nationally recognized clinical practice guidelines" means

18 evidence-based guidelines developed by independent organizations or
19 medical professional societies utilizing transparent methodologies and
20 reporting structures and conflict-of-interest policies that (A) establish
21 standards of care informed by a systematic review of evidence and
22 assessments of the benefits and costs of alternative care options, and (B)
23 include recommendations intended to optimize patient care.

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

39 (c) Nothing in this section shall be construed to limit the ability of the
40 Department of Social Services to require prior authorization to ensure
41 that a request for biomarker testing meets the standards under this
42 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.*