



General Assembly

**Amendment**

February Session, 2024

LCO No. 3931



Offered by:

SEN. LESSER, 9<sup>th</sup> Dist.

SEN. SEMINARA, 8<sup>th</sup> Dist.

To: Subst. Senate Bill No. 307

File No. 317

Cal. No. 211

**"AN ACT CONCERNING MEDICAID COVERAGE OF BIOMARKER TESTING."**

1 Strike everything after the enacting clause and substitute the  
2 following in lieu thereof:

3 "Section 1. (NEW) (*Effective July 1, 2024*) (a) As used in this section:

4 (1) "Biomarker" means a characteristic, including, but not limited to,  
5 a gene mutation or protein expression that can be objectively measured  
6 and evaluated as an indicator of normal biological processes, pathogenic  
7 processes or pharmacologic responses to a specific therapeutic  
8 intervention for a disease or condition.

9 (2) "Biomarker testing" means the analysis of a patient's tissue, blood  
10 or other biospecimen for the presence of a biomarker, including, but not  
11 limited to, tests for a single substance, tests for multiple substances,  
12 diseases or conditions, and whole genome sequencing.

13 (3) "Clinical utility" means the test result provides information that is

14 used in the formulation of a treatment or monitoring strategy that  
15 informs a patient's outcome and impacts the clinical decision. The most  
16 appropriate test may include both information that is actionable and  
17 some information that cannot be immediately used in the formulation  
18 of a clinical decision.

19 (4) "Consensus statements" means statements developed by an  
20 independent, multidisciplinary panel of experts utilizing a transparent  
21 methodology and reporting structure and with a conflict-of-interest  
22 policy that are (A) aimed at specific clinical circumstances, and (B) based  
23 on the best available evidence for the purpose of optimizing clinical care  
24 outcomes.

25 (5) "Nationally recognized clinical practice guidelines" means  
26 evidence-based guidelines developed by independent organizations or  
27 medical professional societies utilizing transparent methodologies and  
28 reporting structures and conflict-of-interest policies that (A) establish  
29 standards of care informed by a systematic review of evidence and  
30 assessments of the benefits and costs of alternative care options, and (B)  
31 include recommendations intended to optimize patient care.

32 (b) The Commissioner of Social Services, to the extent permissible  
33 under federal law, shall provide coverage for biomarker testing for the  
34 purpose of diagnosis, treatment, appropriate management or ongoing  
35 monitoring of a Medicaid enrollee's disease or condition. The  
36 commissioner shall ensure that such coverage is medically necessary  
37 pursuant to section 17b-259b of the general statutes and, to assist in such  
38 determination of medical necessity, shall analyze relevant information  
39 and use applicable clinical guidelines to help inform such  
40 determination, including medical and scientific evidence supporting  
41 such test when the test provides clinical utility as demonstrated by  
42 medical and scientific evidence, including, but not limited to, one or  
43 more of the following: (1) Approval of such test by the federal Food and  
44 Drug Administration or recommendations on labels of drugs approved  
45 by the federal Food and Drug Administration to conduct such test, (2)  
46 national coverage determinations or local coverage determinations for

47 Medicare Administrative Contractors by the Centers for Medicare and  
 48 Medicaid Services, or (3) nationally recognized clinical practice  
 49 guidelines and consensus statements. Nothing in this section shall  
 50 change the requirement in section 17b-259b of the general statutes that  
 51 policies, guidelines and similar information shall be used solely as  
 52 guidelines and shall not be the basis for a final determination of medical  
 53 necessity.

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

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

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

This act shall take effect as follows and shall amend the following sections:		
Section 1	July 1, 2024	New section