



General Assembly

**Amendment**

February Session, 2024

LCO No. 3873



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) "Consensus statements" means statements developed by an

14 independent, multidisciplinary panel of experts utilizing a transparent  
15 methodology and reporting structure and with a conflict-of-interest  
16 policy that are (A) aimed at specific clinical circumstances, and (B) based  
17 on the best available evidence for the purpose of optimizing clinical care  
18 outcomes.

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

26 (b) The Commissioner of Social Services, to the extent permissible  
27 under federal law, shall provide coverage for biomarker testing for the  
28 purpose of diagnosis, treatment, appropriate management or ongoing  
29 monitoring of a Medicaid enrollee's disease or condition. The  
30 commissioner shall ensure that such coverage is medically necessary  
31 pursuant to section 17b-259b of the general statutes by (1) analyzing  
32 relevant information, including, but not limited to, medical and  
33 scientific evidence supporting the clinical utility of such testing, and (2)  
34 utilizing applicable clinical guidelines. In making such medical  
35 necessity determination, the commissioner shall consider one or more  
36 of the following: (A) (i) Approval of such testing by the federal Food and  
37 Drug Administration, or (ii) recommendations provided on the labels of  
38 certain prescription drugs approved by the federal Food and Drug  
39 Administration that such testing should be conducted prior to the use  
40 of such drugs, (B) national coverage determinations or local coverage  
41 determinations for Medicare Administrative Contractors by the Centers  
42 for Medicare and Medicaid Services, or (C) nationally recognized  
43 clinical practice guidelines and consensus statements.

44 (c) Nothing in this section shall be construed as (1) changing or  
45 superseding the provisions of section 17b-259b of the general statutes  
46 that require that policies, guidelines and similar information be used

47 solely as guidelines and not the basis for a final determination of  
48 medical necessity, and (2) restricting the ability of the Department of  
49 Social Services to require prior authorization for coverage of biomarker  
50 testing to assure that a request for biomarker testing meets the  
51 provisions of this section.

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

55 (e) The Commissioner of Social Services shall ensure that coverage of  
56 biomarker testing pursuant to this section is provided in a manner that  
57 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