

SENATE BILL NO. 118

BY SENATORS TALBOT, BERNARD, BOUDREAUX, BOUIE, CARTER, FESI,
HARRIS, LUNEAU, MIZELL, POPE, PRICE, SMITH, STINE,
TARVER AND WOMACK

1 AN ACT

2 To amend and reenact R.S. 22:1028.3(B)(2), (C), and (D)(introductory paragraph) and (2)
3 and to enact R.S. 22:1028.3(D)(3) and (4), relative to the medical necessity for
4 genetic testing of certain cancer mutations; to require medical necessity for genetic
5 testing of certain cancer mutations if based on nationally recognized clinical practice
6 guidelines; to provide for definitions; and to provide for related matters.

7 Be it enacted by the Legislature of Louisiana:

8 Section 1. R.S. 22:1028.3(B)(2), (C), and (D)(introductory paragraph) and (2) are
9 hereby amended and reenacted and R.S. 22:1028.3(D)(3) and (4) are hereby enacted to read
10 as follows:

11 §1028.3. Required coverage for genetic testing for cancer

12 B.(1) * * *

13 (2) The coverage provided in this Section may be subject to annual
14 deductibles, coinsurance, and copayment provisions as are consistent with those
15 established under the health coverage plan. ~~The coverage provided under this Section~~
16 ~~may be subject to applicable evidence-based medical necessity criteria under the~~
17 ~~plan.~~ **The biomarker test shall be covered for the purposes of diagnosis,**
18 **treatment, appropriate management or ongoing monitoring of an individual's**
19 **disease or condition when the test is supported by medical and scientific**
20 **evidence, including any one of the following:**

21 **(a) Labeled indications for diagnostic tests to direct treatment decisions**
22 **that are approved or cleared by the United States Food and Drug**

1 Administration or indicated diagnostics tests for a drug that is approved by the
 2 United States Food and Drug Administration.

3 (b) Centers for Medicare and Medicaid Services National Coverage
 4 Determinations or Medicare Administrative Contractor Local Coverage
 5 Determinations.

6 (c) Nationally recognized consensus statements and clinical practice
 7 guidelines such as but not limited to those of the National Comprehensive
 8 Cancer Network or the American Society of Clinical Oncology.

9 C. For purposes of this Section, "health coverage plan" means any hospital,
 10 health, or medical expense insurance policy, hospital or medical service contract,
 11 employee welfare benefit plan, contract, or other agreement with a health
 12 maintenance organization or a preferred provider organization, health and accident
 13 insurance policy, or any other insurance contract of this type in this state, including
 14 a group insurance plan, a or self-insurance plan, and the office of group benefits
 15 programs. "Health coverage plan" ~~shall~~ **does** not include a plan providing coverage
 16 for excepted benefits defined in R.S. 22:1061, limited benefit health insurance plans,
 17 ~~and~~ short-term policies that have a term of less than twelve months, **nor any plan**
 18 **offered through the office of group benefits.**

19 D. As used in this Section, the following definitions ~~shall~~ apply unless the
 20 context indicates otherwise:

21 * * *

22 (2) "Biomarker testing" is **means** the analysis of a patient's tissue, blood, or
 23 fluid biospecimen for the presences of a biomarker. Biomarker testing includes but
 24 is not limited to single-analyte tests, multi-plex panel tests, and partial or whole
 25 genome, **whole exome, and whole transcriptome** sequencing.

26 **(3) "Consensus statements" means statements developed by an**
 27 **independent, multidisciplinary panel of experts utilizing a transparent**
 28 **methodology and reporting structure and with a conflict-of-interest policy. Such**
 29 **statements are aimed at specific clinical circumstances and based on the best**
 30 **available evidence for the purpose of optimizing the outcomes of clinical care.**

1 (4) "Nationally recognized clinical practice guidelines" means evidence-
2 based clinical guidelines developed by independent organizations or medical
3 professional societies utilizing a transparent methodology and reporting
4 structure and with a conflict-of-interest policy. Such guidelines establish
5 standards of care informed by a systematic review of evidence and an
6 assessment of the benefits and costs alternative care options and include
7 recommendations intended to optimize patient care.

8 Section 2. This Act shall become effective on January 1, 2023.

PRESIDENT OF THE SENATE

SPEAKER OF THE HOUSE OF REPRESENTATIVES

GOVERNOR OF THE STATE OF LOUISIANA

APPROVED: _____