AN ACT

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

Be it enacted by the Legislature of Louisiana:

Section 1. R.S. 22:1028.3(B)(2) is hereby amended and reenacted and R.S. 22:1028.3(D)(3) and (4) are hereby enacted to read as follows:

§1028.3. Required coverage for genetic testing for cancer

B.(1) * * *

(2) The coverage provided in this Section may be subject to annual deductibles, coinsurance, and copayment provisions as are consistent with those established under the health coverage plan. The coverage provided under this Section may be subject to applicable evidence-based medical necessity criteria under the plan. The biomarker test shall be covered for the purposes of diagnosis, treatment, appropriate management or ongoing monitoring of an individual's...
disease or condition when the test is supported by medical and scientific
evidence, including but not limited to the following:

(a) Labeled indications for tests are approved or cleared by the United
States Food and Drug Administration or indicated tests for a drug that is
approved by the United States Food and Drug Administration.

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

(c) Nationally recognized clinical practice guidelines and consensus
statements.

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

(1) "Consensus statements" means statements developed by an
independent, multidisciplinary panel of experts utilizing a transparent
methodology and reporting structure and with a conflict-of-interest policy and
these statements are aimed at specific clinical circumstances and base the
statements on the best available evidence for the purposes of optimizing the
outcomes of clinical care.

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

Section 2. This Act shall become effective on July 1, 2022.
The original instrument and the following digest, which constitutes no part of the legislative instrument, were prepared by Beth O'Quin.

DIGEST
SB 118 Engrossed 2022 Regular Session Talbot

Present law provides coverage can be subject to annual deductibles, coinsurance, copayment provisions established under a health coverage plan and coverage for genetic testing of certain cancer mutations can be subject to applicable evidence-based medical necessity criteria under a health plan.

Proposed law retains present law, but requires an insurer to cover biomarker testing for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of an individual’s disease or condition when the test is supported by, but not limited to the labeled indications for tests approved or cleared by the United States Food and Drug Administration (FDA), or indicated tests for drugs approved by the FDA, or the Centers for Medicare and Medicaid Services National Coverage Determinations, or Medicare Administrative Contractor Local Coverage Determinations, or a nationally recognized clinical practice guidelines and consensus statements.

Present law provides definitions for "biomarker" and "biomarker test".

Proposed law retains present law but adds definitions for "consensus statements" and "nationally recognized clinical practice guidelines".

Effective on July 1, 2022.

(Amends R.S. 22:1028.3(B)(2); adds R.S. 22:1028.3(D)(3) and (4))

Summary of Amendments Adopted by Senate

Committee Amendments Proposed by Senate Committee on Insurance to the original bill

1. Makes technical changes.

2. Adds provision requiring an insurer cover biomarker testing for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of an individual’s disease or condition when the test is supported by, but not limited to labeled indications for tests approved or cleared by the United States Food and Drug Administration (FDA), or indicated tests for drugs approved by the FDA, or the Centers for Medicare and Medicaid Services National Coverage Determinations, or Medicare Administrative Contractor Local Coverage Determinations, or a nationally recognized clinical practice guidelines and consensus statements.

3. Adds definitions for "consensus statements" and a "nationally recognized clinical practice guidelines".