AN ACT

To amend and reenact R.S. 22:1028.3(B)(2), (C), and (D)(introductory paragraph) and (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 if based on nationally recognized clinical practice guidelines; to provide for definitions; and to provide for related matters.

Be it enacted by the Legislature of Louisiana:

Section 1.  R.S. 22:1028.3(B)(2), (C), and (D)(introductory paragraph) and (2) are 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 any one of the following:

(a) Labeled indications for diagnostic tests to direct treatment decisions that are approved or cleared by the United States Food and Drug
Administration or indicated diagnostics 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 consensus statements and clinical practice
guidelines such as but not limited to those of the National Comprehensive
Cancer Network or the American Society of Clinical Oncology.

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

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

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

(3) "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. Such
statements are aimed at specific clinical circumstances and based on the best
available evidence for the purpose 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. Such 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 January 1, 2023.

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PRESIDENT OF THE SENATE

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SPEAKER OF THE HOUSE OF REPRESENTATIVES

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GOVERNOR OF THE STATE OF LOUISIANA

APPROVED: ____________________________