

INSURANCE CODE

TITLE 8. HEALTH INSURANCE AND OTHER HEALTH COVERAGES

SUBTITLE E. BENEFITS PAYABLE UNDER HEALTH COVERAGES

CHAPTER 1372. COVERAGE FOR BIOMARKER TESTING

Sec. 1372.001. DEFINITIONS. In this chapter:

(1) "Biomarker" means a characteristic that is objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes, or pharmacologic responses to a specific therapeutic intervention. The term includes:

(A) gene mutations; and

(B) protein expression.

(2) "Biomarker testing" means the analysis of a patient's tissue, blood, or other biospecimen for the presence of a biomarker. The term includes:

(A) single-analyte tests;

(B) multiplex panel tests; and

(C) whole genome sequencing.

(3) "Consensus statements" means statements that:

(A) address specific clinical circumstances based on the best available evidence for the purpose of optimizing clinical care outcomes; and

(B) are developed by an independent, multidisciplinary panel of experts that uses a transparent methodology and reporting structure and is subject to a conflict of interest policy.

(4) "Nationally recognized clinical practice guidelines" means evidence-based clinical practice guidelines that:

(A) establish a standard of care informed by a systematic review of evidence and an assessment of the benefits and costs of alternative care options;

(B) include recommendations intended to optimize patient care; and

(C) are developed by an independent organization or medical professional society that uses a transparent methodology

and reporting structure and is subject to a conflict of interest policy.

Added by Acts 2023, 88th Leg., R.S., Ch. 279 (S.B. [989](#)), Sec. 1, eff. September 1, 2023.

The following section was amended by the 89th Legislature. Pending publication of the current statutes, see H.B. [1620](#), 89th Legislature, Regular Session, for amendments affecting the following section.

Sec. 1372.002. APPLICABILITY OF CHAPTER. (a) This chapter applies only to a health benefit plan that provides benefits for medical or surgical expenses incurred as a result of a health condition, accident, or sickness, including an individual, group, blanket, or franchise insurance policy or insurance agreement, a group hospital service contract, or an individual or group evidence of coverage or similar coverage document that is offered by:

- (1) an insurance company;
- (2) a group hospital service corporation operating under Chapter [842](#);
- (3) a health maintenance organization operating under Chapter [843](#);
- (4) an approved nonprofit health corporation that holds a certificate of authority under Chapter [844](#);
- (5) a multiple employer welfare arrangement that holds a certificate of authority under Chapter [846](#);
- (6) a stipulated premium company operating under Chapter [884](#);
- (7) a fraternal benefit society operating under Chapter [885](#);
- (8) a Lloyd's plan operating under Chapter [941](#); or
- (9) an exchange operating under Chapter [942](#).

- (b) Notwithstanding any other law, this chapter applies to:
- (1) a small employer health benefit plan subject to Chapter [1501](#), including coverage provided through a health group cooperative under Subchapter B of that chapter;
 - (2) a standard health benefit plan issued under Chapter [1507](#);

- (3) a basic coverage plan under Chapter [1551](#);
 - (4) a basic plan under Chapter [1575](#);
 - (5) a primary care coverage plan under Chapter [1579](#);
 - (6) a plan providing basic coverage under Chapter [1601](#);
 - (7) the state Medicaid program, including the Medicaid managed care program operated under Chapter [533](#), Government Code;
 - (8) the child health plan program under Chapter [62](#), Health and Safety Code; and
 - (9) a self-funded health benefit plan sponsored by a professional employer organization under Chapter [91](#), Labor Code.
- Added by Acts 2023, 88th Leg., R.S., Ch. 279 (S.B. [989](#)), Sec. 1, eff. September 1, 2023.

Sec. 1372.003. COVERAGE REQUIRED. (a) Subject to Subsection (b), a health benefit plan must provide coverage for biomarker testing for the purpose of diagnosis, treatment, appropriate management, or ongoing monitoring of an enrollee's disease or condition to guide treatment when the test is supported by the following kinds of medical and scientific evidence:

- (1) a labeled indication for a test approved or cleared by the United States Food and Drug Administration;
- (2) an indicated test for a drug approved by the United States Food and Drug Administration;
- (3) a national coverage determination made by the Centers for Medicare and Medicaid Services or a local coverage determination made by a Medicare administrative contractor;
- (4) nationally recognized clinical practice guidelines; or
- (5) consensus statements.

(b) A health benefit plan issuer must provide coverage under Subsection (a) only when use of biomarker testing provides clinical utility because use of the test for the condition:

- (1) is evidence-based;
- (2) is scientifically valid based on the medical and scientific evidence described by Subsection (a);
- (3) informs a patient's outcome and a provider's

clinical decision; and

(4) predominately addresses the acute or chronic issue for which the test is being ordered, except that a test may include some information that cannot be immediately used in the formulation of a clinical decision.

(c) A health benefit plan must provide coverage under Subsection (a) in a manner that limits disruptions in care, including limiting the number of biopsies and biospecimen samples. Added by Acts 2023, 88th Leg., R.S., Ch. 279 (S.B. [989](#)), Sec. 1, eff. September 1, 2023.