310-KK – BIOMARKERS TESTING

EFFECTIVE DATE: 03/17/23

APPROVAL DATE: 12/01/22

I. PURPOSE

This Policy applies to ACC, ACC-RBHA, ALTCS E/PD, DCS/CHP (CHP), and DES/DDD (DDD) Contractors; Fee-For-Service (FFS) Programs including: the American Indian Health Program (AIHP), Tribal ALTCS, TRBHA; and all FFS populations, excluding Federal Emergency Services Program (FES). (For FES, refer to AMPM Chapter 1100). This Policy establishes the coverage requirements of Biomarker Testing.

II. DEFINITIONS

For purposes of this Policy:

BIOMARKER	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 which includes gene mutations or protein expression.
BIOMARKER TESTING	The analysis of a patient's tissue, blood or other biospecimen for the presence of a biomarker, which includes single-analyte tests, multiplex panel tests and whole genome sequencing.
CLINICAL UTILITY	The test result provides information that is used in the formulation of a treatment or monitoring strategy that informs a patient's outcome and impacts the clinical decision. The most appropriate test may include both information that is actionable and some information that cannot be immediately used in the formulation of a clinical decision.

Additional definitions are located on the AHCCCS website at: AHCCCS Contract and Policy Dictionary.

III. POLICY

A. BIOMARKER TESTING

1. The Contractor and FFS providers shall cover medically necessary non-experimental Biomarker Testing for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a member's disease or condition to guide treatment decisions when the test provides Clinical Utility as demonstrated by medical and scientific evidence, including any of the following:
   a. Labeled indications for tests that are approved or cleared by the United States Food and Drug Administration (FDA) or indicated tests for a drug that is approved by the FDA,
   b. Centers for Medicare and Medicaid Services (CMS) national coverage determinations or Medicare administrative contractor local coverage determinations, or
   c. Nationally recognized clinical practice guidelines and consensus statements as outlined in A.R.S. § 20-841.13.

2. The Contractor and FFS providers shall cover Biomarker Testing with the same scope duration and frequency as the system otherwise provides to members pursuant to A.R.S. § 36-2907.03.

3. The Contractor and FFS providers shall ensure that coverage is provided in a manner that limits disruptions in care, including the need for multiple biopsies or biospecimen samples.

4. Prior authorization for Biomarker Testing is required.

5. The Contractor and AHCCCS/DFSM shall have a clear and readily available process to accept electronic requests from providers for exceptions to a coverage policy. Refer to AMPM Policy 810 for FFS prior authorization submission requirements.