

310-KK – BIOMARKERS TESTING

EFFECTIVE DATES: 03/17/23, 06/12/25

APPROVAL DATES: 12/01/22, 03/05/25

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 (FESP). (For FESP, refer to AMPM Chapter 1100). This Policy establishes the coverage requirements of Biomarker Testing as outlined in ARS 36-2907.03.

II. DEFINITIONS

Refer to the [AHCCCS Contract and Policy Dictionary](#) for common terms found in this Policy.

For purposes of this Policy, the following terms are defined as:

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 as specified in ARS 36-2907.03.

III. POLICY

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.

1. Medical necessity can be supported by but not limited to the following:
 - a. The member displays clinical features suggestive of a condition where biomarker is essential for diagnosis, treatment planning, or monitoring,
 - b. The test result will directly impact clinical decision making, clinical outcome, and the member intends to act upon the results,
 - c. The test is scientifically validated to be safe and effective for identifying the specific disease or condition, such as the 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,
 - d. Centers for Medicare and Medicaid Services (CMS) national coverage determinations or Medicare administrative contractor local coverage determinations, or
 - e. Nationally recognized clinical practice guidelines and consensus statements that support actions informed by the biomarker test will likely improve clinical outcomes.
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 ARS 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 optional and can be used with Attachment A. Depending upon the specific clinical situation, requests may be treated as expedited as specified in ACOM Policy 414. Expedited requests must be indicated by selecting the checkbox option in Attachment A.
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 820 for FFS Prior Authorization requirements.
6. The Contractor shall ensure an integrated process or system is designed to assure appropriate utilization of health care resources, in the amount and duration necessary to achieve the desired health outcomes, across the continuum of care, from preventive care to hospice care and as specified in Contract.

AHCCCS reserves the right to monitor data analysis standards and other metrics as appropriate to monitor cost effectiveness and to prevent waste as specified in AMPM Policy 1020 and Contract.