310-KK BIOMARKER TESTING

REVISION DATE: 1/7/2026
REVIEW DATES: 8/21/2025, 12/12/2024
EFFECTIVE DATE: December 13, 2023
REFERENCES: AMPM 310-KK

PURPOSE

This policy establishes the coverage requirements of Biomarker Testing for the Administrative Services Subcontractors (AdSS).

DEFINITIONS

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 which includes gene mutations or protein expression.
2. "Biomarker Testing" means 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.

3. "Clinical Utility" means 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 20-841.135.
4. "Member" means the same as "Client" a person receiving developmental disabilities services from the Division, as specified in A.R.S. § 36-551.

POLICY

A. BIOMARKER TESTING

1. The AdSS 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.

2. The AdSS shall require medical necessity be supported by the following:
    a. The Member displays clinical features suggestive of a condition where biomarker is essential for:
        i. Diagnosis,
        ii. Treatment planning, or
        iii. Monitoring.
    b. The test result will directly impact clinical decision making, clinical outcome, and the Member intends to act upon the results; and
    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; or

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.

3. The AdSS 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.

4. The AdSS shall ensure that coverage is provided in a manner that limits disruptions in care, including the need for multiple biopsies or biospecimen samples.

5. The AdSS may require prior authorization for Biomarker Testing as specified in AMPM 310-KK.

6. The AdSS shall treat requests listed above in (5) as expedited depending upon the specific clinical situation as specified in ACOM 414.

7. The AdSS shall have a clear and readily available process to accept electronic requests from providers for exceptions to a coverage policy.
8. The AdSS 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.

Vicki D. Copeland

Signature of Chief Medical Officer

Vicki D. Copeland

Name

2025-12-24

Date