

310-KK BIOMARKER TESTING

REVIEW DATE:

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.
4. “Member” means the same as “Client” as defined 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 the following medical and scientific evidence:

- 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 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.
 3. 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.
 4. The AdSS shall require prior authorization for Biomarker Testing.
 5. The AdSS shall have a clear and readily available process to accept electronic requests from providers for exceptions to a coverage policy.

Signature of Chief Medical Officer: 
[Anthony Dekker \(Dec 7, 2023 10:16 MST\)](#)
Anthony Dekker, D.O.