

310-N LABORATORY

REVISION DATES: 2/18/2026, 3/12/2025, 7/3/2015, 9/15/2014
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EFFECTIVE DATE: June 30, 1994
REFERENCES: AMPM 310-N

PURPOSE

This policy establishes requirements for medically necessary Laboratory services.

DEFINITIONS

1. "Clinical Laboratory Improvement Act (CLIA)" means a certificate issued on the basis of the Laboratory's accreditation by an organization approved by the Centers for Medicare and Medicaid (CMS) in accordance with 42 CFR 493.61.
2. "Laboratory" means a facility for the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or that otherwise describes the

presence or absence of various substances or organisms in the body as defined in 42 CFR 493.2.

POLICY

A. CLINICAL LABORATORY, RADIOLOGICAL, AND MEDICAL IMAGING SERVICES (ACUTE CARE SERVICES)

1. The Division shall cover medically necessary Laboratory tests, procedures, and screenings performed by any contracted Laboratory that has the proper CLIA certifications and is an AHCCCS registered provider.
2. The Division shall cover medically necessary Laboratory services for diagnostic, screening and monitoring purposes when ordered by a Member's Primary Care Provider (PCP), other attending physician or dentist and provided by a:
 - a. Free-standing Laboratory or hospital Laboratory;
 - b. Clinic;
 - c. Physician office; or
 - d. Other health care facility Laboratory with CLIA licensure or a Certificate of Waiver.

3. The Division shall require all clinical Laboratory, radiological, and medical imaging service providers:
 - a. Have the proper CLIA certifications;
 - b. Satisfy all applicable State license and certification requirements;
 - c. Be registered with the Arizona Health Care Cost Containment System (AHCCCS); and
 - d. Perform only those services specific to their license and certification.
4. The Division shall refer to AMPM Policy 310-II for requirements regarding Genetic Testing and AMPM Policy 310-KK for requirements regarding Biomarkers Testing.
5. The Division shall refer to the AHCCCS Covered Behavioral Health Services Guide on the Medical Coding and Resource website for information on presumptive and definitive urine drug testing guidance and requirements.

Vicki D. Copeland, MD

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Signature of Chief Medical Officer

Name

2026-02-08

Date