310-II GENETIC TESTING

REVISION DATE: 5/14/2025
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REFERENCES: AMPM 310-II

PURPOSE

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

DEFINITIONS

1. "Genetic Testing" means the sequencing of human Deoxyribonucleic Acid (DNA) obtained from a small sample of body fluid or tissue in order to discover genetic differences, anomalies, or mutations.
2. "Member" means the same as "Client", a person receiving developmental disabilities services from the Division, as specified in A.R.S. § 36-551.
3. "Prior Authorization" or "PA" means approval from a health plan that may be required before a Member gets a service. This is not a promise that the health plan will cover the cost of the service.

4. "Rapid Whole Genome Sequencing" means an investigation of the entire human genome, including coding and noncoding regions and mitochondrial deoxyribonucleic acid, that identifies disease-causing genetic changes and that returns the preliminary positive results within five days and final results within 14 days which includes:
    a. Member only whole genome sequencing,
    b. Duo whole genome sequencing,
    c. Trio whole genome sequencing of the Member, and
    d. The Member's biological parent.

POLICY

A. GENETIC TESTING

1. The AdSS shall cover medically necessary, nonexperimental, cost-effective genetic testing, Rapid Whole Genome Sequencing, and newborn screening within the requirements specified in this policy.
2. The AdSS shall cover medically necessary Genetic Testing and counseling when the following criteria are met:

a. When the Member:
    i. Displays clinical features of a suspected genetic condition;
    ii. Is at direct risk of inheriting the genetic condition in question which could be due to:
        a) A causative familial variant has been identified in a close family member, or
        b) The Member's family history indicates a high risk.
    iii. Is being considered for treatment which has significant risk of serious adverse reactions, or is ineffective, in a specific genotype.
b. The results of the Genetic Testing are necessary to:
    i. Differentiate between treatment options;
    ii. The Member has indicated they will pursue treatment based on the results of the testing; and
    iii. An improved clinical outcome is probable as evidenced by:

a) Clinical studies of fair-to-good quality published in peer-reviewed medical literature have established that actions taken as a result of the test will improve clinical outcome for the Member; or

b) Treatment has been demonstrated to be safe and likely to be effective based on the weight of opinions from specialists who provide the service or related services if the condition is rare.

c. The test is proven to be scientifically valid for the identification of the specific genetically-linked disease or clinical condition; and

d. A licensed genetic counselor or the ordering provider has counseled the Member about the medical treatment options prior to the genetic test being conducted.

2. The AdSS shall cover the following medically necessary Genetic Testing and counseling, irrespective of the requirements listed above:
    a. The results of the Genetic Testing will confirm either:
        i. A diagnosis and by so doing avoid further testing that is invasive and has risks of complications; or
        ii. A significant developmental delay in an infant or child and the cause has not been determined through routine testing with one of the following met:
            a) The genetic testing is limited to Chromosomal Microarray (CMA),
            b) Chromosomal testing for Fragile X, or
            c) Any further gene testing meets all other criteria in this policy.
    b. The test is proven to be scientifically valid for the identification of the specific genetically-linked disease or clinical condition; and

c. A licensed genetic counselor or the ordering provider has counseled the Member prior to the genetic test being conducted.

B. LIMITATIONS

1. The AdSS shall not cover Genetic Testing under the following circumstances:
   a. To determine specific diagnoses or syndromes when such diagnoses would not definitively alter the medical treatment of the Member except as described above in A (2)(a);
   b. To determine the likelihood of associated medical conditions occurring in the future;
   c. As a substitute for ongoing monitoring or testing of potential complications or sequelae of a suspected genetic anomaly;
   d. For purposes of determining current or future reproductive decisions;
   e. For determining eligibility for a clinical trial; or

f. Paying for panels or batteries of tests that include one or more medically necessary tests, along with tests that are not medically necessary, when the medically necessary tests are available individually.

C. PRIOR AUTHORIZATIONS

1. The AdSS shall require that Prior Authorization requests include documentation regarding how the Genetic Testing is consistent with the Genetic Testing coverage and include:
   a. Recommendations from a licensed genetic counselor or ordering provider;
   b. Clinical findings including family history and any previous test results;
   c. A description of how the genetic test results will differentiate between treatment options for the Member or meet the requirements of section A(2)(a) or A(2)(b);
   d. The rationale for choosing one of these types of genetic testing:
      i. Full gene sequencing,

ii. Deletion or duplication,

iii. Microarray, and

iv. Individual variants.

e. Medical literature citations as applicable.

D. RAPID WHOLE GENOME SEQUENCING

1. The AdSS shall cover Rapid Whole Genome Sequencing for Members who meet the criteria as specified in 2023 Arizona Senate Bill 1726.
2. The AdSS shall require PA for Whole Genome Sequencing and the request shall include documentation with the coverage criteria.

SUPPLEMENTAL INFORMATION

Pursuant to A.R.S. §36-694, all babies born in Arizona are tested for specific congenital disorders through the Arizona Department of Health Newborn Screening Program. Newborn screening including confirmatory testing is not subject to the requirements of this Policy.

Vicki Copeland, MD

Signature of Chief Medical Officer

Vicki Copeland

Name

05/13/2025

Date