310 – II - GENETIC TESTING

EFFECTIVE DATES: 01/01/18, 11/27/18, 12/03/24

APPROVAL DATES: 09/21/17, 10/30/18, 09/12/24

I. PURPOSE

This Policy applies to ACC, ACC-RBHA , ALTCS E/PD, DCS CHP (CHP), DES DDD (DDD) Contractors; and Fee-For-Service (FFS) Programs including: the American Indian Health Program (AIHP), DES DDD Tribal Health Program (DDD THP), Tribal ALTCS, TRBHA; and all FFS populations, excluding Federal Emergency Services Program (FESP). (For FESP, refer to AMPM Chapter 1100). This Policy establishes requirements for genetic testing.

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:

RAPID WHOLE GENOME SEQUENCING	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. Includes member only whole genome sequencing, duo whole genome sequencing, trio whole genome sequencing of the member, and the member's biological parent.

III. POLICY

The Contractor and Fee-For-Service (FFS) programs shall cover medically necessary, non-experimental, cost-effective genetic testing, Rapid Whole Genome Sequencing, and newborn screening within the requirements specified in this policy.

A. GENETIC TESTING

1. Genetic testing and counseling are considered medically necessary when the following criteria are met:
   a. The member:
      i. Displays clinical features of a suspected genetic condition, or
      ii. Is at direct risk of inheriting the genetic condition in question (e.g., a causative familial variant has been identified in a close family member or the member's family history indicates a high risk), or
      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 differentiate between treatment options, the member has indicated they will pursue treatment based on the results of the testing, and an improved clinical outcome is probable as evidenced by:
   i. 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
   ii. If the condition is rare, 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.
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. Irrespective of the requirements of 1, above, genetic testing and counseling are also considered medically necessary when:
   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. In this case, genetic testing is limited to Chromosomal Microarray (CMA) and chromosomal testing for Fragile X. Any further gene testing shall meet 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

Genetic testing is not covered under the following circumstances:

1. To determine specific diagnoses or syndromes when such diagnoses would not definitively alter the medical treatment of the members except as described in 2.a.i. or 2.a.ii.

2. To determine the likelihood of associated medical conditions occurring in the future.

3. As a substitute for ongoing monitoring or testing of potential complications or sequelae of a suspected genetic anomaly.

4. For purposes of determining current or future reproductive decisions.

5. For determining eligibility for a clinical trial.

6. 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. GENETIC TESTING PRIOR AUTHORIZATION

Genetic testing requires Prior Authorization (PA). The PA requests shall include documentation regarding how the genetic testing is consistent with the genetic testing coverage described in this Policy, and at a minimum shall include:

1. Recommendations from a licensed genetic counselor or ordering provider.
2. Clinical findings including family history and any previous test results.
3. A description of how the genetic test results will differentiate between treatment options for the member or meet the requirements of 2.a or 2.b.
4. The rationale for choosing the particular type of genetic test requested (e.g., full gene sequencing, deletion/duplication, microarray, individual variants).
5. Medical literature citations as applicable.

D. RAPID WHOLE GENOME SEQUENCING

AHCCCS covers Rapid Whole Genome Sequencing for members who meet the criteria as specified in 2023 Arizona Senate Bill 1726; Laws 2023, Chapter 139 Section 9.

The PA for Rapid Whole Genome Sequencing is required and requests shall include documentation consistent with the coverage criteria.

E. NEWBORN SCREENING

Pursuant to ARS 36-694, all babies born in Arizona are tested for specific congenital disorders through the Arizona Department of Health Services (ADHS) Newborn Screening Program. Newborn screening including confirmatory testing is not subject to the requirements of this Policy. For further details refer to AMPM Policy 430.