

310 – II GENETIC TESTING

EFFECTIVE DATES: 01/01/18, 11/27/18

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

I. PURPOSE

This Policy applies to AHCCCS Complete Care (ACC), ALTCS E/PD, DCS/CMDP, DES/DDD, RBHA Contractors; and Fee-For-Services (FFS) Programs and populations as delineated within Policy. This Policy does not apply to Federal Emergency Services (FES).

II. DEFINITIONS

GENETIC TESTING Genetic testing is the sequencing of human DNA obtained from of a small sample of body fluid or tissue in order to discover genetic differences, anomalies, or mutations.

III. POLICY**A. GENETIC TESTING**

1. Genetic testing and counseling are considered medically necessary when criteria 1.a. through 1.d. are all 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, the 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 member 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, or
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. PRIOR AUTHORIZATION

Genetic testing requires prior authorization. Prior authorization 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), and
5. Medical literature citations as applicable.

D. NEWBORN SCREENING

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.