TITLE Genetic Testing Prior Authorization Guideline
RESPONSIBLE AREA Health Services
History of Review: 04/17/13, 04/16/14, 1/23/15, 7/1/16, 7/7/17, 12/9/18; 06/03/19 **Approval Date:** 06/03/19

DESCRIPTION

This guideline is used in the prior authorization and decision-making process regarding requests for genetic testing. This guideline applies to, but is not limited to:

- Karyotype (chromosome banding)
- High Resolution Chromosome Analysis
- Fluorescent in-situ Hybridization (FISH)
- Chromosome Microarray Testing (CMA)
- Genomic Sequencing Procedures
- Pharmacogenetic Testing
- Whole Exome and Whole Genome Sequencing

This guideline does not represent a standard of care, nor is it intended to dictate an exclusive course of management. Since medical research, physician practice patterns, and health care technology are continuously evolving, please note the information contained in this guideline may be updated.

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.

CLINICAL GUIDELINE

Criteria for Coverage

Genetic testing is covered when all 4 criteria below are met:

1. The child:
    a. Has features of a suspected genetic condition, or
    b. Is at direct risk of inheriting the suspected genetic condition (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
    c. Is being considered for treatment which
        i. significant risk of serious adverse reactions in a specific genotype, or

ii. is ineffective, in a specific genotype.

2. The results of the genetic testing are necessary to
    a. differentiate between treatment options,
    b. the child and family has indicated they will pursue treatment based on the results of the testing, and
    c. an improved clinical outcome is likely, based on:
        i. Clinical studies (of fair-to-good quality) published in peer-reviewed medical literature have established that actions taken as a result of the genetic testing will improve clinical outcome for the child, 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.
3. The test is proven to be scientifically valid for the identification of the specific genetically-linked disease or clinical condition, and
4. A licensed genetic counselor or the ordering provider has counseled the child and family about the medical treatment options prior to the genetic testing.

Genetic testing is also covered when all the following are met:

1. The results of the genetic testing will confirm either:
    a. A diagnosis and by so doing avoid further testing that is invasive and has risks of complications, or
    b. 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 genetic testing shall meet all other criteria in this guideline.
2. The test is proven to be scientifically valid for the identification of the specific genetically-linked disease or clinical condition, and
3. A licensed genetic counselor or the ordering provider has counseled the member prior to the genetic test being conducted.

Genetic Testing is NOT covered

1. To determine specific diagnoses or syndromes when such diagnoses would not definitively alter the medical treatment of the member except as noted above (to avoid invasive testing and developmental delay).
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.

Prior Authorization

1. ALL genetic testing requires prior authorization.
2. Prior authorization requests should include
    a. Documentation that addresses the criteria in this authorization guideline.
    b. Recommendations from a licensed genetic counselor or ordering provider.
    c. Clinical findings including family history and any previous test results.
    d. A description of how the genetic test results will differentiate between treatment options for the member or meet the requirements of this authorization guideline.
    e. The rationale for choosing the particular type of genetic test requested (e.g., full gene sequencing, deletion/duplication, microarray, individual variants), and
    f. Medical literature citations as applicable.
    g. Providers must provide the specific requested and specify the number of units.

Newborn Screening confirmatory testing

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.

PLEASE NOTE: State and Federal law take precedence over prior authorization guidelines. CMDP reserves the right to review and update guidelines periodically.

REFERENCES

MPM 310-II Genetic Testing