# MEDICAL REVIEW GUIDELINE

## Genetic Testing

Adopted by Medical Care Management Committee on May 26, 2011
MCMC Approval Date: October 16, 2025

COMMUNITY HEALTH CHOICE
COMMUNITY CARES

## Genetic Testing

*This Medical Review Guideline (Guideline) is provided for informational purposes only and does not constitute medical advice. It is intended solely for the use of Community Health Choice, Inc. (Community) clinical staff as a guideline for use in determining medical necessity of requested procedures and therapy. This Guideline does not specifically address eligibility or benefit coverage. Other Policies and Coverage Determination Guidelines may apply. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the plan benefit coverage prior to use of this Medical Review Guideline. If there is a discrepancy between this Guideline and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern. Community reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary.*

### APPLIES TO

☒ STAR
☒ Health Insurance Marketplace
☒ STAR+PLUS
☒ CHIP/CHIP-P
☐ Medicare Advantage (i.e. D-SNP)

### PURPOSE

Genetic disorders are often diagnosed based on symptoms, physical findings and biochemical tests. The field of genetic testing is rapidly evolving. In some situations, genetic testing may be used to arrive at a diagnosis when other tests are not available or are not helpful. However, there are also limitations. A specific genetic abnormality may be observed but this may or may not reliably identify a disorder and may or may not result in improved care or treatment of the individual.

TEXAS BIOMARKER LAW, S.B. No. 989
Community covers genetic testing, in alignment with the Texas Biomarker Law, for the purpose of diagnosis, treatment, appropriate management, or ongoing monitoring of a member's disease or condition to guide treatment when the test is supported by medical and scientific evidence. In accordance with the law, in order for the test to be covered, the test must provide clinical utility because use of the test for the condition:

- Is evidence-based
- Is scientifically valid
- Is outcome focused
- Predominately addresses the acute issue for which the test is being ordered

This Guideline is intended to facilitate the utilization management process by providing an overview of how Community appropriately determines medical necessity. The goal of Community in adopting this guideline is not to disrupt the physician-patient relationship nor to diminish

physician autonomy. Instead, it is to promote patient safety and improved clinical outcomes through the adherence to evidence-based practices. Community has developed this Guideline via an ongoing process that includes a review of the most current evidence-based literature and input from clinical and program staff, and often from external clinical experts. Deeming a particular service or supply medically necessary, does not guarantee that the service or supply is covered and will be paid by Community for a particular member.

## GUIDELINE

Community considers genetic testing to be medically necessary for diagnostic purposes when **all** of the following criteria are met:

1. The member displays clinical features, or is at direct risk of inheriting the mutation in question (pre-symptomatic); ***and***
2. The results of the test, either positive or negative, are essential to the medical management of the member (e.g. will result in initiation of new course of therapy, alter an existing or proposed therapy, or determine future care); ***and***
3. A definitive diagnosis remains uncertain after history, physical examination, pedigree analysis, genetic counseling, and the suspected genetic disorder cannot be diagnosed by biochemical or other laboratory test; ***and***

The test has been established by clear and convincing evidence in scientific literature to be reliably associated with the specific disease or disorder.

## PROCESS FOR REVIEW

**Situations where genetic testing is specifically considered not medically necessary:**

1. Testing for screening purposes, or without a reasonable likelihood of confirming a specific genetic disorder.
2. When the diagnosis can be made clinically.
3. Testing of family members (Exception for Texas Medicaid members under age 21: Whole Genome Sequencing CPT 81426 for family members when documentation shows how comparator genome information affects treatment of the member).
4. Repeat genetic testing.
5. Direct-to-Consumer (at-home) genetic testing.

**SPECIFIC CONDITIONS**:
The following are guidelines for genetic testing for specific conditions:

Autism Spectrum Disorder (ASD) or Pervasive Developmental Disorder (PDD)

- The member has been evaluated by a Board-Certified or Board-Eligible Medical Geneticist, Developmental/Behavioral Pediatrician, Pediatric or Adult Neurologist to evaluate if the genetic test is warranted.
- Chromosomal Microarray Analysis (CMA) is a first line test for children with ASD/PDD.
- Karyotyping may be warranted if a balanced translocation is suspected.
- FMR1 gene testing for fragile X syndrome is appropriate.
- Additional genetic testing (beyond CMA, fragile X, and possibly karyotype) is considered only for individuals with dysmorphic features, microcephaly, macrocephaly, or cognitive impairment. Specific testing should be guided by the member's individual clinical profile.
    - Whole-genome sequencing (WGS) testing is not medically necessary for suspected or diagnosed autism spectrum disorder per InterQual. Exception for Texas Medicaid members under age 21: refer to the Texas Medicaid Provider Procedures Manual, Radiology and Laboratory Services Handbook, Authorization Requirements for Whole Genome Sequencing.

<u>Genetic Testing in Intellectual Disability (ID)/Global Developmental Delay (GDD)</u>

- The member has been evaluated by a Board-Certified or Board-Eligible Medical Geneticist, Developmental/Behavioral Pediatrician, Pediatric or Adult Neurologist to evaluate if the genetic test is warranted.
- If a specific diagnosis is suspected, it should be confirmed using appropriate diagnostic studies including single-gene tests if necessary or CMA.
- If diagnosis is unknown or not clinically suspected the following evaluation is recommended:
    - CMA
    - Fragile X gene testing
    - Consider specific metabolic testing based on history and physical examination findings, and may include serum total homocysteine, acyl-carnitine profile, amino acids; and urine organic acids, glycosaminoglycans, oligosaccharides, purines, pyrimidines, GAA/creatine metabolites.
    - Additional genetic testing (beyond CMA, fragile X, and possibly karyotype) is considered only for individuals with dysmorphic features, microcephaly or macrocephaly. For Texas Medicaid members under age 21, refer to the Texas Medicaid Provider Procedures Manual, Radiology and Laboratory Services Handbook, Authorization Requirements for Whole Genome Sequencing.

<u>Genetic Testing in Major Congenital Anomalies</u>

- CMA and additional genetic testing may be indicated when a major malformation or multiple clinical findings and laboratory values suggest a genetic etiology but when the clinician is unable to give a clear diagnosis for which the results would be essential to medical management.

Prenatal Screening for Fetal RHD (CPT 81403, 0494U, 0488U)

Community considers measurement of cell-free DNA for fetal genotyping for RHD status medically necessary when all of the following criteria are met:

- Pregnancy is at risk for alloimmunization due to maternal RHD NEGATIVE or the presence of red cell antigen antibodies
- Paternal antigen typing is unavailable or heterozygous
- Amniocentesis is declined or contraindicated

Multigene panel testing for genetic mutations in cancer

Community considers a multigene panel testing in cancer to be medically necessary when **all** of the following criteria are met:

- The member has a diagnosis of cancer; ***and***
- The member has pretest genetic counseling with a health professional who does not work for a testing laboratory; ***and***
- All the genetic tests in the panel are essential and will affect the cancer treatment options; ***and***
- The panel must meet National Comprehensive Cancer Network (NCCN) or InterQual guidelines' genetic testing criteria and management recommendations.

## REFERENCES

ACOG Clinical Practice Update: Paternal and Fetal Genotyping in the Management of Alloimmunization in Pregnancy. Obstetrics & Gynecology 144(2): p e47-e49, August 2024.

InterQual® 2025, Oct. 2025 Release, CP: Molecular Diagnostics, Whole Genome Sequencing (WGS), Whole Exome Sequencing (WES), and Chromosomal Microarray (CMA) for Congenital or Hereditary Disorders

National Comprehensive Cancer Network (NCCN) Guidelines

Texas Biomarker Law, Chapter 1372 of Subtitle E, Title 8 of the Texas Insurance Code (TIC), as added by S.B. No. 989

Texas Medicaid Provider Procedure Manual, Radiology and Laboratory Services Handbook, Section 3.2.1 Authorization Requirements for Whole Genome Sequencing, Accessed October 7, 2025.

UpToDate review on "Autism spectrum disorder: Diagnosis" (August, 2025)

***This Guideline is reviewed annually and is approved by the Medical Care Management Committee.***

| POLICY HISTORY (reviews and revisions) | Date | Approval Date |
|---|---|---|
| Policy developed | | |
| Archived policies: annually reviewed but policy history not recorded | -- | -- |
| Added Direct-to-Consumer testing and Multigene panel testing for genetic mutations in cancer | 6/2023 | 07/2024 |
| Added Whole-genome sequencing testing; added health plans, references, and policy history | 8/2024 | 10/17/2024 |
| Added Texas Biomarker Law information. Changes for readability. Updated references. Added Fetal RHD criteria. | 10/2025 | 10/16/2025 |