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Genetic Services Biomarker Testing Expanded Carrier Screening Criteria for Prior Authorization

Background:

Effective for dates of service on or after September 1, 2024, genetic services biomarker testing for expanded carrier screening (ECS) will become a benefit of Texas Medicaid. This update is mandated by Senate Bill (S.B.) 989 (88th Legislature, Regular Session 2023). Refer to the MCO notice, *Genetic Services Biomarker Testing Benefits for Texas Medicaid Effective September 1, 2024*, for information regarding updates to the Texas Medicaid Provider Procedures Manual (TMPPM) related to this mandate.

Key Details:

This article serves as interim guidance for traditional fee-for-service (FFS) Medicaid for the ECS benefit and related prior authorization criteria until future TMPPM updates are finalized.

MCOs can utilize the following criteria as a framework for their prior authorization guidelines, or they may opt to develop their own. All services must be rendered with the same amount, duration, and scope available to FFS members.

Carrier Screening Overview/Scope

Carrier screening is a genetic test that identifies whether a person carries a genetic mutation that could increase the risk of their children inheriting a genetic disorder. Carrier screening targets genetic disorders inherited through autosomal recessive or X-linked patterns. Individuals are considered carriers if they are asymptomatic but carry the genetic variant responsible for the disorder. Children can inherit autosomal recessive disorders when receiving two copies of the gene associated with the disorder, one from each parent, while X-linked disorders are caused by mutations in genes on the X chromosome.

Carrier screening may be performed in the preconception or prenatal periods. Risk-based carrier screening is performed on individuals with an increased risk of being a carrier of a specific disorder, based on population carrier frequency, family history, or ethnicity. Carrier screening typically tests for a single gene, or a small number of genes, known to have the disorder-causing variant(s).

ECS uses a panel test that simultaneously screens for many genes linked to disorders that are present in the general population and may have increased frequency in specific populations. The genes tested in an ECS panel vary by laboratory and may not all test for the same genes. ECS panels can test for as few as five genes or as many as several hundred.

A targeted screening approach may be appropriate instead of ECS. Instances when targeted screening would be appropriate include but are not limited to:

- The individual or their reproductive partner is a known carrier for one or more conditions being screened.
- The individual or their reproductive partner has a first- or second-degree relative who is affected by a condition being screened.
- The individual or their reproductive partner has a first-degree relative with offspring affected by the condition being screened.

- The individual or their reproductive partner is a member of a population known to have a carrier frequency rate that exceeds the threshold for American College of Medical Genetics and Genomics (ACMG) Tier 1 risk-based screening.

ECS, procedure code 81443, is limited to once per lifetime with any provider.

Note: A first-degree relative is defined as a blood relative with whom an individual shares approximately 50% of his/her genes, including the individual's parents, full siblings, and children. A second-degree relative is defined as a blood relative with whom an individual shares approximately 25% of his/her genes, including the individual's grandparents, grandchild, uncle, aunt, niece, nephew, or half-sibling.

Prior Authorization Requirements

Prior authorization may be granted for ECS using procedure code 81443 when the following criteria are met:

- The individual being tested is female, between 10 and 55 years of age, and pregnant or considering pregnancy.
- Pre-screening genetic counseling has been performed by one of the following provider types:
    - A physician board-certified in one or more of the following:
        - Medical genetics
        - Maternal-fetal medicine
        - Obstetrics/gynecology
        - Family medicine
    - A board-certified genetic counselor
    - A physician assistant, nurse practitioner, clinical nurse specialist, or certified nurse midwife with training and expertise in genetics and genetic counseling
- The ECS panel meets all the specifications in the following section.

ECS Panel Specifications

- The ECS panel must screen for conditions having all the following characteristics:
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    - Childhood onset
    - Can be diagnosed prenatally
    - Possess a well-defined phenotype
    - Known to cause cognitive or physical impairment
    - Associated with a known pathogenic or likely pathogenic gene variant
- The ECS panel must include sequencing of at least 15 genes, including:
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    - Conditions in ACMG Tier 2, with a carrier frequency of 1 in 100 or greater
    - Conditions in ACMG Tier 1
    - X-linked conditions

- The ECS panel must not include genes associated with known adult-onset conditions, including but not limited to hereditary cancers, dementia, or blood clotting disorders (e.g., hereditary breast and ovarian cancer, Lynch Syndrome, Alzheimer's Disease, Huntington's Disease, or Factor V Leiden).

Uses of an ECS Panel

Knowledge of the pathogenic variant(s) may be used for the management of:

- Pregnancy or antenatal interventions
- Delivery or other care planning for the potentially affected fetus of a pregnant individual

- Preconception family planning

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