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Genetic Services Biomarker Testing Whole Genome Sequencing Criteria for Prior Authorization

Background:

Effective for dates of service on or after September 1, 2024, genetic services biomarker testing for whole genome sequencing (WGS) 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 WGS 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.

Whole Genome Sequencing Overview/Scope

Whole genome sequencing (WGS) is defined as the sequencing of the entire human genome, including protein-coding regions (exons) and noncoding regions. WGS captures most genomic variation in a single test and is useful for patients with rare disorders where hypothesis-driven approaches have failed to produce a diagnosis. WGS can identify or confirm the genetic etiology of a disorder in patients (procedure code 81425). When needed for additional diagnostic insight, comparator genomes can be used from a relative such as parents or siblings (procedure code 81426). Reevaluation of the genome is also available when needed for additional diagnostic yield (procedure code 81427). Procedure codes 81425 and 81427 may be a benefit once per lifetime with any provider. Procedure code 81426 may be a benefit up to a maximum of twice per lifetime.

Prior Authorization Requirements

Prior authorization may be granted for WGS for individuals under 21 years of age when it is considered medically necessary, which requires that all the following criteria are met:

- The individual has received pretest genetic counseling.
- The individual has been evaluated by a physician board-certified in one of the following fields:
    - Medical genetics
    - Maternal-fetal medicine
    - Neonatology
    - Neurology
    - Developmental pediatrics

  This evaluation may be performed in person or via synchronous audio-visual telemedicine in consultation with a consulting physician who has personally examined the individual.

- A three-generation pedigree must be completed, as appropriate.
- The ordering physician must conduct a mandatory pretest and commit to conducting post-test follow-up counseling.
- Test results are expected to directly impact clinical decision-making or clinical outcome for the individual being tested.
- No other causative circumstances (e.g., environmental exposures, injury, prematurity, or infection) can explain the individual's symptoms.
- A genetic etiology is considered the most likely explanation for the phenotype, based on multiple congenital abnormalities affecting unrelated organ systems or any two of the following:
    - Abnormality affecting at minimum a single organ system
    - Profound global developmental delay, intellectual disability, symptoms of a complex neurodevelopmental disorder, or severe neuropsychiatric condition
    - Family history strongly suggestive of a genetic etiology, including consanguinity
    - Period of unexplained developmental regression
    - Biochemical findings suggestive of an inborn error of metabolism where targeted testing is not available

- Clinical presentation does not fit a well-described syndrome for which single-gene or targeted panel testing is available (e.g., comparative genomic hybridization [CGH] /chromosomal microarray analysis [CMA]).
- WGS is more practical than the separate single gene tests or panels that would be recommended based on the differential diagnosis.
- WGS results may preclude the need for multiple or invasive procedures, follow-up, or screening that would be recommended in the absence of testing.

Conditions that may be considered to qualify for WGS include, but are not limited to, the following:

- Unexplained or global developmental delay
- Moderate, severe, or profound intellectual disability diagnosed before 21 years of age
- Epileptic encephalopathy with onset before three years of age
- Clinical history strongly suggests a genetic cause and two or more of the following features are present:
    - Congenital anomaly
    - Significant hearing or visual impairment diagnosed before 21 years of age
    - Laboratory abnormalities suggestive of an inborn error of metabolism (IEM)
    - Autism spectrum disorder or neuropsychiatric condition (e.g., bipolar disorder, schizophrenia, or obsessive-compulsive disorder)
    - Hypotonia or hypertonia in infancy
    - Dystonia, ataxia, hemiplegia, neuromuscular disorder, movement disorder, or other neurologic abnormality
    - Unexplained developmental regression, unrelated to autism or epilepsy
    - Growth abnormality (e.g., failure to thrive, short stature, microcephaly, macrocephaly, or overgrowth)
    - Persistent and severe immunologic or hematologic disorder
    - Dysmorphic features
    - Consanguinity
    - Other first- or second-degree family member(s) with similar clinical features

Reevaluation (procedure code 81427) of a previously obtained WGS sequence (procedure code 81425) is considered medically necessary when the above criteria for WGS and any of the following conditions are met:

- Onset of additional symptoms that broadens the phenotype assessed during the original exome/genome evaluation
- Birth or diagnosis of a similarly affected first-degree relative* that has expanded the clinical picture
- New scientific knowledge that suggests a previously unknown link between the individual's findings and specific genes/pathogenic or likely pathogenic variants and that at least 18 months have passed since the last analysis

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.

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