DRAFT POLICY -- OPEN FOR PUBLIC COMMENT

This drafted policy is open for a two-week public comment period. This box is not part of the drafted policy language itself and is intended for use only during the comment period to provide readers with a summary of what has changed.

HHSC is performing a targeted review of Genetic Services Medicaid medical benefits for the implementation of S.B. 989, 88th Regular Session. Whole Genome Sequencing (WGS), which includes procedure codes 81425, 81426, and 81427, is being considered as part of this review. Prior authorization requirements for WGS are published for comment. Concurrently, a comprehensive review of the Genetic Services policy is underway and will include language for WGS in the Texas Medicaid Provider Procedures Manual (TMPPM) upon completion of the review and effective date of the updated policy.

The following is a summary of all new policy language in scope for this review:

- Prior authorization requirements for WGS services for procedure codes 81425, 81426, and 81427.

  WGS services will be made a benefit effective 9/1/2024. Language for prior authorization requirements is being published for comment ahead of benefit implementation. Formal policy will follow upon completion of a comprehensive review of the Genetic Services policy currently in progress and will include the prior authorization requirements for WGS at that time.

Note: The current language regarding the genetic services benefit can be found in the Texas Medicaid Provider Procedures Manual (TMPPM), Vol 2 Medical and Nursing Specialists, Physicians, and Physician Assistants Handbook, Section 5.2.-5.4.2.

Whole Genome Sequencing Criteria for Prior Authorization

Whole Genome Sequencing Overview/Scope

Whole Genome Sequencing (WGS) describes 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). Re-evaluation 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 Whole Genome Sequencing (WGS)when the following criteria are met.

1. WGS is considered medically necessary when all of the following criteria are met for individuals under 21 years of age:

1.1 Pre-test genetic counseling is required for any individual undergoing WGS.

1.2 The individual has been evaluated by a physician board-certified in one of the following fields:

1.2.1 Medical genetics

1.2.2 Maternal-fetal medicine

1.2.3 Neonatology

1.2.4 Neurology

1.2.5 Developmental Pediatrics

1.3 The evaluation may be:

1.3.1 In person, or,

1.3.2 via synchronous audio-visual telemedicine in consultation with a consulting physician who has personally examined the individual.

1.4 A three-generation pedigree must be completed, as appropriate.

1.5 The ordering physician must conduct a mandatory pre-test and commits to conducting post-test follow-up counseling.

1.6 Test results are expected to directly impact clinical decision-making and/or clinical outcome for the individual being tested.

1.7 No other causative circumstances (e.g., environmental exposures, injury, prematurity, infection) can explain symptoms.

1.8 A genetic etiology is considered the most likely explanation for the phenotype, based on either of the following:

1.8.1 Multiple congenital abnormalities affecting unrelated organ systems, or two of the following:

- Abnormality affecting at minimum a single organ system.
- Profound global developmental delay, intellectual disability, symptoms of a complex neurodevelopmental disorder, and/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

1.9 Clinical presentation does not fit a well-described syndrome for which single-gene or targeted panel testing (e.g., when comparative genomic hybridization [CGH]/chromosomal microarray analysis [CMA]) is available).

1.10 The differential diagnosis list and/or phenotype warrant testing of multiple genes and one of the following:

1.10.1 Whole genome sequencing is more practical than the separate single gene tests or panels that would be recommended based on the differential diagnosis.

1.10.2 Whole genome sequencing results may preclude the need for multiple and/or invasive procedures, follow-up, or screening that would be recommended in the absence of testing.

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

2.1 Unexplained or global developmental delay.

2.2 Moderate, severe, or profound Intellectual disability diagnosed before 21 years of age.

2.3 Epileptic encephalopathy with onset before three years of age.

2.4 Clinical history strongly suggests a genetic cause and two or more of the following features are present:

2.4.1 Congenital anomaly

2.4.2 Significant hearing or visual impairment diagnosed before 21 years of age.

2.4.3 Laboratory abnormalities suggestive of an inborn error of metabolism (IEM)

2.4.4 Autism spectrum disorder neuropsychiatric condition (e.g., bipolar disorder, schizophrenia, obsessive-compulsive disorder)

2.4.5 Hypotonia or hypertonia in infancy

2.4.6 Dystonia, ataxia, hemiplegia, neuromuscular disorder, movement disorder, or other neurologic abnormality

2.4.7 Unexplained developmental regression, unrelated to autism or epilepsy

2.4.8 Growth abnormality (e.g., failure to thrive, short stature, microcephaly, macrocephaly, or overgrowth).

2.4.9 Persistent and severe immunologic or hematologic disorder

2.4.10 Dysmorphic features

2.4.11 Consanguinity

2.4.12 Other first- or second-degree family member(s) with similar clinical features

3. Re-evaluation (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:

3.1 Onset of additional symptoms that broadens the phenotype assessed during the original exome/genome evaluation.

3.2 Birth or diagnosis of a similarly affected first-degree relative* that has expanded the clinical picture.

3.3 New scientific knowledge suggests a previously unknown link between the individual's findings and specific genes/pathogenic or likely pathogenic variants AND 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 percent of his/her genes, including the individual's parents, full siblings, and children.