

	<p>Genetic Testing Guidelines</p>	
<p>Guideline # 6181</p>	<p>Categories Clinical → Care Coordination, Care Coordination – Utilization management , TCHP Guidelines</p>	<p>This Guideline Applies To: Texas Children's Health Plan</p>
		<p>Document Owner Lisa Fuller</p>

GUIDELINE STATEMENT:

Texas Children's Health Plan (TCHP) performs authorization of genetic testing requests.

PRIOR AUTHORIZATION GUIDELINES

1. Genetic testing conducted by out-of-network providers will be treated as out-of-network requests and will comply with the out-of-network authorization Guidelines.
2. Requests for Noninvasive Prenatal Testing will comply with TCHP Noninvasive Prenatal Testing Guidelines.
3. All requests for prior authorization for genetic testing are received via fax, phone or mail by the Utilization Management Department and processed during normal business hours.
4. The Utilization Management professional receiving the request evaluates the submitted information to determine if the documentation supports the genetic testing as an eligible service.
5. To request prior authorization for genetic testing, documentation supporting the medical necessity of the test requested must be provided.
6. TCHP will apply clinical criteria in the current Texas Medicaid Provider Manual (TMPPM) at the time of the request when applicable for the following:
 - 6.1. BRCA gene mutation analysis
 - 6.2. Genetic Testing for colorectal cancer
 - 6.3. Cytogenetic testing
 - 6.4. Pharmacogenetic Testing

6.5. A request for retroactive authorization must be submitted no later than seven calendar days beginning the day after the lab draw is performed per TMPPM

7. Whole genome sequencing (code 81415) requires preauthorization on a case-by-case basis.

8. Texas Children's Health Plan does not cover genetic testing involving non-Texas Children's Health Plan members even when it will provide genetic information for a TCHP member. This includes but is not limited to:

8.1 Trio Whole exome sequencing (WES procedure code 81416)

9. Utilization Management professionals will utilize the most recent available version of InterQual criteria for genetic testing to establish medical necessity when applicable.

10. TCHP considers the following as indications for medically necessary genetic testing:

10.1. Preconception or prenatal carrier screening recommended by the American College of Obstetricians and Gynecologists (ACOG):

10.1.1 Spinal Muscular Atrophy, Cystic Fibrosis, Hemoglobinopathies, Fragile X syndrome, Genetic Conditions in Individuals of Eastern and Central European Jewish Descent, and Tay-Sachs Disease

10.1.2. Preconception or prenatal carrier screening for couples of Ashkenazi Jewish ancestry with a panel of genetic tests as recommended by the American College of Medical Genetics (ACMG) and American College of Obstetricians and Gynecologists (ACOG)

10.1.2.1. The panel should include:

10.1.2.1. Tay-Sachs disease

10.1.2.2. Canavan disease

10.1.2.3. Cystic fibrosis

10.1.2.4. Familial dysautonomia

10.1.2.5. Bloom syndrome

10.1.2.6. Familial Hyperinsulinism,

10.1.2.7. Niemann-Pick disease

10.1.2.8. Usher Syndrome

10.1.2.9. Mucopolysaccharidosis IV

10.1.2.10. Fanconi anemia

10.1.2.11. Gaucher Disease

10.1.2.12. Glycogen Storage Disease type I

10.1.2.13. Joubert Syndrome

10.1.2.14. Maple Syrup Urine Disease

10.1.3 Preconception or prenatal carrier screening for cystic fibrosis and spinal muscular atrophy does not require prior authorization and is a benefit once per lifetime of the member

10.1.4. A request for retroactive authorization must be submitted no later than seven calendar days beginning the day after the lab draw is performed

10.2. Genetic testing of the individual's genome for inherited diseases is considered **medically necessary** when the following criteria are met:

10.2.1. The individual for whom the test is requested:

1. Is asymptomatic but is judged to be at significant risk, as determined by the likelihood of future disease and burden of suffering, for a genetic disease (for example, based on family history); **Or**
2. Is currently symptomatic with suspicion of a known genetic disease; **AND**

10.2.2. All of the following criteria apply:

- 10.2.2.1. A specific mutation, or set of mutations, has been established in the scientific literature to be reliably associated with the disease; **AND**
- 10.2.2.4. Results of the genetic test, whether affirmative or negative, will impact the clinical management (predictive, diagnostic, prognostic or therapeutic) of the Individual. For example, genetic test results will guide treatment decisions, surveillance recommendations or preventive strategies; **AND**
- 10.2.2.5. The findings of the genetic test will likely result in an anticipated improvement in net health outcomes; that is, the expected health benefits of the interventions outweigh any harmful effects (medical or psychological) of the intervention;

AND

10.2.2.6. Testing is accompanied by genetic counseling.

10.3. The individual is suspected of having one of the following diagnosis (this list is not all-inclusive):

- 10.3.1. Achondroplasia (FGFR3)
- 10.3.2. Albinism
- 10.3.3. Alpha-1 antitrypsin deficiency (SERPINA1)
- 10.3.4. Classical lissencephaly
- 10.3.5. Congenital adrenal hyperplasia/21 hydroxylase deficiency (CYP21A2)*
- 10.3.6. Congenital amegakaryocytic thrombocytopenia
- 10.3.7. Congenital central hypoventilation syndrome (PHOX2B)
- 10.3.8. Congenital muscular dystrophy
- 10.3.9. Type 1C (MDC1C) (FKRP (Fukutin related protein))
- 10.3.10. Crouzon syndrome (FGFR2, FGFR3)
- 10.3.11. Dentatorubral-pallidoluysian atrophy
- 10.3.12. Dysferlin myopathy

- 10.3.13. Ehlers-Danlos syndrome
- 10.3.14. Emery-Dreifuss muscular dystrophy (EDMD1, 2, and 3)
- 10.3.15. Familial Mediterranean fever (MEFV)
- 10.3.16. Facioscapulohumeral muscular dystrophy (FSHMD1A)
- 10.3.17. Friedreich's ataxia (FRDA (frataxin))
- 10.3.18. Gitelman's syndrome
- 10.3.19. Hemoglobin E thalassemia
- 10.3.20. Hemoglobin S and/or C
- 10.3.21. Hereditary amyloidosis (TTR variants)
- 10.3.22. Hereditary deafness (GJB2 (Connexin-26, Connexin-32))
- 10.3.23. Hereditary hemorrhagic telangiectasia (HHT)
- 10.3.24. Hereditary hemochromatosis (HFE) (see below)
- 10.3.25. Hereditary leiomyomatosis and renal cell cancer (HLRCC) syndrome (fumarate hydratase (FH) gene)
- 10.3.26. Hereditary neuropathy with liability to pressure palsies (HNPP)
- 10.3.27. Hereditary non-polyposis colorectal cancer (HNPCC) (MLH1, MSH2, MSH6. MSI) (see below)
- 10.3.28. Hereditary pancreatitis (PRSS1) (see below)
- 10.3.29. Hereditary paraganglioma (SDHD, SDHB)
- 10.3.30. Hypochondroplasia (FGFR3)
- 10.3.31. Jackson-Weiss syndrome (FGFR2) Kallmann syndrome (FGFR1)
- 10.3.32. Kennedy disease (SBMA)
- 10.3.33. Leber hereditary optic neuropathy (LHON)
- 10.3.34. Leigh Syndrome and NARP (neurogenic muscle weakness, ataxia, and retinitis pigmentosa)
- 10.3.35. Limb girdle muscular dystrophy (LGMD1, LGMD2) (FKRP (Fukutin related protein))
- 10.3.36. Malignant hyperthermia (RYR1)
- 10.3.37. McArdle's disease
- 10.3.38. Medium chain acyl coA dehydrogenase deficiency (ACADM)
- 10.3.39. Medullary thyroid carcinoma
- 10.3.40. MELAS (mitochondrial encephalomyopathy with lactic acidosis and stroke-like episodes) (MTTL1, tRNA^{Leu})
- 10.3.41. Mucopolysaccharidoses type 1 (MPS-1)
- 10.3.42. Muenke syndrome (FGFR3)
- 10.3.43. Multiple endocrine neoplasia type 1
- 10.3.44. Muscle-Eye-Brain disease (POMGNT1)
- 10.3.45. MYH-associated polyposis (MYH) (see below)
- 10.3.46. Myoclonic epilepsy (MERRF) (MTTK (tRNA^{Lys}))
- 10.3.47. Myotonic dystrophy (DMPK, ZNF-9)
- 10.3.48. Nephrotic syndrome, congenital (NPHS1, NPHS2)
- 10.3.49. Neurofibromatosis type 1 (NF1, neurofibromin)
- 10.3.50. Neurofibromatosis type 2 (Merlin)
- 10.3.51. Neutropenia, congenital cyclic
- 10.3.52. Phenylketonuria (PAH)
- 10.3.53. Pfeiffer syndrome (FGFR1)
- 10.3.54. Prader-Willi-Angelman syndrome (SNRPN, GABRA5, NIPA1, UBE3A, ANCR, GABRA)

- 10.3.55. Primary dystonia (TOR1A (DYT1))
- 10.3.56. Prothrombin (F2 (Factor II, 20210G> A mutation))
- 10.3.57. Pyruvate kinase deficiency (PKD)
- 10.3.58. Retinoblastoma (Rh)
- 10.3.59. Saethre-Chotzen syndrome (TWIST, FGFR2)
- 10.3.60. Smith-Lemli-Opitz syndrome
- 10.3.61. Spinocerebellar ataxia (SCA types 1, 2, 3 (MJD), 6 (CACNA1A), 7, 8, 10, 17 and DRPLA)
- 10.3.62. Thanatophoric dysplasia (FGFR3)
- 10.3.63. Von Gierke disease (G6PC, Glycogen storage disease, Type 1a)
- 10.3.64. Walker-Warburg syndrome (POMGNT1)
- 10.3.65. 22q11 deletion syndromes (DCGR (CATCH-22))

10.3. In the following condition specific situations:

- 10.3.1. Suspicion of Catecholaminergic polymorphic ventricular tachycardia (CPVT) in:
 - 10.3.1.1. Children or young adults (less than 40 years of age) with a 1st degree relative with a clinical diagnosis of CPVT, or a 1st or 2nd degree relative with a defined CPVT mutation; or
 - 10.3.1.2. Persons who display exercise- or emotion-induced PVT or ventricular fibrillation, occurring in a structurally normal heart.

10.3.2. Factor V Leiden genetic testing for members with any of the following indications:

- 10.3.2.1. Age less than 50, any venous thrombosis; **Or**
- 10.3.2.2. Myocardial infarction in female smokers under age of 50; **Or**
- 10.3.2.3. Recurrent venous thrombosis; or
- 10.3.2.4. Relatives of individuals with venous thrombosis under age of 50; **Or**
- 10.3.2.5. Venous thrombosis and a strong family history of thrombotic disease; **Or**
- 10.3.2.6. Venous thrombosis in pregnant women or women taking oral contraceptives; **Or**
- 10.3.2.7. Venous thrombosis in unusual sites (such as hepatic, mesenteric, and cerebral veins).

10.3.3. Genetic testing in **asymptomatic** blood relatives of persons with genetically confirmed Thoracic Aortic Aneurysms (TAAD).

10.3.4. Genetic testing for COL1A1 and COL1A2 gene sequencing in the management of osteogenesis imperfecta types I to IV for the following indications:

- 10.3.4.1. Genetic testing for sequence variants in COL1A1/2 to confirm the presence of mosaicism in the asymptomatic parent of a child with OI caused by sequence variants in COL1A1/2 for reproductive decision making purposes; **Or**
- 10.3.4.2. Preimplantation genetic diagnosis or prenatal diagnosis for sequence variants in COL1A1/2 in couples in which 1 or both members have OI caused by sequence variants in COL1A1/2.

10.3.5. Cadherin-1 (e-cadherin, CDH1) for hereditary diffuse gastric cancer (HDGC) necessary for persons who meet the following criteria:

- 10.3.5.1. Individuals with HDGC for the purpose of identifying a CDH1 gene sequence variant that may be used to screen at-risk first- and second-degree relatives; **Or**
- 10.3.5.2. Presymptomatic testing of first- and second-degree at-risk relatives for a known familial variant in the CDH1 gene.

10.3.6. Genetic testing for maturity-onset diabetes of the young (MODY) in persons with hyperglycemia or non-insulin-dependent diabetes who have any of the following:

- 10.3.6.1. A family history of abnormal glucose metabolism in at least 2 consecutive generations.
- 10.3.6.2. ≥ 1 family members diagnosed before age 25.

10.3.7. TP53 gene testing in individuals with a suspected or known clinical diagnosis of Li-Fraumeni syndrome (LFS) or Li-Fraumeni-Like syndrome, or a known family history of a TP53 mutation.

10.4 For the members with a diagnosis of Autism

the following genetic testing may be considered medically necessary if documentation supporting the medical necessity of the test requested is submitted as recommended by the American College of Medical Genetics (ACMG):

- 10.4.1 Chromosomal Microarray (CMA)
- 10.4.2 Fragile X syndrome
- 10.4.3 Methyl-CPG-binding protein 2 (MECP2) spectrum disorders
- 10.4.4 Phosphatase and tensin homolog (PTEN) related conditions
- 10.4.5 Karyotype

10.5. Clinical risk verified by TCHP Medical Director/Physician Reviewer

11. In the absence of specific information regarding advances in the knowledge of mutation characteristics for a particular disorder, the current literature indicates that genetic tests for inherited disease need only be conducted once per lifetime of the member.

12. Genetic testing of Texas Children's Health Plan members is excluded from coverage under Texas Children's Health Plan's benefit plans if the testing is performed primarily for the medical management of other family members who are not covered under a Texas Children's Health Plan benefit plan. In these circumstances, the insurance carrier for the family members who are not covered by Texas Children's Health Plan should be contacted regarding coverage of genetic testing. Texas Children's Health Plan does not cover genetic testing for heritable disorders in non-Texas Children's Health Plan members

13. Requests that do not meet the criteria established by this procedure will be referred to a TCHP Medical Director/Physician Reviewer for review and the Denial Policy will be followed.

14. Preauthorization is based on medical necessity and not a guarantee of benefits or eligibility. Even if preauthorization is approved for treatment or a particular service, that authorization applies

only to the medical necessity of treatment or service. All services are subject to benefit limitations and exclusions. Providers are subject to State and Federal Regulatory compliance and failure to comply may result in retrospective audit and potential financial recoupment.

REFERENCES:**Government Agency, Medical Society, and Other Authoritative Publications:**

American College of Obstetricians and Gynecologists' Committee on Genetics in collaboration with committee members Britton Rink, MD; Stephanie Romero, MD; Joseph R. Biggio Jr, MD; Devereux N. Saller Jr, MD; and Rose Giardine, MS. Carrier Screening for Genetic Conditions, Committee Opinion 691, March 2021

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American College of Medical Genetics and Genomics:

Carrier screening in individuals of Ashkenazi Jewish descent Susan J. Gross, MD1 , Beth A. Pletcher, MD2 , and Kristin G. Monaghan, PhD3 , for the Professional Practice and Guidelines Committee 2008

Clinical genetics evaluation in identifying the etiology of autism spectrum disorders: 2013 guideline revisions, G. Bradley Schaefer, MD1 and Nancy J. Mendelsohn, MD2 ; for the Professional Practice and Guidelines Committee, March 21, 2013

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