

Department of Origin: Integrated Healthcare Services	Effective Date: 12/03/24
Approved by: Medical Policy Quality Management Subcommittee	Date Approved: 12/03/24
Clinical Policy Document: Genetic Testing, Reproductive Carrier Screening	Replaces Effective Clinical Policy Dated: 12/12/23
Reference #: MC/L017	Page: 1 of 9

PURPOSE:

The intent of this clinical policy is to ensure services for genetic testing for reproductive carrier screening on a pregnant member, reproductive partner, or prospective parent (greater than or equal to 12 years of age) are medically necessary.

Please refer to the member's benefit document for specific information. To the extent there is any inconsistency between this policy and the terms of the member's benefit plan or certificate of coverage, the terms of the member's benefit plan document will govern.

POLICY:

Benefits must be available for health care services. Health care services must be ordered by a provider. Licensed Genetic Counselors may also order genetic tests if it is within the scope of practice of their state licensure. Health care services must be medically necessary, applicable conservative treatments must have been tried, and the most cost-effective alternative must be requested for coverage consideration.

GUIDELINES:

Medical Necessity Criteria - Must satisfy the following: I, and any of II - IV

I. Requests for genetic testing – must satisfy all of the following: A - C

- A. Member (includes fetus) displays clinical features (symptomatic), or is at direct risk of inheriting the mutation in question (presymptomatic); and
- B. A *health care professional trained in genetics*, independent of the laboratory performing the testing, has reviewed and documented family history, advised the member of the potential harms/benefits of the testing and implications of the test results, and obtained written formal consent; and

[Note: Members who have no knowledge of their genetic family history (such as members who are adopted) will be considered to be at high risk.]

- C. After history, physical examination and completion of conventional diagnostic studies, a definitive diagnosis remains uncertain and a valid specific test exists for the suspected condition – as evidenced by all of the following: 1 - 3
 - 1. Each test has been approved for its intended use by the appropriate regulatory/oversight body (implies *analytic validity*); and
 - 2. Each test has sufficient sensitivity or specificity (*clinical validity*) for targeting the member's specific clinical condition; and
 - 3. The results of each test will directly impact clinical decision-making and clinical care (*clinical utility*) for the individual, such as but not limited to the following a - c
 - a. Guiding surveillance for complications (eg, referral to maternal-fetal-medicine physician, increase in frequency of prenatal ultrasounds).
 - b. Employing direct risk reduction strategies (eg, fetal interventions).
 - c. Determining avenues of medical therapy (eg, medication, early labor induction).

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- II. The pregnant member, reproductive partner, or prospective parent (greater than or equal to 12 years of age) are at increased risk for a specific genetic disorder, including but not limited to one of the following: A - D
- A. All couples considering pregnancy or women who are currently pregnant, regardless of ethnicity – any of the following: 1 - 3
1. Cystic Fibrosis transmembrane regulator – CFTR gene analysis-common variants¹ (CPT 81220); or
[Note: Complete analysis of CFTR sequencing by DNA analysis is not appropriate for routine carrier screening – CPT 81223]
 2. Spinal muscular atrophy (SMA) – SMN1/SMN2 gene analysis^{1,3} (CPTs 81329, 81336, 81337, 0236U); or
 3. Thalassemias and hemoglobinopathies - HBA1/HBA2, HBB gene analysis^{1,2,3} (CPTs 81257, 81258, 81259, 81269, 81361, 81362, 81363, 81364, S3845, S3846, S3850)
- B. Ashkenazi Jewish (Eastern and Central European) ethnicity¹ – any of the following: 1 – 13 (panels CPTs 81412, 81443)
1. Bloom syndrome – BLM gene (CPT 81209)
 2. Canavan disease – ASPA gene (CPT 81200)
 3. Familial dysautonomia – IKBKAP gene (CPT 81260)
 4. Familial hyperinsulinism – ABCC8 gene¹ (CPT 81401, 81407)
 5. Fanconi Anemia, group C – FANCC gene (CPT 81242)
 6. Gaucher disease – GBA gene (CPT 81251)
 7. Glycogen storage disease type 1 (von Gierke disease) - G6PC gene (CPT 81250)
 8. Joubert syndrome – most common gene mutations⁴ – genes AHI1 (81407), CC2D2A, CEP290, CPLANE1, INPP5E, KIAA0586, MEM67, MKS1, NPHP1 (CPTs 81405, 81406), RPGRIP1L, TCTN2, TMEM216
 9. Maple Syrup Urine Disease – BCKDHA gene (CPTs 81400, 81405); BCKDHB gene (CPTs 81205, 81406); DBT gene (CPTs 81405, 81406)
 10. Mucopolysaccharidosis, Type IV - MCLON1 gene (CPT 81290)
 11. Niemann-Pick disease, Type A - SMPD1 gene (CPT 81330, S3849)
 12. Tay-Sachs disease - HEXA gene (CPT 81255)
 13. Usher syndrome, Type 1F - gene PCDH15 (CPTs 81400, 81406, 81407); Type III gene CLRN1 (CPT 81404)
- [NOTE: If only one partner is of Ashkenazi Jewish ancestry, testing of that partner is considered medically necessary. Testing of the other partner is considered medically necessary only if the result of testing of the Ashkenazi Jewish partner is positive.]
- C. Tay-Sachs disease (HEXA gene enzyme testing) (CPT 81255) - French-Canadian or Cajun ethnicity
- D. Fragile X gene analysis - FMR1 gene (CPTs 81243, 81244) is appropriate for females with any of the following: 1 or 2
1. A family history of autism, Fragile X related disorders, developmental delay, or unexplained intellectual disability; or
 2. A personal history of premature ovarian insufficiency or failure, or an elevated follicle stimulating hormone (FSH) level before age 40.

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- III. To determine carrier status due to family history *and* the disease/sickness/defect is associated with a potentially severe disability or has a lethal natural history – must satisfy any of the following: A - D
- A. There is a known gene mutation of a moderate or high-risk gene associated with an inherited condition/syndrome in a biologically related *close blood relative* – must satisfy any of the following: 1 or 2
 1. There is a known familial variant gene mutation, ie, the location of the mutation is known – single site testing should be performed; or
 2. There is a known gene mutation and the specific location of the mutation is not known – full sequence analysis, full duplication analysis, and/or common and uncommon deletion testing may be performed (see gene level criteria for CPT codes).
 - B. A *first-degree relative* with *autosomal dominant* condition (eg, Huntington's disease, Marfan syndrome, neurofibromatosis, polycystic kidney disease); or
 - C. An affected child is identified with either an *autosomal recessive* condition, an *x-linked disorder*, or an inherited disorder with variable *penetrance*; or
 - D. One or both prospective parent(s) have one of the following: 1 or 2
 1. Another *first* or *second degree relative* who is affected; or
 2. A *first degree relative* has an affected child, with either an *autosomal recessive* condition, an *x-linked disorder*, or an inherited disorder with variable *penetrance* and genetic testing is performed to determine the pattern of inheritance.
- IV. If a pregnant member, reproductive partner, or prospective parent is a known carrier of a specific condition, screening/testing should be performed on the other reproductive partner.

EXCLUSIONS (not limited to):

Refer to member's Certificate of Coverage or Summary Plan Description

Direct-to-consumer testing

DEFINITIONS:

Analytic Validity:

How accurately and reliably the test measures the genotype of interest. A major component in the validation of an analytical technique is the technique's ability to accurately determine the presence of the substance it is seeking. It must measure the target substance without a great range of variation over a number of trials. The technique also must be proven to work reliably at multiple labs to be validated by this testing.

Autosomal:

Pertaining to a chromosome that is not a sex chromosome. People normally have 22 pairs of autosomes (44 autosomes) in each cell, together with 2 sex chromosomes, X and Y in a male and X and X in a female.

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Autosomal dominant:

A pattern of inheritance in which an affected individual has one copy of a mutant gene and one normal gene on a pair of autosomal chromosomes. Individuals with autosomal dominant diseases have a 50-50 chance of passing the mutant gene and therefore the disorder onto each of their children. Examples of autosomal dominant diseases include Huntington disease, neurofibromatosis, and polycystic kidney disease.

Autosomal recessive:

A genetic condition that appears only in individuals who have received two copies of an autosomal gene, one copy from each parent. The gene is on an autosome, a nonsex chromosome. The parents are carriers who have only one copy of the gene and do not exhibit the trait because the gene is recessive to its normal counterpart gene. If both parents are carriers, there is a 25% chance of a child inheriting both abnormal genes and, consequently, developing the disease. There is a 50% chance of a child inheriting only one abnormal gene and of being a carrier, like the parents, and there is a 25% chance of the child inheriting both normal genes. Cystic fibrosis (CF) is an example of an autosomal recessive disorder. A CF child has the CF gene on both chromosome 7s and so is said to be homozygous for CF. The parents each have one CF and one normal paired gene and so are said to be heterozygous for CF.

Chromosome:

In the nucleus of each cell, the DNA molecule is packaged into thread-like structures called chromosomes. Each chromosome is made up of DNA tightly coiled many times around proteins called histones that support its structure.

Clinical Utility:

The evidence of improved measurable clinical outcomes, and its usefulness and added value to patient management decision-making compared with current management without the testing.

Clinical Validity:

How consistently and accurately the test detects or predicts the intermediate or final outcomes of interest.

Close blood relative:

First-, second-, or third-degree blood relative from the same side of the family.

First-degree relative:

A blood relative who shares 50% of the individual's genes (parents, full siblings, and children)

Genetic Test:

A genetic test involves the analysis of chromosomes, deoxyribonucleic acid (DNA), ribonucleic acid (RNA), genes, or gene products (eg, enzymes and other proteins) to detect heritable or somatic variations related to disease or health. Whether a laboratory method is considered a genetic test also depends on the intended use, claim or purpose of a test.

Health care professionals trained in genetics:

A genetics professional has experience and an educational background in genetics, counseling, and hereditary syndromes to provide accurate risk assessment and empathetic genetic counseling to patients and their families. Genetics professionals include the following:

- An individual board-certified/board eligible by American Board of Genetic Counseling (ABGC) or American Board of Medical Genetics and Genomics (ABMGG)⁵ board-certified/board eligible or a licensed genetic counselor

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- An individual with an Advanced Genetics Nursing Certification (AGN-BC) from the American Nurses Credentialing Center (ANCC)⁵
- An individual with Advanced Clinical Genomics Nurse (ACGN) credential from the Nurse Portfolio Credentialing Commission (NPCC)⁵
- An individual with Clinical Genomics Nurse (CGN) certification from the Nurse Portfolio Credentialing Commission (NPCC)⁵
- Completion of City of Hope Intensive Course in Genomic Cancer Risk Assessment⁵
- A qualified, licensed, health care professional with Cancer Genetic Risk Assessment (CGRA) certification from the National Consortium of Breast Centers (NCBC)⁵
- A qualified, licensed, health care professional with with Advanced Oncology Certified Nurse Practitioner (AOCNP) credentials, or equivalent certification from the Oncology Nursing Certification Corporation (ONCC)⁵
- Board-certified/board-eligible physician with experience in cancer genetics (defined as providing cancer risk assessment on a regular basis and demonstrating completion of two hours of continuing medical education in cancer genetics and hereditary cancer predisposition syndromes each calendar year)⁵
- Board-certified specialty care physician with experience in the diagnosis and treatment of the hereditary condition, eg, cardiologist ordering genetic testing for hypertrophic cardiomyopathy

Karyotype (G-banded) analysis:

A conventional cytogenetic evaluation that can detects larger chromosomal abnormalities (eg, loss or gain of an entire chromosome or of large parts of chromosomes), or chromosomal rearrangements such as translocations (ie, when a portion of a chromosome breaks off and rejoins with another chromosome). Cells from blood, tissue, or body fluid (eg, bone marrow, amniotic fluid) are cultured so that the chromosomes are visible; these cells are then treated to reveal banding patterns that are specific to each chromosome. Examination of these cells by standard light microscopy permits trained technologists and cytogeneticists to examine the chromosomes for abnormalities of number or structure. Examples of constitutional conditions (ie, those present at birth) detectable by karyotype analysis include Down Syndrome (trisomy 21), Turner Syndrome (monosomy X), and Klinefelter syndrome (XXY). Acquired conditions (ie, those that develop after birth, typically associated with malignancy) can also be detected.

Regulatory/oversight body:

Such as, but not limited to, Clinical Laboratory Improvement Amendments (CLIA), Food and Drug Administration (FDA) or The Joint Commission

Second-degree relative:

A blood relative who shares 25% of the individual's genes (grandparents, grandchildren, aunts, uncles, nephews, nieces, and half siblings)

Sex chromosome:

The X or Y chromosome in humans.

X-linked Disorder:

In males (who have only one X chromosome), one altered copy of the gene in each cell is sufficient to cause the condition. In females (who have two X chromosomes), a mutation would have to occur in both copies of the gene to cause the disorder. Because it is unlikely that females will have two altered copies of this gene, males are affected by X-linked recessive disorders much more frequently than females. A characteristic of X-linked inheritance is that fathers cannot pass X-linked traits to their sons.

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BACKGROUND:

Testing is recommended when there is a carrier frequency of 1/100 or greater, have a well-defined phenotype, have a detrimental effect on quality of life, cause cognitive or physical impairment, require surgical or medical intervention, or have an onset early in life. Additionally, screened conditions should be able to be diagnosed prenatally and may afford opportunities for antenatal intervention to improve perinatal outcomes, changes to delivery management to optimize newborn and infant outcomes, and education of the parents about special care needs after birth.¹

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Prior Authorization: Yes, per network provider agreement

CODING:

CPT® or HCPCS

81200 ASPA (aspartoacylase) (eg, Canavan disease) gene analysis, common variants (eg, E285A, Y231X)

81205 BCKDHB (branched-chain keto acid dehydrogenase E1, beta polypeptide) (eg, maple syrup urine disease) gene analysis, common variants (eg, R183P, G278S, E422X)

81209 BLM (Bloom syndrome, RecQ helicase-like)(e.g. Bloom syndrome) gene analysis, 2281 del6ins7 variant

81220 CFTR (cystic fibrosis transmembrane conductance regulator) (eg, cystic fibrosis) gene analysis; common variants (eg, ACMG/ACOG guidelines)

81242 FANCC (Fanconi anemia, complementation group C) (eg, Fanconi anemia, type C) gene analysis, common variant (eg, IVS4+4A>T)

81243 FMR1 (Fragile X mental retardation 1) (eg, fragile X mental retardation) gene analysis; evaluation to detect abnormal (eg, expanded) alleles

81244 FMR1 (fragile X mental retardation 1) (eg, fragile X mental retardation) gene analysis; characterization of alleles (eg, expanded size and promoter methylation status)

81250 G6PC (glucose-6-phosphatase, catalytic subunit) (eg, Glycogen storage disease, type 1a, von Gierke disease) gene analysis, common variants (eg, R83C, Q347X)

81251 GBA (glucosidase, beta, acid) (eg, Gaucher disease) gene analysis, common variants (eg, N370S, 84GG, L444P, IVS2+1G>A)

81255 HEXA (hexosaminidase A [alpha polypeptide]) (eg, Tay-Sachs disease) gene analysis, common variants (eg, 1278insTATC, 1421+1G>C, G269S)

81257 HBA1/HBA2 (alpha globin 1 and alpha globin 2) (eg, alpha thalassemia, Hb Bart hydrops fetalis syndrome, HbH disease), gene analysis, for common deletions or variant (eg, Southeast Asian, Thai, Filipino, Mediterranean, alpha3.7, alpha4.2, alpha20.5, and Constant Spring)

81258 HBA1/HBA2 (alpha globin 1 and alpha globin 2) (eg, alpha thalassemia, Hb Bart hydrops fetalis syndrome, HbH disease), gene analysis; known familial variant

81259 HBA1/HBA2 (alpha globin 1 and alpha globin 2) (eg, alpha thalassemia, Hb Bart hydrops fetalis syndrome, HbH disease), gene analysis; full gene sequence

81260 IKBKAP (inhibitor of kappa light polypeptide gene enhancer in B-cells, kinase complex-associated protein) (eg, familial dysautonomia) gene analysis, common variants (eg, 2507+6T>C, R696P)

81269 HBA1/HBA2 (alpha globin 1 and alpha globin 2) (eg, alpha thalassemia, Hb Bart hydrops fetalis syndrome, HbH disease), gene analysis; duplication/deletion variants

81290 MCOLN1 (mucolipin 1) (eg, Mucopolipidosis, type IV) gene analysis, common variants (eg, IVS3-2A>G, del6.4kb)

81329 SMN1 (survival of motor neuron 1, telomeric) (eg, spinal muscular atrophy) gene analysis; dosage/deletion analysis (eg, carrier testing), includes SMN2 (survival of motor neuron 2, centromeric) analysis, if performed

81330 SMPD1 (sphingomyelin phosphodiesterase 1, acid lysosomal) (eg, Niemann-Pick disease, Type A) gene analysis, common variants (eg, R496L, L302P, fsP330)

81336 SMN1 (survival of motor neuron 1, telomeric) (eg, spinal muscular atrophy) gene analysis; full gene sequence

81337 SMN1 (survival of motor neuron 1, telomeric) (eg, spinal muscular atrophy) gene analysis; known familial sequence variant(s)

81361 HBB (hemoglobin, subunit beta) (eg, sickle cell anemia beta thalassemia, hemoglobinopathy); common variant(s) (eg, HbS, HbC, HbE)

81363 HBB (hemoglobin, subunit beta) (eg, sickle cell anemia beta thalassemia, hemoglobinopathy); duplication/deletion variant(s)

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81364 HBB (hemoglobin, subunit beta) (eg, sickle cell anemia beta thalassemia, hemoglobinopathy); full gene sequence

81400 Molecular pathology procedure, Level 1 (eg, identification of single germline variant [eg, SNP], by techniques such as restriction enzyme digestion or melt curve analysis

81401 Molecular pathology procedure, Level 2 (eg, 2-10 SNPs, 1 methylated variant, or 1 somatic variant [typically using non-sequencing target variant analysis], or detection of a dynamic mutation disorder/triplet repeat)

81402 Molecular pathology procedure, Level 3 (eg, >10 SNPs, 2-10 methylated variants [typically using non-sequencing target variant analysis], immunoglobulin and T-cell receptor gene arrangements, duplication/deletion variants of 1 exon, loss of heterozygosity [LOH], uniparental disomy [UPD])

81404 Molecular pathology procedure, Level 5 (eg, analysis of 2-5 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of 6-10 exons, or characterization of a dynamic mutation disorder/triplet repeat by Southern blot analysis

81405 Molecular pathology procedure, Level 6 (eg, analysis of 6-10 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of 11-25 exons, regionally targeted cytogenomic array analysis

81406 Molecular pathology procedure, Level 7 (eg, analysis of 11-25 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of 26-50 exons, cytogenomic array analysis for neoplasia

81407 Molecular pathology procedure, Level 8 (eg, analysis of 26-50 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of > 50 exons, sequence analysis of multiple genes on 1 platform)

81412 Ashkenazi Jewish associated disorders (eg, Bloom syndrome, Canavan disease, cystic fibrosis, familial dysautonomia, Fanconi anemia group C, Gaucher disease, Tay-Sachs disease), genomic sequence analysis panel, must include sequencing of at least 9 genes, including ASPA, BLM, CFTR, FANCC, GBA, HEXA, IKBKAP, MCOLN1, and SMPD1

81443 Genetic testing for severe inherited conditions (eg, cystic fibrosis, Ashkenazi Jewish-associated disorders [eg, Bloom syndrome, Canavan disease, Fanconi anemia type C, mucopolidosis type VI, Gaucher disease, Tay-Sachs disease], beta hemoglobinopathies, phenylketonuria, galactosemia), genomic sequence analysis panel, must include sequencing of at least 15 genes (eg, ACADM, ARSA, ASPA, ATP7B, BCKDHA, BCKDHB, BLM, CFTR, DHCR7, FANCC, G6PC, GAA, GALT, GBA, GBE1, HBB, HEXA, IKBKAP, MCOLN1, PAH

81632 HBB (hemoglobin, subunit beta) (eg, sickle cell anemia beta thalassemia, hemoglobinopathy); known familial variant(s)

0236U SMN1 (survival of motor neuron 1, telomeric) and SMN2 (survival of motor neuron 2, centromeric) (eg, spinal muscular atrophy) full gene analysis, including small sequence changes in exonic and intronic regions, duplications and deletions, and mobile element insertions

0400U Obstetrics (expanded carrier screening), 145 genes by next-generation sequencing, fragment analysis and multiplex ligation-dependent probe amplification, DNA, reported as carrier positive or negative

S3845 Genetic testing for alpha-thalassemia

S3846 Genetic testing for hemoglobin E beta-thalassemia

S3849 Genetic testing for Niemann-Pick disease

S3850 Genetic testing for sickle cell anemia

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REFERENCES:

Cited in clinical policy

1. American College of Obstetricians and Gynecologists (ACOG) Committee on Genetics. Committee Opinion: Carrier Screening for Genetic Conditions. Number 691, March 2017, 2020. Retrieved from <https://www.acog.org/-/media/project/acog/acogorg/clinical/list-of-titles/committee-opinions.pdf>. Accessed 10-09-24.
2. American College of Obstetricians and Gynecologists (ACOG) Committee on Genetics. ACOG Committee Opinion: Carrier Screening in the Age of Genomic Medicine. Number 690. March 2017, Reaffirmed 2020. Retrieved from <https://www.acog.org/-/media/project/acog/acogorg/clinical/list-of-titles/committee-opinions.pdf>. Accessed 10-09-24.
3. American Congress of Obstetricians and Gynecologists (ACOG). ACOG Practice Bulletin. Hemoglobinopathies in Pregnancy. Number 78, January 2007, Reaffirmed 2021. Retrieved from <https://www.acog.org/clinical/clinical-guidance/practice-bulletin>. Accessed 10-09-24.
4. National Organization for Rare Disorders (NORD). Rare Disease Database. Joubert Syndrome. 2021. Retrieved from <https://rarediseases.org/rare-diseases/joubert-syndrome/> Accessed 10-09-24.
5. American College of Surgeons. Commission on Cancer. Optimal Resources for Cancer Care. 2020 Standards. Updated September 2024. Personnel and Services Resources. Chapter 4.4: Genetic Counseling and Risk Assessment. Retrieved from <https://www.facs.org/quality-programs/cancer-programs/commission-on-cancer/standards-and-resources/2020/>. Accessed 10-09-24.

Not cited in clinical policy

- Integrated Healthcare Services Process Manual: UR015 Use of Medical Policy and Criteria
- Clinical Policy: MP/C009 Coverage Determination Guidelines
- Clinical Policy: MP/G001 Genetic Testing, Hereditary and Somatic Conditions.
- American College of Obstetricians and Gynecologists (ACOG) Committee on Genetics. ACOG Committee Opinion: Ethical Issues in Genetic Testing. Number 410, June 2008, Reaffirmed 2020. Retrieved from <https://www.acog.org/-/media/project/acog/acogorg/clinical/list-of-titles/committee-opinions.pdf>. Accessed 10-09-24.
- American College of Obstetricians and Gynecologists (ACOG) Committee on Genetics. ACOG Committee Opinion: Counseling About Genetic Testing and Communication of Genetic Test Results. Number 693, April 2017, Reaffirmed 2020. Retrieved from <https://www.acog.org/-/media/project/acog/acogorg/clinical/list-of-titles/committee-opinions.pdf>. Accessed 10-09-24.
- American College of Obstetricians and Gynecologists (ACOG) Committee on Genetics. Committee Opinion: Consumer Testing for Disease Risk. Number 816, December 2020, Reaffirmed 2023. Retrieved from <https://www.acog.org/-/media/project/acog/acogorg/clinical/list-of-titles/committee-opinions.pdf>. Accessed 10-09-24.
- American College of Obstetricians and Gynecologists (ACOG). Practice Bulletin: Prenatal Diagnostic Testing for Genetic Disorders. Number 162, May 2016, Reaffirmed 2024. Retrieved from <https://www.acog.org/clinical/clinical-guidance/practice-bulletin>. Accessed 10-09-24.
- National Center for Biotechnology Information. National Library of Medicine. National Institutes of Health. Genetic Testing Registry. Retrieved from: <https://www.ncbi.nlm.nih.gov/gtr/>

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PreferredOne Community Health Plan Nondiscrimination Notice

PreferredOne Community Health Plan (“PCHP”) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. PCHP does not exclude people or treat them differently because of race, color, national origin, age, disability, or sex.

PCHP:

Provides free aids and services to people with disabilities to communicate effectively with us, such as:

- Qualified sign language interpreters
- Written information in other formats (large print, audio, accessible electronic formats, other formats)

Provides free language services to people whose primary language is not English, such as:

- Qualified interpreters
- Information written in other languages

If you need these services, contact a Grievance Specialist.

If you believe that PCHP has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:

Grievance Specialist
PreferredOne Community Health Plan
PO Box 59052
Minneapolis, MN 55459-0052
Phone: 1.800.940.5049 (TTY: 763.847.4013)
Fax: 763.847.4010
customerservice@preferredone.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, a Grievance Specialist is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>.

Language Assistance Services

ATTENTION: If you do not speak English, language assistance services, free of charge, are available to you. Call 1.800.940.5049 (TTY: 763.847.4013).

ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1.800.940.5049 (TTY: 763.847.4013).

LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1.800.940.5049 (TTY: 763.847.4013).

XIYYEEFFANNAA: Afaan dubbattu Oroomiffa, taiaaajila gargaarsa afaanij, kanfaltiidhaan ala, ni argama. Bilbilaa 1.800.940.5049 (TTY: 763.847.4013).

CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1.800.940.5049 (TTY: 763.847.4013).

注意：如果您使用繁體中文，您可以免費獲得語言援助服務。請致電 1.800.940.5049 (TTY: 763.847.4013)。

ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 1.800.940.5049 (телетайп: 763.847.4013).

ໂປດຊາບ: ຖ້າວ່າທ່ານເວົ້າພາສາລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ, ໂດຍບໍ່ເສຍຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທ 1.800.940.5049 (TTY: 763.847.4013).

ማስታወሻ: የሚገኙት ቋንቋ አማርኛ ከሆነ የትርጉም እርዳታ ድርጅቶች፣ በነጻ ሊያግዝዎት ተዘጋጅተዋል፡ ወደ ሚከተለው ቁጥር ይደውሉ፡ 1.800.940.5049 (መለስማት ለተሳናቸው፡ 763.847.4013)፡

ဟ်သ့ဟ်သး- နမၤကတိၤ ကသီၤ ကျိၣ်အယိၤ, နမၤန့ၣ် ကျိၣ်အတၢ်မၤစၢၤလၢ တလၢၣ်ဘျီၣ်လၢၣ်စၢၤ နီၣ်တမံၤဘၣ်သ့န့ၣ်လီၤ. ကိး 1.800.940.5049 (TTY: 763.847.4013).

ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 1.800.940.5049 (TTY: 763.847.4013).

ប្រយ័ត្ន៖ បើសិនជាអ្នកនិយាយ ភាសាខ្មែរ, សេវាជំនួយផ្នែកភាសា ដោយមិនគិតល្បួល គឺអាចមានសំរាប់អ្នក។ ចូរ ទូរស័ព្ទ 1.800.940.5049 (TTY: 763.847.4013)។

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Provides free aids and services to people with disabilities to communicate effectively with us, such as:

- Qualified sign language interpreters
- Written information in other formats (large print, audio, accessible electronic formats, other formats)

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- Information written in other languages

If you need these services, contact a Grievance Specialist.

If you believe that PIC has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:

Grievance Specialist
PreferredOne Insurance Company
PO Box 59212
Minneapolis, MN 55459-0212
Phone: 1.800.940.5049 (TTY: 763.847.4013)
Fax: 763.847.4010
customerservice@preferredone.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, a Grievance Specialist is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>.

Language Assistance Services

ATTENTION: If you do not speak English, language assistance services, free of charge, are available to you. Call 1.800.940.5049 (TTY: 763.847.4013).

ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1.800.940.5049 (TTY: 763.847.4013).

LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1.800.940.5049 (TTY: 763.847.4013).

XIYYEEFFANNAA: Afaan dubbattu Oroomiffa, tajaajila gargaarsa afaanii, kanfaltiidhaan ala, ni argama. Bilbilaa 1.800.940.5049 (TTY: 763.847.4013).

CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1.800.940.5049 (TTY: 763.847.4013).

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បំពេញ: ប្រសិនបើ អ្នកនិយាយភាសាខ្មែរ, សេវាជំនួយភាសា ដោយមិនគិតថ្លៃ គឺអាចមានសំរាប់អ្នក។ ហៅ 1.800.940.5049 (TTY: 763.847.4013).

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ဟံသာဝတီ: နမူနာတို့ ကညီ ကျိအသိ, နမူနာ ကျိအတိအကျတို့ တလက်ကွက်လက်စွာ နှိတ်မိသည့်သို့လိ။ ကိ: 1.800.940.5049 (TTY: 763.847.4013).

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