

Department of Origin: Integrated Healthcare Services	Effective Date: 03/05/24
Approved by: Medical Policy Quality Management Subcommittee	Date Approved: 03/05/24
Clinical Policy Document: Genetic Testing, Comparative Genomic Hybridization/ Chromosomal Microarray - Non-Oncology	Replaces Effective Clinical Policy Dated: 06/06/23
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PURPOSE:

The intent of this clinical policy is to ensure care is 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 any of the following: I - IV

- I. Comparative genomic hybridization (CGH) testing for chromosomal abnormalities in individuals is considered medically necessary when the request meets all of the following: A - D
 - A. *A health care professional trained in genetics*, independent of the laboratory performing the testing, has reviewed and documented family history, advised the parent/legal guardian of the potential harms of the testing and implications of the test results, and obtained written informed consent; and
 - B. If warranted, biochemical tests for metabolic disease have been performed and results are non-diagnostic; and
 - C. CGH testing is requested for one of the following: 1 - 4
 1. Nonsyndromic global developmental delay or intellectual disability (DD/ID); or
 2. Autism spectrum disorder (ASD); or
 3. Multiple congenital abnormalities (MCA) not specific to a well-defined genetic syndrome. (See Attachment A); or
 4. Isolated severe congenital heart disease.
 - D. The results of the genetic testing have the potential to impact the clinical management of the member.
- II. Comparative genomic hybridization testing in the prenatal setting is considered medically necessary for the following: A, and one of B - D
 - A. *A health care professional trained in genetics*, independent of the laboratory performing the testing, has reviewed and documented family history, advised the parent/legal guardian of the potential harms of the testing and implications of the test results, and obtained written informed consent; and

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- B. The member is pregnant with a fetus with one or more major structural abnormalities identified on ultrasound, fetal magnetic resonance imaging; or
 - C. The member is undergoing invasive prenatal testing (ie, amniocentesis, chorionic villus sampling or fetal tissue sampling); or
 - D. Evaluation of fetal death (stillbirth) at one of the following: 1 - 2
 - 1. 20 weeks or greater of gestation; or
 - 2. A weight greater than or equal to 350 grams if the gestational age is not known.
- III. Comparative genomic hybridization testing when member is a prospective parent or carrier testing (equal to or greater than age 12) – must have all of the following: A - D
- A. A *health care professional trained in genetics*, independent of the laboratory performing the testing, has reviewed and documented family history, advised the parent/legal guardian of the potential harms of the testing and implications of the test results, and obtained written informed consent; and
 - B. CGH testing of a previous fetus or child confirms a genetic condition or syndrome that puts future children at high risk for the specific inheritable disease, sickness, or defect; and
 - C. Conventional cytogenetic genetic testing is not adequate; and
 - D. Outcome of testing is required to determine carrier status of inherited disorders and to guide subsequent reproductive decisions.
- IV. Comparative genomic hybridization testing for chromosomal abnormalities in *neonates* is medically necessary as a first-line test when the *neonate* has multiple anomalies not specific to a well-defined genetic syndrome.

EXCLUSIONS (not limited to):

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

CGH for all other indications is considered investigative (see Investigative List)

DEFINITIONS:

Copy Number Variants (CNVs):

An alteration of the DNA of a genome that results in the cell having an abnormal number of copies of one or more sections of the DNA.

Cytogenetics:

A branch of genetic science that focuses on the study of the structure and function of the cell, especially the chromosomes. Cytogenetics includes but is not limited to G-banded karyotyping, fluorescent in situ hybridization (FISH) and comparative genomic hybridization (CGH). Conventional cytogenetic testing is used to identify balanced rearrangements (eg, translocations or inversions), alterations in chromosome structure, sequence alterations, copy number changes (deletion, duplication and amplification), single-

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base pair mutation, 20% or lower level of mosaicism, and some types of polyploidy, including triploidy and tetraploidy. Conventional cytogenetic tests identify known genetic abnormalities associated with specific clinical syndromes. These tests may be used when a specific clinical syndrome is suspected.

FISH:

An established technique that labels specific regions of deoxyribonucleic acid (DNA), using sequence specific oligonucleotides (ie, short sequences of DNA) to identify chromosomal deletions, additions or rearrangements. Because FISH uses individual probes, it reveals DNA aberrations of only the probe-targeted segments. Locus-specific FISH detects subtelomeric and interstitial submicroscopic chromosomal arrangements (usually 3–5 megabases [Mb] in size) associated with particular phenotypes.

G-banded Karyotyping:

A molecular chromosome analysis technique which employs Giemsa dye to stain DNA strands. This method is indicated for evaluation of specific chromosome disorders, such as Down syndrome, sex chromosome abnormalities, and trisomy 13/18.

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 people certified in any of the following ways:

- American Board of Genetic Counseling (ABGC) or American Board of Medical Genetics and Genomics (ABMGG) board certified/board eligible²¹ or a licensed genetic counselor
- Advanced Genetics Nursing Certification (AGN-BC)²¹
- Advanced Clinical Genomics Nurse (ACGN) credential²¹
- Clinical Genomics Nurse (CGN) certification²¹
- Cancer Genetic Risk Assessment (CGRA) certification²¹
- Advanced practice oncology nurse or physician assistant with specialized education in cancer genetics and hereditary cancer predisposition syndromes²¹
- Board-certified/board-eligible physician with experience in cancer genetics (defined as education resulting in a certification and undergoing ongoing continuing medical education in cancer genetics and hereditary cancer predisposition syndromes)²¹
- A registered nurse with specialized education in cancer genetics and hereditary cancer predisposition syndromes (defined as education resulting in a certification and undergoing ongoing continuing medical education in cancer genetics and hereditary cancer predisposition syndromes)²¹
- Board-certified specialty care physician with experience in the diagnosis and treatment of the hereditary condition, eg, cardiologist ordering genetic testing for hypertrophic cardiomyopathy

Karyotypes:

The number and appearance of chromosomes under a light microscope.

Neonate:

A newborn infant equal to or less than four weeks of age

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BACKGROUND:

Comparative genomic hybridization (CGH) or chromosomal microarray analysis is a laboratory method to aid in the detection of chromosomal imbalances. It allows for the detection of alterations (copy number variants or CNVs) in the genomic content of an individual. The technique works by comparing the DNA content of the individual with a normal control individual to identify pathogenic CNVs that may be responsible for the suspected disorder. Tens of thousands to millions of different DNA fragments (probes) are attached to identifiable locations on a glass slide or gene chip. Array CGH (aCGH) is a variation of CGH that detects chromosomal abnormalities at a higher resolution than conventional CGH, or chromosome-based CGH.

The three basic types of CGH are bacterial artificial chromosomes (BAC), oligonucleotide (oligo) and single nucleotide polymorphism (SNP) arrays. Arrays are often described as targeted or whole genome or genome-wide. Targeted arrays are high-resolution and contain only specific sections or regions of DNA containing known, clinically significant CNVs. Whole genome or genome-wide arrays cover the entire genome at varying levels of resolution. Whole genome arrays detect known CNVs, like targeted arrays, and may also detect the discovery of new CNVs.

IHC involves designing monoclonal antibodies that bind to the molecule being assessed. Formalin-fixed paraffin-embedded tissue is stained with the antibodies and the expression of the protein is assessed under a microscope. FISH is an established technique that labels specific regions of deoxyribonucleic acid (DNA), using sequence specific oligonucleotides (i.e., short sequences of DNA) to identify chromosomal deletions, additions or rearrangements. Because FISH uses individual probes, it reveals DNA aberrations of only the probe-targeted segments. Locus-specific FISH detects subtelomeric and interstitial submicroscopic chromosomal arrangements (usually 3–5 megabases [Mb] in size) associated with particular phenotypes. When high resolution G-banding is used, chromosomes are first treated with trypsin, an enzyme that degrades proteins. The chromosomes are then stained with Giemsa which produces a banding pattern of light and dark stripes enabling identification of each chromosome. G-band karyotyping is limited to a resolution of 5–10 Mb. PCR is an established laboratory method used to make numerous copies of a specific DNA sequence, utilizing pairs of oligonucleotide primers to replicate and alternate rounds of DNA. Real-time polymerase chain reaction, also called quantitative real time polymerase chain reaction (Q-PCR/qPCR/qrt-PCR) or kinetic polymerase chain reaction (KPCR), is a PCR technology used to simultaneously amplify and quantify the targeted DNA molecule. In reverse transcriptase PCR (RT-PCR) an RNA strand is reverse transcribed into its DNA complement (cDNA). Methylation-specific PCR (MSP) assesses the methylation status of DNA (American Association of Clinical Chemistry [AACC], 2010; Kibel and Reiter, 2007).

Conventional cytogenetic testing is used to identify balanced rearrangements (e.g., translocations or inversions), alterations in chromosome structure, sequence alterations, copy number changes (deletion, duplication and amplification), single-base pair mutation, 20% or lower level of mosaicism, and some types of polyploidy, including triploidy and tetraploidy. Conventional cytogenetic tests identify known genetic abnormalities associated with specific clinical syndromes. These tests may be used when a specific clinical syndrome is suspected.

DSM-5 Diagnostic Criteria for Autism Spectrum Disorders is available at the following website:
<http://www.autismspeaks.org/what-autism/diagnosis/dsm-5-diagnostic-criteria>

DSM-5 Diagnostic Criteria for Intellectual Disability is available at the following website:
<http://aaidd.org/intellectual-disability/definition>

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DSM-5 defines global developmental delay (GDD) as occurring in children less than five years of age who fail to meet expected developmental milestones in multiple areas of functioning. Developmental milestones are available at the following website:

<http://www.cdc.gov/ncbddd/actearly/milestones/index.html>

Major defects are structural abnormalities that affect the way a person looks and require medical and/or surgical treatment. Minor defects are abnormalities that do not cause serious health or social problems. When multiple birth defects occur together and have a similar cause, they are called syndromes. If two or more defects tend to appear together but do not share the same cause, they are called associations.

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Prior Authorization: Yes, per network provider agreement, outpatient setting.

CODING:

CPT®

81228 Cytogenomic (genome-wide) analysis for constitutional chromosomal abnormalities; interrogation of genomic regions for copy number variants, comparative genomic hybridization [CGH] microarray analysis

81229 Cytogenomic (genome-wide) analysis for constitutional chromosomal abnormalities; interrogation of genomic regions for copy number and single nucleotide polymorphism (SNP) variants, comparative genomic hybridization (CGH) microarray analysis

81349 Cytogenomic (genome-wide) microarray analysis for constitutional chromosomal abnormalities; interrogation of genomic regions for copy number and loss of heterozygosity variants, low-pass sequencing analysis

0209U Cytogenomic constitutional (genome-wide) analysis; interrogation of genomic regions for copy number changes and areas of homozygosity for chromosomal abnormalities

S3870 Comparative genomic hybridization (CGH) microarray testing for developmental delay, autism spectrum disorders and/or intellectual disability

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DOCUMENT HISTORY:

Created Date: 02/12/2014
Reviewed Date: 12/30/14, 12/30/15, 12/16/16, 12/15/17, 12/14/18, 12/14/19, 12/14/20, 11/16/21, 10/20/22, 10/19/23
Revised Date: 02/11/15, 02/01/16, 01/25/17, 07/30/19, 01/08/20, 08/20/20, 01/18/21, 11/16/21, 01/31/23, 05/05/23, 06/06/23

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Attachment A

Major Congenital Malformations		
Head and Craniofacial Structures	<u>Skull</u> <ul style="list-style-type: none"> Anencephaly Encephalocele (occipital, frontal) Holoprosencephaly Hydrocephaly 	<u>Ears</u> <ul style="list-style-type: none"> Microtia (types II through IV)
	<u>Eyes</u> <ul style="list-style-type: none"> Microphthalmia Anophthalmia Colobomas (iris, retina) 	<u>Mouth and throat</u> <ul style="list-style-type: none"> Cleft lip Cleft palate Severe micrognathia (Robin sequence) Macro- or microglossia
Neck	<ul style="list-style-type: none"> Cystic hygroma 	
Chest	<ul style="list-style-type: none"> Pectus excavatum Absent or hypoplastic clavicles 	
Back	<ul style="list-style-type: none"> Meningomyelocele Spina bifida 	
Abdomen	<ul style="list-style-type: none"> Omphalocele Gastroschisis 	
Genitalia	<ul style="list-style-type: none"> Ambiguous genitalia 	
Extremities	<u>Arms</u> <ul style="list-style-type: none"> Absent or limb deficiencies 	<u>Hands and Feet</u> <ul style="list-style-type: none"> Polydactyly, complete syndactyly, polysyndactyly Absent digits Ectrodactyly
	<ul style="list-style-type: none"> Tetralogy of Fallot Truncus arteriosus Hypoplastic left heart Ventricular or atrial septal defect 	<ul style="list-style-type: none"> Transposition of the great vessels Interrupted aortic arch type B Total anomaly of pulmonary venous return Hypoplasia or coarctation of the aorta

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Attachment A (continued)

Minor Congenital Malformations		
Head and craniofacial Structures	<u>Skull</u> <ul style="list-style-type: none"> Abnormal hair whorls (absence, more than two) Frontal bossing Plagiocephaly Flat occiput Metopic fontanel 	<u>Ears</u> <ul style="list-style-type: none"> Ear lobe - attached, creases, notches, or bifid Small ears (type I microtia) Lop ear Cup-shaped ear Protruding ear Ear tags Preauricular sinuses
	<u>Eyes</u> <ul style="list-style-type: none"> Epicanthal folds Hypotelorism Hypertelorism Upslanting or downslanting palpebral fissures Short palpebral fissures Synophrys Ptosis 	<u>Nose</u> <ul style="list-style-type: none"> Flat bridge Anteverted nostrils Philtrum long, short, flat <u>Mouth and jaw</u> <ul style="list-style-type: none"> Microstomia Macrostomia Bifid uvula Multiple frenula Micrognathia Retrognathia
Neck	<ul style="list-style-type: none"> Short neck Webbing 	<ul style="list-style-type: none"> Redundant skin Branchial sinuses
Chest	<ul style="list-style-type: none"> Extra nipples Widely spaced nipples Low-placed nipples 	
Back	<ul style="list-style-type: none"> Sacral dimple 	
Genitalia	<ul style="list-style-type: none"> Shawl scrotum Vaginal tags Minor hypospadias 	
Extremities	<u>Arms</u> <ul style="list-style-type: none"> Cubitus valgus Dimples over major joints 	<u>Hands</u> <ul style="list-style-type: none"> Fifth finger clinodactyly Single transverse palmar crease Bridge crease Tapered fingers Nail hypoplasia Persistent finger pads (fetal pads)
	<u>Feet</u> <ul style="list-style-type: none"> Partial syndactyly between two to three toes Nail hypoplasia Prominence of the heels Overlapping digits 	
Skin	<ul style="list-style-type: none"> Nevi Hypo- or hyperpigmented macules Hemangioma 	

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Attachment B

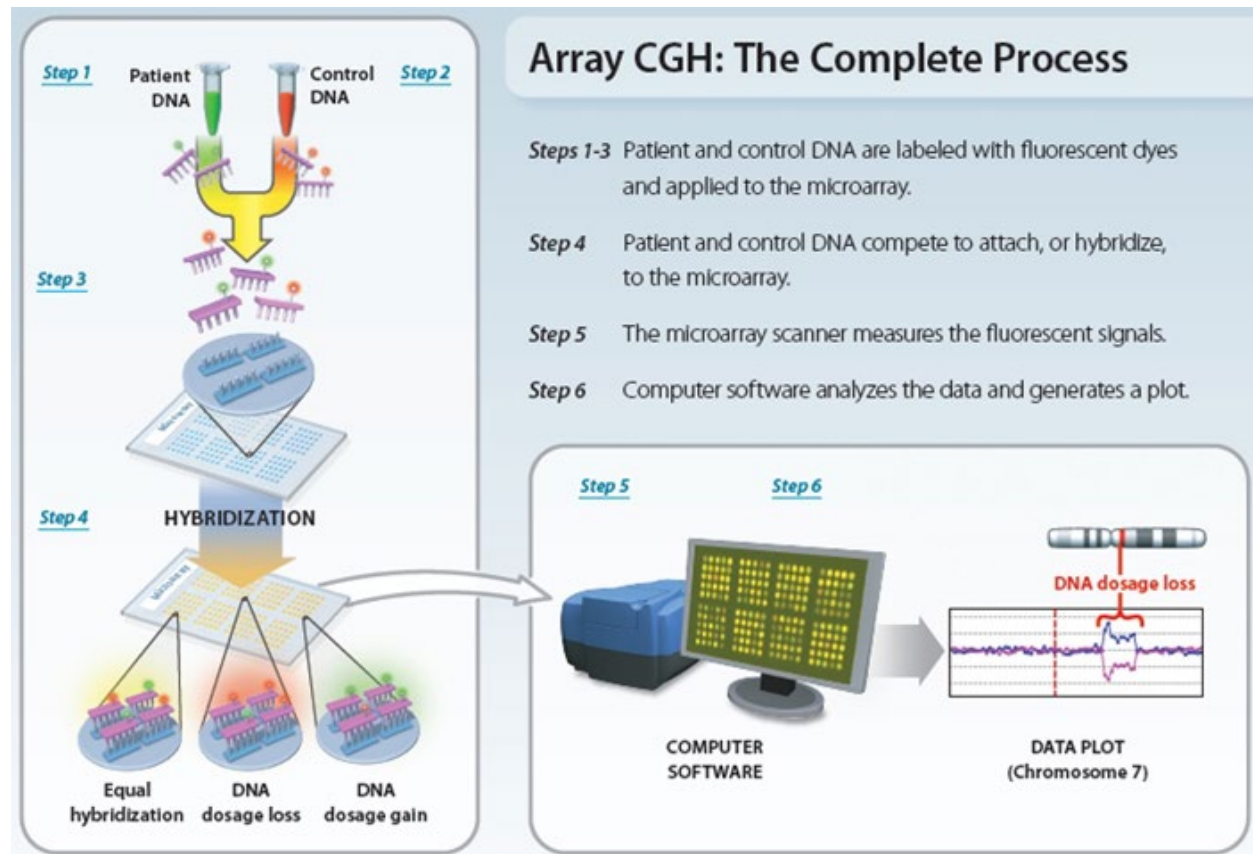


Diagram of the microarray-based comparative genomic hybridization (aCGH) process Source: [nature.com](https://www.nature.com)

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 ሊያግኝዎት ተዘጋጅተዋል፡ ወደ ሚከተለው ቁጥር ይደውሉ፡ 1.800.940.5049 (መለስማት ለተሳናቸው፡ 763.847.4013)፡

ဟ်သ့ဟ်သး- နမၤကတိၤ ကသီၤ ကျိၣ်အယိၤ, နမၤန့ၣ် ကျိၣ်အတၢ်မၤစၢၤလၢ တလၢၣ်ဘျဉ်လၢၣ်စၢၤ 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)។

ملحوظة: إذا كنت تتحدث اذكر اللغة، فإن خدمات المساعدة اللغوية تتوافر لك بالمجان. اتصل برقم 1.800.940.5049 (رقم هاتف الصم والبكم: 763.847.4013).

ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1.800.940.5049 (TTY: 763.847.4013).

주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1.800.940.5049 (TTY: 763.847.4013), 번으로 전화해 주십시오.

PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nang walang bayad. Tumawag sa 1.800.940.5049 (TTY: 763.847.4013).

PreferredOne Insurance Company Nondiscrimination Notice

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PIC:

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 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).

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

CHÚ Y: 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).

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

ማስታወሻ: የሚናገሩት ቋንቋ አማርኛ ከሆነ የትርጉም እርዳታ ድርጅቶች፡ በነጻ ሊያገኙት ተዘጋጅተዋል፡ ወደ ሚከተለው ቁጥር ይደውሉ 1.800.940.5049 (ማስማት ለተሳናቸው: 763.847.4013) .

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

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ប្រយ័ត្ន: បើសិនជាអ្នកនិយាយភាសាខ្មែរ, សេវាជំនួយភាសា ដោយមិនគិតថ្លៃ គឺអាចមានសំរាប់អ្នក។ ហៅ 1.800.940.5049 (TTY: 763.847.4013).

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