Department of Origin: Integrated Healthcare Services	**Effective Date:** 12/06/22
Approved by: Medical Policy Quality Management Subcommittee	**Date Approved:** 12/06/22
Clinical Policy Document: Genetic Testing, Comparative Genomic Hybridization - Non-Oncology	**Replaces Effective Clinical Policy Dated:** 03/08/22
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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 testing for neurodevelopmental 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 formal 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 - 3
      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)

   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 formal consent; and

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 pregnant with a structurally normal fetus and CGH is done in conjunction with invasive diagnostic testing, eg, chorionic villus sampling (CVS) or amniocentesis; 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 formal 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-

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 (ABMGG) board certified/board eligible or licensed genetic counselor
- American College of Medical Genetics physician board certified in medical genetics
- Advanced Practice Nurse in Genetics (APNG)
- Advanced Genetics Nursing Certification (AGN-BC) credentialed through the American Nurses Credentialing Center (ANCC)
- Genetics Clinical Nurse (GCN)
- Advanced practice nurse or physician assistant who is prepared at the graduate level with specialized education in genetics and hereditary cancer predisposition syndromes
- Board-certified/board eligible physician with experience in cancer genetics
- Board-certified specialty care physician with experience in the diagnosis and treatment of the hereditary condition eg, cardiologist ordering genetic testing for hypertrophic cardiomyopathy
- 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)

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-imbedded 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

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.

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

REFERENCES:

1. Integrated Healthcare Services Process Manual: UR015 Use of Medical Policy and Criteria
2. Clinical Policy: MP/C009 Coverage Determination Guidelines
3. Clinical Policy: MP/G001 Genetic Testing, Heritable and Somatic Conditions
4. Clinical Policy: MC/L017 Genetic Testing, Reproductive Carrier Screening
5. Clinical Policy: MC/L021 Genetic Testing, Whole Exome/Whole Genome Sequencing
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Attachment A

Major Congenital Malformations		
Head and Craniofacial Structures	Skull • Anencephaly • Encephalocele (occipital, frontal) • Holoprosencephaly • Hydrocephaly Eyes • Microphthalmia • Anophthalmia • Colobomas (iris, retina)	Ears • Microtia (types II through IV) Mouth and throat • Cleft lip • Cleft palate • Severe micrognathia (Robin sequence) • Macro- or microglossia
Neck	• Cystic hygroma	
Chest	• Pectus excavatum • Absent or hypoplastic clavicles	
Back	• Meningomyelocele • Spina bifida	
Abdomen	• Omphalocele • Gastroschisis	
Genitalia	• Ambiguous genitalia	
Extremities	Arms • Absent or limb deficiencies	Hands and Feet • Polydactyly, complete syndactyly, polysyndactyly • Absent digits • Ectrodactyly
Cardiovascular and great vessels	• Tetralogy of Fallot • Truncus arteriosus • Hypoplastic left heart • Ventricular or atrial septal defect	• Transposition of the great vessels • Interrupted aortic arch type B • Total anomaly of pulmonary venous return • Hypoplasia or coarctation of the aorta

Attachment A (continued)

Minor Congenital Malformations		
Head and craniofacial Structures	Skull • Abnormal hair whorls (absence, more than two) • Frontal bossing • Plagiocephaly • Flat occiput • Metopic fontanel Eyes • Epicanthal folds • Hypotelorism • Hypertelorism • Upslanting or downslanting palpebral fissures • Short palpebral fissures • Synophrys • Ptosis	Ears • Ear lobe - attached, creases, notches, or bifid • Small ears • Lop ear • Cup-shaped ear • Protruding ear • Ear tags • Preauricular sinuses Nose • Flat bridge • Anteverted nostrils • Philtrum long, short, flat Mouth and jaw • Microstomia • Macrostomia • Bifid uvula • Multiple frenula • Micrognathia • Retrognathia
Neck	• Short neck • Webbing	• Redundant skin • Branchial sinuses
Chest	• Extra nipples • Widely spaced nipples • Low-placed nipples	
Back	• Sacral dimple	
Genitalia	• Shawl scrotum • Vaginal tags • Minor hypospadias	
Extremities	Arms • Cubitus valgus • Dimples over major joints Feet • Partial syndactyly between two to three toes • Nail hypoplasia • Prominence of the heels • Overlapping digits	Hands • Fifth finger clinodactyly • Single transverse palmar crease • Bridge crease • Tapered fingers • Nail hypoplasia • Persistent finger pads (fetal pads)
Skin	• Nevi • Hypo- or hyperpigmented macules • Hemangioma	

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Attachment B

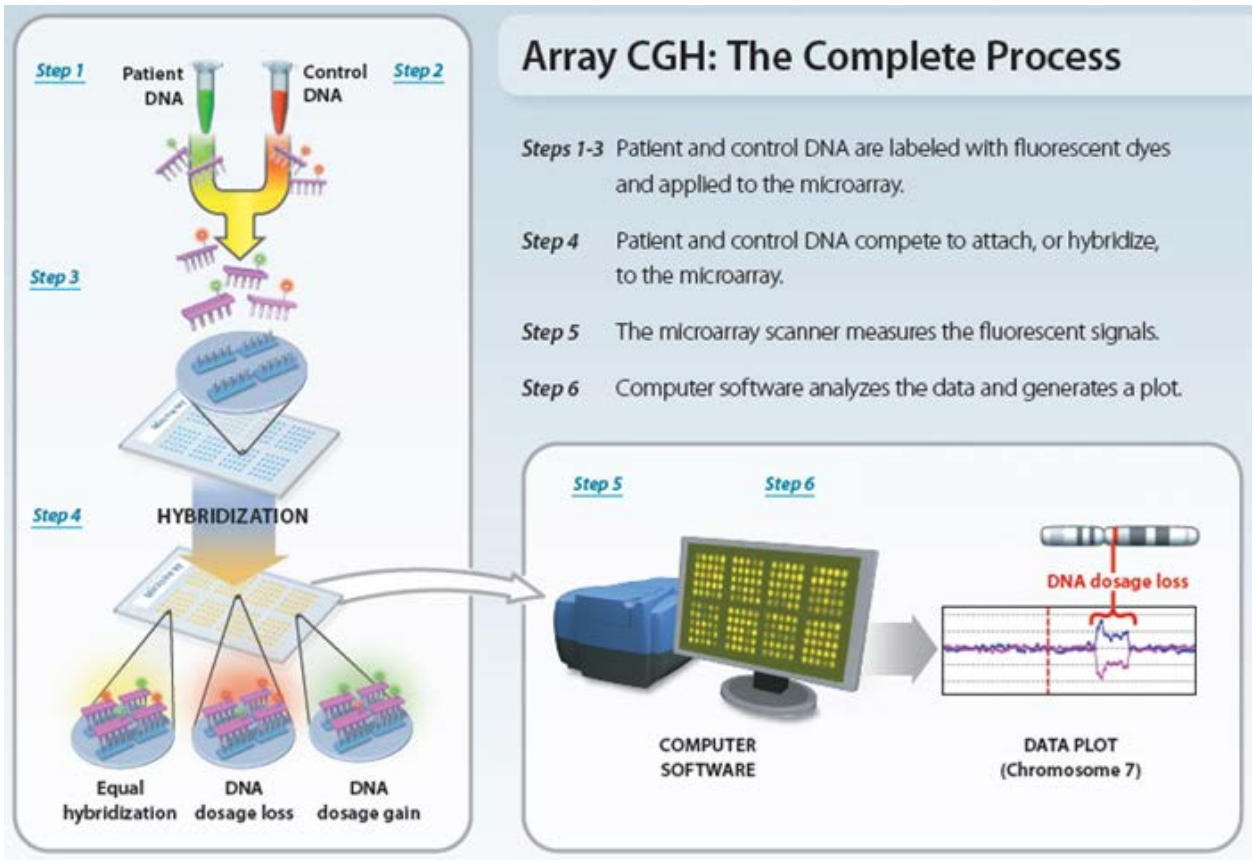

Diagram of the microarray-based comparative genomic hybridization (aCGH) process Source: nature.com

Nondiscrimination & Language Access Policy

Aspirus Health Plan, Inc. complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. *We* do not exclude people or treat them differently because of race, color, national origin, age, disability, or sex.

We will:

- Provide 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)
- Provide 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 *us* at the phone number shown on the inside cover of this *COC*, *your* id card, or aspirushealthplan.com.

If *you* believe that *we* have 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:

Nondiscrimination Grievance Coordinator
Aspirus Health Plan, Inc.
PO Box 1062
Minneapolis, MN 55440
Phone: 1. 866.631.5404 (TTY: 1.866.631.8597)
Fax: 763.847.4010
Email: customerservice@aspirushealthplan.com

You can file a grievance in person or by mail, fax, or email. If *you* need help filing a grievance, the Nondiscrimination Grievance Coordinator 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

Albanian: KUJDES: Nëse flitni shqip, për ju ka në dispozicion shërbime të asistencës gjuhësore, pa pagesë.Telefononi në 1.866.631.5404 (TTY: 1.866.631.8597).

تنبيه :إذا كنت تتحدث اللغة العربية، فإن خدمات المساعدة اللغوية 1.866.631.5404(رقم هاتف الصم والبك : 1.866.631.8597) متاحة لك مجاناً. اتصل بن اعلى رقم الهاتف **Arabic**

French: ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1.866.631.5404 (ATS : 1.866.631.8597).

German: ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zurVerfügung. Rufnummer: 1.866.631.5404 (TTY: 1.866.631.8597).

Hindi: _यान द_: य_द आप ि◌हंदी बोलते ह_ तो आपके ि◌लए मु_त म_ भाषा सहायता सेवाएं उपल_ध ह_।1-800-332-650 (TTY: 1.866.631.8597) पर कॉल कर_।

Hmong: LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1.866.631.5404 (TTY: 1.866.631.8597).

Korean: 주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다.1.866.631.5404 (TTY: 1.866.631.8597)번으로 전화해 주십시오.

Polish: UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer 1.866.631.5404 (TTY: 1.866.631.8597).

Russian: ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода.Звоните 1.866.631.5404 (телетайп: 1.866.631.8597).

Spanish: ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1.866.631.5404 (TTY: 1.866.631.8597).

Tagalog: PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nangwalang bayad. Tumawag sa 1.866.631.5404 (TTY: 1.866.631.8597).

Traditional Chinese: 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 1.866.631.5404 (TTY：1.866.631.8597)

Vietnamese: CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1.866.631.5404 (TTY: 1.866.631.8597).

Pennsylvania Dutch: Wann du Deitsch (Pennsylvania German / Dutch) schwetzscht, kannscht du mitaus Koschte ebbergricke, ass dihr helft mit die englisch Schprooch. Ruf selli Nummer uff: Call 1.866.631.5404 (TTY: 1.866.631.8597).

Lao: ໂປດຊາບ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ,ໂດຍບໍ່ເສັງຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທຣ 1.866.631.5404 (TTY: 1.866.631.8597).