Health Plans

Manual: IU Health Plans
Department: Utilization Management
Policy # MP013
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Medicare Advantage X Commercial

Chromosomal Microarray Policy

I. Purpose

Indiana University Health Plans (IU Health Plans) considers clinical indications when making a medical necessity determination for Chromosomal Microarray Policy.

II. Scope

This policy applies to all Utilization Management staff having decision- making responsibilities where authorization is required for Fully insured commercial plans.

III. Exceptions

Chromosomal Microarray (CMA)/Comparative genomic hybridization (CGH) testing is **NOT** considered medically necessary and therefore not covered for **any of the following**:

1. Members with multiple miscarriages, infertility, or who are suspected to have sex chromosome abnormalities, such as Turner or Klinefelter syndromes
2. Members with any symptoms, conditions, or diagnoses not included in the indications section of this policy
3. Members with suspected balanced chromosome rearrangements, such as balanced translocations and inversions
4. Members without documentation of informed consent completed prior to testing
5. Members who have not participated in counseling with a BC/BE genetics counselor or a medical geneticist before and after testing
6. Members for whom there is not a high index of suspicion of conditions due to a copy number variant
7. Members who present with signs and/or symptoms classic for a specific condition (a specific test should be ordered in lieu of a CMA)

IV. Definitions

Chromosomal Microarray Analysis (CMA) - Chromosomal microarray analysis is a molecular cytogenetic method used for the detection of chromosomal imbalances. Chromosomal microarray analysis may be performed utilizing array-based comparative genomic hybridization or single nucleotide polymorphism arrays. It is utilized in evaluating:

Prenatal Testing

Autism Spectrum Disorder
Developmental Delay
Congenital Anomalies
Intellectual Disabilities

VII. Policy Statements

IU Health Plans considers Chromosomal Microarray Testing medically necessary when **ALL of the following** criteria is met:

1. Genetic counseling has been performed, as indicated by ALL of the following:
   a. Healthcare professional with education and training in genetic issues, free of commercial bias, and discloses financial and intellectual conflicts of interests.
   b. Process involves individual or family and/or family with all of the following:
      1. Three generation calculation and communication of genetic risks with 3 generation family history
      2. Discussion of possible impacts of testing
      3. Discussion of possible test outcomes
      4. Explanation of potential benefits, risks, and limitation of testing
      5. Explanation of purpose of evaluation
      6. Identification of medical management issues including prevention, surveillance, and treatment options and implications
      7. Obtaining informed consent for genetic test

2. Member meets **ONE of the following** indications:
   a. Autism Spectrum Disorder/Developmental Delay
      1. Absence of clinically recognized syndrome caused by a single gene disorder (Cowden syndrome, neurofibromatosis, tuberous sclerosis)
      2. Absence of clinically recognized syndrome caused by a single chromosome disorder (Down syndrome, Turner syndrome, Klinefelter syndrome, Prader-Willi syndrome, Angelman syndrome, fragile X syndrome)
   b. Prenatal Testing
      1. Abnormal fetal ultrasound or MRI with one or more major structural abnormalities identified
         a. Congenital anomaly plus another fetal risk factor (eg, fetal growth retardation, fetal overgrowth, oligohydramnios, or polyhydramnios)
         b. High-risk congenital anomaly (eg, cerebellar hypoplasia, cleft lip and/or cleft palate, holoprosencephaly, hypoplastic left heart, omphalocele)
         c. Multiple congenital anomalies
         d. Nonimmune hydrops fetalis
         e. Nuchal translucency of 3.5 mm or greater
         f. Unexplained Intrauterine growth restriction before 32 weeks gestation
      2. Fetal demise or stillbirth
   c. Congenital Anomalies
      1. Multiple congenital anomalies
      2. Absence of clinically recognizable genetic syndrome
   d. Developmental Delay/Intellectual Disability- Members with apparently non-

syndromic developmental delay/intellectual disability as indicated by **ALL** of the following:

1. Absence of clinically recognizable syndrome caused by single gene disorder (neurofibromatosis, tuberous sclerosis)
2. Absence of clinically recognizable syndrome caused by chromosomal disorder (Down syndrome, Turner syndrome, Klinefelter syndrome, Prader-Willi syndrome, Angelman syndrome, fragile X syndrome)

e. Members with 2 or more miscarriages prior to 20 weeks gestation

f. The signs and symptoms of the member do not suggest a classic condition for which there is a validated specific test.

g. The results of the molecular/genetic test will specifically determine medication, treatment, and/or clinical management of the patient, or family member covered by IU Health Plans.

CODES

Code	Description
81228	Cytogenomic constitutional (genome-wide) microarray analysis; interrogation of genomic regions for copy number variants (e.g. bacterial artificial chromosome (BAC) or oligo-based comparative genomic hybridization (CGH) microarray analysis)
81229	Cytogenomic constitutional (genome-wide) microarray analysis; interrogation of genomic regions for copy number and single nucleotide polymorphism (SNP) variants for chromosomal abnormalities
81406	Tier 2 molecular pathology procedure
83870	Comparative genomic hybridization (CGH) microarray testing for developmental delay, autism spectrum disorder (ASD), and/or intellectual disability
96040	Medical genetics counseling services
S0265	Genetic counseling, 15-minute increments
S3870	Comparative genomic hybridization (cgh) microarray testing for developmental delay, autism spectrum disorder, and/or intellectual disability

VIII. Procedures

None

IX. References/Citations

1. American College of Obstetricians and Gynecologists (ACOG) (2016, May). Prenatal Diagnostic Testing for Genetic Disorders. Prenatal Diagnostic Testing for Genetic Disorders | ACOG
2. American College of Obstetricians and Gynecologists (ACOG) (Initial September 2018,

Reaffirmed 2023). *Modern Genetics in Obstetrics and Gynecology*. Modern Genetics in Obstetrics and Gynecology | ACOG

3. MCG Health Ambulatory Care 26th edition. Chromosomal Microarray Analysis (CMA)-Autism Spectrum Disorders: ACG:A-0588 (AC). Last Update February 15, 2022
4. MCG Health Ambulatory Care 26th edition. Chromosomal Microarray Analysis (MA)-Developmental Delay ACG: A-0810 (AC). Last Update February 15, 2022
5. MCG Health Ambulatory Care 26th edition. Chromosomal Microarray Analysis (CMA)-Prenatal Testing ACG:A-0812 (AC). Last Updated February 15, 2022.
6. MCG Health Ambulatory Care 26th edition. Chromosomal Microarray Analysis (CMA)- Congenital Anomalies ACG:A-0917 (AC). Last Updated February 15, 2022.
7. MCG (Milliman Care Guidelines) Health Ambulatory Care 26th edition. Chromosomal Microarray Analysis (CMA)-Intellectual Disability ACG:A-0924 (AC). Last Update February 15, 2022.
8. U.S. National Library of Medicine. (2021, May 13). *Genetics*. MedlinePlus. https://medlineplus.gov/genetics/.

X. Forms/Appendices

None

XI. Responsibility

Medical Director