I. Policy: Comparative Genomic Hybridization or Chromosomal Microarray Analysis (CMA) for Evaluation of Developmental Delay

II. Purpose/Objective:
To provide a policy of coverage regarding Comparative Genomic Hybridization or Chromosomal Microarray Analysis (CMA) for Evaluation of Developmental Delay

III. Responsibility:
A. Medical Directors
B. Medical Management

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards of good medical treatment practiced by the general medical community.
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment
Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:
(i) The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
(ii) The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.
(iii) The service or benefit will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for members of the same age.

DESCRIPTION:
Comparative Genomic Hybridization (CGH), or Chromosomal Microarray Analysis (CMA), is an array-based cytogenetic test that is used for the detection of submicroscopic genomic abnormalities or imbalances (e.g., deletions, duplications or amplifications).

INDICATIONS: *Requires Prior Authorization by a Plan Medical Director or designee

Array-based comparative genomic hybridization may be considered medically necessary when ordered by a Medical Geneticist*, Certified Genetic Counselor*, Pediatric Neurologist or Developmental Pediatrician for:

Evaluation of chromosomal imbalances in children when all of the following criteria are met:
1. One of the following conditions apply:
   a. Child exhibits symptoms suspected of autism spectrum disorder; or
   b. Child exhibits symptoms of a non-syndromic developmental delay, intellectual disability or loss of developmental milestones; or
   c. Child exhibits congenital malformation(s), anomalies or dysmorphic features that are not specific to a well delineated genetic syndrome

   And

2. Fragile X (FMR1) gene analysis (unless clinically contraindicated) is negative; and
3. The genetic testing results have a reasonable potential to be useful in the clinical management or preventive surveillance strategies of the child; and
4. The parents or legal guardians have participated in in-person genetic counseling with a licensed or certified genetic counselor; Medical Geneticist, Certified Genetic Counselor, Pediatric Neurologist or Developmental Pediatrician who are involved in the child’s care.

LIMITATIONS:
In general, the following limitations apply to all genetic testing:
- Testing for the purposes of confirming a suspected diagnosis of a disorder that can be diagnosed based on clinical evaluations alone will not be covered.
- Testing for conditions for which the treatment plan cannot be impacted will not be covered.
- Testing solely for the purpose of informing the care or management of an insured individual’s family member(s) will not be covered.
- Testing must be performed at a contracted laboratory when available.

FOR MEDICAID BUSINESS SEGMENT: This service is typically not covered. Requests for comparative genomic hybridization requires a program exception consideration.

SEE ALSO: MP232 Autism Spectrum Disorder – Evaluation and Medical Management

Genetic testing is appropriate only when offered in a setting where there are licensed or certified genetic counselor; Medical Geneticist, Certified Genetic Counselor, Pediatric Neurologist or Developmental Pediatrician who are involved in the individual’s care and medical necessity is supported by ALL of the following criteria:

The information is needed to adequately assess risk in the insured individual; and
The information will be used in the immediate care plan of the insured individual; and
Pedigree analysis establishes that the insured individual is in a high risk group for the disease; or
Clinical presentation of symptomatology is evident but diagnosis cannot be established with conventional evaluation testing.

*A genetic counselor is considered by the Plan to be qualified if the following are met:

M.S. or Ph.D. degree from a genetic counseling program approved/ certified by the American Board of Genetic Counseling or the American Board of Medical Genetics

or
Board certified or board qualified/eligible in the orderly process of obtaining board certification by the American Board of Genetic Counseling or American Board of Medical Genetics and Proof of current competence and demonstrated ability (minimum of two years recent and continual experience within the past three years)

EXCLUSIONS:
The Plan does NOT provide coverage for the use of genetic testing for array based comparative genomic hybridization for the purposes of routine prenatal genetic testing in the absence of the recommendation of a geneticist or genetic counselor because it is considered experimental, investigational or unproven for routine screening purposes. The Geisinger Technology Assessment Committee evaluated this technology and concluded that there is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this test on health outcomes when compared to established tests or technologies.

The Plan does NOT provide coverage for the use of Comparative Genomic Hybridization or Chromosomal Microarray Analysis for the purposes of any of the following:
- Pre-natal testing
- Population screening
- Confirmation of a syndrome or disorder routinely established on the basis of clinical evaluation alone such as, but not limited to learning disability, speech delay, growth retardation, attention deficit/hyperactivity disorder.

The Plan does NOT provide coverage for the use of panel testing using advanced sequencing in all cases of suspected genetic abnormality in children with developmental delay/intellectual disability or autism spectrum disorder.

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.

CODING ASSOCIATED WITH: Comparative Genomic Hybridization or Chromosomal Microarray Analysis (CMA) for Evaluation of Developmental Delay

The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.

S3870 Comparative genomic hybridization (CGH) microarray testing for developmental delay, autism spectrum disorder and/or mental retardation.

81228 Cytogenomic constitutional (genome-wide) microarray analysis; interrogation of genomic regions for copy number variants (eg, 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

LINE OF BUSINESS:
Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD’s and NCD’s will supersede this policy. For PA Medicaid Business segment, this policy applies as written.

REFERENCES:


ECRI Institute. HTAIS. Array-based Comparative Genomic Hybridization. 9/30/10


This policy will be revised as necessary and reviewed no less than annually.

Devised: 5/11

Revised: 5/15; 1/17 (revise criteria)

Reviewed: 5/12, 5/13, 5/14, 1/18, 1/19