Clinical Policy: Genetic Testing

Reference Number: IL.CP.MP.537 Coding Implications
Last Review Date: 06/21 Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Genetic tests which are done for clinical purposes including the diagnosis of diseases in children and adults, or for the prediction of drug efficacy require prior authorization.

Policy/Criteria
All requests must contain the following in addition to any relevant criteria listed in the non-specific or specific diagnoses sections below:

1. The genetic testing must be ordered by a physician (MD or DO) who is an enrolled provider.
2. Testing should be accompanied by both documentation of pretest counseling and documentation of planned posttest follow-up where the possible risks and benefits of early detection are reviewed and accepted by the member.

Non-specific Diagnoses:

1. There must be evidence that the requested test is clinically appropriate. Detailed documentation is provided that supports test results will be used to significantly alter the management or treatment of the member (e.g. surgery, the extent of surgery, a change in surveillance, hormonal manipulation, choice of medication, or a change from standard therapeutic or adjuvant chemotherapy).
2. Clinical documentation should be submitted that suggests a key genetic disorder is present, which can be indicated by the following:
    a. Clinical features indicative of a condition or disease with suspected genetic etiology**; OR**
    b. High risk of inheriting the disease based upon personal history, family history, documentation of a genetic mutation and/or ethnic background; **OR**
    c. Following history, physical examination, pedigree analysis and completion of conventional diagnostic testing, a definitive diagnosis remains uncertain and a hereditary diagnosis is suspected

Specific Diagnoses:

Suspected Genetic Conditions/Diagnostic testing- Pediatrics (17 years old or younger):
MHP will cover chromosomal microarray (CMA) or comparative genomic hybridization (CGH) to confirm suspected genetic conditions only when ordered by a specialist within the scope of their practice or a genetic counselor working under direction of a specialist and in the presence of the following:

1. There must be evidence that the requested test is clinically appropriate. Detailed documentation is provided that supports that results will be used to significantly alter the management or treatment of the member (e.g. surgery, the extent of surgery, a change in surveillance, hormonal manipulation, choice of medication or a change from standard therapeutic or adjuvant chemotherapy). **AND**
2. Congenital malformation(s); **OR**
3. Conditions with a known or suspected genetic etiology; **OR**
4. Unexplained global developmental delay

Prenatal Testing:

1. The following prenatal tests are eligible for coverage:
    a. Fetal Karyotype via amniocentesis or CVS
    b. Nuchal Translucency
    c. Quad screen test
    d. Sequential screen
    e. First Screen
2. Penta screen:
    a. **NOT A COVERED BENEFIT**
    b. This test is considered experimental and investigational. Currently, limited data exists to compare accuracy with other second trimester screening tests.
3. Cell-free DNA tests (including MaterniT21 and Harmony)
    a. Reviewed with Centene Policy: CP.MP.84
4. Carrier Screening in Preganancy (including Cystic Fibrosis and SMA)
    a. Reviewed with Centene Policy: CP.MP.83

Testing is not a covered benefit for the following:

1. Criteria other than those outlined above
2. Testing to confirm a diagnosis or disorder that can be diagnosed by conventional diagnostic methods
3. Testing for conditions or purposes where the test results would not directly influence the management or treatment of the disease or condition (e.g., a disease without known treatment)
4. Testing for informational purposes or management of a beneficiary's family member
5. Confirmatory testing for validation of laboratory results
6. Screening for investigational or research purposes
7. Minors under the age of 18 for adult onset conditions that have no preventative or therapeutic treatments
8. Testing that has not been performed in a CLIA-certified laboratory
9. The sole purpose of family planning counseling and infertility services
10. Testing attributable to standing laboratory orders. Testing must be ordered for a specific beneficiary and the medical record and/or order must clearly document the medical necessity of the specific diagnostic test to be performed
11. Laboratory services when not specifically required by the condition for which the patient is being treated such as blanket "rule out" or open-ended tests

Coding Implications

This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2019, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

CPT®* Codes	Description

CPT®* Codes	Description

HCPCS ®* Codes	Description

ICD-10-CM Diagnosis Codes that Support Coverage Criteria
+ Indicates a code(s) requiring an additional character

ICD-10-CM Code	Description

Reviews, Revisions, and Approvals	Date	Approval Date
Original approval date		

References

1. American College of Obstetricians and Gynecologists and Society for Maternal-Fetal Medicine. Practice Bulletin # 162, May 2016. Prenatal Diagnostic Testing for Genetic Disorders
2. American College of Obstetricians and Gynecologists and Society for Maternal-Fetal Medicine. Committee Opinion # 727,January 2018. Cascade Testing: Testing Women for Known Hereditary Genetic Mutations Associated with Cancer.
3. Attia, J, Guyatt, G. ED, Raby, B.A., Tirnauer, J.S. Genetic association studies: Principles and applications. UptoDate. Dec 17, 2020.
4. Burke W, Zimmern RL, Kroese M. Defining purpose: a key step in genetic test evaluation. *Genet Med*. 2007; (9); 675-681.
5. Ellison J.W., Ravnan J.B., Rosenfeld J.A. et al. Clinical Utility of Chromosomal Microarray Analysis. *Pediatrics*. 2012; 130(5):e1085-e1095. Retrieved from: http://pediatrics.aappublications.org/content/130/5/e1085.abstract
6. GeneTests.org funded by the National Institutes of Health. www.genetests.org
7. Gudgeon JM, McClain MR, Palomaki GE, Williams MS. Rapid ACCE: experience with rapid and structured approach to evaluating gene-based testing. *Genet Med*. 2007;9(7):473-478.
8. Library of Congress. Genetics Information Nondiscrimination Act of 2008(HR 493).Retrieved from:https://www.congress.gov/bill/110th-congress/house-bill/493
9. Raby, B.A., Kohlman, W, Venne, V. ED, Slavotinek, A, Tirnauer, J.S. Genetic testing. UptoDate. July 14, 2020

10. Illinois Medicaid Fee Schedule (located at: https://www.illinois.gov/hfs/medicalproviders/medicaidreimbursement/feeschedule/default.aspx)
11. Illinois Medicaid Provider Handbook, https://www.illinois.gov/hfs/SiteCollectionDocuments/09232020PractitionerHandbookPolicyPhysicianAssistantChangesFinal.pdf, Issued September 23, 2020, Section 225.1, Page 50

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

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Note: For Medicaid members/enrollees, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members/enrollees, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.

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