Clinical Policy: Genetic Testing

Reference Number: CP.FC.49
Date of Last Revision: 12/2024
All LOB Except Medicare

Revision Log

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

Description

This policy includes criteria for making medical necessity determinations for genetic tests when specific criteria are not available for the requested genetic. Genetic testing is the analysis of human DNA, RNA, or chromosomes in order to detect heritable disease-related genotypes, mutations, or karyotypes for clinical purposes. Such purposes include predicting risk of disease, identifying carrier status, and establishing prenatal and clinical diagnosis or prognosis. There are currently more than 150,000 genetic tests available on the market.

Note:

- This policy should only be used if there are no other clinical policies or clinical decision support criteria available for the requested genetic test.
- Requests for genetic panels will be reviewed to determine if all included gene analyses are medically necessary.

Policy/Criteria

I. It is the policy of Fidelis Care that genetic testing is **medically necessary** when *all* the following criteria are met:

A. The member/enrollee displays clinical features, or is at direct risk of having inherited the mutation or genetic disorder in question;

B. The test results will be used to develop a clinically useful approach or course of treatment, or to cease unnecessary monitoring or treatments for the individual being tested. Clinically useful test results allow providers to do at least one of the following:

1. Inform interventions that could prevent or delay disease onset,
2. Detect disease at an earlier stage when treatment is more effective,
3. Manage the treatable progression of an established disease,
4. Treat current symptoms significantly affecting a member/enrollee's health,
5. Guide decision making for the member/enrollee's current or planned pregnancy;

C. The genetic disorder could not be diagnosed through completion of conventional diagnostic studies, pedigree analysis and genetic counseling, when available;

D. The member/enrollee has not previously undergone genetic testing for the disorder, unless significant changes in testing technology or treatments indicate that test results or outcomes may change due to repeat testing;

E. Clinical performance of the genetic test is supported by published peer-reviewed medical literature.

II. It is the policy of Fidelis Care that all other requests for genetic not meeting the above stated criteria, including direct-to-consumer testing and genetic banking/DNA storage, are considered **not medically necessary**.

III. General Tumor Biomarker Analysis

General tumor biomarker analysis is **medically necessary** when:

A. The member/enrollee has a confirmed neoplasm and/or malignancy, **AND**
B. The test has clinical utility, as demonstrated by at least one of the following:
    1. The test will determine if a particular therapeutic intervention is effective (or ineffective) in the member/enrollee, or if a particular intervention may be harmful, **OR**
    2. The test will directly impact the clinical management, **OR**
    3. The test will determine prognosis, **AND**
C. The test shows clinical validity, **AND**
D. Testing is being performed in a Clinical Laboratory Improvement Amendments (CLIA) approved laboratory.

IV. General tumor biomarker analysis is considered **investigational** for all other indications.

Testing in Children

Testing in children should take into account the availability of evidenced based risk reduction strategies and the probability of developing a serious medical condition during childhood. Unless there is a clinical intervention appropriate in childhood, parents should be encouraged to defer genetic testing for adult-onset conditions until adulthood. Advocating for the best interests of the child is necessary until he/she is able to make the personal choice to have genetic testing. [5]

Background

Genetic testing identifies changes in chromosomes, genes or proteins. Genetic testing results can confirm or rule out a suspected genetic condition or can help determine a person's chance of developing or passing on a genetic disorder. Test results can direct a person towards appropriate prevention, monitoring and treatment options. There are three methods used for genetic tests: gene tests, chromosomal tests and biochemical tests. Gene tests look at DNA or RNA taken from blood or body fluids such as saliva or other tissue. These tests can look for large changes, such as missing or added sections of a gene, or small changes, such as a missing, added, or altered chemical base within a DNA strand. They can also detect genes with too many copies, those that are too active, turned off, or lost entirely. Genes can be tested using DNA probes or rely on DNA or RNA sequencing.

Chromosomal tests look at features of chromosomes for changes such as pieces being deleted, expanded, or switched to a different chromosomal location. There are two types of chromosomal tests, karyotype and FISH (florescent *in situ* hybridization) analysis. A karyotype test gives a picture of all of a person's chromosomes and can identify changes in chromosome number and large changes in DNA structure. FISH analysis can identify irregularities in certain regions of chromosomes using fluorescent DNA probes. Additionally, FISH analysis can identify small changes that can be missed by overall karyotype testing.

Biochemical tests measure the amount or activity of proteins or particular enzymes. Genes contain the DNA code for making proteins. An abnormal amount or activity of proteins can

indicate that genes are not working normally. These tests are most commonly used for newborn screening to detect conditions such as phenylketonuria (PKU).

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Policy developed and approved	3/23	
Annual Review. Added section III: "General Tumor Biomarker Analysis" and criteria. Added section IV: "General tumor biomarker analysis is considered investigational for all other indications". References reviewed and updated.	4/24	
Changed Product type from "All LOB" to "All LOB Except Medicare".	12/24	

References

1. LabCorp website. Test menu. https://www.labcorp.com/test-menu/search. Accessed April 14, 2024.
2. National Human Genome Research Institute. Frequently asked questions about genetic testing. https://www.genome.gov/FAQ/Genetic-Testing. Published February 13, 2019. Accessed April 14, 2024.
3. Hamid R. New guidelines on genetic testing and screening in children. *AAP Grand Rounds*. September 2013; 30 (3): 36. doi.org/10.1542/gr.30-3-36
4. Summar ML, Lanpher BC, Hofherr SE. Next-gen sequencing: expanded genetic testing in the real world. Medscape. https://www.medscape.com/viewarticle/831333. Published September 15, 2014. Accessed April 14, 2023.
5. Botkin JR, Belmont JW, Berg JS, et al. Points to Consider: Ethical, Legal, and Psychosocial Implications of Genetic Testing in Children and Adolescents [published correction appears in Am J Hum Genet. 2015 Sep 3;97(3):501]. *Am J Hum Genet*. 2015;97(1):6-21. doi:10.1016/j.ajhg.2015.05.022
6. Kohlmann WSlavotinek A. Genetic Testing. UpToDate. www.uptodate.com. October 07, 2022. Accessed April 14, 2024.
7. Committee Opinion No. 693: Counseling About Genetic Testing and Communication of Genetic Test Results. *Obstet Gynecol*. 2017;129(4):e96-e101. doi:10.1097/AOG.0000000000002020
8. Concert Genetics Genetic Testing: General Approach to Genetic and Molecular Testing V1.2024 Date of Last Revision: 10/1/2023
9. Paragraph 11-c of subsection (i) of section 3216 of the insurance law, as added by a chapter of the laws of 2023

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 Fidelis Care.

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.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members/enrollees and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members/enrollees and their representatives agree to be bound by such terms and conditions by providing services to members/enrollees and/or submitting claims for payment for such services.

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.