



Genetic Testing Clinical Coverage Criteria

Overview

Genetic testing refers to the laboratory analysis of human genetic material including deoxyribonucleic acid (DNA), ribonucleic acid (RNA) and/or chromosomes to detect genetic changes. Genetic changes are referred to as variations or variants (sometimes called mutations). Gene variants, as they relate to genetic disorders are classified as pathogenic, likely pathogenic, variant of uncertain significance, likely benign or benign. Genetic testing is often referred to as molecular diagnostics or molecular diagnostic testing.

Genetic testing may be done for several purposes, including but not limited to, diagnosing or predicting susceptibility for inherited conditions, determining carrier status, diagnostic and prognostic testing, screening for common disorders, or selecting appropriate treatments (also known as pharmacogenetic testing).

Policy

This Policy applies to the following Fallon Health products:

- Fallon Medicare Plus, Fallon Medicare Plus Central (Medicare Advantage)
- MassHealth ACO
- NaviCare HMO SNP (Dual Eligible Medicare Advantage and MassHealth)
- NaviCare SCO (MassHealth-only)
- PACE (Summit Eldercare PACE, Fallon Health Weinberg PACE)
- Community Care (Commercial/Exchange)

Fallon Health requires prior authorization (approval in advance) for genetic testing. For laboratory testing, including genetic testing, approval in advance means obtaining the necessary authorization from the Plan before the laboratory specimen is collected.

The ordering physician (or other qualified healthcare provider, i.e., nurse practitioner, clinical nurse specialist, physician assistant) is responsible for obtaining prior authorization.

Information for processing laboratories: When a specimen comes into your lab for genetic testing, before you analyze the specimen, please verify that there is an approved authorization for the test and the CPT and/or HCPCS codes approved as part of that authorization.

Requests for prior authorization must include: (1) the gene(s) and/or gene variants to be tested, (2) the name of the test and the name and address of the lab performing the test, (3) all CPT and HCPCS codes and units of service for each (codes not authorized will not be reimbursed), (4) an explanation of how the results of the test will be clinically useful to the medical management of the member, and (6) clinical documentation from the treating physician's medical records that clearly supports the medical necessity of the test. Failure to provide this information will result in a denial of the request.

Fallon Health Clinical Coverage Criteria

Fallon Health Clinical Coverage Criteria apply to (1) requests for genetic testing for Community Care members, and (2) requests for genetic testing for MassHealth members that are outside of the scope of MassHealth's published Guidelines (see MassHealth Variation below).

Fallon Health uses the InterQual Criteria in effect on the date of service when making medical necessity determinations for genetic testing:

- CP: Molecular Diagnostics

When InterQual Criteria are not available, Fallon Health will consider coverage on an individual case-by-case basis in accordance with the definition of medical necessity.

Fallon Health makes InterQual® criteria available through the Transparency Tool on our website, effective January 1, 2024.

Guidelines for Genetic Testing

The following Guidelines apply to all requests for genetic testing:

1. The results of the test must be clinically useful to the medical management of the member (e.g., initiate a new course of therapy, alter an existing therapy, or determine level of surveillance).
2. Clinical documentation in the treating physician's medical records clearly supports the medical necessity of the test.
3. There is sufficient evidence in the scientific literature to support the validity and predictive accuracy of the test.
4. The test must be performed by a contracted laboratory unless none is available.

The Guidelines for Genetic Testing apply to all requests for genetic testing. This is in addition to InterQual Criteria, when InterQual Criteria are available.

In regard to panel testing, prior authorization is required for each component and/or gene/gene variant of a panel test when the panel is represented by multiple CPT codes. If any tests included in the panel do not meet criteria the entire panel will be denied.

Medicare Variation

Medicare is a defined benefit program. In order to be considered for Medicare coverage, an item or service must fall within a statutory benefit category. Although the Medicare Benefit Policy Manual, Chapter 15, Section 10 identifies "Diagnostic X-Ray tests, laboratory tests, and other diagnostic tests;" as a benefit category; Sec. 1862 (1)(A) Statutory Exclusion "except for items and services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member," must also be applied. In order to be paid under this benefit category, a diagnostic test must be ordered by a physician (or other qualified healthcare practitioner) who is treating the beneficiary and the results used in the management of a beneficiary's specific medical condition.

Medicare statutes and regulations do not have coverage criteria for genetic testing. Medicare has two NCDs related to genetic testing (Medicare Coverage Database search 02/23/2025):

- [NCD 90.1 Pharmacogenomic Testing for Warfarin Response](#) – Coverage criteria for pharmacogenomic testing of CYP2C9 or VKORC1 alleles to predict warfarin responsiveness are fully established by Medicare and is only covered when provided to Medicare beneficiaries who are candidates for anticoagulation therapy with warfarin who meet coverage criteria in NCD 90.1
- [NCD 90.2 Next Generation Sequencing \(NGS\)](#) – Coverage criteria for next generation sequencing (NGS) tests with FDA-approval or clearance as an approved companion in vitro diagnostic test are fully established by Medicare.
 - FDA-approved or cleared companion diagnostic or in vitro test are found on the FDA website. The "Indication" column on this website can be used to determine if the NCD is applicable.
 - If the test is an FDA-approved or cleared companion in vitro diagnostic test being used for a different indication than it was approved for (i.e., a different cancer type), then the testing does not meet the NCD coverage criteria, and local guidance should be applied (see National Government Services, Inc. Genomic Sequence Panel Tests L37606 and L37810 below).

- If the test does not have FDA-approval or clearance as a companion invitro diagnostic test, the Medicare Administrative Contractor (MAC) may determine coverage of NGS when criteria in D.1 Somatic (acquired) cancer or D.2. Germline (Inherited) Cancer are met (see National Government Services, Inc. Genomic Sequence Panel Tests L37606 and L37810 below).

National Government Services, Inc., the Part A/B Medicare Administrative Contractor (MAC) with jurisdiction in the Plan's service area. National Government Services, Inc. has six LCDs related to genetic testing (Medicare Coverage Database search 02/23/2025):

- [L37851 Biomarker Testing for Neuroendocrine Tumors/Neoplasms](#) – Coverage criteria for biomarker testing for neuroendocrine tumors/neoplasms are fully established by Medicare. National Government Services, Inc. will not provide coverage for biomarker testing for neuroendocrine tumors/neoplasms. Proprietary Laboratory Analyses (PLA) code CPT code 0007M is considered not medically necessary and will be denied as a noncovered procedure.
- [L37606 Genomic Sequence Analysis Panels in the Treatment of Hematolymphoid Diseases](#) – Coverage criteria for genomic sequence analysis panels in the treatment of hematolymphoid diseases are fully established by Medicare.
- [L37810 Genomic Sequence Analysis Panels in the Treatment of Solid Organ Neoplasms](#) - Coverage criteria for genomic sequence analysis panels in the treatment of solid organ neoplasms are fully established by Medicare.
- [L39726 KidneyIntelX and KidneyIntelX.dkd Testing](#) – Coverage criteria for the KidneyIntelX or KidneyIntelX.dkd test are fully established by Medicare (Proprietary Laboratory Analyses (PLA) code CPT codes 0105U and 0407U, respectively).
- [L35000 Molecular Pathology Procedures](#) - Coverage criteria for the molecular pathology procedures (Tier 1 and Tier 2) described in this LCD are fully established by Medicare
- [L38968 Thyroid Nodule Molecular Testing](#) – Coverage criteria for thyroid nodule testing are fully established by Medicare (Proprietary Laboratory Analyses (PLA) code CPT code 0026U).

Coverage criteria for genetic testing that is included in the scope of these NCDs and LCDs is fully established by Medicare, therefore Fallon Health Clinical Coverage Criteria are not applicable.

For Genetic Testing Performed by a Laboratory Outside of the Plan's Service Area:

A MAC outside of the Plan's service area sometimes has exclusive jurisdiction over a Medicare covered item or service. "In some instances, one Medicare Part A/B MAC processes all of the claims for a particular Medicare-covered item or service for all Medicare beneficiaries around the country. In this situation, MA plans must follow the coverage requirements or LCD of the MAC that enrolled the supplier and processes all of the Medicare claims for that item, test or service (Medicare Managed Care Manual, Chapter 4, §90.4.1)."

In addition, "Jurisdiction of payment requests for laboratory services furnished by an independent laboratory, except where indicated in §50.5.1 and §50.5.2, lies with the A/B MAC (B) serving the area in which the laboratory test is performed. Jurisdiction is not affected by whether or not the independent laboratory uses a central billing office and whether or not the laboratory provides services to customers outside its A/B MAC (B)'s service area. The location where the independent laboratory performed the test determines the billing jurisdiction. Therefore, even if the sample originates in a different jurisdiction from where the sample is being tested, the claim would still be filed in the jurisdiction where the test was performed (Medicare Claims Processing Manual Chapter 1, §50.5 – Jurisdiction of Laboratory Claims)."

Go to the Medicare Coverage Database to search for an LCD issued by a MAC with jurisdiction over a test furnished by an independent laboratory: <https://www.cms.gov/medicare-coverage-database/search.aspx>. MolDX

The Molecular Diagnostic (MolDX) Program¹ administered by Palmetto GBA determines coverage, coding and reimbursement for molecular diagnostic tests that fall under the scope of

¹ <https://www.palmettogba.com/palmetto/moldxv2.nsf>

the program. Four Medicare Administrative Contractors have an operating agreement with the MoIDX Program: Palmetto GBA, Noridian Healthcare Solutions, Wisconsin Physician Services and CGS Administrators, LLC. The MoIDX Program coordinates LCD development with the four participating MACs.

While four MACs participate with MoIDX, the program is not currently national in scope; therefore, it is important to know which MAC jurisdiction's policy will apply when trying to determine coverage. MACs that have not chosen to participate in the MoIDX Program may create their own molecular diagnostic testing LCDs, except when an independent laboratory is the only provider of a particular molecular diagnostic test, as previously discussed, the MAC with jurisdiction will determine coverage policy for all Medicare beneficiaries. When the MAC with jurisdiction is one of the four MACs who participate with MoIDX, the MoIDX program may issue an LCD.

At this time, National Government Services, Inc., Novitas Solutions, Inc., and First Coast Service Options do not participate in the MoIDX Program.

Go to the Medicare Coverage Database to search for an MoIDX LCD:
<https://www.cms.gov/medicare-coverage-database/search.aspx>.

The scope of the MoIDX Program is outlined in LCD MoIDX: Molecular Diagnostic Tests (MDT) (L35025).

Molecular Diagnostic Test (MDT): Any test that involves the detection or identification of nucleic acid(s) deoxyribonucleic acid/ribonucleic acid (DNA/RNA), proteins, chromosomes, enzymes, cancer chemotherapy sensitivity and/or other metabolite(s). The test may or may not include multiple components. A MDT may consist of a single mutation analysis/identification, and/or may or may not rely upon an algorithm or other form of data evaluation/derivation.

In addition to the MDT definition, this coverage policy applies to all tests that meet at least one of the following descriptions:

- All non-FDA approved/cleared laboratory developed tests (LDT)
- All modified FDA-approved/cleared kits/tests/assays
- All tests/assays billed with more than one code from a HIPAA compliant code set to identify the service, including combinations of method-based, serology-based, and anatomic pathology codes
- All tests that meet the first three bullets and are billed with a Not Otherwise Classified (NOC) code

Laboratory developed test (LDT): Any test developed by a laboratory developed without Food and Drug Administration (FDA) approval or clearance.

Please review Local Coverage Article: Billing and Coding: MoIDX Molecular Diagnostic Tests (MDT) (A56853) for a list of diagnostic services that fall within the scope of MoIDX but does not automatically imply coverage: <https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=56853>.

Labs must report MDTs and LDTs with the CPT and/or HCPCS code(s) that most accurately describes the specific test performed. Tests that are not described by a specific code require the use of an unlisted code. The MoIDX Program requires laboratories to obtain a DEX Z-Code that is unique to the specific test. When reported in conjunction with the appropriate CPT/HCPCS code, the DEX Z-Code allows payers to determine the exact test that has been performed.

MassHealth Variation

MassHealth has four Guidelines for Medical Necessity Determination for genetic testing (MassHealth website search 02/23/2025):

- [Guidelines for Medical Necessity Determination for Chromosomal Microarray Analysis](#) (CPT 81228, 81229)
- [Guidelines for Medical Necessity Determination for Fragile X Carrier Screening](#) (CPT 81243)

- [Guidelines for Medical Necessity Determination for Gene Expression Profiling Tests for Breast Cancer \(CPT 81519\)](#)
 - Note: Several gene expression profiling tests are in varying stages of development and clinical investigation. Of these tests, MassHealth only covers Oncotype DX, a multiplex, 21-gene, real-time, PCR-based assay. MassHealth considers other gene expression profiling tests experimental and investigational.
- [Guidelines for Medical Necessity Determination for Genetic Testing for BRCA related Breast and/or Ovarian Cancer \(CPT codes: 81162, 81163, 81164, 81165, 81166, 81167, 81212, 81215, 81216, 81217, 81307, 81308, 81479\)](#)

Fallon Health will apply Fallon Health Clinical Coverage Criteria when reviewing requests for genetic testing that are outside of the scope of these four MassHealth Guidelines.

Exclusions

- Genetic testing that is not medically necessary and/or was not ordered by member's treating physician.
- Claims for genetic testing that are incorrectly coded. Genetic testing must be reported with the CPT and/or HCPCS code(s) that most accurately describes the specific test performed.
- Direct-to-consumer genetic testing, including, but not limited to, "home-test kits" or genetic tests ordered by the member over the telephone or Internet.

Summary of Evidence

N/A

Analysis of Evidence (Rationale for Determination)

N/A

References

1. Centers for Medicare & Medicaid Services, Inc.. National Coverage Determination (NCD) Pharmacogenomic Testing for Warfarin Response (90.1). Version Number 1. Effective Date of this Version: 08/03/09. Accessed 02/23/2025.
2. Centers for Medicare & Medicaid Services. NCD Next Generation Sequencing (90.2). Version 2. Effective Date of this Version 01/27/2020. Accessed 02/23/2025.
3. National Government Services, Inc. Local Coverage Determination (LCD) Genomic Sequence Analysis Panels in the Treatment of Solid Organ Neoplasms L37810. Original Effective Date For services performed on or after 04/01/2019. Revision Effective Date For services performed on or after 04/01/2022. Accessed 02/23/2025.
4. National Government Services, Inc. Local Coverage Determination (LCD) Genomic Sequence Analysis Panels in the Treatment of Hematolymphoid Diseases L37606. Original Effective Date For services performed on or after 08/01/2018. Revision Effective Date For services performed on or after 10/03/2019. Accessed 02/23/2025.
5. National Government Services, Inc. Local Coverage Determination (LCD) Molecular Pathology Procedures L35000. Original Effective Date For services performed on or after 10/01/2015. Revision Effective Date 08/01/2024. Accessed 02/25/2025.
6. National Government Services, Inc. Local Coverage Determination (LCD) Biomarker Testing for Neuroendocrine Tumors/Neoplasms L37851. Original Effective Date For services performed on or after 04/01/2019. Revision Effective Date For services performed on or after 01/10/2022. Accessed 02/23/2025.
7. National Government Services, Inc. Local Coverage Determination (LCD) KidneyIntelX and KidneyIntelX.dkd Testing L39726. Original Effective Date For services performed on or after 08/01/2024. Revision Effective Date N/A. Accessed 02/23/2025.

8. National Government Services, Inc. Local Coverage Determination (LCD) Thyroid Nodule Testing L38968. Original Effective Date For services performed on or after 12/01/2021. Revision Effective Date N/A. Accessed 02/23/2025.

Policy history

Origination date: 05/2002
Review/Approval(s): Technology Assessment Committee: 05/23/2006, 11/06/2013, 01/28/2015 (updated template, added language regarding panel testing) 01/27/2016 (added requirement that all requests come directly from the ordering provider) 01/25/2017 (added language regarding Z-Code submission on claims), 01/24/2018 (clarified panel testing will be denied if one test does not meet criteria), 01/23/2019 (annual review, no updates), 02/27/2019 (added information regarding cystic fibrosis testing in relation to pregnancy), 03/27/2019 (added language in relation to spinal muscular atrophy testing related to pregnancy), 02/01/2022 (Added clarifying language related to Medicare Advantage, NaviCare and PACE under Policy section; added references), 02/25/2025 (annual review; updated Medicare Advantage regulatory information and created new section for Medicare Variation; updated MassHealth regulatory information and created new section for MassHealth Variation; removed requirements for DEX codes; updated Exclusions and References section; added new section: Instructions for Use).
Utilization Management Committee 03/18/2025 (review and approval).

Instructions for Use

Fallon Health complies with CMS's national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan's service area, and applicable Medicare statutes and regulations when making medical necessity determinations for Medicare Advantage members. When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health may create internal coverage criteria under specific circumstances described at § 422.101(b)(6)(i) and (ii).

Fallon Health generally follows Medical Necessity Guidelines published by MassHealth when making medical necessity determinations for MassHealth members. In the absence of Medical Necessity Guidelines published by MassHealth, Fallon Health may create clinical coverage criteria in accordance with the definition of Medical Necessity in 130 CMR 450.204.

For plan members enrolled in NaviCare, Fallon Health first follow's CMS's national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan's service area, and applicable Medicare statutes and regulations when making medical necessity determinations. When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, or if the NaviCare member does not meet coverage criteria in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health then follows Medical Necessity Guidelines published by MassHealth when making necessity determinations for NaviCare members.

Each PACE plan member is assigned to an Interdisciplinary Team. PACE provides participants with all the care and services covered by Medicare and Medicaid, as authorized by the interdisciplinary team, as well as additional medically necessary care and services not covered by Medicare and Medicaid. With the exception of emergency care and out-of-area urgently needed

care, all care and services provided to PACE plan members must be authorized by the interdisciplinary team.

Not all services mentioned in this policy are covered for all products or employer groups. Coverage is based upon the terms of a member's particular benefit plan which may contain its own specific provisions for coverage and exclusions regardless of medical necessity. Please consult the product's Evidence of Coverage for exclusions or other benefit limitations applicable to this service or supply. If there is any discrepancy between this policy and a member's benefit plan, the provisions of the benefit plan will govern. However, applicable state mandates take precedence with respect to fully-insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, federal mandates will apply to all plans.