LCD - MolDX: Lab-Developed Tests for Inherited Cancer Syndromes in Patients with Cancer (L38974)

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Noridian Healthcare Solutions, LLC	A and B MAC	02102 - MAC B	J - F	Alaska
Noridian Healthcare Solutions, LLC	A and B MAC	02201 - MAC A	J - F	Idaho
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MolDX: Lab-Developed Tests for Inherited Cancer Syndromes in Patients with Cancer

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Issue

Issue Description

This LCD outlines limited coverage for this service with specific details under **Coverage Indications, Limitations and/or Medical Necessity.**

Issue - Explanation of Change Between Proposed LCD and Final LCD

The Proposed LCD was modified to be inclusive of non-NGS methodologies as well as NGS. The new title and other minor changes made for clarification are reflective of this.

CMS National Coverage Policy

Title XVIII of the Social Security Act (SSA), §1862(a)(1)(A), states that no Medicare payment shall be made for items or 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.

42 CFR §410.32 Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions.

CMS Internet-Only Manual, Pub. 100-02, Medicare Benefit Policy Manual, Chapter 15, §80 Requirements for

Diagnostic X-Ray, Diagnostic Laboratory, and Other Diagnostic Tests, §80.1.1 Certification Changes.

National Coverage Determination (NCD) 90.2, which allows contractors to cover next generation sequencing tests as a diagnostic laboratory test for patients with cancer in specific circumstances

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

This policy describes and clarifies coverage for Lab-Developed Tests (LDTs), Federal Drug Administration (FDA)-cleared, and FDA-approved clinical laboratory tests in hereditary cancer tests including Next Generation Sequencing (NGS) tests as allowable under the National Coverage Determination (NCD) 90.2, under section D describing Medicare Administrative Contractor (MAC) discretion for coverage. This policy's scope is specific for hereditary germline testing, and is exclusive of polygenic risk scores, solid tumor, hematologic malignancies, circulating tumor deoxyribonucleic acid (DNA) testing (ctDNA), and other acquired cancer-related tests.

Criteria for Coverage

All the following must be present for coverage eligibility:

- The patient must have
    - Any cancer diagnosis
    - AND a clinical indication for germline (inherited) testing for hereditary cancer
    - AND a risk factor for germline (inherited) cancer
    - AND has not been previously tested with the same germline genetic content.
- The test has satisfactorily completed a Technical Assessment (TA) by Molecular Diagnostic Services Program (MolDX®) for the stated indications of the test.
- The test performed includes **at least** the minimum genetic content (genes or genetic variants) with definitive or well-established guidelines-based evidence required for clinical decision making for its intended use that can be reasonably detected by the test.
    - Because these genes and variants will change as the literature and drug indications evolve, they are listed separately in associated documents, such as the MolDX® TA forms.
    - A single gene or variant may be tested if it is the only gene or variant considered to be reasonable and necessary for a cancer type.
- If a previous test was performed with a similar/duplicative intended use, a subsequent test is only reasonable and necessary if the non-duplicative genetic content of the second test is reasonable and necessary.
- If the test is an NGS test, it must abide by all conditions listed in the NCD 90.2.

Situations in which a test should not be used or coverage is denied:

The test in question will be non-covered if:

- It is an NGS tests and does not fulfill all the criteria set forth in the NCD 90.2
- A previous test was performed for the same genetic content
- It is a panel or single gene test used to identify a known familial variant(s) that could be identified with a test targeted to that specific variant(s)
- It is a panel or single gene test used to confirm a variant(s) detected by somatic tumor testing that can be confirmed by a test targeted to that specific variant(s)
- A satisfactory TA is not completed

- For tests that are currently covered but a TA submission has not been made, providers must submit complete TA materials by the original effective date of the policy or coverage will be denied.

Summary of Evidence

An estimated 5-10% of cancers have a heritable component, and there are a growing number of hereditary cancer syndromes.[1-5] Identifying pathogenic variants in genes associated with hereditary cancer syndromes can uncover genomic mechanisms that have predictive, diagnostic, and prognostic utility to patients and are used to better their management.[6-8] Pathogenic variants in germline genes have been associated with an increased lifetime risk of hereditary breast and ovarian (HBOC), colorectal (CRC), as well as other cancers, such as endometrial, pancreatic, prostate, and melanoma. Traditionally, testing of genes associated with hereditary cancers was performed based on specific gene-disease relationships and an individual's personal or family history, often in a single-gene reflex fashion. However, the growing number of genes known to be associated with hereditary cancer syndromes and the overlap between clinical presentations has challenged this paradigm.

The application of NGS technology has facilitated multi-gene panel testing for definitive genes associated with many hereditary cancer syndromes. NGS has been shown to be more efficient than single-gene sequential testing, and is becoming a routine component of the diagnostic process.[1,9-11] For example, *BRCA1* and *BRCA2 (BRCA1/2)* have historically been the most frequently tested genes in HBOC. Yet, it is now estimated that more than half of the individuals with hereditary breast cancer carry pathogenic variants in genes other than *BRCA1/2.*[10,12-14] Breast cancer is also a component of several other hereditary cancer syndromes, such as Li-Fraumeni syndrome, Cowden syndrome, hereditary diffuse gastric cancer, and Peutz-Jeghers syndrome.[15-19] Studies estimate that approximately 30% of all CRC cases are an inherited form of disease[20-22] and nearly 5% are associated with highly penetrant hereditary clinical presentations. Lynch syndrome (LS), previously known as hereditary non-polyposis colorectal cancer (HNPCC), is the most common hereditary CRC syndrome accounting for 2-3% of all CRC. It is caused by germline pathogenic variants in 5 mismatch repair genes, *MHL1*, *MSH2, MSH6, EPCAM* and *PMS2.* Traditionally, a testing cascade of microsatellite instability (MSI) analysis and/or immunohistochemistry was performed followed by testing of individual single genes. However, NGS allows for a majority of the genes to be tested simultaneously, reducing the time to diagnosis and reducing costs.[11,23] The National Comprehensive Cancer Network (NCCN) guidelines have also expanded to incorporate testing of multiple genes into medical management recommendations.[5,24-26] The established Centers for Medicare and Medicaid Services (CMS) NCD 90.2 confirms testing using NGS to be both reasonable and necessary in Medicare beneficiaries.

Clinical Indications and Risk Factors

Although inherited cancer syndromes each have their own clinical criteria for testing, there are some findings that are associated more frequently with hereditary cancers when compared to those that are acquired including: diagnosis at an earlier age than what is typically seen for that cancer type, 2 or more affected close blood relatives (first-, second-, and third-degree relatives) on the same side of the family with the same type of cancer, multiple affected generations within 1 family. Additional findings include multiple cancer types occurring in the same individual, cancers that develop bilaterally, and presence of congenital conditions known to be associated with a particular cancer syndrome.[3,27]

Additional factors are specific to certain cancer types. For example, factors that significantly predict for a germline *BRCA1/2* pathogenic variant in breast cancer include Ashkenazi Jewish heritage, triple-negative breast cancer, tumor histologic grade 3, and diagnosis prior to the age of 50.[12] Multi-gene testing should also be considered in individuals with CRC with adenomatous polyposis, colonic polyposis with an unknown histology, or when more than 1 syndrome may explain the presentation. For example, 10 or more adenomas are more likely to be associated with pathogenic mutations in genes that cause classical familial adenomatous polyposis (FAP) or attenuated FAP or MUTYH-associated

polyposis (MAP). Whereas 2 or more hamartomatous polyps are indicative of Peutz-Jeghers, Juvenile polyposis, and Cowden/PTEN hamartoma syndromes.[5] The risk of melanoma is influenced by sensitivity to Ultraviolet (UV) radiation, sunburns during childhood, and sunlight exposure.[28,29] The NCCN has defined criteria for which testing of well-established germline genes is appropriate for a variety of inherited cancers.[5,24-26]

Test Description

NGS is currently the most common methodology utilized for hereditary cancer gene testing. NGS is not a specific test, but a sequencing methodology utilized to capture genomic information. Unlike Sanger sequencing (the prior standard technology) that typically provides sequence information for a single DNA strand/molecule, NGS allows for massively parallel sequencing of millions of DNA molecules concurrently.[30,31] This allows for capturing many relevant genomic targets simultaneously, usually by utilizing technologies, such as by polymerase chain reaction (PCR) amplification or hybrid capture. As such, NGS tests for use in germline cancer are often comprised of gene panels whose content is either relevant to a specific cancer type or condition, or a larger panel of genes that can be used for multiple cancer types.

NGS tests can vary significantly for many reasons. While NGS defines a broad methodology for massively parallel sequencing, different technologies that have different strengths, weaknesses, and technical limitations or liabilities are available.[32] The most common sequencing platforms in clinical use today sequence by synthesis similar to Sanger sequencing; these platforms utilize different chemistries, signal amplification, and detection methods. Gene panels can include only the portions of genes that contain the most critical clinically-relevant information, or be comprehensive, containing entire exonic gene regions (coding regions), introns (non-coding regions), and even sequence ribonucleic acid (RNA) for detecting abnormal transcripts. Downstream from the pre-analytic processes mentioned above, the bioinformatics used to process and assess the resultant sequencing reads, and identify variants/mutations can yield different results based on the software used and what types of variants the test is attempting to detect. These software tools must take the resultant sequencing file (generally starting with the FASTQ format), align all possible sequences with a reference genome (BAM/SAM), and identify variants from the reference (typically a VCF file). Once such variants are identified, they must be assessed for validity and subsequently, for their clinical relevance.

The types of genomic information reported can vary, as tests can uncover a myriad of genomic alterations, such as single nucleotide variants (SNVs), Insertions/Deletions (INDELs), Copy Number Alterations ([CNAs]; these can be simply amplifications at a single locus or chromosomal gains and losses), Structural Alterations ([SAs]; inversions, insertions, translocations) and abnormal RNA splice site variants. All these variant classes have demonstrated clinical utility in germline testing. Additionally, NGS testing is highly complex and requires expertise from handling the specimen, running the complex equipment, understanding the required bioinformatics, interpreting the findings and creating an actionable medical report. Guidelines for validating clinical NGS panel tests and bioinformatics pipelines have been published.[33-35] Variant interpretation is also a crucial component of NGS testing in hereditary cancers, the American College of Medical Genetics (ACMG) and the Association for Molecular Pathology (AMP) have published standards and guidelines for both sequencing and copy number variant interpretation that have been widely adopted by clinical laboratories around the world.[36-38]

Multi-gene hereditary cancer panels offered by diagnostic clinical laboratories vary on the number of genes that are included. The Clinical Genome Resource (ClinGen) has developed a clinical validity framework that evaluates evidence in the literature and determines the strength of association of genes with disease using a point-based system. Genes that have been repeatedly demonstrated in both the research and clinical diagnostic settings to be associated with a particular disorder with no contradicting evidence are considered definitive.[39] Lee, et al., and Seifert, et al., describe the assessment of genes frequency tested in hereditary breast and ovarian, and colorectal cancer and polyposis multi-gene panels, respectively, using the ClinGen Gene Curation framework.[40,41] These assessments considered multiple lines of evidence including case reports, familial and case-control association

studies, and segregation data and describe genes that are considered definitive for these cancer types.

Analysis of Evidence (Rationale for Determination)

Given the abundant literature on genetic and genomic testing in hereditary cancer diagnosis and care, this contractor feels strongly that testing for inherited cancer syndromes is appropriate for use in Medicare beneficiaries. However, given the variability for what information tests can provide, additional information must be submitted by providers to ensure the contractor A) understands what test is being performed; B) Why it is being performed; C) If the test is both reasonable and necessary for cancer care for its intended use.

Based on the evidence, guidance, and current best practices, a multi-gene panel must contain more than 1 single gene on that panel necessary for proper patient care to be considered reasonable and necessary for the indicated cancer type. Additionally, a gene panel must contain, at a minimum, all the necessary relevant gene content required for their indicated use to meet clinical utility requirements. Such minimum criteria are determined by experts including the NCCN, ASCO, ACMG and the AMP and are considered during the TA. A multi-gene panel is not considered reasonable and necessary, if only a single gene on the panel is considered reasonable and necessary. In some cases, a single gene may be tested, if it is the only gene considered to be reasonable and necessary for a cancer type. For example, the only gene associated with multiple endocrine neoplasia type 1 is *MEN1.*[26,42,43] However, testing for additional genes for that encounter will, therefore, not be considered reasonable and necessary.

Analytical Validity and Clinical Utility

Because of the number of variables described above, additional work must be performed to assess if any given test is both reasonable and necessary for Medicare beneficiaries and to ensure that Medicare claims are properly understood and executed. MolDX has instituted a process for completing a TA that ensures that tests are appropriate for their indications and are properly validated according to published guidelines described above (when applicable). Specifically, in order to understand if a test is both reasonable and necessary, it must be delineated if a test has the properly-validated technology, variant types, gene and variant coverage, and bioinformatics capability to deliver a clinically useful result for the Medicare beneficiary, given their diagnosis.

Labs seeking coverage for LDTs, FDA-cleared, or FDA-approved tests that are not nationally covered must submit documentation to allow MolDX® to complete a TA. Forms to complete the process are available on the MolDX® website. Tests that are currently covered by Noridian Healthcare Solutions are not exempt from this process. Tests that are currently covered and have not undergone a TA by MolDX® will be non-covered unless complete documents to perform a TA are submitted in a timely manner.

General Information

Associated Information

N/A

Sources of Information

N/A

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Revision History Information

N/A

Associated Documents

Attachments

N/A

Related Local Coverage Documents

Articles

A58681 - Billing and Coding: MolDX: Lab-Developed Tests for Inherited Cancer Syndromes in Patients with Cancer

A59131 - Response to Comments: MolDX: Lab-Developed Tests for Inherited Cancer Syndromes in Patients with Cancer

LCDs

DL38974 - MolDX: Next-Generation Sequencing Lab-Developed Tests for Inherited Cancer Syndromes

Related National Coverage Documents

NCDs

90.2 - Next Generation Sequencing (NGS)

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