LCD - MolDX: Next-Generation Sequencing Lab-Developed Tests for Myeloid Malignancies and Suspected Myeloid Malignancies (L38125)

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Noridian Healthcare Solutions, LLC	A and B MAC	02101 - MAC A	J - F	Alaska
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
Noridian Healthcare Solutions, LLC	A and B MAC	02202 - MAC B	J - F	Idaho
Noridian Healthcare Solutions, LLC	A and B MAC	02301 - MAC A	J - F	Oregon
Noridian Healthcare Solutions, LLC	A and B MAC	02302 - MAC B	J - F	Oregon
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LCD Information

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MolDX: Next-Generation Sequencing Lab-Developed Tests for Myeloid Malignancies and Suspected Myeloid Malignancies

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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 Code of Federal Regulations (CFR) §410.32 Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions.

CMS On-Line Manual, Publication 100-02, Medicare Benefit Policy Manual, Chapter 15, §80.0, Requirements for Diagnostic X-Ray, Diagnostic Laboratory, and Other Diagnostic Tests, §80.1.1, Certification Changes

CMS Internet-Only Manual, Pub 100-03, Medicare National Coverage Determinations Manual, Chapter 1, Part 2, §90.2 Next-Generation Sequencing (NGS) for Patients with Advanced Cancer.

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

This policy describes and clarifies coverage for Lab-Developed Tests (LDTs) and Food and Drug Administration (FDA)-approved or cleared clinical laboratory tests utilizing Next-Generation Sequencing (NGS) in cancer as allowable under the National Coverage Determination (NCD) 90.2, under section D describing Medicare Administrative Contractor (MAC) discretion for coverage, as well as for use of NGS in suspected myeloid neoplasms. This policy's scope is specific for myeloid malignancies and suspected malignancies, and is exclusive of solid tumor testing, circulating tumor DNA (ctDNA) testing, and other cancer-related uses of NGS, such as in germline testing.

Summary of Evidence

NGS testing in solid tumors is becoming a routine component of the diagnostic process[1]; the results can uncover the genomic mechanisms of cancer that have predictive, diagnostic, and prognostic utility to the patient and are used to better their management.[2] Understanding the mechanisms of disease and targeting treatment based on those aberrant processes (i.e., targeted therapies) has improved patient outcomes in many tumor types and is the basis of Precision Medicine.[3] NGS adds the ability to capture abundant genomic data both efficiently, relatively cheaply, and its use is showing to improve patient outcomes although studies in this regard are ongoing.[4] The established NCD 90.2 confirms tests based on this methodology to be both reasonable and necessary in Medicare beneficiaries.

Professional Society Clinical Practice Guidelines

Guidelines for validating clinical NGS tests for use in cancer have been published in a joint effort by the Association for Molecular Pathology and the College of American Pathologists.[5] Guidelines for employing bioinformatics pipelines for NGS testing have also been published by these groups,[6] as well as guidelines for interpreting somatic variants in these panels, by these entities in collaboration with the American Society of Clinical Oncology.[7]

Guidelines for care of Acute myeloid Leukemia (AML) suggests or recommends to the use of NGS testing for comprehensive prognosis and risk stratification.[8]

NGS Test Description

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 deoxyribonucleic acid (DNA) strand/molecule, NGS allows for massively parallel sequencing of millions of DNA molecules concurrently.[9,10] This allows for capturing many relevant genomic targets simultaneously, usually by utilizing capture technologies such as by polymerase chain reaction (PCR) amplification or hybrid capture. As such, NGS tests for use in cancer are often comprised of gene panels whose content is either relevant to a specific tumor type or condition, or a larger panel of genes that can be used for multiple tumor types, including in hematopoietic malignancies.

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.[11] The most common sequencing platforms in clinical use today are from Illumina and Thermo Fisher. While both 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 gene fusions. 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 variant 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).[6] 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), and gene fusions/translocations. The resultant information can also be used to calculate additional relevant information, such as Tumor Mutation Burden (TMB), or the presence of microsatellite instability (MSI). All of these variant classes have demonstrated clinical utility. As such, NGS testing in cancer comprises a large heterogeneous group of assays that are substantially different from each other. Additionally, NGS testing is highly complex and requires expertise from handling the specimen, to running complex equipment, to understanding the required bioinformatics, to interpreting the findings and creating an actionable medical report.

Two types of tests are considered for coverage, "Hot-spot" tests and comprehensive genomic profile tests (CGP). The definition of these terms, in addition to appropriate coding information is located in Coverage Articles associated with this Local Coverage Determination. These tests can detect any combination of the previously described variant types, but in general, Hot-spot tests are limited to SNVs and small INDELs, whereas CGPs can detect those variants in addition to CNAs, larger INDELs, gene fusions/translocations, and be used to calculate MSI status and TMB when relevant.

Analytical Validity

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. Molecular Diagnostic Services Program (MolDX®) has instituted a process for completing a Technical Assessment (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 or FDA-approved tests that are not nationally covered utilizing NGS in cancer must submit documentation to the MolDX contractor to allow MolDX to complete a TA. Forms to complete the process are available on the MolDX website. Tests that are currently covered by this contractor 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 described below in the coverage section.

Clinical Utility in Myeloid Malignancies

Myeloid stem cell disorders are a heterogenous group of malignancies with clinical and genomic overlap. According to the World Health Organization (WHO) classification, myeloid disorders can be classified as myelodysplastic syndrome (MDS), myeloproliferative neoplasms (MPN), overlap myelodysplastic/myeloproliferative neoplasms (MDS/MPN), and AML.

These disorders can comprise a continuum of tumor evolution that ultimately results in AML in many instances.[12] Clonal hematopoiesis may also be detected in elderly patients without overt evidence of myeloid neoplasia. Due to increased risk of developing myeloid neoplasia, such patients need to be closely monitored over time, and genomic profiling plays a role in this process.

Currently, laboratories utilize NGS panels and DNA-based cytogenomic microarray in laboratory work-up of myeloid disorders and AML.[13] NGS, with its ability to identify numerous relevant biomarkers concurrently, is demonstrating a unique clinical utility in the diagnosis, prognosis/risk stratification, and identification of targeted therapies in myeloid malignancies.[14-16]

Laboratories typically use a multiplex NGS panel in the evaluation of peripheral blood or bone marrow aspirate samples in patients suspected of having an acute or chronic myeloid stem cell disorder.[17] With the recent and ongoing explosion of literature spanning chronic and acute myeloid disorders, laboratories have designed NGS panels encompassing anywhere from a handful of genes to greater than 90 genes. In a recently published paper,[13] more than 70 genes that are clinically informative in acute and chronic myeloid disorders were identified.

The utility of genomic testing in myeloid malignancies includes:

To assist with Diagnosis

In the setting of MDS, MDS/MPN, and MPN, establishing a diagnosis of a clonal myeloid disorder needs to occur prior to initiation of any therapy. In all of these disorders, the diagnostic classification relies on a multi-parameter testing approach in addition to clinical and morphologic findings.[18] In other contexts, having mutations can support a diagnosis of a clonal myeloid disease (versus a benign/reactive condition) when there is a high clinical index of suspicion and/or morphologic findings are low-grade or subtle.[19] NGS detection of clonal hematopoiesis with mutation detection in patients with unexplained cytopenias (> 4 months) is a strong predictor of who has or will have myeloid disorder.[20] When patients have a mutation with >10% variant allele frequency, or they have 2 or more mutations identified (in a 40 gene NGS panel), the positive predictive value is 0.86 and 0.88 respectively.[21] Additionally, molecular profiling can help differentiate myeloid neoplasms from benign conditions with overlapping histologic findings, like aplastic anemia, as well as to assess the latter in its likelihood of transformation into MDS.[22]

In AML, certain aberrations such as a *RUNX1* or *NPM1* mutation similarly define a specific molecular classification of diseases in the 2017 WHO Classification. In the setting of AML, there are well defined mutations in genes such as *JAK2, SRSF2, CSF3R, U2AF1, SF3B1, ZRSR2, ASXL1, EZH2, STAG2*, and *BCOR* that strongly indicate an underlying myeloid stem cell disorder.[23] Genomic profiling, thus, provides a molecular-based diagnostic classification of AML.

To assist with Risk Stratification

NGS testing is used to identify a category of AML patients who typically do not respond to standard induction and consolidation chemotherapy. Rather, these patients are at a high risk for relapse, disease progression, and poor outcome and will benefit from strategies other than traditional induction and consolidation regimens, in particular hematopoietic stem cell transplant (HSCT).[24] There are now more than 50 genes that can render diagnostic and risk stratification information across the spectrum of myeloid stem cell disorders.[8, 25, 26] The appropriate therapy can be administered in patients only after an accurate diagnosis is rendered.

According to evidence based guidelines from the American Society of Blood and Bone Marrow, HSCT is considered a valuable therapeutic option in high risk myeloid disorders and acute leukemia, provided that patients don't have certain mutations that are associated with poor outcome in the transplant setting.[27] Certain mutations are associated with a poor prognosis in patients undergoing HSCT.[28-30] In these situations, NGS testing can help refine who is unlikely to benefit from HSCT.

Minimum residual disease (MRD) analysis is a useful risk stratification tools to guide the choice of treatment intensity by providing information on: 1) early response to treatment; 2) early detection of relapse after treatment; 3) surveillance before and after stem cell transplantation. Recently, multiple studies have demonstrated the utility of NGS-based analysis for this purpose.[31-35] Additionally, NGS provides advantages to other methods in its sensitivity and in its ability to overcome clonal evolution and detect new mutations.[34, 36]

To Assist with Targeted Therapies

FDA approved targeted therapies are now available that are directed against specific molecular aberrations in acute leukemia, such as Midostaurin and Enasidenib, among others.[37-39] Clinical trials are currently evaluating additional therapies in patients with high risk myeloid disorders for patients with these and other AML-associated mutations.

Additionally, NGS can be used to monitor patients for response to their selected therapies, by measuring changes in allelic ratios of tumor-specific mutations, in addition to identifying when a different therapy may be necessary.[32]

Criteria for Coverage

The following must be present for coverage eligibility:

- For tests that are specifically indicated in patients whom are known to have a myeloid malignancy at the time of testing, NCD 90.2 applies.
- The patient has a diagnosis of AML, MDS, or MPN. AML, MDS, and MPN are herein classified as refractory and/or metastatic cancers and fulfil the NCD 90.2 criteria.
- The test has satisfactorily completed a TA by MolDX for the stated indications of the test.
- The assay performed includes *at least* the minimum genes and positions indicated for its intended use, as described in an associated coverage Article or found in the TA forms.
- For patients that do not have a diagnosis of a myeloid malignancy, where one is suspected, the patient must

have an undefined cytopenia for greater than 4 months, other possible causes have been reasonably excluded.
- Testing is performed on bone marrow biopsies, bone marrow aspirates, bone marrow clots, peripheral blood samples, or extramedullary sites suspected of harboring a myeloid malignancy.

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

The test in question will be non-covered if:

- A TA has not been satisfactorily completed by MolDX. For tests that are currently covered but a TA submission has not been made, providers must submit completed TA materials by February 10th, 2020 or coverage will be denied.
- Another NGS test was performed on the same surgical specimen/ blood draw (specimen obtained on the same date of service).
- Testing falls within scope of NCD 90.2 and has been tested with the same test for the same genetic content.

Analysis of Evidence (Rationale for Determination)

Level of Evidence

Quality: Strong/variable depending on biomarker and specific test
Strength: Strong/variable depending on biomarker and specific test
Weight: Strong/variable depending on biomarker and specific test

Given the abundant literature on genetic and genomic testing in cancer diagnosis and care, this contractor feels strongly that NGS methodology for testing 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 necessary and reasonable for cancer care for its intended use.

General Information

Associated Information

N/A

Sources of Information

N/A

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Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
07/08/2021	R1	Under CMS National Coverage Policy removed regulation Pub 100-02, Medicare Benefit Policy Manual, Chapter 15, §80.2. Clinical Laboratory services. Under Bibliography changes were made to citations to reflect AMA citation guidelines. Formatting, punctuation and typographical errors were corrected throughout the LCD. Acronyms were inserted where appropriate throughout the LCD.	• Provider Education/Guidance

Associated Documents

Attachments

N/A

Related Local Coverage Documents

Articles

A57892 - Billing and Coding: MolDX: Next-Generation Sequencing Lab-Developed Tests for Myeloid Malignancies and Suspected Myeloid Malignancies

A56518 - Billing and Coding: MolDX: Targeted and Comprehensive Genomic Profile Next-Generation Sequencing Testing in Cancer

A57909 - Response to Comments: MolDX: Next Generation Sequencing Lab-Developed Tests for Myeloid Malignancies and Suspected Myeloid Malignancies

LCDs

DL38125 - (MCD Archive Site)

Related National Coverage Documents

N/A

Public Versions

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Some older versions have been archived. Please visit the MCD Archive Site to retrieve them.		

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