

# November 2023



Client Communication

## Medicare Local Coverage Determination Policy: CGS

### Coverage Policy

### L38070 - MoIDX: Next-Generation Sequencing Lab-Developed Tests for Myeloid Malignancies and Suspected Myeloid Malignancies

CPT: 81450, 81479

Revision Effective Date: 08/17/2023

#### 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.

#### 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 MoIDX® 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.

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Diagnosis codes must be applicable to the patient's symptoms or conditions and must be consistent with the patient's medical record. Sonic Healthcare does not recommend any diagnosis codes and will only submit diagnosis information provided to us by the ordering physician or his/her designated staff.

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- 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.

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CPT: 81450, 81479

The ICD10 codes listed below are the top 40 diagnosis codes Sonic most commonly receives from ordering physicians for this limited-coverage test. Medicare supports provider utilization of all the diagnosis codes listed below, except those notated in bold. If you are providing a diagnosis code that is **bolded** below, please submit a valid ABN form with the order. To view the complete policy and the full list of medically supported diagnosis codes, please refer to the CMS website for guidance:

<https://www.cms.gov/medicare-coverage-database/search.aspx>

Code	Description
<b>E03.8</b>	<b>Other specified hypothyroidism</b>
E29.1	Testicular hypofunction
E72.11	Homocystinuria
E78.2	Mixed Hyperlipidemia
<b>R53.83</b>	<b>Other Fatigue</b>
R79.82	Elevated C-reactive protein (CRP)
<b>R94.4</b>	<b>Abnormal results of kidney function studies</b>

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