

# Medical necessity for Medicare beneficiaries

## Noridian local coverage determination (LCD): MolDX®: Next-Generation Sequencing Lab-Developed Tests for Myeloid Malignancies and Suspected Myeloid Malignancies (L38123 & A57891)

### Applicable tests

|   |
|---|
| NeoTYPE® AML Prognostic Profile                   |
| NeoTYPE® MDS/CMML Profile                         |
| Neo Comprehensive™ – Heme Cancers                 |
| Neo Comprehensive™ – Heme Cancers (DNA Only)      |
| Neo Comprehensive™ – Myeloid Disorders            |
| Neo Comprehensive™ – Myeloid Disorders (DNA Only) |

### Applicable CPT codes

|       |       |       |
|-------|-------|-------|
| 81450 | 81479 | 81451 |
|-------|-------|-------|

To learn more, call NeoGenomics Client Services at 866.776.5907, option 3

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### Criteria for coverage

#### The following must be present for coverage eligibility

- For tests that are specifically indicated in patients who 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 fulfill 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 a test should not be used or coverage is denied

The test in question will be non-covered if:

- A technical assessment has not been satisfactorily completed by MolDX. For tests that are currently covered but a TA submission has not been made, providers must submit complete TA materials by February 10<sup>th</sup>, 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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ICD-10 codes supporting medical necessity numerical listing, Noridian LCA (L38123)

| ICD-10 Code   | ICD-10 CM Description  |
|---------------|--|
| <b>C92.00</b> | Acute myeloblastic leukemia, not having achieved remission                         |
| <b>C92.01</b> | Acute myeloblastic leukemia, in remission  |
| <b>C92.02</b> | Acute myeloblastic leukemia, in relapse  |
| <b>C92.10</b> | Chronic myeloid leukemia, BCR/ABL-positive, not having achieved remission          |
| <b>C92.11</b> | Chronic myeloid leukemia, BCR/ABL-positive, in remission                           |
| <b>C92.12</b> | Chronic myeloid leukemia, BCR/ABL-positive, in relapse                             |
| <b>C92.20</b> | Atypical chronic myeloid leukemia, BCR/ABL-negative, not having achieved remission |
| <b>C92.21</b> | Atypical chronic myeloid leukemia, BCR/ABL-negative, in remission                  |
| <b>C92.22</b> | Atypical chronic myeloid leukemia, BCR/ABL-negative, in relapse                    |
| <b>C92.30</b> | Myeloid sarcoma, not having achieved remission                                     |
| <b>C92.31</b> | Myeloid sarcoma, in remission  |
| <b>C92.32</b> | Myeloid sarcoma, in relapse  |
| <b>C92.40</b> | Acute promyelocytic leukemia, not having achieved remission                        |
| <b>C92.41</b> | Acute promyelocytic leukemia, in remission   |
| <b>C92.42</b> | Acute promyelocytic leukemia, in relapse   |
| <b>C92.50</b> | Acute myelomonocytic leukemia, not having achieved remission                       |
| <b>C92.51</b> | Acute myelomonocytic leukemia, in remission  |
| <b>C92.52</b> | Acute myelomonocytic leukemia, in relapse  |
| <b>C92.60</b> | Acute myeloid leukemia with 11q23-abnormality not having achieved remission        |
| <b>C92.61</b> | Acute myeloid leukemia with 11q23-abnormality in remission                         |
| <b>C92.62</b> | Acute myeloid leukemia with 11q23-abnormality in relapse                           |
| <b>C92.A0</b> | Acute myeloid leukemia with multilineage dysplasia, not having achieved remission  |
| <b>C92.A1</b> | Acute myeloid leukemia with multilineage dysplasia, in remission                   |
| <b>C92.A2</b> | Acute myeloid leukemia with multilineage dysplasia, in relapse                     |

| ICD-10 Code   | ICD-10 CM Description   |
|---------------|---|
| <b>C92.Z0</b> | Other myeloid leukemia not having achieved remission                |
| <b>C92.Z1</b> | Other myeloid leukemia, in remission                                |
| <b>C92.Z2</b> | Other myeloid leukemia, in relapse                                  |
| <b>C92.90</b> | Myeloid leukemia, unspecified, not having achieved remission        |
| <b>C92.91</b> | Myeloid leukemia, unspecified in remission                          |
| <b>C92.92</b> | Myeloid leukemia, unspecified in relapse                            |
| <b>C93.00</b> | Acute monoblastic/monocytic leukemia, not having achieved remission |
| <b>C93.01</b> | Acute monoblastic/monocytic leukemia, in remission                  |
| <b>C93.02</b> | Acute monoblastic/monocytic leukemia, in relapse                    |
| <b>C93.10</b> | Chronic myelomonocytic leukemia not having achieved remission       |
| <b>C93.12</b> | Chronic myelomonocytic leukemia, in relapse                         |
| <b>C93.Z0</b> | Other monocytic leukemia, not having achieved remission             |
| <b>C93.Z2</b> | Other monocytic leukemia, in relapse                                |
| <b>C93.90</b> | Monocytic leukemia, unspecified, not having achieved remission      |
| <b>C93.92</b> | Monocytic leukemia, unspecified in relapse                          |
| <b>C94.00</b> | Acute erythroid leukemia, not having achieved remission             |
| <b>C94.01</b> | Acute erythroid leukemia, in remission                              |
| <b>C94.02</b> | Acute erythroid leukemia, in relapse                                |
| <b>C94.21</b> | Acute megakaryoblastic leukemia, in remission                       |
| <b>C94.40</b> | Acute panmyelosis with myelofibrosis not having achieved remission  |
| <b>C94.41</b> | Acute panmyelosis with myelofibrosis, in remission                  |
| <b>C94.42</b> | Acute panmyelosis with myelofibrosis, in relapse                    |
| <b>C94.6</b>  | Myelodysplastic disease, not elsewhere classified                   |
| <b>D45</b>    | Polycythemia vera   |
| <b>D46.0</b>  | Refractory anemia without ring sideroblasts, so stated              |
| <b>D46.1</b>  | Refractory anemia with ring sideroblasts                            |

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## ICD-10 codes supporting medical necessity numerical listing, Noridian LCA (L38123)

| ICD-10 Code    | ICD-10 CM Description   |
|----------------|---|
| <b>D46.20</b>  | Refractory anemia with excess of blasts, unspecified  |
| <b>D46.21</b>  | Refractory anemia with excess of blasts 1   |
| <b>D46.22</b>  | Refractory anemia with excess of blasts 2   |
| <b>D46.A</b>   | Refractory cytopenia with multilineage dysplasia  |
| <b>D46.B</b>   | Refractory cytopenia with multilineage dysplasia and ring sideroblasts                        |
| <b>D46.C</b>   | Myelodysplastic syndrome with isolated del(5q) chromosomal abnormality                        |
| <b>D46.4</b>   | Refractory anemia, unspecified  |
| <b>D46.Z</b>   | Other myelodysplastic syndromes   |
| <b>D46.9</b>   | Myelodysplastic syndrome, unspecified   |
| <b>D47.02</b>  | Systemic mastocytosis   |
| <b>D47.1</b>   | Chronic myeloproliferative disease  |
| <b>D47.3</b>   | Essential (hemorrhagic) thrombocythemia   |
| <b>D47.4</b>   | Osteomyelofibrosis  |
| <b>D47.Z9</b>  | Other specified neoplasms of uncertain behavior of lymphoid, hematopoietic and related tissue |
| <b>D61.09</b>  | Other constitutional aplastic anemia  |
| <b>D61.3</b>   | Idiopathic aplastic anemia  |
| <b>D61.818</b> | Other pancytopenia  |
| <b>D61.89</b>  | Other specified aplastic anemias and other bone marrow failure syndromes                      |

| ICD-10 Code    | ICD-10 CM Description                                      |
|----------------|--|
| <b>D61.9</b>   | Aplastic anemia, unspecified                               |
| <b>D64.9</b>   | Anemia, unspecified  |
| <b>D69.49</b>  | Other primary thrombocytopenia                             |
| <b>D69.59</b>  | Other secondary thrombocytopenia                           |
| <b>D69.6</b>   | Thrombocytopenia, unspecified                              |
| <b>D69.8</b>   | Other specified hemorrhagic conditions                     |
| <b>D70.4</b>   | Cyclic neutropenia   |
| <b>D70.8</b>   | Other neutropenia  |
| <b>D72.818</b> | Other decreased white blood cell count                     |
| <b>D72.820</b> | Lymphocytosis (symptomatic)                                |
| <b>D72.821</b> | Monocytosis (symptomatic)                                  |
| <b>D72.829</b> | Elevated white blood cell count, unspecified               |
| <b>D75.1</b>   | Secondary polycythemia                                     |
| <b>D75.81</b>  | Myelofibrosis  |
| <b>D75.838</b> | Other thrombocytosis                                       |
| <b>D75.89</b>  | Other specified diseases of blood and blood-forming organs |
| <b>Q82.2</b>   | Congenital cutaneous mastocytosis                          |
| <b>R16.1</b>   | Splenomegaly, not elsewhere classified                     |
| <b>R16.2</b>   | Hepatomegaly with splenomegaly, not elsewhere classified   |

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