Medical necessity for Medicare beneficiaries

Noridian local coverage determination (LCD): MolDX[®]: Genetic testing for BCR-ABL negative Myeloproliferative disease (L36180 & A57421)

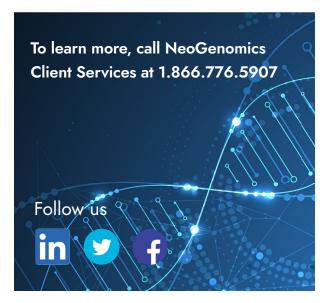
Applicable tests

NeoTYPE® MPN Profile	MPL Mutation Analysis
JAK2, JAK2 exons 12-14, JAK2 V617F	MPN Standard Reflex Panel
CALR Mutation Analysis	MPN Extended Reflex Panel

Applicable CPT Codes/ HCPCS Codes

0027U
004OU
81206
81207
81208
81219
81270

81402	
81279	
81338	
81339	
81450	
81479	



Limitations

For laboratories performing single gene technologies, a sequential genetic testing approach is expected. Once a positive result is obtained and the following sequence of genetic tests produce a negative result:

- 1. BCR-ABL negative test results, progress to #2.
- 2. |AK2, cv negative test results, progress to #3 or #4.
- 3. JAK2 exon 12 (JAK2 exon 12 is only done when PV is suspected).
- **4.** CALR/MPL is only done when either ET or PMF is suspected; testing for CALR/MPL does NOT require a negative JAK2 exon 12, just a negative JAK2 V617F result).
- 5. Genetic testing of the JAK2 V617F mutation is medically necessary when the following criteria are met:
 - Genetic testing impacts medical management; and
 - Patient would meet World Health Organization's (WHO) diagnostic criteria for myeloproliferative disease (i.e., PV, ET, PMF) if JAK2 V617F were identified.
- 6. Genetic testing of JAK2 exon 12, performed to identify PV, is medically necessary when the following criteria are met:
 - Genetic testing impacts medical management; and
 - Patient would meet WHO's diagnostic criteria for PV, if JAK2 exon 12 testing were positive; and
 - JAK2 V617F mutation analysis was previously completed and was negative.
- 7. Genetic testing of the CALR gene (only found in ET and PMF) is medically necessary when the following criteria are met:
 - Genetic testing impacts medical management; and
 - JAK2 V617F mutation analysis was previously completed and negative; and
 - Patient would meet WHO's diagnostic criteria for MPD (i.e., ET, PMF) if a clonal marker were identified.



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ICD-10 codes supporting medical necessity numerical listing

C88.8	Other malignant immunoproliferative diseases
C91.00	Acute lymphoblastic leukemia not having achieved remission
C91.01	Acute lymphoblastic leukemia, in remission
C91.02	Acute lymphoblastic leukemia, in relapse
C92.10	Chronic myeloid leukemia, BCR/ABL-positive, not having achieved remission
C92.11	Chronic myeloid leukemia, BCR/ABL-positive, in remission
C92.20	Atypical chronic myeloid leukemia, BCR/ABL-negative, not having achieved remission
C92.21	Atypical chronic myeloid leukemia, BCR/ABL-negative, in remission
C92.22	Atypical chronic myeloid leukemia, BCR/ABL-negative, in relapse
C93.10	Chronic myelomonocytic leukemia not having achieved remission
C94.40	Acute panmyelosis with myelofibrosis not having achieved remission
C94.41	Acute panmyelosis with myelofibrosis, in remission
C94.42	Acute panmyelosis with myelofibrosis, in relapse
C94.6	Myelodysplastic disease, not classified
D45	Polycythemia vera
D46.0	Refractory anemia without ring sideroblasts, so stated

D46.1	Refractory anemia with ring sideroblasts
D46.21	Refractory anemia with excess of blasts 1
D46.22	Refractory anemia with excess of blasts 2
D46.A	Refractory cytopenia with multilineage dysplasia
D46.B	Refractory cytopenia with multilineage dysplasia and
D46.C	Myelodysplastic syndrome with isolated del(5q)
D46.Z	Other myelodysplastic syndromes
D47.02	Systemic mastocytosis
D47.1	Chronic myeloproliferative disease
D47.3	Essential (hemorrhagic) thrombocythemia
D47.4	Osteomyelofibrosis
D47.Z9	Other specified neoplasms of uncertain behavior of
D72.821	Monocytosis (symptomatic)
D75.1	Secondary polycythemia
D75.838	Other thrombocytosis
D75.89	Other specified diseases of blood and blood-forming organs

Noridian Healthcare Solutions, LLC is the Medicare Administrative Contractor (MAC) for Jurisdiction E and processes Medicare Part A and Part B claims for California, Nevada, Hawaii, Guam, American Samoa and Northern Mariana Islands.



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ICD-10 codes supporting medical necessity alphabetical listing

C91.00	Acute lymphoblastic leukemia not having achieved remission
C91.02	Acute lymphoblastic leukemia, in relapse
C91.01	Acute lymphoblastic leukemia, in remission
C94.40	Acute panmyelosis with myelofibrosis not having achieved remission
C94.42	Acute panmyelosis with myelofibrosis, in relapse
C94.41	Acute panmyelosis with myelofibrosis, in remission
C92.22	Atypical chronic myeloid leukemia, BCR/ABL-negative, in relapse
C92.21	Atypical chronic myeloid leukemia, BCR/ABL-negative, in remission
C92.20	Atypical chronic myeloid leukemia, BCR/ABL-negative, not having achieved remission
C92.12	Chronic myeloid leukemia, BCR/ABL-positive, in relapse
C92.11	Chronic myeloid leukemia, BCR/ABL-positive, in remission
C92.10	Chronic myeloid leukemia, BCR/ABL-positive, not having achieved remission
C93.10	Chronic myelomonocytic leukemia not having achieved remission
D47.1	Chronic myeloproliferative disease
D47.3	Essential (hemorrhagic) thrombocythemia

D72.821 Monocytosis (symptomatic)	Chronic myeloproliferative disease
C94.6	Myelodysplastic disease, not classified
D46.C	Myelodysplastic syndrome with isolated del(5q) chromosomal abnormality
D75.81	Myelofibrosis
C88.8	Other malignant immunoproliferative diseases
D46.Z	Other myelodysplastic syndromes
D75.89	Other specified diseases of blood and blood forming organs
D47.Z9	Other specified neoplasms of uncertain behavior
D75.838	Other thrombocytosis
D45	Polycythemia vera
D46.21	Refractory anemia with excess of blasts 1
D46.22	Refractory anemia with excess of blasts 2
D46.1	Refractory anemia with ring sideroblasts
D46.0	Refractory anemia without ring sideroblasts, so stated
D46.A	Refractory cytopenia with multilineage dysplasia
D46.B	Refractory cytopenia with multilineage dysplasia and ring sideroblasts
C79.63	Secondary malignant neoplasm of bilateral ovaries
D75.1	Secondary polycythemia

The accuracy and relevance of this information should be verified by reference to the current version of the Coding Manual of the American Medical Association (AMA) or by visiting the Centers for Medicare and Medicaid Services (CMS) website at www.cms.hhs.gov/home/medicare. asp. This information is not intended to suggest reimbursement or provide direction for coding and was obtained online at www.cms.hhs.gov/home/medicare.asp. Codes listed are effective as of April 1, 2023.

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