Medicare Local Coverage Determination Policy

JM Palmetto – MolDX: Genetic Testing for BCR-ABL Negative Myeloproliferative Disease

CPT: 81206, 81207, 81208, 81219, 81270, 81402, 81403, 81445, 81450, 81455, 81479

CMS Policy for Alabama, Georgia, North Carolina, South Carolina, Tennessee, Virginia, and West Virginia

Local policies are determined by the performing test location. This is determined by the state in which your performing laboratory resides and where your testing is commonly performed.

Medically Supportive ICD Codes are listed on subsequent page(s) of this document.

Coverage Indications, Limitations, and/or Medical Necessity

Indications and Limitations of Coverage

This policy provides coverage for multi-gene non-NGS panel testing and NGS testing for the diagnostic workup for myeloproliferative disease (MPD), and limited coverage for single-gene testing of patients with BCR-ABL negative MPD. MPD includes polycythemia vera (PV), essential thrombocytopenia (ET), and primary myelofibrosis (PMF).

For laboratories performing single gene technologies, a sequential genetic testing approach is expected. Once a positive result is obtained and the appropriate diagnosis is established, further testing should stop. Reflex testing to the next gene will be considered reasonable and necessary if the following sequence of genetic tests produce a negative result:

1. BCR-ABL negative test results, progress to #2
2. JAK 2, cv negative test results, progress to #3 or #4
3. JAK, exon 12 (JAK2 exon 12 is only done when PV is suspected)
4. CALR/MPL (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)

Genetic testing of the JAK2 V617F mutation (81270) is medically necessary when the following criteria are met:

- Genetic testing impacts medical management; and
- Patient would meet World Health Organization's diagnostic criteria for myeloproliferative disease (i.e. polycythemia vera, essential thrombocytopenia, primary myelofibrosis) if JAK2 V617F were identified.

Genetic testing of JAK2 exon 12 (81403), performed to identify PV, is medically necessary when the following criteria are met:

- Genetic testing impacts medical management; and
- Patient would meet World Health Organization's diagnostic criteria for PV, if JAK2 exon 12 testing were positive; and
- JAK2 V617F mutation analysis was previously completed and was negative.

Genetic testing of the CALR gene (81219) (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 World Health Organization's diagnostic criteria for MPD (i.e. ET, PMF) if a clonal marker were identified.

Genetic testing of the MPL gene (81402) 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 World Health Organization's diagnostic criteria for MPD (i.e. ET, MPF) if a clonal marker were identified.

Note: In a single-gene sequential approach (not mandated by this policy), CALR would be a higher priority single gene test than MPL because:

- CALR mutations is more prevalent than MPL mutations in ET/PMF patients; and
- CALR mutations are reported to predict a more indolent disease course than that of patients with JAK2 mutations.

For laboratories performing next generation sequencing (NGS or "hotspot") testing platforms: Molecular testing for BCR-ABL, JAK 2, JAK, exon 12, and CALR/MPL genes by NGS is covered as medically necessary for the identification of myeloproliferative disorders.

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CMS Policy for Alabama, Georgia, North Carolina, South Carolina, Tennessee, Virginia, and West Virginia (continued)

Associated Information

Documentation Requirements

The patient's medical record must contain documentation that fully supports the medical necessity for services included within this LCD. (See “Coverage Indications, Limitations, and/or Medical Necessity") This documentation includes, but is not limited to, relevant medical history, physical examination, and results of pertinent diagnostic tests or procedures.

Documentation supporting the medical necessity should be legible, maintained in the patient's medical record, and must be made available to the MAC upon request.

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There is a frequency associated with this test. Please refer to the Limitations or Utilization Guidelines section on previous page(s).

The ICD10 codes listed below are the top diagnosis codes currently utilized by ordering physicians for the limited coverage test highlighted above that are also listed as medically supportive under Medicare's limited coverage policy. **If you are ordering this test for diagnostic reasons that are not covered under Medicare policy, an Advance Beneficiary Notice form is required.**

Code	Description
C92.10	Chronic myeloid leukemia, BCR/ABL-positive, not having achieved remission
C92.11	Chronic myeloid leukemia, BCR/ABL-positive, in remission
C94.6	Myelodysplastic disease, not elsewhere classified
D45	Polycythemia vera
D46.9	Myelodysplastic syndrome, unspecified
D47.1	Chronic myeloproliferative disease
D47.3	Essential (hemorrhagic) thrombocythemia
D72.821	Monocytosis (symptomatic)
D72.829	Elevated white blood cell count, unspecified
D75.1	Secondary polycythemia
D75.89	Other specified diseases of blood and blood-forming organs

Visit **QuestDiagnostics.com/MLCP** to view current limited coverage tests, reference guides, and policy information.

To view the complete policy and the full list of medically supportive codes, please refer to the CMS website reference www.cms.gov ▶

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