November 2023

SONIC HEALTHCARE USA

Client Communication

Medicare Local Coverage Determination Policy: CGS

Coverage Policy

L36117 - MolDX: Genetic Testing for BCR-ABL Negative Myeloproliferative Disease

CPT: 81206, 81207, 81208, 81219, 81270, 81279, 81338, 81339 81450 81479, 0027U, 0040U

Revision Effective Date: 07/06/2023

Coverage Indications, Limitations, and/or Medical Necessity

Indications and Limitations of Coverage

This policy provides coverage for multi-gene non-next generation sequencing (NGS) panel testing and NGS testing for the diagnostic workup for myeloproliferative disease (MPD), also known as myeloproliferative neoplasms (MPNs), and limited coverage for single-gene testing of patients with BCR-ABL negative MPD. BCR-ABL negative MPD includes polycythemia vera (PV), essential thrombocythemia (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. Calreticulin (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 is medically necessary when the following criteria are met:

- Genetic testing impacts medical management; and

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- Patient would meet World Health Organization's (WHO) diagnostic criteria for myeloproliferative disease (i.e., PV, ET, PMF) if JAK2 V617F were identified.

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.

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.

Genetic testing of the MPL gene 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, 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 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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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

Codes	Description
D64.9	**Anemia, Unspecified**
I10	**Essential (primary) hypertension**
G40.802	**Other epilepsy, not intractable, without status epilepticus**
I50.9	**Heart Failure, Unspecified**
R53.83	**Other Fatigue**
E29.1	**Testicular hypofunction**
D75.1	Secondary polycythemia
E03.9	**Hypothyroidism, Unspecified**
E55.9	**Vitamin D deficiency, unspecified**
E03.8	**Other specified hypothyroidism**
R73.09	**Other abnormal glucose**
D51.9	**Vitamin B deficiency anaemia, unspecified**
R79.89	**Other specified abnormal findings of blood chemistry**
D52.9	**Folate deficiency anaemia, unspecified**
R94.4	**Abnormal results of kidney function studies**
L23.6	**Allergic contact dermatitis due to food in contact with the skin**
Z79.890	**Hormone replacement therapy**
R63.4	**Abnormal weight loss**
A09	**Other gastroenteritis and colitis of infectious and unspecified origin**
R79.82	**Elevated C-reactive protein (CRP)**
C92.10	Chronic myeloid leukemia, BCR/ABL-positive, not having achieved remission

D80.9	Immunodeficiency with predominantly antibody defects, unspecified
E72.11	Homocystinuria
Z79.899	Other long term (current) drug therapy
E78.2	Mixed Hyperlipidemia
E88.81	Metabolic syndrome