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The Department of Vermont Health Access Clinical Criteria

Subject: Janus Kinase 2 (JAK2) Genetic Test
Last Review: July 1, 2023*
Past Revisions: April. 5, 2022, October 3, 2019, January 3, 2017, December 29, 2015

***Please note: Most current content changes will be highlighted in yellow.**

Description of Service or Procedure

The JAK2 protein plays an important part in controlling the production of blood cells from hematopoietic stem cells located in the bone marrow. These cells have the potential to develop into red blood cells, white blood cells and platelets. JAK2 genetic testing is used to diagnose myeloproliferative disorders (MPD) or myeloproliferative neoplasms (MPN) which are a large group of relatively rare pathogenetically related diseases arising in the bone marrow and are characterized by the proliferation of one or more myeloid cell lines in the bone marrow resulting in increased numbers of moderately mature neoplastic cells in the peripheral blood. A point mutation (V617F) in the JAK2 gene has been identified and found to be expressed in some individuals with one of three myeloproliferative diseases: polycythemia vera (PV), essential thrombocythemia (ET), and primary myelofibrosis (PMF).

JAK2 genetic testing may provide a diagnostic tool to identify patients with either a myeloproliferative neoplasm (MPN) or an increased susceptibility to develop an MPN and may also serve as a target for drug therapy.

This testing requires a peripheral blood or a bone marrow sample and is available at multiple laboratories and manufacturers. The JAK2 gene is present on average in 80-95% of PV patients, up to 60% of patients with essential thrombocythemia or primary myelofibrosis.

Disclaimer

Coverage is limited to that outlined in Medicaid Rule or Health Care Administrative Rules that pertains to the member's aid category. Prior Authorization (PA) is only valid if the member is eligible for the applicable item or service on the date of service.

Medicaid Rule

Medicaid and Health Care Administrative Rules can be found at https://humanservices.vermont.gov/rules-policies/health-care-rules/health-care-administrative-rules-hcar/adopted-rules

7102.2 Prior Authorization Determination
7405 Laboratory and Radiology Services
4.101 Medical Necessity for Covered Services
4.104 Medicaid Non-Covered Services
4.106 Early and Periodic Screening, Diagnostic and Treatment (EPSDT) Services

Coverage Position

JAK2 testing may be covered for members:

- When testing is prescribed by a licensed medical provider, enrolled in the Vermont Medicaid program, operating within their scope of practice as described on the Vermont's Office of Professional Regulation's website Statute*, or rule who is knowledgeable regarding genetic testing and who provides medical care to the member AND
- When the clinical criteria below are met.

* Vermont's Office of Professional Regulation's website: https://sos.vermont.gov/opr/

Coverage Criteria

JAK2 genetic testing may be covered for members who:

- Are 18 years or older, AND
- Meet criteria for polycythemia vera (PV), essential thrombocythemia (ET) or primary myelofibrosis (PMF) in accordance with the World Health Organization's diagnostic criteria for myeloproliferative neoplasms, AND
- Medical management will be impacted by this genetic testing.

The World Health Organization's diagnostic criteria for myeloproliferative neoplasms can be found at: https://ashpublications.org/blood/article/127/20/2391/35255/The-2016-revision-to-the-World-Health-Organization

Considerations: Providers requesting this test should provide pre- and post-test genetic counseling for the member and family, if applicable.

Early and Periodic Screening, Diagnostic and Treatment (EPSDT): Vermont Medicaid will provide comprehensive services and furnish all Medicaid coverable, appropriate, and medically necessary services needed to correct and ameliorate health conditions for Medicaid members under age 21.

Please note, Vermont Medicaid Clinical Criteria is reviewed based on available literature, evidence- based guidelines/standards, Medicaid rule and policy, and Medicare coverage determinations that may be appropriate to incorporate when applicable.

Clinical criteria for repeat service or procedure

Repeat service is not applicable for this genetic testing. If JAK 2 results are negative, Vermont Medicaid does not cover BCR-ABL genetic testing.

Type of service or procedure covered

- JAK2 Gene Analysis, Quantitative and Qualitative
- JAK2 Exon 12 and Exon 13 Mutation Analysis by PCR

Type of service or procedure not covered (this list may not be all inclusive)

- For children younger than 18 years of age.
- Quantitative assessment of $JAK2^{V617F}$ allele burden after qualitative detection of $JAK2^{V617F}$.
- JAK2 testing for the following situations, which is considered **investigational**:
    - Diagnosis of nonclassic forms of myeloproliferative neoplasms
    - Molecular phenotyping of patients with myeloproliferative neoplasms
    - Monitoring, management, or selecting treatment in patients with myeloproliferative neoplasms

Coding guidelines

If CPT 81270 is negative, reflex to CPT 81219. If CPT 81219 is negative, reflex to CPT 81339.

Please see the Medicaid Portal at http://vtmedicaid.com/#/feeSchedule for fee schedules, code coverage, and applicable requirements.

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