

The Department of Vermont Health Access Medical Policy

Subject: Janus Kinase 2 (JAK2) Genetic Test

Last Review: January 3, 2017

Revision 3:

Revision 2:

Revision 1:

Original Effective: 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 that reside 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 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).

This 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 ET or Primary Myelofibrosis.

Disclaimer

Coverage is limited to that outlined in Medicaid Rule 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

7102.2 Prior Authorization Determination

7103 Medical Necessity

Medicaid Rules can be found at <http://humanservices.vermont.gov/on-line-rules>

Coverage Position

JAK2 Genetic Testing may be covered for beneficiaries:

- When the JAK2 genetic testing is prescribed by a licensed medical provider, enrolled in the Vermont Medicaid program, operating within their scope of practice in accordance with the Vermont State Practice Act, who is knowledgeable in the use of JAK2 genetic testing and who provides medical care to the beneficiary. AND
- When the clinical criteria below are met.

Coverage Criteria

JAK2 genetic testing may be covered for beneficiaries who:

- Are 18 years or older
- Have symptoms associated with polycythemia vera (PV), essential thrombocythemia(ET) or primary myelofibrosis (PMF) and the following has been assessed:
 - Family history
 - Previous diagnostic tests are consistent with PV, such as:
 - Increased red cell mass
 - Enlarged spleen
 - Increased
 - platelet count
 - Leukocyte alkaline phosphate
 - Vitamin B12 binding protein
 - Neutrophilia
 - Previous diagnostic tests are consistent with ET, such as:
 - Elevated platelet count and normal red cell mass
 - Enlarged spleen
 - Previous diagnostic tests are consistent with PMF, such as:
 - Absence of PV criteria
 - Abnormal blood counts
 - Collagen fibrosis
 - Increased cellularity of the bone marrow

Clinical guidelines for repeat service or procedure

Repeat service is not applicable for this genetic testing. If a negative JAK2 result occurs, Vermont Medicaid does not cover MPL testing or 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}.

References

Hammaren, H., Ungureanu, D., Grisouard, J., Skoda, R., Hubbard, S., & Silvennoinen, O. (2015). ATP binding to the pseudokinase domain of JAK2 is critical for pathogenic activation. *PNAS*, *112*(15). Retrieved on 10/27/2015
<http://www.pnas.org/content/112/15/4642.full.pdf>

Hayes, Inc. GTE Algorithm. *JAK2 Testing in Myeloproliferative Neoplasms*. Landsdale, PA: Hayes, Inc.; June 2015.

Hayes, Inc. GTE Report. *Janus Kinase 2 (JAK2) p. Val617Phe Testing for Myeloproliferative Neoplasms*. Landsdale, PA: Hayes, Inc.; April 2013.

LCD for Genetic Testing (L24308), (2013). *NHIC, Corp.* Retrieved November 12, 2015, from:
[https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=24308&ContrId=358&ver=77&ContrVer=1&CtrctrSelected=358*1&Ctrctr=358&name=Noridian+Healthcare+Solutions%2c+LLC\(Noridian+Healthcare+Solutions%2c+LLC++\(02402%2c+A+and+B+MAC%2c+J+-+F\)\)&s=56&DocType=All&bc=AggAAAIAAAAAAAA%3d%3d&](https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=24308&ContrId=358&ver=77&ContrVer=1&CtrctrSelected=358*1&Ctrctr=358&name=Noridian+Healthcare+Solutions%2c+LLC(Noridian+Healthcare+Solutions%2c+LLC++(02402%2c+A+and+B+MAC%2c+J+-+F))&s=56&DocType=All&bc=AggAAAIAAAAAAAA%3d%3d&)

Scott, L. M., Tong, W., Levine, R. L., Scott, M., Beer, P. A., Stratton, M. R., et al. (2007). JAK2 exon 12 mutation in polycythemia vera and idiopathic erythrocytosis. *New England Journal of Medicine*, *356*(5). Retrieved December 16, 2015, from: <http://www.nejm.org/doi/pdf/10.1056/NEJMoa065202>

Steensma, D. P. (2006). AJAK2 V617F in myeloid disorders: Molecular diagnostic techniques and their clinical utility. *Journal of Molecular Diagnostics*, *8*(4). Retrieved December 16, 2015, from: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1867618/pdf/JMD008000397.pdf>

Tefferi, A. & Pardanani, A. (2006). Mutation screening for JAK2^{V617F}: When to order the test and how to interpret the results. *Leukemia Research*, *30*: 739-744. Retrieved December 16, 2015, from: http://www.nlm.it/www.nlm.it/documents/2006_how_to_interpret_the_result-Tefferi.pdf

This document has been classified as public information.