I. Policy: Janus Kinase 2 (JAK 2) Gene Mutation Analysis

II. Purpose/Objective:
To provide a policy of coverage regarding Janus Kinase 2 (JAK 2) Gene Mutation Analysis

III. Responsibility:
A. Medical Directors
B. Medical Management

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards of good medical treatment practiced by the general medical community.
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment
Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

(i) The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
(ii) The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.
(iii) The service or benefit will assist the Member to achieve or maintain maximum functional
capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for members of the same age.

DESCRIPTION:
Janus Kinase 2 (JAK 2, JAK 2\textsuperscript{V617F}) mutation analysis has been proposed as a laboratory test to aid in the diagnosis and clinical management of patients with myeloproliferative disorder.

INDICATIONS:
Janus Kinase 2 (JAK 2, JAK 2\textsuperscript{V617F}) mutation analysis is considered medically necessary in the evaluation of:

Adults, age 21 or older, presenting with clinical, laboratory, or pathological findings suggesting classic forms of polycythemia vera; or

Adult's Initial diagnostic evaluation of clinical or laboratory findings suggestive of either:
- essential thrombocythemia
- primary myelofibrosis

In individuals with isolated idiopathic erythrocytosis, JAK2 testing may be considered only in those with a serum erythropoietin level that is below 10.

EXCLUSIONS:
Testing for Janus Kinase 2 (JAK 2, JAK 2\textsuperscript{V617F}) gene mutation is considered not medically necessary for any other indication including but not limited to:
- Myeloproliferative disorders (MPD) in children under the age of 21
- Quantitative JAK 2\textsuperscript{V617F} allele burden subsequent to qualitative detection of JAK 2\textsuperscript{V617F}.

CODING ASSOCIATED WITH: Janus Kinase 2 (JAK 2) Gene Mutation Analysis

The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.

81270  JAK2 (Janus kinase 2) (eg, myeloproliferative disorder) gene analysis, p.Val617Phe (V617F)
variant


LINE OF BUSINESS: Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD’s and NCD’s will supersede this policy. For PA Medicaid Business segment, this policy applies as written.

REFERENCES:


Winifred S. Hayes, GTE Report. Janus kinase 2 (JAK2) Sequence Variants (including V617F) for Chronic Myeloproliferative Disorders. May, 2008


This policy will be revised as necessary and reviewed no less than annually.

Devised: 04/12/07

Revised: 04/08, 4/09 (wording); 4/10 (exclusion added); 3/11 (criteria clarification), 10/13; 10/15 (indication clarification)

Reviewed: 3/12, 3/13, 10/14, 10/16, 9/17