Clinical Policy: Ruxolitinib (Jakafi)

Reference Number: PA.CP.PHAR.98
Effective Date: 01/18
Last Review Date: 07/18

Coding Implications
Revision Log

Description
The intent of the criteria is to ensure that patients follow selection elements established by Pennsylvania Health and Wellness® clinical policy for ruxolitinib (Jakafi®).

FDA Approved Indication(s)
Jakafi is indicated:

- For treatment of patients with intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis and post-essential thrombocythemia myelofibrosis;
- For treatment of patients with polycythemia vera who have had an inadequate response to or are intolerant to hydroxyurea.

Policy/Criteria
It is the policy of Pennsylvania Health and Wellness that Jakafi is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Myelofibrosis (must meet all):

1. Diagnosis of intermediate or high-risk myelofibrosis (includes primary myelofibrosis, post-polycythemia vera myelofibrosis and post-essential thrombocythemia myelofibrosis);
2. Prescribed by or in consultation with a hematologist or oncologist;
3. Age ≥ 18 years;
4. Dose does not exceed 25 mg twice daily.

Approval duration: 6 months

B. Polycythemia Vera (must meet all):

1. Diagnosis of polycythemia vera;
2. Prescribed by or in consultation with a hematologist or oncologist;
3. Age ≥ 18 years;
4. Failure (i.e., inadequate response) of hydroxyurea unless contraindicated or clinically significant adverse effects are experienced;
5. Dose does not exceed 25 mg twice daily.

Approval duration: 6 months

C. Other diagnoses/indications: Refer to PA.CP.PMN.53

II. Continued Approval

A. All Indications in Section I (must meet all)**:**
1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 25 mg twice daily.

Approval duration: 12 months

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.CP.PMN.53

Background

Description/Mechanism of Action:

Ruxolitinib, a kinase inhibitor, inhibits Janus Associated Kinases (JAKs) JAK1 and JAK2 which mediate the signaling of a number of cytokines and growth factors that are important for hematopoiesis and immune function. JAK signaling involves recruitment of STATs (signal transducers and activators of transcription) to cytokine receptors, activation and subsequent localization of STATs to the nucleus leading to modulation of gene expression. Myelofibrosis (MF) and polycythemia vera (PV) are myeloproliferative neoplasms (MPN) known to be associated with dysregulated JAK1 and JAK2 signaling. In a mouse model of JAK2V617F-positive MPN, oral administration of ruxolitinib prevented splenomegaly, preferentially decreased JAK2V617F mutant cells in the spleen and decreased circulating inflammatory cytokines (e.g., TNF-α, IL-6).

Formulations:

Tablets: 5 mg, 10 mg, 15 mg, 20 mg and 25 mg

Appendices

Appendix A: Abbreviation Key

JAK: Janus Associated Kinase
MF: myelofibrosis
MPN: myeloproliferative neoplasms
PV: polycythemia vera
STAT: signal transducer and activator of transcription

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
N/A	

Reviews, Revisions, and Approvals	Date	Approval Date
Removed request for bloodwork. Removed NCCN off-label use for myelofibrosis. References reviewed and updated.	02/18	

References

1. Jakafi Prescribing Information. Wilmington, DE: Incyte Corporation; October 2017. Available at http://www.jakafi.com. Accessed November 2017.
2. Hydroxyurea. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2017. Available at: http://www.clinicalpharmacology-ip.com/.
3. Myeloproliferative neoplasms (Version 2.2018). In: National Comprehensive Cancer Network Guidelines. Available at NCCN.org. Accessed November 2017.