MEDICAL MUTUAL®

Drug Policy

Policy:	Jakafi (ruxolitinib)	Annual Review Date: 10/17/2024 Last Revised Date: 10/17/2024

OVERVIEW

Jakafi, a kinase inhibitor, is indicated for treatment of patients with intermediate or high-risk myelofibrosis (MF), including primary MF, post-polycythemia vera MF, and post-essential thrombocythemia MF. Jakafi inhibits Janus Associated Kinases (JAKs), specifically JAK1 and JAK2 which mediate the signaling of many cytokines and growth factors that are essential for hematopoiesis and immune function. JAK signaling involves recruitment of signal transducers and activators of transcription (STATs) to cytokine receptors, activation, and subsequent localization of STATs to the nucleus leading to modulation of gene expression. MF is a myeloproliferative neoplasm (MPN) known to be associated with dysregulated JAK1 and JAK2 signaling.

POLICY STATEMENT

This policy involves the use of Jakafi. Prior authorization is recommended for pharmacy benefit coverage of Jakafi. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Jakafi as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Jakafi be prescribed by or in consultation with a physician who specializes in the condition being treated. In order to be considered for coverage, Jakafi must be prescribed by or in consultation with a hematologist or oncologist. All approvals for initial therapy are provided for the initial approval duration noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Jakafi is recommended in those who meet the following criteria:

1. **Myelofibrosis (MF), including primary MF, post-polycythemia vera MF, and post-essential thrombocytopenia MF**
   Criteria. *Approve if patient is 18 years of age or older*
2. **Polycythemia Vera**
   Criteria. *Patient must meet the following criteria.*
   A. The patient is 18 years of age or older; AND

B. Patient has tried hydroxyurea

3. **Graft Versus Host Disease (GVHD), acute or chronic**
Criteria. *Patient must meet the following criteria.*

A. The patient is 12 years of age or older; AND
B. The patient has steroid-refractory disease

4. **Pedicatric Acute Lymphoblastic Leukemia**
Criteria. *Patient must meet the following criteria.*

A. The patient is 12 years of age or older; AND
B. The patient has steroid-refractory disease

5. **Myelodysplastic Syndrome/Myeloproliferative Neoplasm (MDS/MPN) Overlap Neoplasms**
Criteria. *Approve for chronic disease.*

6. **Another indication that is not listed but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation**
Criteria. *Prescriber will provide specific diagnosis for documentation. Approve.*

7. **Patient has been started on Jakafi**
Criteria. *Approve for an indication or condition addressed as an approval in this document.*

Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year
B) *Extended Approval:* 1 year

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Jakafi has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. **Treatment of Alopecia.** Alopecia is considered cosmetic. Cosmetic uses are excluded from coverage in a typical medical or pharmacy plan benefit.

2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Jakafi® tablets [prescribing information]. Wilmington, DE: Incyte; Jan 2020.
2. The NCCN Drugs and Biologics Compendium. © 2015 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed 17 June 2019. Search term:. Ruxolitinib.
3. Ruxolitinib Phosphate. In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated 6 December 2019. Accessed on 21 May 2020
4. The NCCN Drugs and Biologics Compendium. © 2020 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org/professionals/physician_gls/pdf/ped_all.pdf. Accessed 21 May 2020 Search term:. Jakafi.