Generic Name: Ruxolitinib

Therapeutic Class or Brand Name: Jakafi®

Applicable Drugs (if Therapeutic Class): N/A

Preferred: N/A

Non-preferred: N/A

Date of Origin: 2/1/2013

Date Last Reviewed / Revised: 11/18/2024

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through IV are met)

I. Documented diagnosis of one of the following conditions A through J AND must meet criteria listed under applicable diagnosis:

FDA-Approved Indication(s)

A. Myelofibrosis, including but not limited to primary myelofibrosis, post-polycythemia vera myelofibrosis, and post-essential thrombocythemia myelofibrosis AND all the following criteria are met:
   i. Minimum age requirement: 18 years old.

B. Polycythemia vera AND all the following criteria are met:
   i. Documented inadequate response, contraindication to or intolerance to hydroxyurea.
   ii. Minimum age requirement: 18 years old.

C. Steroid-refractory acute graft-versus-host disease AND all the following criteria are met:
   i. Documentation trial and failure of steroids.
   ii. Minimum age requirement: 12 years old.

D. Chronic graft-versus-host disease AND all the following criteria are met:
   i. Documented failure of at least one line of systemic therapy.
   ii. Minimum age requirement 12 years old.

Other Uses with Supportive Evidence

E. Immunotherapy-related concomitant myositis and myocarditis AND all the following criteria are met:
   i. Documented concomitant myositis and myocarditis related to immunotherapy.
   ii. Documented trial and failure of steroids.
   iii. Minimum age requirement: 18 years old.

F. Myeloid/Lymphoid neoplasms AND all the following criteria are met:
   i. Documentation of myeloid, lymphoid, or mixed phenotype neoplasm with eosinophilia.
   ii. Documentation of JAK2 rearrangement.

iii. Minimum age: 18 years old.

G. Chronic myelomonocytic leukemia (CMML)-2 AND all the following criteria are met:
   i. Used in combination with a hypomethylating agent (ex: azacitidine, decitabine)
   ii. Used for symptom management or splenomegaly.
   iii. Minimum age: 18 years old.

H. Myelodysplastic/myeloproliferative neoplasm (MDS/MPN) or atypical chronic myeloid leukemia (aCMP) AND all the following criteria are met:
   i. Documentation of neutrophilia.
   ii. Documentation that patient is BCR-ABL negative.
   iii. Minimum age: 18 years old.

I. Pediatric acute lymphoblastic leukemia
   i. Documentation of ONE of the following:
      a) Induction therapy as a component of Total Therapy XVII regimen + ruxolitinib
      b) Consolidation therapy as a component of COG AAL 1521 regimen + ruxolitinib
      c) Consolidation therapy as a component of Total Therapy XVII regimen (SR/HR arm) + ruxolitinib

J. T-cell lymphocytic leukemia (T-LGLL) and meets ONE of the following criteria (i, ii, or iii):
   i. Diagnosis of T-cell large granular lymphocytic leukemia AND all the following (a, b, and c):
      a) Used as second-line therapy.
      b) Documentation of progressive or refractory disease.
      c) Minimum age: 18 years old.
   ii. Diagnosis of T-cell prolymphocytic leukemia AND all the following (a, b, and c):
      a) Documentation of symptomatic disease.
      b) Used as second-line or subsequent therapy.
      c) Minimum age: 18 years old.
   iii. Diagnosis of T-cell prolymphocytic leukemia AND all the following (a, b, c, and d):
      a) Documentation of symptomatic disease.
      b) Used as second line or subsequent therapy.
      c) Used as single agent.
      d) Minimum age: 18 years old.

II. Treatment must be prescribed by or in consultation with an oncologist or a hematologist.

III. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

IV. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

Exclusion Criteria

- N/A

Other Criteria

- N/A

Quantity / Days Supply Restrictions

- Quantities of up to 60 tablets per 30 days.

Approval Length

- **Authorization:** 1 year.
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective.

Appendix

N/A

References

1. Jakafi. Prescribing Information. Incyte; January 2023. Available at: http://www.jakafi.com/pdf/prescribing-information.pdf.
2. National Comprehensive Cancer Network. Myelodysplastic Syndromes. Version 3.2024. Updated July 25, 2024. Accessed October 15, 2024. https://www.nccn.org/professionals/physician_gls/pdf/mds.pdf.
3. National Comprehensive Cancer Network. Myeloproliferative Neoplasms. Version 2.2024. Updated August 8, 2024. Accessed October 15, 2024. https://www.nccn.org/professionals/physician_gls/pdf/mpn.pdf.
4. National Comprehensive Cancer Network. Hematopoietic Cell Transplantation (HCT). Version 2.2024. Updated August 30, 2024. Accessed October 15, 2024. https://www.nccn.org/professionals/physician_gls/pdf/hct.pdf.

5. National Comprehensive Cancer Network. Management of Immunotherapy-Related Toxicities. Version 1.2024. Updated December 7, 2023. Accessed October 18, 2024. www.nccn.org/professionals/physician_gls/pdf/immunotherapy.pdf
6. National Comprehensive Cancer Network. Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Gene Fusions. Version 2.2024. Updated June 19, 2024. Accessed October 18, 2024. www.nccn.org/professionals/physician_gls/pdf/mlne.pdf
7. National Comprehensive Cancer Network. Pediatric Acute Lymphoblastic Leukemia. Version 1.2025. Updated August 28, 2024. Accessed October 18, 2024. www.nccn.org/professionals/physician_gls/pdf/ped_all.pdf
8. National Comprehensive Cancer Network. T-Cell Lymphomas. Version 4.2024. Updated May 28, 2024. Accessed October 18, 2024. www.nccn.org/professionals/physician_gls/pdf/t-cell.pdf