

# Jakafi (ruxolitinib)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Jakafi (ruxolitinib)	May be subject to quantity limit

## **APPROVAL CRITERIA**

Requests for Jakafi (ruxolitinib) may be approved if the following are met:

- I. Individual has a diagnosis of low, intermediate, or high-risk myelofibrosis including any of the following (Label, NCCN 2A):
  - A. Primary myelofibrosis; **OR**
  - B. Post-polycythemia vera myelofibrosis; **OR**
  - C. Post-essential thrombocythemia myelofibrosis;
- OR**
- II. Individual has a diagnosis of polycythemia vera with an inadequate response, loss of response, or intolerance to prior cytoreductive treatment (Label, NCCN 2A);
- OR**
- III. Individual has a diagnosis of essential thrombocythemia with an inadequate response or loss of response to hydroxyurea, interferon therapy, or anagrelide (NCCN 2A);
- OR**
- IV. Individual is 12 years and older; **AND**
- V. Individual has a diagnosis of steroid-refractory acute graft versus host disease (GVHD);
- OR**
- VI. Individual is 12 years and older; **AND**
- VII. Individual has a diagnosis of chronic graft versus host disease (GVHD); **AND**
- VIII. Individual experienced treatment failure of up to two (2) prior lines of systemic therapy for GVHD;
- OR**
- IX. Individual is undergoing immune checkpoint inhibitor therapy for a cancer diagnosis (NCCN 2A); **AND**
- X. Individual is experiencing immunotherapy-related myositis and myocarditis;
- OR**
- XI. Individual has a diagnosis of pediatric BCR::ABL1-like B-ALL (acute lymphoblastic leukemia) (NCCN 2A); **AND**
- XII. Individual is using as part of consolidation therapy in COG AALL 1521 regimen;
- OR**

XIII. Individual is using as part of Total Therapy XVII regimen;

**OR**

XIV. Individual has a diagnosis of T-Cell large granular lymphocytic leukemia (NCCN 2A); **AND**

XV. Individual is using as second-line therapy; **AND**

XVI. Individual is using as a single agent therapy;

**OR**

XVII. Individual has a diagnosis of T-Cell prolymphocytic leukemia (NCCN 2A); **AND**

XVIII. Individual is using as second-line or subsequent therapy; **AND**

XIX. Individual is using as a single agent therapy;

**OR**

XX. Individual has a diagnosis for lymphoid, myeloid or mixed lineage neoplasms with eosinophilia (NCCN 2A); **AND**

XXI. Individual has a JAK2 rearrangement mutation;

**OR**

XXII. Individual has a diagnosis of chronic myelomonocytic leukemia (CMML)-2 (NCCN 2A); **AND**

XXIII. Individual is using in combination with a hypomethylating agent;

**OR**

XXIV. Individual has a diagnosis of myelodysplastic/myeloproliferative neoplasm (MDS/MPN) with neutrophilia (NCCN 2A); **AND**

XXV. Individual is using as a single agent or in combination with a hypomethylating agent.

**OR**

XXVI. Individual has a diagnosis of cytokine release syndrome (NCCN 2A); **AND**

XXVII. Disease is refractory to high-dose corticosteroids and anti-IL-6 therapy.

#### **Key References:**

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Updated periodically.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc. Updated periodically.
4. Gotlib J. How I treat atypical chronic myeloid leukemia. *Blood*. 2017;129(7):838-845. doi:10.1182/blood-2016-08-693630
5. Inaba H, Azzato EM, Mullighan CG. Integration of Next-Generation Sequencing to Treat Acute Lymphoblastic Leukemia with Targetable Lesions: The St. Jude Children's Research Hospital Approach. *Front Pediatr*. 2017;5:258. Published 2017 Dec 4. doi:10.3389/fped.2017.00258. Available at: <https://www.frontiersin.org/articles/10.3389/fped.2017.00258/full>. Accessed October 17, 2021.
6. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2024; Updated periodically.
7. NCCN Clinical Practice Guidelines in Oncology™. © 2024 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on September 9, 2024.
  - a. Hematopoietic Cell Transplantation. V2.2024. Revised August 30, 2024.
  - b. Management of Immunotherapy-Related Toxicities. V1.2024. Revised December 7, 2023.
  - c. Myelodysplastic Syndromes. V3.2024. Revised July 25, 2024.
  - d. Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes. V2.2024. Revised June 19, 2024.
  - e. Myeloproliferative Neoplasms. V2.2024. Revised August 8, 2024.
  - f. Pediatric Acute Lymphoblastic Leukemia. V1. 2025. Revised August 28, 2024.

