# Jakafi (ruxolitinib)

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

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
- 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: <a href="https://www.frontiersin.org/articles/10.3389/fped.2017.00258/full">https://www.frontiersin.org/articles/10.3389/fped.2017.00258/full</a>. 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: <a href="http://www.nccn.org/index.asp">http://www.nccn.org/index.asp</a>. 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.

- g. T-cell Lymphomas. V4.2024. Revised May 28, 2024.
- Padron E, Dezern A, Andrade-Campos M, et al. A Multi-Institution Phase I Trial of Ruxolitinib in Patients with Chronic Myelomonocytic Leukemia (CMML). Clin Cancer Res. 2016;22(15):3746-3754. doi:10.1158/1078-0432.CCR-15-2781
- Rumi E, Milosevic JD, Casetti I, et al. Efficacy of ruxolitinib in chronic eosinophilic leukemia associated with a PCM1-JAK2 fusion gene. J Clin Oncol. 2013;31(17):e269-e271. doi:10.1200/JCO.2012.46.4370. Available at: <a href="https://ascopubs.org/doi/10.1200/JCO.2012.46.4370?url\_ver=Z39.88-2003&rfr\_id=ori%3Arid%3Acrossref.org&rfr\_dat=cr\_pub++0pubmed&">https://ascopubs.org/doi/10.1200/JCO.2012.46.4370?url\_ver=Z39.88-2003&rfr\_id=ori%3Arid%3Acrossref.org&rfr\_dat=cr\_pub++0pubmed&</a>.
- 10. Rumi E, Milosevic JD, Selleslag D, et al. Efficacy of ruxolitinib in myeloid neoplasms with PCM1-JAK2 fusion gene. Ann Hematol. 2015;94(11):1927-1928. doi:10.1007/s00277-015-2451-7
- 11. Schwaab J, Knut M, Haferlach C, et al. Limited duration of complete remission on ruxolitinib in myeloid neoplasms with PCM1-JAK2 and BCR-JAK2 fusion genes. Ann Hematol. 2015;94(2):233-238. doi:10.1007/s00277-014-2221-y
- 12. Schwaab J, Naumann N, Luebke J, et al. Response to tyrosine kinase inhibitors in myeloid neoplasms associated with PCM1-JAK2, BCR-JAK2 and ETV6-ABL1 fusion genes. Am J Hematol. 2020;95(7):824-833. doi:10.1002/ajh.25825. Available at: https://onlinelibrary.wiley.com/doi/full/10.1002/ajh.25825.
- 13. Tasian SK, Assad A, Hunter DS, et al. A phase 2 study of ruxolitinib with chemotherapy in children with Philadelphia chromosome-like acute lymphoblastic leukemia (INCB18424-269/AALL1521): Dose-finding results from the Part 1 safety phase. Blood 2018;ASH Abstract 555.
- Results from the part 1 safety phase. Blood. 2018;132(supplement 1):555 [abstract]. Available at: https://doi.org/10.1182/blood-2018-99-110221.

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