PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Jakafi Prior Authorization Policy
- Jakafi® (ruxolitinib tablets – Incyte)

REVIEW DATE: 02/23/2022; selected revision 06/22/2022

OVERVIEW

Jakafi, an inhibitor of Janus Associated Kinases (*JAKs*) *JAK1* and *JAK2*, is indicated the following uses:[1]

- **Graft versus host disease**, acute treatment of steroid-refractory disease, in patients ≥ 12 years of age.
- **Graft versus host disease**, chronic treatment, after failure of one or two lines of systemic therapy in patients ≥ 12 years of age.
- **Myelofibrosis**, intermediate or high risk, including primary myelofibrosis, post-polycythemia vera myelofibrosis, and post-essential thrombocythemia myelofibrosis in adults.
- **Polycythemia vera**, in adults who have had an inadequate response to or are intolerant of hydroxyurea.

Guidelines

Jakafi is discussed in guidelines by the National Comprehensive Cancer Network (NCCN):[2]

- **Graft versus host disease:** NCCN has guidelines regarding hematopoietic cell transplantation that discuss graft versus host disease (version 5.2021 – September 30, 2021) that include Jakafi.[3] Jakafi is recommended among patients with steroid-refractory chronic graft versus host disease in the acute and chronic setting (both category 1).[3]
- **Myelodysplastic syndromes:** NCCN guidelines (version 3.2022 – January 13, 2021) state that patients with atypical chronic myeloid leukemia with *CSF3R* or *JAK2* mutations may respond to Jakafi (category 2A).[4] Additionally, in patients with chronic monomyelocytic leukemia 2, benefits have been shown in patients receiving hypomethylating agents with Jakafi (category 2A).
- **Myeloid/lymphoid neoplasms with eosinophilia and tyrosine kinase fusion genes**: NCCN guidelines (version 4.2021 – July 9, 2021) recommend Jakafi for treatment of myeloid/lymphoid neoplasms with eosinophilia and *JAK2* rearrangement in chronic phase (category 2A).[5] The guidelines also recommend Jakafi for treatment in combination with acute lymphocytic leukemia or acute myeloid leukemia type induction chemotherapy followed by allogeneic hematopoietic stem cell transplantation (if eligible) for lymphoid, myeloid, or mixed lineage neoplasms with eosinophilia and *JAK2* rearrangement in blast phase.
- **Myeloproliferative neoplasms:** NCCN guidelines (version 2.2021 –August 18, 2021) recommend Jakafi among patients with lower- and higher-risk myelofibrosis (category 2A).[6] It is also a recommended therapy for patients with low- or high-risk polycythemia vera after other agents (e.g., hydroxyurea) [category 2A]. The guidelines also recommend Jakafi for treatment of essential thrombocythemia for inadequate response or loss of response to hydroxyurea, peginterferon alfa-2a therapy, or anagrelide (useful in certain circumstances) [category 2A].
- **Pediatric acute lymphoblastic leukemia:** NCCN guidelines (version 1.2022 – October 1, 2021) recommend Jakafi in a variety of regimens for pediatric patients and young adults with

acute lymphoblastic leukemia (category 2A).[7] The utility of Jakafi is described primarily in patients in which the mutation/pathway is *JAK*-related.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Jakafi. All approvals are provided for the duration noted below.

Automation: The ICD-9/ICD-10 codes for myelofibrosis (ICD-9: 289.83 and ICD-10: D75.81) will be used as part of automation to allow approval of the requested medication.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indications

1. **Graft versus Host Disease, Acute.** Approve for 1 year if the patient meets the following criteria (A and B):
   A) Patient is ≥ 12 years of age; AND
   B) Patient has tried one systemic corticosteroid.

2. **Graft versus Host Disease, Chronic.** Approve for 1 year if the patient meets the following criteria (A and B):
   A) Patient is ≥ 12 years of age; AND
   B) Patient has tried one conventional systemic treatment for graft versus host disease.
   Note: Examples include systemic corticosteroids (methylprednisolone, prednisone), cyclosporine, tacrolimus, mycophenolate mofetil, Imbruvica (ibrutinib capsules and tablets), and imatinib.

3. **Myelofibrosis (MF), including Primary MF, Post-Polycythemia Vera MF, and Post-Essential Thrombocythemia MF.** Approve for 1 year if the patient is ≥ 18 years of age.

4. **Polycythemia Vera.** Approve for 1 year if the patient meets the following criteria (A and B):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has tried hydroxyurea.

Other Uses with Supportive Evidence

5. **Acute Lymphoblastic Leukemia.** Approve for 1 year if the patient meets the following criteria (A and B)
   A) Patient is < 21 years of age; AND
   B) The mutation/pathway is Janus Associated Kinase (*JAK*)-related.

6. **Atypical Chronic Myeloid Leukemia.** Approve for 1 year if the patient meets the following criteria (A or B):
   A) Patient has a *CSF3R* mutation; OR
   B) Patient has a Janus Associated Kinase 2 (*JAK2*) mutation.

7. **Chronic Monomyelocytic Leukemia-2.** Approve for 1 year if the patient meets the following criteria (A and B):
   A) Patient is ≥ 18 years of age; AND
   B) Patient is also receiving a hypomethylating agent.
   Note: Examples of hypomethylating agents include azacitidine and decitabine.

8. **Essential Thrombocythemia.** Approve for 1 year if the patient meets the following criteria (A and B):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has tried hydroxyurea, peginterferon alfa-2a, or anagrelide.

9. **Myeloid or Lymphoid Neoplasms.** Approve for 1 year if the patient meets the following criteria (A, B, and C):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has eosinophilia; AND
   C) The tumor has a Janus Associated Kinase 2 (*JAK2)* rearrangement.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Jakafi is not recommended in the following situations:

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

REFERENCES

1. Jakafi® tablets [prescribing information]. Wilmington, DE: Incyte; September 2021.
2. The NCCN Drugs and Biologics Compendium. © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed February 21, 2022. Search term: ruxolitinib.
3. The NCCN Hematopoietic Cell Transplantation: Pre-Transplant Recipient Evaluation and Management of Graft-Versus-Host Disease Clinical Practice Guidelines in Oncology (version 5.2021 – September 30, 2021). © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on February 21, 2022.
4. The NCCN Myelodysplastic Syndromes Clinical Practice Guidelines in Oncology (version 3.2022 – January 13, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. . Accessed on February 21, 2022.
5. The NCCN Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes Clinical Practice Guidelines in Oncology (version 4.2021– July 9, 2021). © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed February 21, 2022.
6. The NCCN Myeloproliferative Neoplasms Clinical Practice Guidelines in Oncology (version 2.2021 – August 18, 2021). © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. . Accessed on February 21, 2022.
7. The NCCN Pediatric Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (version 1.2022 – October 1, 2021). © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. . Accessed on February 21, 2022.