PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 03/20/2024

OVERVIEW

Jakafi, an inhibitor of Janus Associated Kinases (*JAKs*) *JAK1* and *JAK2*, is indicated for 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 3.2023 – October 9, 2023) that include Jakafi.[3] Jakafi is recommended among patients with steroid-refractory acute graft versus host disease, or chronic graft versus host disease, after failure of one or two lines of systemic therapy (both category 1).[3]
- **Myelodysplastic Syndromes:** NCCN guidelines (version 1.2024 – February12, 2024) recommend Jakafi for patients with chronic myelomonocytic leukemia-2, with hypomethylating agents (HMA) and/or allogenic hematopoietic stem cell transplant (category 2A).[4] Jakafi ± HMA is also recommended for myelodysplastic syndrome/myeloproliferative neoplasm with neutrophilia (atypical chronic myeloid leukemia); there is a footnote, which states that rare patients with *CSF3R* or *JAK2* mutations may respond to Jakafi due to their JAK-STAT pathway activation (category 2A).
- **Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Gene Fusions**: NCCN guidelines (version 1.2024 – December 21, 2023) recommend Jakafi for treatment of myeloid/lymphoid neoplasms with eosinophilia and *JAK2* rearrangement in chronic or blast 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 phenotype neoplasms with eosinophilia and *JAK2* rearrangement in blast phase (category 2A).
- **Myeloproliferative Neoplasms:** NCCN guidelines (version 1.2024 – December 21, 2023) recommend Jakafi among patients with lower- or higher-risk myelofibrosis (category 2A; category 1 for the initial treatment of higher-risk myelofibrosis).[6] It is also recommended as "Other Recommended Regimens" for the management of myelofibrosis associated anemia with the presence of symptomatic splenomegaly and/or constitutional symptoms in combination with other medications (category 2A). It is also a recommended as "Other Recommended Regimens" for high-risk polycythemia vera a as initial treatment (category 2A) and as "Preferred" therapy for patients with hydroxyurea resistance or intolerance (category 1). The guidelines also recommend Jakafi for treatment of essential

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thrombocythemia for inadequate response or loss of response to hydroxyurea, Pegasys® (peginterferon alfa-2a subcutaneous injection) therapy, or anagrelide as "Useful in Certain Circumstances" (category 2A).

- **Pediatric Acute Lymphoblastic Leukemia:** NCCN guidelines (version 4.2024 – February 7, 2024) 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.
- **T-Cell Lymphoma**: NCCN guidelines (version 2.2024 – March 14, 2024) recommend Jakafi as a single-agent for symptomatic disease as second-line or subsequent therapy for T-cell prolymphocytic leukemia (category 2A).[8] It is also recommended for T-cell large granular lymphocytic leukemia if the patient had no response to first-line therapy, or if patient had progressive or refractory disease after first-line therapy (category 2A).[8]

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 BOTH of the following (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 BOTH of the following (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, tablets, and oral solution), 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 BOTH of the following (A and B):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has tried hydroxyurea, Pegasys (peginterferon alfa-2a subcutaneous injection), or Besremi (ropeginterferon alfa-2b-njft subcutaneous injection).

Other Uses with Supportive Evidence

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5. **Acute Lymphoblastic Leukemia.** Approve for 1 year if the patient meets BOTH of the following (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 one of following (A or B):
   A) Patient has a *CSF3R* mutation; OR
   B) Patient has a Janus Associated Kinase 2 (*JAK2*) mutation.

7. **Chronic Myelomonocytic Leukemia-2.** Approve for 1 year if the patient meets BOTH of the following (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 BOTH of the following (A and B):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has tried hydroxyurea, Pegasys (peginterferon alfa-2a subcutaneous injection), or anagrelide.

9. **Myeloid or Lymphoid Neoplasms.** Approve for 1 year if the patient meets ALL of the following (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.

10. **T-Cell Lymphoma**. Approve for 1 year if the patient meets ALL of the following (A, B, and C):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has one of the following (i or ii):
      i. T-cell prolymphocytic leukemia; OR
      ii. T-cell large granular lymphocytic leukemia; AND
   C) Patient has tried at least one systemic regimen.
   Note: Examples of a systemic regimen include one or more of the following products: methotrexate, corticosteroids, cyclosporine, Lemtrada (alemtuzumab intravenous infusion), fludarabine, mitoxantrone, or cyclophosphamide.

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. © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed March 15, 2024. Search term: ruxolitinib.

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3. The NCCN Hematopoietic Cell Transplantation Clinical Practice Guidelines in Oncology (version 3.2023 – October 9, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 13, 2024.
4. The NCCN Myelodysplastic Syndromes Clinical Practice Guidelines in Oncology (version 1.2024– February 12, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 13, 2024.
5. The NCCN Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Gene Fusions Clinical Practice Guidelines in Oncology (version 1.2024 – December 21, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed March 13, 2024.
6. The NCCN Myeloproliferative Neoplasms Clinical Practice Guidelines in Oncology (version 1.2024 – December 21, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 15, 2024.
7. The NCCN Pediatric Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (version 4.2024 – February 7, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 15, 2024.
8. The NCCN T-Cell Lymphoma Clinical Practice Guidelines in Oncology (version 2.2024 – March 14, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 15, 2024.

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