PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 03/22/2023

INSTRUCTIONS FOR USE

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CIGNA NATIONAL FORMULARY COVERAGE:

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 3.2022 – January 24, 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 1.2023 – September 12, 2022) 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 fusion genes**: NCCN guidelines (version 2.2022 – October 18, 2022) 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 lineage neoplasms with eosinophilia and *JAK2* rearrangement in blast phase (category 2A).
- **Myeloproliferative neoplasms:** NCCN guidelines (version 3.2022 – August 11, 2022) 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 a recommended "Preferred" therapy for patients with symptomatic low-risk (category 2A) or high-risk (category 1) polycythemia vera after other agents (e.g., hydroxyurea or Pegasys® [peginterferon alfa-2a subcutaneous injection]). The guidelines also recommend Jakafi for treatment of essential thrombocythemia for inadequate response or loss of response to hydroxyurea, Pegasys therapy, or anagrelide as "Useful in Certain Circumstances" (category 2A).
- **Pediatric acute lymphoblastic leukemia:** NCCN guidelines (version 1.2023 – November 9, 2022) 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.

Jakafi® (ruxolitinib tablets (Incyte)
is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

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 or Pegasys (peginterferon alfa-2a subcutaneous injection).

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 one of following criteria (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 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, Pegasys (peginterferon alfa-2a subcutaneous injection), 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 COVERED

Jakafi® (ruxolitinib tablets (Incyte) is(are) considered experimental, investigational, or unproven for ANY other use(s).

REFERENCES

1. Jakafi® tablets [prescribing information]. Wilmington, DE: Incyte; September 2021.
2. The NCCN Drugs and Biologics Compendium. © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed March 7, 2023. Search term: ruxolitinib.
3. The NCCN Hematopoietic Cell Transplantation Clinical Practice Guidelines in Oncology (version 3.2022 – January 24, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 7, 2023.
4. The NCCN Myelodysplastic Syndromes Clinical Practice Guidelines in Oncology (version 1.2023– September 12, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 7, 2023.
5. The NCCN Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes Clinical Practice Guidelines in Oncology (version 2.2022 – October 18, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed March 7, 2023.
6. The NCCN Myeloproliferative Neoplasms Clinical Practice Guidelines in Oncology (version 3.2022 – August 11, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 7, 2023.
7. The NCCN Pediatric Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (version 1.2023 – November 9, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 7, 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date
Early Annual Revision	**Atypical Chronic Myeloid Leukemia:** Patient has a Janus Associated Kinase mutation was revised to Janus Associated Kinase-2 (*JAK2*) mutation. **Essential Thrombocythemia:** Indication and criteria were added Other Uses with Supportive Evidence based on NCCN guidelines. **Myeloid or Lymphoid Neoplasms:** Indication and criteria were added to Other Uses with Supportive Evidence based on NCCN guidelines.	02/23/2022
Selected Revision	**All indications**: The duration of approval was changed from 3 years to 1 year.	06/22/2022
Annual Revision	**Polycythemia Vera:** Pegasys **(**peginterferon alfa-2a subcutaneous injection) was added to the list of agents that patient has tried; previously it was just a trial of hydroxyurea.	03/22/2023