**Effective Date** ..... **1/15/2024**
**Next Review Date…** ..... **1/15/2025**
**Coverage Policy Number** ..... **IP0318**

# Jakafi (Ruxolitinib) for Non-Oncology Indications

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## Related Coverage Resources

Oncology Medications – (1403)

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## Overview

This policy supports medical necessity review for ruxolitinib tablets (**Jakafi®**) for non-oncology indications.

The use of ruxolitinib for oncology indications are addressed in a separate coverage policy. Please refer to the related coverage policy link above (Oncology Medications - 1403).

Receipt of sample product does not satisfy any criteria requirements for coverage.

## Medical Necessity Criteria

**Ruxolitinib (Jakafi) is considered medically necessary when ONE of the following is met:**

1. **Graft versus Host Disease, Acute.** Individual meets **BOTH** of the following criteria:
   A. Age 12 years or older
   B. Documentation of failure, contraindication, or intolerance to **ONE** systemic corticosteroid
2. **Graft versus Host Disease, Chronic.** Individual meets **BOTH** of the following criteria:

A. Age 12 years or older
B. Documentation of failure, contraindication, or intolerance to **ONE** conventional systemic treatment for graft versus host disease (for example, systemic corticosteroids [methylprednisolone, prednisone], cyclosporine, tacrolimus, mycophenolate mofetil, Imbruvica [ibrutinib capsules/tablets), or imatinib)

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When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

## Reauthorization Criteria

Continuation of ruxolitinib (Jakafi) is considered medically necessary for graft versus host disease when the above medical necessity criteria have been met AND there is documentation of beneficial response.

## Authorization Duration

Initial approval duration: up to 12 months.
Reauthorization approval duration: up to 12 months.

## Conditions Not Covered

Ruxolitinib (Jakafi) use for any other non-oncology indication is considered experimental, investigational or unproven.

## Background

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.

## 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.