BlueCross BlueShield
Federal Employee Program
Federal Employee Program®
750 9th St NW
Washington, D.C. 20001
202.942.1000
Fax 202.942.1125

5.21.018

Section:	Prescription Drugs	**Effective Date:**	April 1, 2024
Subsection:	Antineoplastic Agents	**Original Policy Date:**	June 7, 2012
Subject:	Jakafi	**Page:**	1 of 6

Last Review Date: March 8, 2024

Jakafi

Description

Jakafi (ruxolitinib)

Background

Jakafi (ruxolitinib) is a Janus Associated Kinase (JAK) 1 and 2 inhibitor indicated for the treatment of intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis, and post-essential thrombocythemia myelofibrosis. It is also indicated in patients with polycythemia vera who have had an inadequate response to or are intolerant of hydroxyurea, and for the treatment of chronic graft-versus-host disease and steroid-refractory acute graft-versus-host disease. JAK1 and JAK2 mediate the signaling of a number of cytokines and growth factors that are important in hematopoiesis and immune function. Myelofibrosis (MF) and polycythemia vera (PV) are myeloproliferative neoplasms (MPN) known to be associated with dysregulated JAK1 and JAK2 signaling. Inhibition of this overactivity results in a decrease in the inflammatory cytokine signaling and a decrease in overproduction of cells. JAK signaling involves recruitment of signal transducers and activators of transcription (STATs) to cytokine receptors, activation, and subsequent localization of STATs to the nucleus leading to modulation of gene expression. JAK-STAT signaling pathways play a role in regulating the development, proliferation, and activation of several immune cell types important for graft-versus-host disease GVHD pathogenesis (1).

Regulatory Status

FDA-approved indications: Jakafi is a kinase inhibitor indicated for treatment of: (1)

- Intermediate or high-risk myelofibrosis, 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.
- Steroid-refractory acute graft-versus-host disease (GVHD) in adult and pediatric patients 12 years and older.
- Chronic graft-versus-host disease after failure of one or two lines of systemic therapy in adult and pediatric patients 12 years and older.

Treatment with Jakafi can cause thrombocytopenia, anemia, and neutropenia. Thrombocytopenia should be managed by reducing the dose or temporarily interrupting Jakafi. Platelet transfusions may be necessary. Patients developing anemia may require blood transfusions and or dose modifications of Jakafi. A complete blood count (CBC) must be performed before initiating therapy, every 2 to 4 weeks until dose is stabilized, and then as clinically indicated. CBC with differential, palpable spleen length or spleen volume by magnetic resonance imaging (MRI) or computed tomography (CT) should be performed to monitor disease progression. Patients should be assessed for signs and symptoms of infection. Serious infections should have resolved before starting therapy. Lipid elevations have been reported and lipid levels should be assessed 8 to12 weeks from start of therapy and treated as needed (1).

The safety and effectiveness of Jakafi for the treatment of myelofibrosis or polycythemia vera in pediatric patients have not been established. The safety and effectiveness of Jakafi for the treatment of chronic GVHD and steroid-refractory acute GVHD have been established for the treatment of pediatric patients 12 years of age and older (1).

Related policies
Inrebic, Ojjaara, Vonjo

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Jakafi may be considered **medically necessary** if the conditions indicated below are met.

Jakafi may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age and older

Diagnoses

Patient must have **ONE** of the following:

1. Intermediate-risk or high-risk myelofibrosis
2. Primary myelofibrosis
3. Post-polycythemia vera myelofibrosis
4. Post-essential thrombocythemia myelofibrosis
5. Polycythemia vera
    a. Inadequate treatment response to or intolerance to hydroxyurea

AND ALL of the following:

a. **NO** serious infections
b. Prescriber agrees to monitor CBC, platelet counts
c. Prescriber agrees to assess lipid levels 8 to12 weeks from start of therapy and treat it as needed
d. Prescriber will not exceed the FDA labeled dose of 50 mg/day

Age 12 years of age and older

Diagnoses

Patient must have **ONE** of the following:

1. Acute graft-versus-host disease (GVHD) in allogeneic hematopoietic stem cell transplantation (allo-HCT)
    a. Inadequate treatment response or intolerance to corticosteroid therapy
2. Chronic graft-versus-host disease (GVHD)
    a. Failure of one or two lines of systemic therapy

AND ALL of the following:

a. **NO** serious infections
b. Prescriber agrees to monitor CBC and platelet counts
c. Prescriber agrees to assess lipid levels 8 to 12 weeks from start of therapy and treat it as needed
d. Prescriber will not exceed the FDA labeled dose of 20 mg/day

Prior – Approval *Renewal* Requirements

Age 18 years of age and older

Diagnoses

Patient must have **ONE** of the following:

1. Intermediate-risk or high-risk myelofibrosis
2. Primary myelofibrosis
3. Post-polycythemia vera myelofibrosis
4. Post-essential thrombocythemia myelofibrosis
5. Polycythemia vera

AND ALL of the following:

a. A reduction in palpable spleen length, spleen volume and/or symptomatic improvement
b. Prescriber agrees to monitor CBC and platelet counts
c. Prescriber will not exceed the FDA labeled dose of 50 mg/day

Age 12 years of age and older

Diagnoses

Patient must have **ONE** of the following:

1. Graft-versus-host disease (GVHD) in allogeneic hematopoietic stem cell transplantation (allo-HCT)
2. Chronic graft-versus-host disease (GVHD)

AND ALL of the following:

a. Symptomatic improvement
b. Prescriber agrees to monitor CBC and platelet counts
c. Prescriber will not exceed the FDA labeled dose of 20 mg/day

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 6 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Jakafi (ruxolitinib) is a kinase inhibitor indicated for treatment of patients with intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis, post-essential thrombocythemia myelofibrosis, and polycythemia vera in patients who have had an inadequate response to or are intolerant of hydroxyurea. It is also indicated for the treatment of graft-versus-host disease (GVDH). Thrombocytopenia, anemia, and neutropenia can occur and can be managed by dose reduction, or interruption or transfusion. The safety and effectiveness of Jakafi for the treatment of myelofibrosis or polycythemia vera in pediatric patients have not been established. The safety and effectiveness of Jakafi for the treatment of chronic GVHD and steroid-refractory acute GVHD have been established for the treatment of children 12 years and older (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Jakafi while maintaining optimal therapeutic outcomes.

References

1. Jakafi [package insert]. Wilmington, DE: Incyte Co.; January 2023.
2. NCCN Drugs & Biologics Compendium® Ruxolitinib 2024. National Comprehensive Cancer Network, Inc. Accessed on January 8, 2024.

Policy History

Date	Action
April 2012	New Policy
March 2013	Annual editorial review and reference update
March 2014	Annual review and reference update
December 2014	Addition of new indication polycythemia vera who have had an inadequate response to or are intolerant of hydroxyurea
March 2015	Annual editorial review and reference update
June 2016	Annual editorial review and reference update Policy number changed from 5.04.18 to 5.21.18

June 2017	Annual review and reference update Addition of Graft-versus-host disease (GVHD) in allogeneic hematopoietic stem cell transplantation (allo-HCT)
June 2018	Annual review and reference update
June 2019	Annual review and reference update. Revised indication for GVHD
December 2019	Annual review
June 2020	Annual editorial review and reference update. Addition of PA quantity limit per FEP
April 2021	Removed PA quantity limit. Added attestation question that the prescriber will not exceed the FDA labeled dose and prescriber will monitor CBC and platelet counts
June 2021	Annual review and reference update
October 2021	Addition of indication: chronic graft-versus-host disease
December 2021	Annual review and reference update
March 2022	Annual review and reference update
June 2022	Annual review and reference update
June 2023	Annual review and reference update. Changed policy number to 5.21.018
March 2024	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.