UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Jakafi

Program	Prior Authorization
Medication	Jakafi™ (ruxolitinib)
Markets in Scope	Arizona, California, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	5/2016
Pharmacy and Therapeutics Approval Date	3/2020
Effective Date	5/2020

1. Background:

Jakafi™ (ruxolitinib) is a kinase inhibitor indicated for treatment of patients with intermediate or high-risk myelofibrosis, including primary myelofibrosis (PMF), 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. It is also indicated for the treatment of steroid-refractory acute graft-versus-host disease in adult and pediatric patients 12 years and older.[1]

The National Cancer Comprehensive Network (NCCN) also recommends Jakafi for the treatment of patients with polycythemia vera who have had an inadequate response to interferon therapy.[2]

2. Coverage Criteria:

A. <u>Myelofibrosis</u>

1. **<u>Initial Authorization</u>**

   a. **Jakafi** will be approved based on **<u>one</u>** of the following diagnoses:

      (1) Primary myelofibrosis

      -OR-

      (2) Post-polycythemia vera myelofibrosis

      -OR-

      (3) Post-essential thrombocythemia myelofibrosis

Authorization will be issued for 6 months.

2. **Reauthorization**

a. **Jakafi** will be approved based on the following criteria:

(1) Documentation that patient has evidence of symptom improvement or reduction in spleen volume while on Jakafi

Authorization will be issued for 12 months. NOTE: If documentation does not provide evidence of symptom improvement or reduction in spleen volume while on Jakafi, authorization will be issued for 2 months to allow for dose titration with discontinuation of therapy.

B. Polycythemia vera

1. **Initial Authorization**

a. **Jakafi** will be approved based on **both** of the following:

(1) Diagnosis of polycythemia vera

-AND-

(2) History of failure, inadequate response, contraindication, or intolerance to one of the following:

(a) Hydroxyurea

-OR-

(b) Interferon therapy (e.g., Intron A, Pegasys, PegIntron)

Authorization will be issued for 6 months.

2. **Reauthorization**

a. **Jakafi** will be approved based on the following criteria:

(1) Documentation that patient has evidence of symptom improvement or reduction in spleen volume while on Jakafi

Authorization will be issued for 12 months. NOTE: If documentation does not provide evidence of symptom improvement or reduction in spleen volume while on Jakafi, authorization will be issued for 2 months to allow

for dose titration with discontinuation of therapy.

C. Graft versus host disease (GVHD)

1. **Initial Authorization**

   a. **Jakafi** will be approved based on **both** of the following:

      (1) Diagnosis of GVHD

      -AND-

      (2) Disease is steroid refractory

   Authorization will be issued for 6 months.

2. **Reauthorization**

   a. **Jakafi** will be approved based on the following criterion:

      (1) Documentation that patient has symptom improvement while on Jakafi

   Authorization will be issued for 12 months.

D. NCCN Recommended Regimens

1. Initial Authorization

a. **Jakafi** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Authorization will be issued for 6 months.

2. Reauthorization

a. **Jakafi** will be approved based on the following criterion:

(1) Documentation of positive clinical response to Jakafi therapy

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes

(ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Jakafi [package insert]. Wilmington, DE: Incyte Corporation; January 2020.
2. Ayalew Tefferi and Animesh Pardanani. Brief Report: Serious Adverse Events During Ruxolitinib Treatment Discontinuation in Patients With Myelofibrosis. Mayo Clin Proc. December 2011 86(12):1188-1191.
3. Hill, J, Alousi A, Kebriaei P, et al. New and emerging therapies for acute and chronic graft versus host disease. Ther Adv Hematol. 2018; 9(1):21-46.
4. Zeiser R, Burchert A, Lengerke C, et al. Ruxolitinib in corticosteroid-refractory graft versus host disease after allogeneic stem cell transplantation: a multicenter survey. Leukemia. 2015; 29(10):2062-8.
5. Zeiser R, Blazar BR. Pathophysiology of chronic graft versus host disease and therapeutic target. N Engl J Med. 2017; 377:2565-79.
6. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed February 1, 2019.

Program	Prior Authorization - Jakafi (ruxolitinib)
Change Control	
5/2016	New program
3/2017	Changed all 6 month authorization durations to 12 months. Updated policy template.
5/2017	Changed “criterion” to “criteria” in reauthorization sections
3/2018	Added off-label criteria for management of steroid refractory GVHD based on consultant feedback and review of emerging evidence. Added NCCN recommended review criteria. Updated references.
5/2018	Changed all initial authorization durations to 6 months to align with package insert. Combined 2 month dose taper language into a note per prior authorization team request.
3/2019	Updated background and criteria for polycythemia vera to align with NCCN recommendation. Updated references.
3/2020	Annual review. Updated background and references.