UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Jakafi

Program	Prior Authorization
Medication	Jakafi™ (ruxolitinib)
Issue Date	5/2016
Pharmacy and Therapeutics Approval Date	3/2018
Effective Date	5/2018

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.[1]

2. Coverage Criteria:

A. Myelofibrosis

1. **Initial Authorization**

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

      (1) Primary myelofibrosis

      -OR-

      (2) Post-polycythemia vera myelofibrosis

      -OR-

      (3) Post-essential thrombocythemia myelofibrosis

   Authorization will be issued for 12 months.

2. **Reauthorization**

   a. **Jakafi** will be approved based on **one** of 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.

-OR-

(2) Documentation does not provide evidence of symptom improvement or reduction in spleen volume while on Jakafi, allow for dose titration with discontinuation of therapy[2]

Authorization will be issued for 2 months.

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 hydroxyurea

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Jakafi** will be approved based on **one** of 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.

-OR-

(2) Documentation does not provide evidence of symptom improvement or reduction in spleen volume while on Jakafi, allow for dose titration with discontinuation of therapy[2]

Authorization will be issued for 2 months.

C. Graft versus host disease (GVHD) (off-label)

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 12 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 12 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. References:

1. Jakafi [package insert]. Wilmington, DE: Incyte Corporation; December 2017.
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.

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.