

## Jakafi® (ruxolitinib) (Oral)

Document Number: IC-0073

Last Review Date 06/03/2019

Date of Origin: 03/01/2012

Dates Reviewed: 12/2012, 03/2013, 02/2014, 08/2014, 12/2014, 10/2015, 10/2016, 10/2017, 10/2018, 06/2019

### I. Length of Authorization

Coverage will be provided for six months and may be renewed.

### II. Dosing Limits

#### A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

- 5 mg tablets: 2 tablets per day
- 10 mg tablets: 2 tablets per day
- 15 mg tablets: 2 tablets per day
- 20 mg tablets: 2 tablets per day
- 25 mg tablets: 2 tablets per day

#### B. Max Units (per dose and over time) [Medical Benefit]:

##### Acute GVHD

- 20 mg per day

##### All other indications

- 50 mg per day

### III. Initial Approval Criteria

- Patient is 18 or older (unless otherwise specified); AND
- Patient does not have an active infection, including clinically important localized infections; AND

#### Myelofibrosis (MF) (including primary, post-polycythemia vera and post-essential thrombocythemia MF) †

- Patient has symptomatic low- to intermediate-risk disease ‡ ; OR
- Patient has intermediate to high-risk disease † ; AND
  - Starting platelet count (<30 days old) is  $\geq 50 \times 10^9/L$ ; OR

- Patient has accelerated phase or blast phase/acute myeloid leukemia ‡

#### Polycythemia Vera†

- Patient has had an inadequate response (or intolerance) to a 3 month or longer trial of hydroxyurea † or interferon therapy ‡; **AND**
  - Patient has symptomatic low risk disease with indications for cytoreductive therapy; **OR**
  - Patient has high risk disease

#### Acute Graft Versus Host Disease (aGVHD) †

- Patient age is 12 years or older; **AND**
- Patient has acute, steroid-refractory, grade II-IV disease; **AND**
- Therapy being used for disease related to allogeneic hematopoietic stem cell transplantation

† FDA Approved Indication(s); ‡ Compendia Approved Indication(s)

### IV. Renewal Criteria

Authorizations can be renewed based on the following criteria:

- Patient continues to meet criteria identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include active/severe infections and severe hematologic toxicity (neutropenia, thrombocytopenia, and anemia), de novo neoplasms of the skin, serious infections, etc; **AND**
- **Myelofibrosis:**
  - Treatment response with a decrease in spleen size or improvements in other myelofibrosis symptoms (such as fatigue, bone pain, frequent infections, fever, night sweats, easy bruising/bleeding);
- **Polycythemia Vera:**
  - Treatment response such as hematocrit control and/or spleen volume reduction.
- **aGVHD:**
  - Treatment response such as stabilization or improvement in disease; **AND**
  - In patients who have had a response and have discontinued therapeutic doses of corticosteroids, tapering of Jakafi should be considered

### V. Dosage/Administration

Indication	Dose
Myelofibrosis	<ul style="list-style-type: none"> <li>▪ Platelets &gt;200 X 10<sup>9</sup>/L – Starting dose is 20mg orally twice daily</li> <li>▪ Platelets 100-200 X 10<sup>9</sup>/L –Starting dose is 15mg orally twice daily</li> <li>▪ Platelets 50-100 X 10<sup>9</sup>/L –Starting dose is 5mg orally twice daily</li> </ul>

	<i>Doses may be increased in 5 mg twice daily increments to a maximum of 25 mg twice daily</i>
Polycythemia Vera	10mg orally twice daily. Doses may be titrated based on safety and efficacy up to a maximum of 25 mg twice daily.
aGVHD	<ul style="list-style-type: none"> <li>– Starting dose is 5 mg orally twice daily. Consider increasing the dose to 10 mg twice daily after at least 3 days of treatment if the ANC and platelet counts are not decreased by 50% or more relative to the first day of dosing with Jakafi.</li> <li>– Tapering of Jakafi may be considered after 6 months of treatment in patients with response who have discontinued therapeutic doses of corticosteroids. Taper Jakafi by one dose level approximately every 8 weeks (10 mg twice daily to 5 mg twice daily to 5 mg once daily). If acute GVHD signs or symptoms recur during or after the taper of Jakafi, consider retreatment.</li> </ul>

## VI. Billing Code/Availability Information

### Jcode:

- J8999 – Prescription drug, oral, chemotherapeutic, not otherwise specified

### NDC:

- 5 mg tablets: 50881-0005-xx
- 10 mg tablets: 50881-0010-xx
- 15 mg tablets: 50881-0015-xx
- 20 mg tablets: 50881-0020-xx
- 25 mg tablets: 50881-0025-xx

## VII. References

1. Jakafi [package insert]. Wilmington, DE; Incyte; May 2019. Accessed May 2019.
2. Tefferi A. Primary myelofibrosis: 2013 update on diagnosis, risk-stratification, and management. *Am J Hematol.* 2013 Feb; 88(2):141-50.
3. Reilly JT, McMullin MF, Beer PA, et al. Guideline for the diagnosis and management of myelofibrosis. *Br J Haematol* 2012; 158:453.
4. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) ruxolitinib oral. National Comprehensive Cancer Network, 2019. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed May 2019.

## Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C94.40	Acute panmyelosis with myelofibrosis not having achieved remission

C94.41	Acute panmyelosis with myelofibrosis in remission
C94.42	Acute panmyelosis with myelofibrosis in relapse
C94.6	Myelodysplastic disease, not classified
D45	Polycythemia vera
D47.1	Chronic myeloproliferative disease
D47.4	Osteomyelofibrosis
D75.81	Myelofibrosis
D89.810	Acute graft-versus-host disease

## Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC