Jakafi® (ruxolitinib)
(Oral)

Document Number: IC-0073

Last Review Date 10/30/2018
Date of Origin: 03/01/2012
Dates Reviewed: 12/2012, 03/2013, 02/2014, 8/2014, 12/2014, 10/2015, 10/2016, 10/2017, 10/2018

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]:

- 50 mg per day

III. Initial Approval Criteria

- Patient is 18 or older; **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 ≥ 50 X 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

† 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, 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.

V. Dosage/Administration

Indication	Dose
Myelofibrosis	▪ Platelets >200 X 10^9/L – Starting dose is 20mg orally twice daily ▪ Platelets 100-200 X 10^9/L –Starting dose is 15mg orally twice daily ▪ Platelets 50-100 X 10^9/L –Starting dose is 5mg orally twice daily *Doses may be increased in 5 mg twice daily increments to a maximum of 25 mg twice daily*
Polycythemia Vera	10mg orally twice daily. Doses may be titrated based on safety and efficacy up to a maximum of 25 mg twice daily.

VI. Billing Code/Availability Information

Jcode:

- J8999 – Prescription drug, oral, chemotherapeutic, not otherwise specified
- C9399 – Unclassified drugs or biologicals *(Hospital Outpatient Use ONLY)*

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; December 2017. Accessed September 2018.
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, 2018. 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 September 2018.

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

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)

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
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 Government Benefit Administrators, 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