

PRIOR AUTHORIZATION CRITERIA

BRAND NAME (Generic)	JAKAFI (ruxolitinib)
Status: CVS caremark Criteria	MDC
Type: Initial Prior Authorization	Ref #723-A

FDA-APPROVED INDICATIONS¹

Jakafi is indicated for treatment of patients with intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis and post-essential thrombocythemia myelofibrosis.
 Jakafi is indicated for treatment of patients with polycythemia vera who have had an inadequate response to or are intolerant of hydroxyurea.

<u>CRITERIA FOR APPROVAL</u>		
1	Does the patient have one of following diagnoses: 1) Myelofibrosis, 2) Secondary myelofibrosis due to polycythemia vera (PV), 3) Secondary myelofibrosis due to essential thrombocythemia (ET), 4) Polycythemia vera?	Yes No

Guidelines for Approval	
Duration of Approval	12 months
Set 1	
Yes to question(s)	No to question(s)
1	None

Internal Use Only – Mapping Instructions		
	Yes	No
1.	Approve, 12 months	Deny

RATIONALE

These criteria meet the Medicare Part D definition of a medically accepted indication. This definition includes uses which are approved by the FDA or supported by a citation included, or approved for inclusion, in one of the Medicare approved compendia.

The intent of the criteria is to ensure that patients follow selection elements noted in labeling and/or practice guidelines in order to decrease the potential for inappropriate utilization.

REFERENCE

1. Jakafi [package insert]. Wilmington, DE: Incyte Corporation; March 2016.
2. The NCCN Drugs & Biologics Compendium™ © 2016 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed September 27, 2016.
3. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Myeloproliferative Neoplasms. Version 1.2017. https://www.nccn.org/professionals/physician_gls/PDF/mpn.pdf. Accessed September 27, 2016.

DOCUMENT HISTORY

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Written by: Specialty Clinical Development (AC) 11/2011
Revised: TG 01/2012 (Removed response criteria, extended approval to 12 months), KP 09/2012 (CMS), KP 01/2013, HY 09/2013 (CMS), KF 09/2014 (CMS), IP 12/2014 (label update), 08/2015 (CMS); JP 08/2015, 06/2016 (CMS), TS 08/2016, 09/2016 (new MF NCCN guidelines), 07/2017 (CMS)
Reviewed: CDPR/KP 11/2011, 01/2012, LMS 09/2012; DNC 09/2014, KJC 12/2014, ADA 08/2015, MES 06/2016
External Review: 12/2011, 11/2012, 11/2013, 10/2014, 11/2015, 10/2016