Drug Policy:

Jakafi™ (ruxolitinib)

POLICY NUMBER UM ONC_1242	SUBJECT Jakafi™ (ruxolitinib)		DEPT/PROGRAM UM Dept	PAGE 1 of 3
DATES COMMITTEE REVIEWED 06/16/13, 07/24/14, 12/18/15, 12/21/16, 10/31/17, 11/08/17, 10/10/18, 09/11/19, 12/11/19, 04/08/20, 02/10/21, 04/14/21, 10/13/21, 11/15/21, 02/09/22, 05/11/22, 03/08/23, 03/13/24	APPROVAL DATE March 13, 2024	EFFECTIVE DATE March 29, 2024	COMMITTEE APPROVAL DATES 06/16/13, 07/24/14, 12/18/15, 12/21/16, 10/31/17, 11/08/17, 10/10/18, 09/11/19, 12/11/19, 04/08/20, 02/10/21, 04/14/21, 10/13/21, 11/15/21, 02/09/22, 05/11/22, 03/08/23, 03/13/24	
PRIMARY BUSINESS OWNER: UM		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
NCQA STANDARDS UM 2		ADDITIONAL AREAS OF IMPACT		
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS Commercial, Exchange, Medicaid	

I. PURPOSE

To define and describe the accepted indications for Jakafi (ruxolitinib) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

Evolent is responsible for processing all medication requests from network ordering providers. Medications not authorized by Evolent may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

II. INDICATIONS FOR USE/INCLUSION CRITERIA

A. Continuation requests for a not-approvable medication shall be exempt from this Evolent policy provided:

1. The requested medication was used within the last year, AND
2. The member has not experienced disease progression and/or no intolerance to the requested medication, AND
3. Additional medication(s) are not being added to the continuation request.

B. Myelofibrosis

1. Jakafi (ruxolitinib) will be used as monotherapy in a member with intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis, AND a platelet count greater than or equal to 50 × 10^9/L prior to start of treatment

C. Polycythemia Vera

1. Jakafi (ruxolitinib) will be used as monotherapy in a member with polycythemia vera and has had an inadequate response to or is intolerant to hydroxyurea.

D. Acute Graft-Versus-Host Djsease (aGVHD)

1. Jakafi (ruxolitinib) may be used in adult and pediatric members ≥ 12 years of age with steroid-refractory acute graft-versus-host disease.

E. Chronic Graft-Versus-Host Djsease (cGVHD)

1. Jakafi (ruxolitinib) may be used in adult and pediatric members ≥ 12 years of age with chronic graft-versus-host disease.after failure with one or two lines of systemic treatment.

III. EXCLUSION CRITERIA

A. Disease progression while taking Jakafi (ruxolitinib).

B. Dosing exceeds single dose limit of Jakafi (ruxolitinib) 25 mg (for Myelofibrosis or Polycythemia Vera), or 10 mg (for aGVHD or cGVHD).

C. Treatment exceeds the maximum limit of 60 (5 mg), 60 (10 mg), 60 (15 mg), 60 (20 mg), or 60 (25 mg) tablets/month.

D. Investigational use of Jakafi (ruxolitinib) with an off-label indication that is not sufficient in evidence or is not generally accepted by the medical community. Sufficient evidence that is not supported by CMS recognized compendia or acceptable peer reviewed literature is defined as any of the following:

1. Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.
2. Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
3. Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. Generally, the definitions of Clinically Meaningful outcomes are those recommended by ASCO, e.g., Hazard Ratio of less than 0.80 and the recommended survival benefit for OS and PFS should be at least 3 months.
4. Whether the experimental design, considering the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover).
5. That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs.
6. That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.
7. That abstracts (including meeting abstracts) without the full article from the approved peer-reviewed journals lack supporting clinical evidence for determining accepted uses of drugs.

IV. MEDICATION MANAGEMENT

A. Please refer to the FDA label/package insert for details regarding these topics.

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

A. Verstovsek S, et al. Long-term survival in patients treated with ruxolitinib for myelofibrosis: COMFORT-I and -II pooled analyses. J Hematol Oncol. 2017 Sep 29;10(1):156.

B. Jagasia M, et al. Ruxolitinib for the treatment of steroid-refractory acute GVHD (REACH1): a multicenter, open-label phase 2 trial. Blood. 2020;135(20):1739-1749.

C. Zeiser R, et al. REACH-3 Trial: Ruxolitinib for Glucocorticoid-Refractory Chronic Graft-versus-Host Disease. N Engl J Med 2021; 385:228-238. DOI: 10.1056/NEJMoa2033122

D. Verstovsek S, et al. COMFORT-I Trial. A double-blind, placebo-controlled trial of ruxolitinib for myelofibrosis. N Engl J Med. 2012 Mar 1;366(9):799-807.

E. Vannucchi AM, et al. RESPONSE Trial. Ruxolitinib versus standard therapy for the treatment of polycythemia vera. N Engl J Med. 2015 Jan 29;372(5):426-35.

F. Jakafi prescribing information. Incyte Corporation. Wilmington, DE 2022.

G. Clinical Pharmacology Elsevier Gold Standard 2023.

H. Micromedex® Healthcare Series: Micromedex Drugdex Ann Arbor, Michigan2023.

I. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2023.

J. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs Bethesda, MD 2023.

K. Ellis LM, et al. American Society of Clinical Oncology perspective: Raising the bar for clinical trials by defining clinically meaningful outcomes. J Clin Oncol. 2014 Apr 20;32(12):1277-80.

L. Medicare Benefit Policy Manual Chapter 15 Covered Medical and Other Health Services: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf.