POLICY NUMBER UM ONC_1242	SUBJECT Jakafi™ (ruxolitinib)		DEPT/PROGRAM UM Dept	PAGE 1 OF 2
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	APPROVAL DATE April 8, 2020	EFFECTIVE DATE April 24, 2020	COMMITTEE APPROVAL DATES (latest version listed last) 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	
PRIMARY BUSINESS OWNER: UM APPROVED BY: Dr. Andrew Hertler		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
URAC STANDARDS HUM 1		NCQA STANDARDS UM 2	ADDITIONAL AREAS OF IMPACT	
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS All	

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.

New Century is responsible for processing all medication requests from network ordering providers. Medications not authorized by New Century 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

1. PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:

a. When health plan Medicaid coverage provisions- including any applicable PDLs (Preferred Drug Lists)- conflict with the coverage provisions in this drug policy, health plan Medicaid coverage provisions take precedence per the **Preferred Drug Guidelines OR**

b. When health plan Exchange coverage provisions- including any applicable PDLs (Preferred Drug Lists)- conflict with the coverage provisions in this drug policy, health plan Exchange coverage provisions take precedence per the **Preferred Drug Guidelines OR**

c. For Health Plans that utilize NCH UM Oncology Clinical Policies as the initial clinical criteria, the **Preferred Drug Guidelines shall follow NCH L1 Pathways** when applicable, otherwise shall follow NCH drug policies: http://pathways.newcenturyhealth.com **AND**

d. Continuation requests of previously approved non-preferred medication are not subject to this provision **AND**

e. When available, generic alternatives are preferred over brand-name drugs.

2. Myelofibrosis

a. **NOTE: The preferred agent, per NCH Policies, is Jakafi (ruxolitinib) for all of the following indications,**

b. The member has primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis **AND**

c. The member has splenomegaly and symptoms (i.e. night sweats, itching, abdominal discomfort, pain under ribs on left, feeling of fullness, or muscle/bone pain) **AND**

d. The member has intermediate (2 prognostic factors) or high-risk (3 or more prognostic factors) myelofibrosis. The prognostic factors include the following:

i. Age > 65 years

ii. Hemoglobin < 10 g/l

iii. Leukocyte > 25 × 109/l

iv. Circulating blasts ≥ 1% blasts

v. Platelet count <100 × 109/l

vi. RBC transfusion need

vii. Unfavorable karyotype +8,–7/7q–, i(17q), inv(3), –5/5q–,12p–, 11q23

3. Polycythemia Vera

a. The member has polycythemia vera and have had an inadequate response to or is intolerant to hydroxyurea.

III. EXCLUSION CRITERIA

1. Disease progression while taking Jakafi (ruxolitinib).
2. Member with serious active infections.
3. Dosing exceeds single dose limit of Jakafi (ruxolitinib) 25 mg.
4. Treatment exceeds the maximum limit of 60 (10 mg), (15 mg), (20 mg), or (25 mg) tablets/month.
5. Indications not supported by CMS recognized compendia or acceptable peer reviewed.

IV. MEDICATION MANAGEMENT

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

V. APPROVAL AUTHORITY

1. Review – Utilization Management Department
2. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

None

VII. REFERENCES

1. Jakafi prescribing information. Incyte Corporation. Wilmington, DE. 2019.
2. Clinical Pharmacology Elsevier Gold Standard. 2020.
3. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2020.
4. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2020.
5. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD. 2020.