Clinical Policy: Ruxolitinib (Jakafi)

Reference Number: CP.PHAR.98
Effective Date: 03.01.12
Last Review Date: 02.18
Line of Business: Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Ruxolitinib (Jakafi®) is a kinase inhibitor.

FDA Approved Indication(s)

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;
- For treatment of patients with polycythemia vera who have had an inadequate response to or are intolerant to hydroxyurea.

Policy/Criteria

Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Jakafi is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Myelofibrosis (must meet all)**:**

1. Diagnosis of intermediate or high-risk myelofibrosis (includes primary myelofibrosis, post-polycythemia vera myelofibrosis and post-essential thrombocythemia myelofibrosis);
2. Prescribed by or in consultation with a hematologist or oncologist;
3. Age ≥ 18 years;
4. Dose does not exceed 25 mg twice daily.

Approval duration: 6 months

B. Polycythemia Vera (must meet all)**:**

1. Diagnosis of polycythemia vera;
2. Prescribed by or in consultation with a hematologist or oncologist;
3. Age ≥ 18 years;
4. Failure (i.e., inadequate response) of hydroxyurea unless contraindicated or clinically significant adverse effects are experienced;
5. Dose does not exceed 25 mg twice daily.

Approval duration: 6 months

C. Other diagnoses/indications
1. Refer to CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**
1. Currently receiving medication via Centene benefit or member has previously met all initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 25 mg twice daily.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – CP.PMN.53 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
N/A

Appendix B: Therapeutic Alternatives

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
hydroxyurea (Droxia®, Hydrea®)	Adults: 1000 to 2000 mg PO per day divided into 1 to 3 doses initially. The dose is adjusted as needed to normalize the blood counts of red cells, neutrophils, and platelets.	Individualized.

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: General Information
Examples of positive response to therapy include:
- Myelofibrosis: reduction in spleen size or improvement in symptoms such as pruritus, fatigue, night sweats, bone pain since initiation of therapy;

- Polycythemia vera: reduction in thromboembolic events, spleen size, or phlebotomy requirement, improvement in platelet or white-cell count, or improvement in symptoms such as pruritus, fatigue, or night sweats since initiation of therapy.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Myelofibrosis	5-20 mg PO BID	50 mg/day
Polycythemia vera	10 mg PO BID	50 mg/day

VI. Product Availability

Tablets: 5 mg, 10 mg, 15 mg, 20 mg, 25 mg

VII. References

1. Jakafi Prescribing Information. Wilmington, DE: Incyte Corporation; October 2017. Available at http://www.jakafi.com. Accessed November 2017.
2. Hydroxyurea. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2017. Available at: http://www.clinicalpharmacology-ip.com/.
3. Myeloproliferative neoplasms (Version 2.2018). In: National Comprehensive Cancer Network Guidelines. Available at NCCN.org. Accessed November 2017.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Added new indication for polycythemia vera (PV) throughout policy Added interpretation for all abbreviations addressed in the algorithms Modified safety information to read better Title Jakafi Algorithm was changed to myelofibrosis algorithm Added request for adverse prognostic features Added dosage adjustment questions in Figure 1 For renewal request, added that **current** CBC must be documented; Added the platelet count and TB indications to appendix B Added blood work and infection monitoring to appendix C Added the appendices A, D, E, F,G, H Added tables 2, 3, 4 Added age requirement of ≥ 18 to both algorithms Added dose increase path to Figure 1 (see corresponding new appendix G)	03.01.15	05.15
Policy converted to new template. Myelofibrosis and PV criteria: specialist requirement added; requests for documentation removed; dose titration and drug interaction details removed; max titrated dose added. Myelofibrosis criteria: intermediate- and high-risk diagnostic criteria added per Tefferi and Gangat; symptom improvement/reduction in spleen size informed by PI clinical trials.	03.01.16	04.16

Reviews, Revisions, and Approvals	Date	P&T Approval Date
PV criteria: initial phlebotomy and splenomegaly requirements, and therapeutic response criteria, informed by Vannucchi/PI clinical trials; initial approval period increased to 6 months to allow for response.		
Initial MF criteria: removed requirements related to age and other safety criteria; clarified unfavorable karyotype; added NCCN compendial indications. Initial PV criteria: removed requirements related to age, and other safety criteria. Re-auth MF and PV: removed reasons to discontinue and other safety criteria, added max dose, extended approval duration from 6 months to 12months.	03.01.17	04.17
1Q18 annual review: - Removed request for bloodwork. - Removed NCCN off-label use for myelofibrosis. - References reviewed and updated.	11.22.17	02.18

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.