BOSTON MEDICAL CENTER HEALTHNet PLAN

bmchp.org | 888-566-0008

Pharmacy Medical Necessity Policy

JAK Inhibitors for Myelofibrosis – Unified Formulary

Policy Number: 9.718
Version Number: 2.1
Version Effective Date: 1/1/2022

Product Applicability	☐ **All Plan+ Products**
Well Sense Health Plan ☐ New Hampshire Medicaid	**Boston Medical Center HealthNet Plan** ☒ MassHealth ACO ☒ MassHealth MCO ☐ Qualified Health Plans/ConnectorCare/Employer Choice Direct ☐ Senior Care Options
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit

Note: Disclaimer and audit information is located at the end of this document.

Policy

Reference Table:

Drugs that require PA	No PA
Jakafi® (ruxolitinib)	
Inrebic® (fedratinib)	

Approval Criteria:

Inrebic® (fedratinib)	1. Documented diagnosis of **ONE** of the following: a. Intermediate of high-risk primary myelofibrosis (PMF); **OR** b. Intermediate or high-risk post-polycythemia vera myelofibrosis (post-PV MF); **OR** c. Intermediate or high-risk post-essential thrombocythemia myelofibrosis (post-ET MF) **AND**

	2. Member 18 years of age or older; **AND** 3. Documentation that member has had an inadequate response, adverse reaction, or contraindication to Jakafi® (ruxolitinib) (*Note: Claim history is sufficient*)
Jakafi® (ruxolitinib)	1. Member meets **ONE** of the following: a. Documented diagnosis of acute graft-versus-host disease (aGVHD); **AND** i. Member is 12 years of age or older; **AND** ii. Documentation that member has had an inadequate response, adverse reaction or contraindication to systemic glucocorticoids (*Note: Claims history is NOT sufficient*) **OR** b. Documented diagnosis of **ONE** of the following: i. Intermediate of high-risk primary myelofibrosis (PMF); **OR** ii. Intermediate or high-risk post-polycythemia vera myelofibrosis (post-PV MF); **OR** iii. Intermediate or high-risk post-essential thrombocythemia myelofibrosis (post-ET MF) **OR** c. Documented diagnosis of polycythemia vera (PV); **AND** i. Documentation that member has had an inadequate response or adverse reaction to **ONE** of the following or contraindication to **BOTH** of the following (*Note: Claims history is sufficient*): 1. hydroxyurea 2. Pegasys (peginterferon alfa-2a)
Duration of Initial Authorization:	aGVHD: Prior authorization may be issued for **6 months.** All others: Prior authorization may be issued for **1 year.**

Recertification Approval Criteria:

Recertification Criteria:	1. Appropriate diagnosis for requested drug; **AND** 2. Member has had a positive response to therapy
Duration of Recertification Authorization:	aGVHD: Request can be recertified for up to **6 months.** All others: Request can be recertified for up to **1 year.**

Responsibility and Accountability

Policy History

Original Approval Date	Original Effective Date	Policy Owner	Approved by
12/1/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**
12/1/2020	Created policy for MH Partial Unified Formulary	1/1/2021	P&T Committee
5/13/2021	No criteria or other updates recommended.	9/1/2021	P&T Committee
10/1/2021	MH UPPL Update: Guideline updated with changes for polycythemia vera criteria. The polycythemia vera criteria was updated to allow for trial of hydroxyurea or Pegasys (peginterferon alfa-2a) rather than hydroxyurea specifically	1/1/2022	P&T Committee

Next Review Date

5/2022

Other Applicable Policies

References

1. Inrebic (fedratinib) [prescribing information]. Summit, NJ: Celgene Corporation; August 2019.
2. Jakafi (ruxolitinib) [prescribing information]. Wilmington, Delaware: Incyte Corporation, 2019 May

Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with

.

consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.

.