BOSTON MEDICAL CENTER HEALTHNet PLAN

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Pharmacy Policy

JAK Inhibitors – Unified Formulary

Policy Number: 9.718
Version Number: 2.0
Version Effective Date: 9/1/2021

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

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)	

Procedure:

Approval Diagnosis:	• Acute graft-versus-host disease (aGVHD) • Intermediate or high-risk primary myelofibrosis (PMF) • Intermediate or high-risk post-polycythemia vera myelofibrosis (post-PV MF) • Intermediate or high-risk post-essential thrombocythemia myelofibrosis (post-ET MF) • Polycythemia vera (PV) *Note: Requests for low-risk PMF, post-PV MF, post-ET MF, or chronic Graft-Versus-Host Disease (GVHD) should be reviewed on a case-by-case bases (*See appendix)*

Approval Criteria: **Inrebic®** (fedratinib) *Intermediate or high-risk PMF* *Intermediate or high-risk post-PV MF* *Intermediate or high-risk post-ET MF*	Prescriber provides documentation of **ALL** of the following: 1. Appropriate diagnosis 2. Member ≥18 years of age 3. Inadequate response, adverse reaction, or contraindication to Jakafi® (ruxolitinib) (*Claims are sufficient*) 4. Quantity requested is ≤120 units/30 days
Approval Criteria: **Jakafi®** (ruxolitinib) *aGVHD*	Prescriber provides documentation of **ALL** of the following: 1. Diagnosis of acute graft-versus-host disease (aGVHD)* 2. Age ≥12 years of age 3. Inadequate response, adverse reaction or contraindication to systemic glucocorticoids (*Claims are NOT sufficient*) 4. Quantity requested is ≤60 units/30 days *Notes:* • **Jakafi® (ruxolitinib) is only FDA-approved for the acute subtype of graft-versus-host disease, use in chronic graft-versus-host disease is discussed in the appendix section. If a PA does not specify the type of graft-versus-host disease outreach should be attempted to clarify with the prescribing office and may be taken verbally. The designation of acute or chronic is based on clinical manifestation and therefore, should not be inferred based upon the date of transplant.*
Approval Criteria: **Jakafi®** (ruxolitinib) *Intermediate or high-risk PMF* *Intermediate or high-risk post-PV MF* *Intermediate or high-risk post-ET MF*	Prescriber provides documentation of **ALL** of the following: 1. Appropriate diagnosis 2. Quantity requested is ≤60 units/30 days
Approval Criteria: **Jakafi®** (ruxolitinib) *PV*	Prescriber provides documentation of **ALL** of the following: 1. Appropriate diagnosis 2. Inadequate response, adverse reaction or contraindication to hydroxyurea* (Claims are sufficient) 3. Quantity requested is ≤60 units/30 days *Notes:* • **In polycythemia vera (PV), alkylating agents and interferon alfa are considered alternative treatments to hydroxyurea. If a member has failed one of these agents, a trial with hydroxyurea may be bypassed.*
Denial Criteria:	Cases that do not meet the approval criteria will be denied.

	If a request is denied and the prescriber has additional clinical documentation, a **new** prior authorization request must be submitted.
Duration/Quantity of Authorization:	aGVHD: Prior authorization may be issued for **6 months.** All others: Prior authorization may be issued for **1 year.**
Recertification Criteria:	aGVHD: Resubmission by prescriber will infer a positive response to therapy and request can be recertified for up to **6 months.** All others: Resubmission by prescriber will infer a positive response to therapy and request can be recertified for up to **1 year.**

Appendix:

Stability

Stability on Inrebic® (fedratinib) or Jakafi® (ruxolitinib) for an FDA-approved indication is sufficient rationale to bypass approval criteria.

Grandfathering

Information is not applicable.

Additional Information

Chronic Graft-Versus-Host Disease (GVHD)

Chronic GVHD is a common complication of allogenic hematopoietic stem cell transplant (alloHCT) that typically presents after 100 days post-transplantation. However, classification of chronic or acute GVHD is based on clinical manifestation. Although the choice of initial therapy depends upon several factors, steroids are generally used first-line. For steroid refractory GVHD, adding a calcineurin inhibitor to prednisone is recommended for patients unable or unwilling to participate in a clinical trial. Other treatment options include extracorporeal photopheresis (ECP), psoralen ultraviolet irradiation (PUVA), mycophenolate mofetil, sirolimus, Jakafi® (ruxolitinib), ibrutinib, rituximab, tyrosine kinase inhibitors, ursodeoxycholic acid, and interleukin-2 (IL-2). JAK signaling contributes to inflammation and tissue damage in GVHD via activation of neutrophils; dendritic cell maturation; and T lymphocyte activation, lineage commitment, and survival by signaling through the common gamma chain of interleukins; as such, blockade with a JAK inhibitor such as Jakafi® (ruxolitinib) could reduce chronic GVHD.

Currently, there is an ongoing phase III trial evaluating the safety and efficacy of Jakafi® (ruxolitinib) for the treatment of steroid-refractory chronic GVHD. However, the results of this trial have not yet been published and use in this indication is not FDA-approved.

These requests will be evaluated on a case by case basis, taking into consideration the severity of symptoms and failure of alternative therapies.

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	

Next Review Date

5/2022

Other Applicable Policies

References

Reference to Applicable Laws and Regulations, if Any

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