Inrebic (fedratinib)
Jakafi (ruxolitinib)
Effective 02/01/2023

Plan	☐ MassHealth ☒ MH UPPL ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☒ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit (NLX)		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Specialty Medications**		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions			

Overview

Approval Diagnosis:	• Acute graft-versus-host disease (aGVHD) • Chronic graft-versus-host disease (cGVHD) • 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)

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

Coverage Guidelines

Authorization may be reviewed on a case by case basis for members new to the plan who are currently receiving treatment with the requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs

OR

Authorization may be granted if the member meets all following criteria and documentation has been submitted:

Inrebic® (fedratinib)

1. The member has **ONE** of the following diagnosis:
    a. Intermediate or high-risk primary myelofibrosis (PMF)
    b. Intermediate or high-risk post-polycythemia vera myelofibrosis (post-PV MF)
    c. Intermediate or high-risk post-essential thrombocythemia myelofibrosis (post-ET MF)
2. The member is ≥ 18 years of age
3. Pharmacy claims or physician attestation of inadequate response, adverse reaction, or contraindication to Jakafi® (ruxolitinib)
4. Quantity requested is ≤ 4 units/day

Jakafi® (ruxolitinib)

Graft-versus-host disease

Prescriber provides documentation of **ALL** of the following:

1. Diagnosis of acute graft-versus-host disease (aGVHD) or chronic graft-versus-host disease (cGVHD)
2. Member is ≥ 12 years of age
3. Medical charts documenting inadequate response, adverse reaction or contraindication to systemic glucocorticoids
4. Quantity requested is ≤ 2 units/day

Intermediate or high-risk 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)

Prescriber provides documentation of **ALL** of the following:

1. The member has **ONE** of the following diagnosis*:
    a. Intermediate or high-risk primary myelofibrosis (PMF)
    b. Intermediate or high-risk post-polycythemia vera myelofibrosis (post-PV MF)
    c. Intermediate or high-risk post-essential thrombocythemia myelofibrosis (post-ET MF)
2. Quantity requested is ≤ 2 units/day

** Low-risk myelofibrosis is not an FDA-approved indication; however, the NCCN guideline recommends use of Jakafi® (ruxolitinib) in patients with low-risk myelofibrosis who are symptomatic. Requests for Low-risk myelofibrosis who are symptomatic will be reviewed on a case-by-case basis.*

Polycythemia vera (PV)

Prescriber provides documentation of **ALL** of the following:

1. Diagnosis of polycythemia vera (PV)
2. Pharmacy claims or physician attestation of inadequate response or adverse reaction to **ONE** or contraindication to **BOTH** of the following*:
    a. hydroxyurea
    b. Pegasys (peginterferon alfa-2a)
3. Quantity requested is ≤ 2 units/day

**If prescriber documents a trial with busulfan, refer to appendix.*

Continuation of Therapy

Reauthorization by physician will infer positive response to therapy.

Limitations

1. Initial approvals will be granted for:
    a. aGVHD and cGVHD: 6 months
    b. All other diagnosis: 12 months
2. Reauthorizations will be granted for:
    a. aGVHD and cGVHD: 6 months
    b. All other diagnosis: 12 months
3. The following quantity limits apply:

Inrebic 100mg	120 capsules per 30 days
Jakafi 5mg, 10mg, 15mg, 20mg, and 25mg	60 tablets per 30 days

Appendix

Alternative trials for polycythemia vera

If the prescriber documents a trial with busulfan or if the member has claims for busulfan within the past year, it may be considered to meet low-cost alternative (LCA) trial. Requests for Jakafi for polycuthemia vera will be reviewed on a case-by-case basis of when the trial occurred, what other agents have been tried, etc.

References

1. Inrebic (fedratinib) [prescribing information]. Summit, NJ: Celgene Corporation; August 2019.
2. Jakafi (ruxolitinib) [prescribing information]. Wilmington, DE: Incyte Corporation; September 2021.

Review History

05/20/2020 – Reviewed and approved May P&T. Effective 07/01/20
09/30/2020 – Updated criteria to be in compliance with Masshealth partial unified formulary requirements; removed medical records and testing requirements, added inadequate response, adverse reaction, contraindication to Jakafi, removed baseline platelet count, removed documentation of 35% reduction in spleen volume from recertification criteria and changed initial approval term to 12 months. Split criteria from COMM line of business.
11/17/2021 – Reviewed and Updated for Nov P&T; added Jakafi to criteria to match MH UPPL. The polycythemia vera criteria was updated to allow for trial of hydroxyurea or Pegasys (peginterferon alfa-2a). Effective 01/01/2022
03/16/2022 – Reviewed and Updated for March P&T; Guideline updated to reflect new criteria for Jakafi for cGVHD. Removed appendix for cGVHD. Effective 05/01/2022
11/16/2022 – Reviewed and updated for Nov P&T. Matched MH UPPL. Appendix added for polycythemia vera criteria for Jakafi. Effective 02/1/23.

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