UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 3133-6
Program	Step Therapy
Medication	Inrebic® (fedratinib)
P&T Approval Date	1/2020, 4/2020, 4/2021, 4/2022, 4/2023, 4/2024
Effective Date	7/1/2024

1. Background:

Step Therapy programs are utilized to encourage the use of lower cost alternatives for certain therapeutic classes. This program requires a patient trial of or contraindication to Jakafi® (ruxolitinib) before providing coverage for Inrebic (fedratinib) for the treatment of adult patients with intermediate-2, high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis (MF), or accelerated/blast phase myeloproliferative neoplasm.

Inrebic is a kinase inhibitor indicated for the treatment of adult patients with intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis (MF).[1]

Jakafi (ruxolitinib) is a kinase inhibitor indicated for treatment of patients with intermediate or high-risk myelofibrosis, including primary myelofibrosis (PMF), post-polycythemia vera myelofibrosis and post-essential thrombocythemia myelofibrosis. It is also indicated in patients with polycythemia vera who have had an inadequate response to or are intolerant of hydroxyurea; steroid-refractory acute graft-versus-host disease in adult and pediatric patients 12 years and older; and chronic graft-versus-host disease after failure of one or two lines of systemic therapy in adult and pediatric patients 12 years and older.[2]

In addition, the National Cancer Comprehensive Network (NCCN) also recommends the use of Inrebic or Jakafi for the treatment of accelerated/blast phase myeloproliferative neoplasms.[3]

Members currently on Inrebic therapy as documented in claims history will be allowed to continue on their current therapy. Members new to therapy will be required to meet the coverage criteria below.

Coverage Information:
Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. Coverage Criteria [a,b]:

A. <u>Patients less than 19 years of age</u>

1. **Inrebic** will be approved based on the following criterion:

a. Patient is less than 19 years of age

Authorization will be issued for 12 months.

B. Myelofibrosis/Myeloproliferative Neoplasm

1. **Inrebic** will be approved based on **both** of the following:

a. Diagnosis of **one** of the following;

(1) Primary myelofibrosis

-OR-

(2) Post-polycythemia vera myelofibrosis

-OR-

(3) Post-essential thrombocythemia myelofibrosis

-OR-

(4) Accelerated/blast phase myeloproliferative neoplasm

-AND-

b. **One** of the following:

(1) History of failure, contraindication, or intolerance to Jakafi (ruxolitinib)

-OR-

(2) **Both** of the following:

(a) As continuation of therapy

-AND-

(b) Patient has **not** received a manufacturer supplied sample at no cost in prescriber office, or any form of assistance from the Celgene sponsored Celgene Patient Support® program (e.g. sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Inrebic*

* Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from Celgene sponsored Celgene Patient Support® program shall be required to meet initial authorization criteria as if patient were new to therapy.

C. **Other Indications**

1. **Inrebic** will be approved

   Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.
[b] Coverage of oncology medications may be approved based on state mandates.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits and/or Notification may be in place.
- Coverage of oncology medications may be approved based on state mandates.

4. References:

1. Inrebic [package insert]. Summit, NJ: Celgene Corporation. May 2023.
2. Jakafi [package insert]. Wilmington, DE: Incyte Corporation; January 2023.
3. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at https://www.nccn.org/professionals/drug_compendium/content/ Accessed March 5, 2024.

Program	Step Therapy - Inrebic
Change Control	
1/2020	New program.
4/2020	Updated formatting without change to clinical intent.
4/2021	Annual review without change to clinical intent. Updated background and references.
4/2022	Annual review with no change to clinical criteria. Updated background and references. Updated oncology medications state mandate note.
4/2023	Annual review. Updated references.
4/2024	Annual review. Updated background to include NCCN recommendations. Updated coverage criteria to include diagnosis of accelerated/blast phase myeloproliferative neoplasm. Updated references.