UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2021 P 1294-3
Program	Prior Authorization/Notification
Medication	Inrebic® (fedratinib)
P&T Approval Date	10/2019, 10/2020, 10/2021
Effective Date	2/1/2022; Oxford only: 2/1/2022

1. Background:

Inrebic (fedratinib) 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).

The National Cancer Comprehensive Network (NCCN) also recommends Inrebic for the treatment of myeloid/lymphoid neoplasms with eosinophilia and JAK2 rearrangement.

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. Patients less than 19 years of age

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

1. **Initial Authorization**

   a. **Inrebic** will be approved based on **one** of the following diagnoses:

      (1) Primary myelofibrosis

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-OR-

(2) Post-polycythemia vera myelofibrosis

-OR-

(3) Post-essential thrombocythemia myelofibrosis

Authorization will be issued for 12 months.

2. Reauthorization

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

(1) Documentation that patient has evidence of symptom improvement or reduction in spleen volume while on Inrebic

Authorization will be issued for 12 months.

C. Myeloid/Lymphoid Neoplasms

1. **Initial Authorization**

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

(1) Diagnosis of lymphoid, myeloid, or mixed lineage neoplasms with eosinophilia

-AND-

(2) Patient has a JAK2 rearrangement

Authorization will be issued for 12 months.

2. Reauthorization

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

(1) Patient does not show evidence of progressive disease while on **Inrebic** therapy.

Authorization will be issued for 12 months.

D. NCCN Recommended Regimens

The drug has been recognized for treatment of the cancer indication by The National

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Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

Authorization will be issued for 12 months.

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 may be in place.

4. References:

1. Inrebic [package insert]. Summit, NJ: Celgene Corporation. August 2019.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at https://www.nccn.org/professionals/drug_compendium/content/ Accessed August 19, 2021

Program	Prior Authorization/Notification – Inrebic (fedratinib)
Change Control	
10/2019	New program.
10/2020	Annual review. Updated background and coverage criteria to include NCCN recommended use in myeloid/lymphoid neoplasms. Updated references.
10/2021	Annual review with no change to clinical coverage criteria.

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