

Clinical Pharmacy Program Guidelines for Inrebic

Program	Prior Authorization
Medications	Inrebic [®] (fedratinib)
Markets in Scope	Arizona, California, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	10/2019
Pharmacy and Therapeutics Approval Date	10/2020
Effective Date	12/2020

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.

2. Coverage Criteria:

<p>A. <u>Myelofibrosis</u></p> <p>1. <u>Initial Authorization</u></p> <p style="margin-left: 20px;">a. Inrebic will be approved based on <u>one</u> of the following diagnoses:</p> <p style="margin-left: 40px;">(1) Primary myelofibrosis</p> <p style="margin-left: 100px; text-align: center;">-OR-</p> <p style="margin-left: 40px;">(2) Post-polycythemia vera myelofibrosis</p> <p style="margin-left: 100px; text-align: center;">-OR-</p> <p style="margin-left: 40px;">(3) Post-essential thrombocythemia myelofibrosis</p> <p style="margin-left: 20px;">Authorization will be issued for 12 months.</p> <p>2. <u>Reauthorization</u></p>
--

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.

B. NCCN Recommended Regimens

1. Initial Authorization

a. **Inrebic** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Authorization will be issued for 12 months.

2. Reauthorization

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

(1) Documentation of positive clinical response to Inrebic therapy.

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 28, 2020

Program	Prior Authorization Inrebic
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. Added Additional Clinical Rules section.