UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

| Program Number | 2020 P 3133-2 |
|---|---|
| Program | Step Therapy |
| Medication | Inrebic® (fedratinib) |
| P&T Approval Date | 1/2020, 4/2020 |
| Effective Date | 7/1/2020;<br>Oxford only: 7/1/2020 |

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 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis (MF).

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.[2]

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.

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**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. <u>Myelofibrosis</u>**

1. **Inrebic** will be approved based on **<u>both</u>** of the following:

   a. Diagnosis of **<u>one</u>** of the following;

      (1) Primary myelofibrosis

      **-OR-**

      (2) Post-polycythemia vera myelofibrosis

      **-OR-**

      (3) Post-essential thrombocythemia myelofibrosis

   **-AND-**

   b. **<u>One</u>** of the following:

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

      **-OR-**

      (2) **<u>Both</u>** of the following:

         (a) As continuation of therapy

         **-AND-**

         (b) Patient has **<u>not</u>** 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*

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* 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 used to treat stage four advanced metastatic cancer 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 used to treat stage IV advanced metastatic cancer may be approved based on state mandates.

**4. References:**


1. Inrebic [package insert]. Summit, NJ: Celgene Corporation. August 2019.
2. Jakafi [package insert]. Wilmington, DE: Incyte Corporation; October 2018
3. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp Accessed December 6, 2019.


| Program | Step Therapy - Inrebic |
|---|---|
| **Change Control** | |
| 1/2020 | New program. |
| 4/2020 | Updated formatting without change to clinical intent. |

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