

POLICY NUMBER UM_ONC_1366	SUBJECT Inrebic™ (fedratinib)	DEPT/PROGRAM UM Dept	PAGE 1 OF 2
DATES COMMITTEE REVIEWED 09/11/19, 12/11/19, 04/08/20	APPROVAL DATE April 8, 2020	EFFECTIVE DATE April 24, 2020	COMMITTEE APPROVAL DATES (latest version listed last) 09/11/19, 12/11/19, 04/08/20
PRIMARY BUSINESS OWNER: UM APPROVED BY: Dr. Andrew Hertler	COMMITTEE/BOARD APPROVAL Utilization Management Committee		
URAC STANDARDS HUM 1	NCQA STANDARDS UM 2	ADDITIONAL AREAS OF IMPACT	
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS	APPLICABLE LINES OF BUSINESS All	

## I. PURPOSE

To define and describe the accepted indications for Inrebic (fedratinib) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

New Century is responsible for processing all medication requests from network ordering providers. Medications not authorized by New Century may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

## II. INDICATIONS FOR USE/INCLUSION CRITERIA

### 1. PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:

- When health plan Medicaid coverage provisions- including any applicable PDLs (Preferred Drug Lists)- conflict with the coverage provisions in this drug policy, health plan Medicaid coverage provisions take precedence per the **Preferred Drug Guidelines OR**
- When health plan Exchange coverage provisions- including any applicable PDLs (Preferred Drug Lists)- conflict with the coverage provisions in this drug policy, health plan Exchange coverage provisions take precedence per the **Preferred Drug Guidelines OR**
- For Health Plans that utilize NCH UM Oncology Clinical Policies as the initial clinical criteria, the **Preferred Drug Guidelines shall follow NCH L1 Pathways** when applicable, otherwise shall follow NCH drug policies: **Error! Hyperlink reference not valid.AND**
- Continuation requests of previously approved non-preferred medication are not subject to this provision **AND**
- When available, generic alternatives are preferred over brand-name drugs.

### 2. Myelofibrosis (MF)

- The member has primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis **AND**
- The member has splenomegaly **AND**
- The member has intermediate (2 prognostic factors) or high-risk (3 or more prognostic factors) myelofibrosis. The prognostic factors include the following:
  - Age > 65 years



- ii. Hemoglobin < 10 g/l
- iii. Leukocyte > 25 x 10<sup>9</sup>/l
- iv. Circulating blasts ≥ 1% blasts
- v. Platelet count < 100 x 10<sup>9</sup>/l
- vi. RBC transfusion need
- vii. Unfavorable karyotype +8, -7/7q-, i(17q), inv(3), -5/5q-, 12p-, 11q23

**AND**

- d. The member has failed prior therapy with Jakafi (ruxolitinib).

### **III. EXCLUSION CRITERIA**

- 1. Inrebic (fedratinib) use after disease progression with the same regimen.
- 2. Concurrent use with another Janus Kinase 2 (JAK2) inhibitor (e.g., Ruxolitinib).
- 3. Dosing exceeds single dose limit of Inrebic (fedratinib) 400 mg.
- 4. Treatment exceeds the maximum limit of 30 (400 mg) tablets/month.
- 5. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

#### **I. MEDICATION MANAGEMENT**

Please refer to the FDA label/package insert for details regarding these topics.

#### **II. APPROVAL AUTHORITY**

- 1. Review – UM Department
- 2. Final Approval – UM Committee

#### **III. ATTACHMENTS**

None

#### **IV. REFERENCES**

- 1. Inrebic PI prescribing information. Celgene Corporation. Summit, NJ 2019.
- 2. Clinical Pharmacology Elsevier Gold Standard. 2020.
- 3. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2020.
- 4. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2020.
- 5. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD. 2020.