Inrebic® (fedratinib)
(Oral)

Document Number: IH-0492

Last Review Date 09/03/2019
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I. Length of Authorization

Coverage will be provided for six months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

- 100 mg capsule: 4 capsules per day

B. Max Units (per dose and over time) [Medical Benefit]:

- 400 mg per day

III. Initial Approval Criteria

- Patient must have tried and failed treatment with Jakafi or a contraindication exists; **AND**

- Patient is 18 years or older; **AND**
- Patient has adequate thiamine (vitamin B1) levels as evidenced by baseline testing prior to initiation of therapy; **AND**
- Patient has had a baseline amylase and lipase level tested prior to initiation of therapy; **AND**
- Therapy will not be used with other JAK2-inhibitor type drugs (i.e., ruxolitinib); **AND**
- Therapy will not be used in combination with other systemic chemotherapy (e.g., hydroxyurea, lenalidomide, thalidomide, azacitidine, etc.); **AND**
- Patient will avoid concomitant use with the following drugs:
  - Moderate and strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.); **OR**
  - Dual CYP3A4 and CYP2C19 inhibitors (e.g., ketoconazole, etc.); **AND**

Myelofibrosis (MF) (including primary, post-polycythemia vera and post-essential thrombocythemia MF) †

- Patient has intermediate-2 or high-risk disease† ; **AND**

- Patient has a baseline platelet count (<30 days old) is ≥ 50 X 10^9/L; **AND**
- Patient has palpable splenomegaly (i.e. at least 5 cm below costal margin)

† FDA Approved Indication(s); ‡ Compendia Approved Indication(s)

IV. Renewal Criteria

Authorizations can be renewed based on the following criteria:

- Patient continues to meet criteria identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include severe hematologic toxicity (thrombocytopenia and anemia), hepatotoxicity, severe nausea/vomiting/diarrhea, amylase/lipase elevations etc.; **AND**
- **Myelofibrosis:**
  - Treatment response with a decrease in spleen size or improvements in other myelofibrosis symptoms (such as fatigue, bone pain, frequent infections, fever, night sweats, easy bruising/bleeding, etc.)

V. Dosage/Administration

Indication	Dose
Myelofibrosis	The recommended dosage of Inrebic is 400 mg taken orally once daily for patients with a baseline platelet count of greater than or equal to 50 x 10^9/L. ▪ Inrebic may be taken with or without food. Administration with a high fat meal may reduce the incidence of nausea and vomiting.

VI. Billing Code/Availability Information

Jcode:

- J8999 – Prescription drug, oral, chemotherapeutic, not otherwise specified

NDC:

- 100 mg capsules: 59572-0720-xx

VII. References

1. Inrebic [package insert]. Summit, NJ; Celgene, Corp.; August 2019. Accessed August 2019.
2. Tefferi A. Primary myelofibrosis: 2013 update on diagnosis, risk-stratification, and management. Am J Hematol. 2013 Feb; 88(2):141-50.
3. Reilly JT, McMullin MF, Beer PA, et al. Guideline for the diagnosis and management of myelofibrosis. Br J Haematol 2012; 158:453.
4. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) fedratinib oral. National Comprehensive Cancer Network, 2019. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most

recent and complete version of the Compendium, go online to NCCN.org. Accessed August 2019.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C94.40	Acute panmyelosis with myelofibrosis not having achieved remission
C94.41	Acute panmyelosis with myelofibrosis in remission
C94.42	Acute panmyelosis with myelofibrosis in relapse
C94.6	Myelodysplastic disease, not classified
D47.1	Chronic myeloproliferative disease
D47.4	Osteomyelofibrosis
D75.81	Myelofibrosis

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC