MEDICAL MUTUAL®

Drug Policy

Policy:	Inrebic (fedratinib)	Annual Review Date: 10/17/2024 Last Revised Date: 10/17/2024

OVERVIEW

Inrebic is a JAK2-selective kinase inhibitor to treat adults with intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis (MF). Inrebic has activity against wild type and mutational activated Janus Associated Kinase 2 (JAK2) and FMS like tyrosine kinase 3 (FLT3). Inrebic has a black box warning for encephalopathy, including Wernicke's encephalopathy. Safety and efficacy has not been established for pediatric patients.

POLICY STATEMENT

This policy involves the use of Inrebic. Prior authorization is recommended for pharmacy benefit coverage of Inrebic. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Inrebic as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Inrebic be prescribed by or in consultation with a physician who specializes in the condition being treated. In order to be considered for coverage, Inrebic must be prescribed by or in consultation with a hematologist or oncologist. All approvals for initial therapy are provided for the initial approval duration noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Inrebic is recommended in those who meet the following criteria:

1. **Myelofibrosis, Intermediate-2 or high-risk, primary or secondary**
   Criteria. *Patient must meet the following criteria (a, b, c, d, and e)*
   a) Patient is 18 years of age or older; AND
   b) Thiamine (vitamin B1) levels and nutritional status will be assessed prior to initiating therapy and periodically during treatment; AND
   c) Baseline platelet count is $\geq 50 \times 10^2$/L; AND
   d) CBC with platelets, creatinine and BUN, hepatic panel, and amylase and lipase will be assessed at baseline and periodically during treatment; AND
   e) Patient is not currently using Jakafi (ruxolitinib) or will discontinue prior to initiation of Inrebic.

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Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year
B) *Extended Approval:* 1 year

OTHER USES WITH SUPPORTIVE EVIDENCE

1. **Patients with another indication that is not listed but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation**
   Criteria. *Prescriber will provide specific diagnosis for documentation. Approve.*

2. **Patient has been started on Inrebic**
   Criteria. *Approve for an indication or condition addressed as an approval in this document.*

Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year
B) *Extended Approval:* 1 year

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Inrebic has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. **Treatment of Alopecia.** Alopecia is considered cosmetic. Cosmetic uses are excluded from coverage in a typical medical or pharmacy plan benefit.

2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or

performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Inrebic® capsules [prescribing information]. Summit, NJ: Celgene; August 2019
2. Harrison CN, Schaap N, Vannucchi AM, et al: Janus kinase-2 inhibitor fedratinib in patients with myelofibrosis previously treated with ruxolitinib (JAKARTA-2): a single-arm, open-label, non-randomized, phase 2, multicenter study. Lancet Haematol 2017; 4(7):e317-e324
3. Fedratininb In: DRUGDEX [online database]. Truven Health Analytics. Greenwood Village, CO. Last updated 26 August 2019. Accessed 06 September 2019.