

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Inrebic Prior Authorization Policy

- Inrebic® (fedratinib capsules – Celgene)

REVIEW DATE: 06/26/2024

OVERVIEW

Inrebic, a Janus Associated Kinase 2 (*JAK2*)-selective kinase inhibitor, is indicated for the treatment of **intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis** in adults.¹

Guidelines

Inrebic is discussed in guidelines from the National Comprehensive Cancer Network (NCCN):

- **Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Gene Fusions:** NCCN guidelines (version 2.2024 – June 19, 2024) recommend Inrebic for treatment of myeloid/lymphoid neoplasms with eosinophilia and *JAK2* rearrangement in chronic phase or blast phase (category 2A).² The guidelines also recommend Inrebic for treatment in combination with acute lymphocytic leukemia or acute myeloid leukemia-type induction chemotherapy followed by allogeneic hematopoietic stem cell transplantation (if eligible) for lymphoid, myeloid, or mixed phenotype neoplasms with eosinophilia and *JAK2* rearrangement in blast phase (category 2A).²
- **Myeloproliferative Neoplasms:** NCCN guidelines (version 1.2024 – December 21, 2023) recommend Inrebic for higher-risk patients with myelofibrosis and a platelet count $\geq 50 \times 10^9/L$ (category 1) who are not transplant candidates or transplant is not currently feasible and for patients who did not have a response or lost response to Jakafi® (ruxolitinib tablets), Ojjaara (mometinib tablets), or Vonjo® (pacritinib capsule) [category 2A].^{3,4} Inrebic is also recommended for accelerated or blast phase myeloproliferative neoplasms as bridging therapy followed by allogeneic hematopoietic stem cell transplant in combination with hypomethylating agents or patients who are not a candidate for a transplant. There is a footnote which states that JAK inhibitors can be used in combination with azacitidine or decitabine for the palliation of splenomegaly or other disease-related symptoms. There are very limited data regarding the use of Inrebic, Ojjaara, or Vonjo with hypomethylating agents.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Inrebic. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

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FDA-Approved Indication

- 1. Myelofibrosis.** Approve for 1 year if the patient meets BOTH of the following (A and B):

Note: Examples of myelofibrosis include primary myelofibrosis, post-polycythemia vera myelofibrosis, and post-essential thrombocythemia myelofibrosis.

- A) Patient is ≥ 18 years of age; AND
- B) Patient has intermediate-2 or high-risk disease.

Other Uses with Supportive Evidence

- 2. Myeloid or Lymphoid Neoplasms.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):

- A) Patient is ≥ 18 years of age; AND
- B) Patient has eosinophilia; AND
- C) The tumor has a Janus Associated Kinase 2 (*JAK2*) rearrangement.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Inrebic is not recommended in the following situations:

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

REFERENCES

1. Inrebic[®] capsules [prescribing information]. Summit, NJ: Celgene; May 2023.
2. The NCCN Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Gene Fusion Clinical Practice Guidelines in Oncology (version 2.2024 – June 19, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org/>. Accessed June 20, 2024.
3. The NCCN Myeloproliferative Neoplasms Clinical Practice Guidelines in Oncology (version 1.2024 – December 21, 2023 © 2023 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on June 20, 2024.
4. The NCCN Drugs and Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org/>. Accessed June 20, 2024. Search term: fedratinib.