PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Inrebic Prior Authorization Policy
- Inrebic® (fedratinib capsules – Celgene)

REVIEW DATE: 10/5/2022

OVERVIEW

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

Guidelines

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

- **Myeloid/lymphoid neoplasms with eosinophilia and tyrosine kinase fusion genes**: NCCN guidelines (version 1.2022 – April 14, 2022) 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 lineage neoplasms with eosinophilia and *JAK2* rearrangement in blast phase (category 2A).[2]
- **Myeloproliferative neoplasms**: NCCN guidelines (version 3.2022 – August 11, 2022) recommend Inrebic for higher-risk patients with a platelet count ≥ 100 x 10^9/L (category 1) who are not transplant candidates and for patients who did not have a response or lost response to Jakafi® (ruxolitinib tablets) [category 2A].[3,4]

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:

FDA-Approved Indication

1. **Myelofibrosis.** Approve for 1 year if the patient meets the following criteria (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 the following criteria (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; December 2021.
2. The NCCN Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes Clinical Practice Guidelines in Oncology (version 1.2022 – April 14, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org/. Accessed October 3, 2022.
3. The NCCN Myeloproliferative Neoplasms Clinical Practice Guidelines in Oncology (version 3.2022 – August 11, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on October 3, 2022.
4. The NCCN Drugs and Biologics Compendium. © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org/. Accessed October 3, 2022. Search term: fedratinib.