PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 08/26/2020

OVERVIEW

Inrebic, a Janus Associated Kinase 2 (JAK2)-selective kinase inhibitor, is indicated for the treatment of adult patients with intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis. Inrebic labeling includes a Boxed Warning regarding risk of encephalopathy, including Wernicke's encephalopathy, and states that thiamine (vitamin B1) levels should be assessed prior to starting Inrebic and periodically during treatment.

Disease Overview

Myelofibrosis, polycythemia vera, and essential thrombocythemia are a group of uncommon heterogeneous disorders involving the hematopoietic system.[2-4] In the US, the prevalence of myelofibrosis, essential thrombocythemia, and polycythemia vera were approximately 13,000, 134,000, and 148,000 cases respectively.[2] It is a cancer that impacts the normal production of red blood cells and involves the replacement of bone marrow by fibrous scare tissue. There is a lack of red blood cells, and an overabundance of white blood cells. The symptom profile in myeloproliferative neoplasms is complex and symptoms vary among the subtype. Patients may experience fatigue, pruritus, weight loss, splenomegaly, and various laboratory abnormalities (e.g., erythrocytosis, thrombocytosis, and leukocytosis). The disease can be slowly progressive and early in the disease process patients may be asymptomatic. However, some patients with this condition may have the disease transform into acute myeloid leukemia which is associated with a poor prognosis. The management of myeloproliferative neoplasms involves identification of specific mutations which guide targeted therapies and have resulted in improvement of disease symptoms. Other treatments are symptom-based.

Guidelines

The National Comprehensive Cancer Network has guidelines regarding myeloproliferative neoplasms (version 1.2020 – May 31, 2020) include Inrebic.[2] Inrebic is recommended for higher risk patients with a platelet count $\geq 10 \times 10^9$/L (category 2B). In this clinical scenario, Jakafi® (ruxolitinib capsules), another kinase inhibitor, has a higher recommendation (category 2A). Inrebic is also recommended in patients who have tried Jakafi with no response or who have loss of response. Jakafi is also recommended among patients with lower-risk myelofibrosis.

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 the following criteria:

FDA-Approved Indications

1. **Myelofibrosis (MF), including Primary MF, Post-Polycythemia Vera MF, and Post-Essential Thrombocythemia MF.** Approve Inrebic for 3 years if the patient has intermediate-2 or high-risk disease.

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; August 2019.
2. The NCCN Myeloproliferative Neoplasms Clinical Practice Guidelines in Oncology (Version 1.2020 – May 21, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on August 23, 2020.
3. Tremblay D, Marcellino B, Mascarenhas J. Pharmacotherapy of myelofibrosis. *Drugs*. 2017;77(14):1549-1563.
4. Vannucchi AM, Guglielmelli P. What are the current treatment approaches for patients with polycythemia vera and essential thrombocythemia? *Hematology Am Soc Hematol Educ Program*. 2017;2017(1):480-488.