Reference number
3161-A

SPECIALTY GUIDELINE MANAGEMENT

INREBIC (fedratinib)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indication
Inrebic 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 (MF).

B. Compendial Uses
1. Treatment for myeloid/lymphoid neoplasms with eosinophilia and JAK2 rearrangement in chronic phase
2. Treatment for myeloid, lymphoid, or mixed lineage neoplasms with eosinophilia and JAK2 rearrangement in blast phase
3. Treatment for myeloproliferative neoplasms in accelerated phase or blast phase
4. Treatment for splenomegaly and other disease-related symptoms of MF-associated anemia

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review: Testing or analysis confirming JAK2 rearrangement (if applicable).

III. CRITERIA FOR INITIAL APPROVAL

A. Myelofibrosis/Myeloproliferative Neoplasms
Authorization of 12 months may be granted for the treatment of intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis (MF), splenomegaly and other disease-related symptoms of MF-associated anemia (e.g., fatigue, weakness, shortness of breath, pale skin), accelerated phase or blast phase myeloproliferative neoplasms.

B. Myeloid/Lymphoid Neoplasms
Authorization of 12 months may be granted for the treatment of myeloid and/or lymphoid neoplasms with eosinophilia and JAK2 rearrangement in the chronic phase or blast phase.

IV. CONTINUATION OF THERAPY

A. Myelofibrosis/Myeloproliferative Neoplasms
Authorization of 12 months may be granted for continued treatment in members requesting reauthorization when there is no evidence of unacceptable toxicity and there has been an improvement in symptoms.

B. Myeloid/Lymphoid Neoplasms
Authorization of 12 months may be granted for continued treatment in members requesting reauthorization when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

V. REFERENCES

1. Inrebic [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; May 2023.
2. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed January 6, 2024.