PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Inrebic Prior Authorization Policy
- Inrebic® (fedratinib capsules – Impact Biomedicines/Bristol-Myers Squibb)

REVIEW DATE: 02/19/2025

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

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).

- **Myeloproliferative Neoplasms**: NCCN guidelines (version 2.2024 – August 8, 2024) recommend Inrebic for higher-risk patients with myelofibrosis and a platelet count ≥ 50 x 10^9/L who are not transplant candidates or transplant is not currently feasible and have symptomatic splenomegaly and/or constitutional symptoms (category 1) and for patients who did not have a response or lost response to Jakafi® (ruxolitinib tablets), Ojjaara (momelotinib tablets), or Vonjo® (pacritinib capsule) [category 2A].[3,4] JAK inhibitors are also recommended for accelerated or blast phase myeloproliferative neoplasms for the palliation of splenomegaly or other disease-related symptoms (category 2A). Some examples of disease-related symptoms of myeloproliferative neoplasms include fatigue, fever, night sweats, weight loss, abdominal discomfort, splenomegaly, thrombocytosis, or leukocytosis.

POLICY STATEMENT

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

- **Inrebic® (fedratinib capsules – Impact Biomedicines/Bristol-Myers Squibb)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indication

1. **Myelofibrosis.** Approve for 1 year if the patient meets BOTH of the following (A and B):
   Note: This includes primary myelofibrosis, post-polycythemia vera myelofibrosis, and post-essential thrombocythemia myelofibrosis.
   A) Patient is ≥ 18 years of age; AND
   B) Patient has higher-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.

3. **Accelerated or Blast Phase Myeloproliferative Neoplasm**. Approve for 1 year if the patient meets BOTH of the following (A and B):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has at least one disease-related symptom.

Note: Examples of disease-related symptoms include: fatigue, fever, night sweats, weight loss, abdominal discomfort, splenomegaly, thrombocytosis, or leukocytosis.

CONDITIONS NOT COVERED

- **Inrebic® (fedratinib capsules – Impact Biomedicines/Bristol-Myers Squibb)**

is(are) considered experimental, investigational or unproven for ANY other use(s) including the following; criteria will be updated as new published data are available

REFERENCES

1. Inrebic® capsules [prescribing information]. Princeton, NJ: Impact Biomedicines/Bristol-Myers Squibb; July 2024.
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 February 6, 2025.
3. The NCCN Myeloproliferative Neoplasms Clinical Practice Guidelines in Oncology (version 2.2024 – August 8, 2024) © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on February 6, 2025.
4. The NCCN Drugs and Biologics Compendium. © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org/. Accessed February 6, 2025. Search term: fedratinib.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	10/11/2023
Annual Revision	No criteria changes.	06/26/2024
Early Annual Revision	**Myelofibrosis:** Criterion which states patient has "intermediate-2 or high-risk disease" was changed to "higher-risk disease." **Accelerated or Blast Phase Myeloproliferative Neoplasm:** Condition of approval and criteria were added to "Other Uses with Supportive Evidence."	02/19/2025