PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 10/11/2023

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. 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**: Guidelines (version 2.2023 – July 14, 2023) 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**: Guidelines (version 2.2023 – August 29, 2023) recommend Inrebic for higher-risk patients with a platelet count ≥ 50 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) or Vonjo® (pacritinib capsule) [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.

Inrebic® (fedratinib capsules – Celgene)
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 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 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 COVERED

Inrebic® (fedratinib capsules – Celgene) is(are) considered experimental, investigational, or unproven for ANY other use(s).

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 2.2023 – July 14, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org/. Accessed October 6, 2023.
3. The NCCN Myeloproliferative Neoplasms Clinical Practice Guidelines in Oncology (version 2.2023 – August 29, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on October 6, 2023.
4. The NCCN Drugs and Biologics Compendium. © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org/. Accessed October 6, 2023. Search term: fedratinib.

HISTORY

Type of Revision	Summary of Changes	Review Date

Annual Revision	**Myelofibrosis:** The wording, "Including Primary MF, Post-Polycythemia Vera MF, and Post-Essential Thrombocythemia MF" was removed from the condition of approval and added as a Note. **Myeloid or Lymphoid Neoplasms:** The requirement of eosinophilia was removed from the condition of approval and added to the criteria. The requirement that the patient has a *JAK2* rearrangement was reworded as "Janus Associated Kinase 2 (*JAK2*) rearrangement."	10/05/2022
Annual Revision	No criteria changes.	10/11/2023