# PRIOR AUTHORIZATION POLICY

**POLICY:** Oncology – Scemblix Prior Authorization Policy
- Scemblix® (asciminib tablets – Novartis)

**REVIEW DATE:** 05/01/2024; selected revision 11/13/2024 and 12/11/2024

***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

Scemblix, a kinase inhibitor, is indicated for the following uses:[1]
- **Chronic myeloid leukemia** (CML), Philadelphia chromosome positive (Ph+), chronic phase, in newly diagnosed adults.
- **CML,** Ph+, chronic phase, in adults previously treated).
- **CML**, Ph+, chronic phase with the T315I mutation in adults.

The indication in newly diagnosed patients is approved under accelerated approval based on major molecular response rate. Continued approval for this indication may be contingent upon verification of clinical benefit in a confirmatory trial.

### Guidelines

Scemblix is discussed in guidelines from National Comprehensive Cancer Network (NCCN):
- **CML:** NCCN guidelines (version 3.2025 – November 27, 2024) state that for patients with chronic phase CML with a low risk score, the recommended "Preferred" primary treatment includes a first-generation TKI (imatinib) [category 1], a second-generation TKI (Bosulif® [bosutinib tablets], Sprycel® [dasatinib tablets], or Tasigna® [nilotinib capsules] {all category 1}), an allosteric TKI (Scemblix [category 1]), or a clinical trial (category 2A).[2] For patients with chronic phase CML with an intermediate or high risk score, a second-generation TKI (Bosulif, Sprycel, or Tasigna [all category 1]) or an allosteric TKI (Scemblix [category 1]) is "Preferred". A first-generation TKI (imatinib) is listed under "Other recommended regimen" (category 2A). Scemblix is recommended under "Useful in certain circumstances" (category 2A)

along with imatinib (if second or third generation TKI is contraindicated) for advanced phase CML. Scemblix is a treatment option for chronic phase CML (Ph+ or BCR-ABL1 positive) in patients with the T315I mutation and/or previously treated chronic phase CML (category 2A). Scemblix is contraindicated for use in patients with the following mutations: A337T, P465S, M244V, and F359V/I/C.

- **Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Gene Fusions:** NCCN guidelines (version 1.2024 – December 21, 2023) recommend Scemblix as "other recommended regimens" for *ALB1* rearrangements in chronic phase or blast phase (category 2A). It is also recommended as treatment in combination with acute lymphoblastic leukemia or acute myeloid leukemia-type induction chemotherapy followed by allogeneic hematopoietic stem cell transplantation (HSCT) [if eligible] for lymphoid, myeloid, or mixed lineage neoplasms with eosinophilia and *ABL1* rearrangement in blast phase (category 2A).

**POLICY STATEMENT**

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

- **Scemblix® (asciminib tablets (Novartis)**

**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. **Chronic Myeloid Leukemia.** 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 Philadelphia chromosome-positive chronic myeloid leukemia; AND
   **C)** Patient meets ONE of the following (i, ii, or iii):
      **i.** Patient has newly diagnosed disease; OR
      **ii.** The chronic myeloid leukemia is T315I-positive; OR
      **iii.** Patient has tried at least one other tyrosine kinase inhibitor indicated for use in Philadelphia chromosome-positive chronic myeloid leukemia.
      Note: Examples of tyrosine kinase inhibitors include imatinib tablets, Bosulif (bosutinib tablets and capsules), Iclusig (ponatinib tablets), Sprycel (dasatinib tablets), and Tasigna (nilotinib capsules).

**Other Uses with Supportive Evidence**

2. **Myeloid/Lymphoid Neoplasms with Eosinophilia.** Approve for 1 year if the patient meets BOTH of the following (A and B):
   **A)** Patient is ≥ 18 years of age; AND
   **B)** The tumor has an *ABL1* rearrangement.

**CONDITIONS NOT COVERED**

- **Scemblix® (asciminib tablets (Novartis)**

**is(are) considered experimental, investigational, or unproven for ANY other use(s).**

**REFERENCES**

1. Scemblix® tablets [prescribing information]. East Hanover, NJ: Novartis; October 2024.
2. The NCCN Chronic Myeloid Leukemia Clinical Practice Guidelines in Oncology (version 3.2025 – November 27, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on December 10, 2024.
3. The NCCN Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Gene Fusions Clinical Practice Guidelines in Oncology (version 1.2024 – December 21, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on April 29, 2024.

**HISTORY**

| Type of Revision | Summary of Changes | Review Date |
|---|---|---|
| Annual Revision | **Myeloid/Lymphoid Neoplasms with Eosinophilia:** This new condition of approval was added to "Other Uses With Supportive Evidence" section based on NCCN guideline recommendations. | 05/31/2023 |
| Annual Revision | No criteria changes. | 05/01/2024 |
| Selected Revision | **Chronic Myeloid Leukemia:** Added new criteria to approve for use in patients with newly diagnosed disease based on FDA approval. | 11/13/2024 |
| Selected Revision | **Chronic Myeloid Leukemia:** The criterion of trial at least two other tyrosine kinase inhibitors indicated for use in Philadelphia chromosome-positive chronic myeloid leukemia was changed to "at least one" other tyrosine kinase inhibitor indicated for use in Philadelphia chromosome-positive chronic myeloid leukemia based on updated labeling and NCCN guideline recommendations. | 12/11/2024 |

NCCN – National Comprehensive Cancer Network