

## 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

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### OVERVIEW

Scemblix, a kinase inhibitor, is indicated for the following uses:<sup>1</sup>

- **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 Tassigna® [nilotinib capsules] {all category 1}), an allosteric TKI (Scemblix [category 1]), or a clinical trial (category 2A).<sup>2</sup> For patients with chronic phase CML with an intermediate or high risk score, a second-generation TKI (Bosulif, Sprycel, or Tassigna [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 *ALBI* 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.

**Automation:** None.

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## RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Scemblix is recommended in those who meet one of the following criteria:

### 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  $\geq 18$  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  $\geq 18$  years of age; AND
  - B) The tumor has an *ABL1* rearrangement.

## CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Scemblix 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. Scemblix<sup>®</sup> 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.
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**HISTORY**

<b>Type of Revision</b>	<b>Summary of Changes</b>	<b>Review Date</b>
Annual Revision	<b>Myeloid/Lymphoid Neoplasms with Eosinophilia:</b> 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	<b>Chronic Myeloid Leukemia:</b> Added new criteria to approve for use in patients with newly diagnosed disease based on FDA approval.	11/13/2024
Selected Revision	<b>Chronic Myeloid Leukemia:</b> 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