Generic Name: Asciminib

Therapeutic Class or Brand Name: Scemblix®

Applicable Drugs (if Therapeutic Class): N/A

Preferred: N/A

Non-preferred: N/A

Date of Origin: 5/23/2022

Date Last Reviewed / Revised 11/18/2024

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through V are met)

I. Documentation of the following diagnosis A & B AND must meet all criteria listed under the applicable diagnosis:

FDA-Approved Indication(s)

A. Philadelphia chromosome-positive chronic myelogenous leukemia (Ph+ CML) in chronic phase (CP)and criteria i-iii are met:

i. Patient meets ONE of the following:

1. Documentation of a T315I mutation.
2. Documentation of trial and failure to, or contraindication to at least two other tyrosine kinase inhibitors (TKIs) indicated to treat Ph+ CML in CP (e.g., ponatinib (Iclusig®), bosutinib (Bosulif®), dasatinib (Sprycel®), imatinib (Gleevec®), nilotinib (Tasinga®).

ii. Documentation that no other tyrosine kinase inhibitor (TKI) therapy is indicated.

II. Documentation of negative BCR-ABL1 kinase domain mutation test results for A337T, P465S, M244V, and F359V/I/C mutations.

Other Uses With Supportive Evidence

III. Myeloid/Lymphoid neoplasms with eosinophilia and criteria i-ii are met:

i. Documentation tumor has an ABL1 gene rearrangement.

ii. Documentation disease is in chronic phase OR blast phase.

IV. Minimum age requirement: 18 years old.

V. Treatment must be prescribed by or in consultation with an oncologist or hematologist.

VI. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

VII. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

Exclusion Criteria

- N/A

Other Criteria

- N/A

Quantity / Days Supply Restrictions

- For patients with Ph+ CML in CP and myeloid/lymphoid neoplasms with eosinophilia: Doses are limited to 80 mg per day.
- For patients with Ph+ CML in CP with a T315I mutation: Doses are limited to 400 mg per day.
- The quantity is limited to a maximum of a 30-day supply per fill.

Approval Length

- **Authorization:** 1 year
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective.

Appendix

N/A

References

1. Scemblix. Prescribing Information. Novartis Pharmaceuticals Corporation; 2024. Accessed September 20,2024 https://www.novartis.com/us-en/sites/novartis_us/files/scemblix.pdf
2. Deeks ED. Asciminib: first approval. *Drugs.* 2022;82(2):219-226. doi:10.1007/s40265-021-01662-3
3. Réa D, Mauro MJ, Boquimpani C, et al. A phase 3, open-label, randomized study of asciminib, a STAMP inhibitor, vs bosutinib in CML after 2 or more prior TKIs. *Blood.* 2021;138(21):2031-2041. doi:10.1182/blood.2020009984
4. NCCN Clinical Practice Guidelines in Oncology. Chronic Myeloid Leukemia V.1.2025. Updated August 8, 2024. Accessed September 20, 2024. https://www.nccn.org/professionals/physician_gls/pdf/cml.pdf
5. NCCN Clinical Practice Guidelines in Oncology. Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Gene Fusions V.2.2024. Updated June 9, 2024. Accessed October 9, 2024. https://www.nccn.org/professionals/physician_gls/pdf/mlne.pdf

to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.