MEDICATION POLICY:
Scemblix®

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: 8/12/2023

Prior Authorization Criteria

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

I. Documented diagnosis of the following condition AND must meet criteria listed under applicable diagnosis:

   A. Philadelphia chromosome-positive chronic myelogenous leukemia (Ph+ CML) in chronic phase (CP) and criterion 1 OR 2 is met:

      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.

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

IV. Minimum age requirement: 18 years old

V. The prescribing physician is an oncologist or a hematologist.

Exclusion Criteria

- N/A

Other Criteria

- N/A

Quantity / Days Supply Restrictions

- For patients with Ph+ CML in CP: 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; 2022. Accessed July 23, 2023. 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.1.2024. Updated August 1, 2023. Accessed August 6, 2023. https://www.nccn.org/professionals/physician_gls/pdf/cml.pdf