PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 05/04/2022; selected revision 06/22/2022

OVERVIEW
Scemblix, a kinase inhibitor, is indicated in adults for the following uses:[1]
- **Chronic myeloid leukemia** (CML), Philadelphia chromosome positive, chronic phase, previously treated with two or more tyrosine kinase inhibitors. This indication is approved under accelerated approval based on major molecular response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).
- **CML**, Philadelphia chromosome positive, chronic phase with the T315I mutation.

Guidelines
Scemblix is discussed in guidelines from National Comprehensive Cancer Network (NCCN):
- **Chronic Myeloid Leukemia (CML):** NCCN guidelines for CML (version 3.2022 – January 27, 2022) state that for patients with chronic phase CML with a low risk score, the primary treatment recommended includes a first-generation TKI (imatinib), or a second-generation TKI (Bosulif® [bosutinib tablets], Sprycel® [dasatinib tablets], or Tasigna® [nilotinib capsules] {all category 1}).[2] For patients with chronic phase CML with an intermediate or high risk score, a second-generation TKI is preferred (Bosulif [category 1], Sprycel [category 1], or Tasigna [category 1]). A first-generation TKI (imatinib) is an alternative (category 2A). Iclusig® (ponatanib tablets) is an option for patients with a T315I mutation and/or chronic phase CML with resistance or intolerance to at least two prior TKIs or for patients with accelerated-phase CML or blast-phase CML for whom no other TKI is indicated (category 2A). Scemblix® (asciminib tablets) is a treatment option for chronic phase CML in patients with the T315I mutation and/or chronic phase CML with resistance or intolerance to at least two prior TKIs (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.

RECOMMENDED AUTHORIZATION CRITERIA
Coverage of Scemblix is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Chronic Myeloid Leukemia.** 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 Philadelphia chromosome-positive chronic myeloid leukemia; AND
   - **C)** Patient meets one of the following (i or ii):
     - **i.** The chronic myeloid leukemia is T315I-positive, OR

ii. Patient has tried at least two other tyrosine kinase inhibitors indicated for use in Philadelphia chromosome-positive chronic myeloid leukemia.
Note: Examples of tyrosine kinase inhibitors include imatinib tablets, Bosulif (bosutinib tablets), Iclusig (ponatinib tablets), Sprycel (dasatinib tablets), and Tasigna (nilotinib capsules).

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® tablets [prescribing information]. East Hanover, NJ: Novartis; October 2021.
2. The NCCN Chronic Myeloid Leukemia Clinical Practice Guidelines in Oncology (version 3.2022 – January 27, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on April 28, 2022.