VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 11/03/2021

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 2.2022 – November 15, 2021) state that Scemblix is a treatment option for chronic phase CML with T315I mutation and/or chronic phase CML with resistance or intolerance at least two prior tyrosine kinase inhibitors.[2] For patients with chronic phase CML with a low-risk score, the primary treatment includes a first-generation tyrosine kinase inhibitor (imatinib [brand or generic]), or a second-generation tyrosine kinase inhibitor (Bosulif® [bosutinib tablets], Sprycel® [dasatinib tablets], or Tasigna® [nilotinib capsules] {all category 1}).[2] For intermediate or high-risk score, the preferred regimen is Bosulif, Sprycel, or Tasigna (category 1); imatinib is listed as other recommended regimen (category 2A).[2] NCCN guidelines also state patients with disease resistant to primary treatment with imatinib should be treated with Bosulif, Sprycel, or Tasigna in the second-line setting, taking into account *BCR-ABL1* mutation status. Patients with disease resistant to primary treatment with Bosulif, Sprycel, or Tasigna can be treated with an alternative tyrosine kinase inhibitor (other than imatinib) in the second-line setting, taking into account *BCR-ABL1* mutation status.[2]

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 Indications

1. **Chronic Myeloid Leukemia (CML).** Approve for 3 years 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 2.2022 – November 15, 2021). © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 4, 2022.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	11/03/2021
Update	**01/04/2022**: NCCN Chronic Myeloid Leukemia (CML) guidelines were updated to include Scemblix and these updates were added to the Overview section.	