



Commercial/Healthcare Exchange PA Criteria Effective: February 10, 2022

Prior Authorization: Scemblix

Products Affected: Scemblix (asciminib) oral tablets

Medication Description: Scemblix, is an ABL/BCR-ABL1 tyrosine kinase inhibitor. Asciminib inhibits the ABL1 kinase activity of the BCR-ABL1 fusion protein, by binding to the ABL myristoyl pocket. In studies conducted in vitro or in animal models of CML, asciminib showed activity against wild-type BCR-ABL1 and several mutant forms of the kinase, including the T315I mutation. It is indicated in adults for the following conditions:

- 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.

Covered Uses: 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.

Exclusion Criteria: N/A

Required Medical Information:

1. Diagnosis
2. Philadelphia chromosome status
3. Previous therapies tried

Prescriber Restriction: Prescribed by, or in consultation with, an oncologist.

Age Restriction: 18 years of age and older

Coverage Duration: 12 months

Other Criteria:

Initial Approval Criteria

1. **Chronic Myeloid Leukemia (CML).** Approve if the patient meets all of the following:
 - A. Patient has Philadelphia chromosome-positive chronic myeloid leukemia; **AND**
 - B. Patient meets one of the following (**i or ii**):
 - i. The chronic myeloid leukemia is T315I-positive, **OR**

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- 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).

Renewal Criteria:

- A. Member has responded positively to the treatment as determined by the prescribing physician; **AND**
- B. Member has not experienced unacceptable toxicity from the drug.

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.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	2/10/2022

