Scemblix (asciminib)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Scemblix (asciminib)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Scemblix (asciminib) may be approved if the following criteria are met:

I. Individual is 18 years of age or older; **AND**
II. Individual has newly diagnosed, low risk, chronic phase (CP) Philadelphia chromosome-positive Chronic Myeloid Leukemia (Ph+CML);

AND

A. Individual has been receiving and is maintained on a stable dose of Scemblix. Medication samples/coupons/discount cards are excluded from consideration as a trial.;

OR

B. Individual has had a trial and inadequate response or intolerance to generic imatinib. Medication samples/coupons/discount cards are excluded from consideration as a trial.;

OR

C. Individual has resistance, contraindication or warning to generic imatinib due to current clinical conditions, including but not limited to pulmonary arterial hypertension, pleural or pericardial effusion, or cardiac abnormalities;

OR

III. Individual has newly diagnosed, intermediate or high risk, chronic phase (CP) Philadelphia chromosome positive Chronic Myeloid Leukemia (Ph+CML) (Label, NCCN 2A);

OR

IV. Individual is using as primary treatment for accelerated phase (AP) chronic myeloid leukemia (CML) (NCCN 2A);

OR

V. Individual is 18 years of age or older; **AND**
VI. Individual has a diagnosis of accelerated phase (AP) or chronic phase (CP) Philadelphia chromosome-positive chronic myeloid leukemia (Ph+CML) (Label, NCCN 2A); **AND**
VII. Individual is using as alternate treatment after prior treatment with asciminib, imatinib, bosutinib, or nilotinib (Label, NCCN 2A);

OR

VIII. Individual is 18 years of age or older; **AND**
IX. Individual has high risk, accelerated (AP) or chronic phase (CP) Philadelphia chromosome positive Chronic Myeloid Leukemia (Ph+CML); **AND**
X. Individual has T315I mutation identified disease (Label);

OR

XI. Individual has a diagnosis of Myeloid/lymphoid Neoplasms with eosinophilia and ABL1 rearrangement (NCCN 2A).

Requests for Scemblix (asciminib) may not be approved when the above criteria are not met and for all other indications

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2025. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Updated Periodically
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2025; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2025 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp.
    a. Chronic Myeloid Leukemia. V3.2025. Revised November 27, 2024.
    b. Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Gene Fusions V2.2024. Revised July 19, 2024.