UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 1374-4
Program	Prior Authorization/Notification
Medication	Scemblix® (asciminib)
P&T Approval Date	12/2021, 12/2022, 12/2023, 12/2024
Effective Date	3/1/2025

1. Background:

Scemblix (asciminib) is a kinase inhibitor indicated for the treatment of adult patients with newly diagnosed Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP), previously treated, or with a T315I mutation.

The National Comprehensive Cancer Network (NCCN) recommends the use of Scemblix for treatment in myeloid/lymphoid neoplasms with eosinophilia and ABL1 rearrangement in chronic phase or blast phase and in CML for accelerated phase as primary treatment.

Coverage Information:
Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. Coverage Criteria[a]:

A. Patients less than 19 years of age

1. **Scemblix** will be approved based on the following criterion:

   a. Patient is less than 19 years of age

   Authorization will be issued for 12 months.

B. Philadelphia Chromosome-Positive Chronic Myeloid Leukemia (Ph+CML)

1. Initial Authorization

a. **Scemblix** will be approved based on **all** the following criteria:

(1) Diagnosis of chronic myeloid leukemia (CML)

- AND –

(2) Disease is Philadelphia chromosome (Ph+) or BCR:ABL1-positive

- AND -

(3) **One** of the following:

(a) Used in newly diagnosed chronic phase CML (CP-CML)

- OR -

(b) Used in previously treated chronic phase CML (CP-CML)

- OR -

(c) Used in chronic phase CML (CP-CML) positive for a T315I mutation

- OR -

(d) Used in accelerated phase CML as primary treatment as a single agent

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Scemblix** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Scemblix therapy

Authorization will be issued for 12 months.

C. Myeloid/Lymphoid Neoplasms with Eosinophilia and ABL1 Gene Rearrangement

1. **Initial Authorization**

a. **Scemblix** will be approved based on **both** of the following criteria:

(1) Diagnosis of myeloid/lymphoid neoplasm with eosinophilia and ABL1 rearrangement

- AND -

(2) Disease is in chronic or blast phase

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Scemblix** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Scemblix therapy

Authorization will be issued for 12 months.

D. NCCN Recommended Regimens

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits and/or step therapy may be in place.

4. References:

1. Scemblix [package insert]. East Hanover, New Jersey: Novartis Pharmaceuticals Corporation. October 2024.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed on October 24, 2024.

Program	Prior Authorization/Notification – Scemblix (asciminib)
Change Control	
12/2021	New program.
12/2022	Annual review. Added state mandate and updated references.
12/2023	Annual review. Added criteria for Myeloid/Lymphoid Neoplasms with Eosinophilia and ABL1 Gene Rearrangement. Updated references.
12/2024	Annual review. Updated CML criteria per NCCN guidelines and new expanded indication. Updated background and references.