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Section:	Prescription Drugs	**Effective Date:**	April 1, 2025
Subsection:	Antineoplastic Agents	**Original Policy Date:**	November 19, 2021
Subject:	Scemblix	**Page:**	1 of 5

Last Review Date: March 7, 2025

Scemblix

Description

Scemblix (asciminib)

Background
Scemblix (asciminib) is an anticancer medicine that targets the BCR-ABL tyrosine kinase. The BCR-ABL tyrosine kinase (also called the Philadelphia chromosome) is found in most patients with chronic myelogenous leukemia (CML). The protein coded by the Philadelphia chromosome promotes a variety of pathways that lead to cellular proliferation of immune cells and prevent their destruction through apoptosis (programmed cell death), which can ultimately lead to cancerous changes. Scemblix specifically targets this BCR-ABL protein product and limits the oncologic changes by blocking its function (1-2).

Regulatory Status
FDA-approved indications: Scemblix is a kinase inhibitor indicated for the treatment of adult patients with: (1)

- Newly diagnosed Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP).
- Previously treated Ph+ CML in CP.
- Ph+ CML in CP with the T315I mutation.

Scemblix can cause myelosuppression, pancreatic toxicity, hypertension, cardiovascular toxicity, and embryo-fetal toxicity. Patients should be monitored for thrombocytopenia and neutropenia with complete blood counts regularly. Additionally, serum lipase and amylase should be monitored, and pancreatitis evaluated if abdominal symptoms are also present. Blood pressure should be monitored, and hypertension managed as clinically indicated. In all cases of

toxicity or blood pressure elevation, the dose should be reduced, or treatment discontinued as appropriate. Females of reproductive potential should have their pregnancy status verified prior to starting treatment and should be advised to use effective contraception during treatment with Scemblix and for 1 week after the last dose (1).

The safety and effectiveness of Scemblix in pediatric patients have not been established (1).

Related policies
Bosulif, Gleevec, Iclusig, Sprycel, Tasigna

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Scemblix may be considered **medically necessary** if the conditions indicated below are met.

Scemblix may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

1. Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase

AND ONE of the following:

1. Patient has T315I mutation
2. Newly diagnosed CML
3. Previously treated CML

AND the following:

1. Females of reproductive potential **only**: pregnancy status will be verified prior to starting treatment and patient will be advised to use effective contraception during treatment with Scemblix and for 1 week after the last dose

Prior–Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have **ONE** of the following:

1. Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase **without** T315I mutation
2. Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase **with** T315I mutation

AND the following:

1. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Scemblix and for 1 week after the last dose

Policy Guidelines

Pre–PA Allowance

None

Prior–Approval Limits

Quantity

Diagnosis	Quantity Limit
Ph+ CML **without** T315I mutation	80 mg per day **OR**
Ph+ CML **with** T315I mutation	400 mg per day

Duration 12 months

Prior–Approval *Renewal* Limits

Same as above

Rationale

Summary
Scemblix (asciminib) is a BCR-ABL tyrosine kinase inhibitor indicated for the treatment of Philadelphia-chromosome positive chronic myelogenous leukemia (CML). Scemblix inhibits cellular proliferation and induces apoptosis in cells with the BCR-ABL mutation. Scemblix can cause myelosuppression, pancreatic toxicity, hypertension, cardiovascular toxicity, and embryo-fetal toxicity. The safety and effectiveness of Scemblix in pediatric patients have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Scemblix while maintaining optimal therapeutic outcomes.

References

1. Scemblix [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporations.; October 2024.
2. NCCN Drugs & Biologics Compendium® Asciminib 2025. National Comprehensive Cancer Network, Inc. Accessed on January 13, 2025.

Policy History

Date	Action
November 2021	Addition to PA
December 2021	Annual review
March 2022	Annual review and reference update
December 2022	Annual review and reference update
September 2023	Annual review and reference update
December 2023	Annual review and reference update
July 2024	Per PI update, revised quantity limit
September 2024	Annual review and reference update
November 2024	Per PI update, added indication of newly diagnosed Ph+ CML
December 2024	Annual review and reference update
March 2025	Annual review and reference update

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Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 7, 2025 and is effective on April 1, 2025.