BlueCross BlueShield Federal Employee Program

SCEMBLIX (asciminib)

RATIONALE FOR INCLUSION IN PA PROGRAM

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).

Summary

Scemblix (asciminib) is a BCR-ABL tyrosine kinase inhibitor indicated for the treatment of

BlueCross BlueShield
Federal Employee Program

SCEMBLIX
(asciminib)

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.