Asciminib (SCEMBLIX)
Criteria for Use
October 2023

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

See the VA National PBM-MAP-VPE Monograph on this drug at the *PBM INTRAnet* site for further information.

Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive asciminib.

- ☐ Presence of BCR-ABL1 A337T, P465S, or F359V/I/C mutations
- ☐ Unmanageable drug-drug interaction
- ☐ Pregnancy
- ☐ Lactation

Inclusion Criteria

All of the following criteria must be met.

- ☐ Philadelphia chromosome-positive, chronic myeloid leukemia in chronic phase
- ☐ Eastern Cooperative Oncology Group (ECOG) performance status 0-2

Additional Inclusion Criteria

One of the following criteria must be met.

- ☐ Previous treatment failure or intolerance of at least two other tyrosine kinase inhibitors (TKI)
- ☐ Presence of T315I gatekeeper mutation, previous treatment failure or intolerance to at least one other TKI and not a candidate for ponatinib ^1

1. Patients who may <u>not</u> be a candidate for ponatinib include those with established coronary artery disease, limb-threatening peripheral vascular disease, history of TIA and/or CVA; consider risk vs. benefit.

Additional Inclusion Criteria (Select if applicable)

- ☐ For patients who can become pregnant: Counseling provided on potential risks vs benefits of treatment and the use of effective contraception during therapy and for 1 week after stopping treatment
- ☐ Avoid lactation/breastfeeding during therapy and for 1 week after stopping treatment

Other Justification

- ☐ _____

Prepared: October 2023. Contact: Berni Heron, Pharm.D., BCOP National Clinical Pharmacy Program Manager, VA Pharmacy Benefits Management Services (12PBM)