BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINE

SCEMBLIX® (asciminib)
Generic Equivalent (if available)

This Pharmacy Coverage Guideline (PCG):
- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively "Service") is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider's judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member's benefit plan; and
- Is subject to change as new information becomes available.

Scope
- This PCG applies to Commercial and/or Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

Instructions & Guidance
- To determine whether a member is eligible for the Service, read the entire PCG.
- This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
- Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
- The "Criteria" section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member's benefit plan.
- The "Description" section describes the Service.
- The "Definition" section defines certain words, terms or items within the policy and may include tables and charts.
- The "Resources" section lists the information and materials we considered in developing this PCG
- **We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.**
- Information about medications that require prior authorization is available at www.azblue.com/pharmacy. You must fully complete the request form and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-3126 or email it to Pharmacyprecert@azblue.com.

Medical Necessity Requirements for SCEMBLIX (asciminib)

Criteria for Initial Therapy:

Prescriber Qualifications
- Prescribed by an Oncologist or is in consultation with an Oncologist

Indication
- **ONE** of the following Philadelphia chromosome positive chronic myeloid leukemia (Ph+CML) in chronic phase (CP):
  - Newly diagnosed
  - Previously treated with two or more tyrosine kinase inhibitors (TKIs)

  - Has the T315I mutation
- Other oncologic direct treatment use listed in the National Comprehensive Cancer Network (NCCN) Guidelines with Categories of Evidence and Consensus of 1 and 2A

Age Requirement
- 18 years or older

Baseline Clinical Evaluation
- Negative pregnancy test in a woman of childbearing potential
- Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 2

Brand Specific Criteria
- Have failure, contraindication or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note**: Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Safety
- No concomitant drug use with:
  - Itraconazole oral solution containing hydroxypropyl beta cyclodextrin
  - Rosuvastatin and atorvastatin

Documentation Requirements
- A completed request form must be submitted including:
  - Chart notes
  - Lab results (ECOG status, pregnancy test)
  - Supporting clinical documentation

Initial Therapy Criteria Approval Duration
- 6 months OR end of plan year

Criteria for Continuation of Therapy (renewal therapy):
Note: Manufacturer assistance (e.g., coupons, samples, etc.) are not considered for continuation of therapy.

Prescriber Qualifications
- Continues to be seen by an Oncologist or is in consultation with an Oncologist

Clinical Response
- No evidence of disease progression or unacceptable toxicity

Adherence
- Adherence to the prescribed therapy regimen has been documented

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Safety
- No development of contraindications or significant adverse drug effects that may exclude continued use
  - Myelosuppression (e.g., thrombocytopenia or neutropenia)
  - Pancreatic toxicity (e.g., elevated serum lipases and amylase)
  - Hypertension not medically controlled
  - Hypersensitivity reactions (e.g., rash, edema, bronchospasms)
  - Severe or life threatening cardiovascular toxicity
  - Any severe non hematologic adverse reaction that does not resolve after withholding Scemblix or recurs after dose reduction
- No concomitant drug use with:
  - Itraconazole oral solution containing hydroxypropyl beta cyclodextrin
  - Rosuvastatin and atorvastatin

Documentation Requirements
- Chart notes
- Supporting clinical documentation with evidence of improvement in given indication
- Lab values that confirm safe use from above criteria

Continuation Therapy Criteria Approval Duration
- 12 months OR end of plan year

Criteria for Off-Label Use Requests:

Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

1. Off-Label Use of Non-Cancer Medications

2. Off-Label Use of Cancer Medications

Description:

Scemblix (asciminib) is a kinase inhibitor indicated for the treatment of adult patients with: a) Newly diagnosed Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP); b) previously treated Ph+ CML in CP with two or more tyrosine kinase inhibitors (TKIs); c) Ph+ CML in CP with the T315I mutation.

ORIGINAL EFFECTIVE DATE: 02/17/2022 | ARCHIVE DATE: | LAST REVIEW DATE: 02/19/2026 | LAST CRITERIA REVISION DATE: 02/20/2025

PHARMACY COVERAGE GUIDELINE

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The indication for Ph+ CML in CP is approved under accelerated approval based on major molecular response (MMR). Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

Asciminib is an ABL/BCR-ABL1 tyrosine kinase inhibitor. Asciminib inhibits the ABL1 kinase activity of the BCR-ABL1 fusion protein, by binding to the ABL myristoyl pocket. Studies of asciminib showed activity against wild-type BCR-ABL1 and several mutant forms of the kinase, including the T315I mutation.

Definitions:

U.S. Food and Drug Administration (FDA) MedWatch Forms for FDA Safety Reporting
MedWatch Forms for FDA Safety Reporting | FDA

Resources:

Scemblix (asciminib) tab product information, revised by Novartis Pharmaceuticals Corporation 10-2024. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed November 10, 2025.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Chronic Myeloid Leukemia Version 1.2026 – Updated July 16, 2025. Available at https://www.nccn.org. Accessed January 29, 2026.

Off Label Use of Cancer Medications: A.R.S. §§ 20-826(R) & (S). Subscription contracts; definitions.

Off Label Use of Cancer Medications: A.R.S. §§ 20-1057(V) & (W). Evidence of coverage by health care service organizations; renewability; definitions.