BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 2/17/2022
LAST REVIEW DATE:
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:

SCEMBLIX® (asciminib)

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. **All requested data must be provided.** Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

SCEMBLIX® (asciminib)

Criteria:

- **Criteria for initial therapy:** Scemblix (asciminib) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with an Oncologist

  2. Individual is 18 years of age or older

  3. A confirmed diagnosis of **ONE** of the following:
     a. Philadelphia chromosome-positive chronic myeloid leukemia (Ph+CML) in chronic phase (CP) who have been treated with two or more tyrosine kinase inhibitors (TKIs)

     b. Ph+CML in CP with the T315I mutation after at least one TKI provided that no other effective therapy exists

     c. Other request for a specific oncologic direct treatment use that is found and listed in the National Comprehensive Cancer Network (NCCN) Guidelines with Categories of Evidence and Consensus of 1 and 2A

  4. **ALL** of the following **baseline tests** have been completed before initiation of treatment with continued monitoring as clinically appropriate:
     a. Negative pregnancy test in a woman of childbearing potential
     b. Eastern Cooperative Oncology Group (ECOG) performance status of 0-2

  5. There are no significant interacting drugs

  Initial approval duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Scemblix (asciminib) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with an Oncologist

  2. Individual's condition has responded while on therapy
     a. Response is defined as **TWO** of the following:
        i. No evidence of disease progression
        ii. Documented evidence of efficacy, disease stability and/or improvement
        iii. No evidence individual has developed any significant unacceptable adverse drug reactions that may exclude continued use

  3. Individual has been adherent with the medication

SCEMBLIX® (asciminib)

4. Individual has not developed any contraindications or other significant adverse drug effects that may exclude continued use
    a. Significant adverse effect such as:
        i. Myelosuppression such as thrombocytopenia or neutropenia
        ii. Pancreatic toxicity
        iii. Hypertension that is not medically controlled
        iv. Cardiovascular toxicity
        v. Any severe non-hematologic adverse reaction that does not resolve after withholding Scemblix (asciminib)

5. There are no significant interacting drugs

Renewal duration: 12 months

- 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) Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP), previously treated with two or more tyrosine kinase inhibitors (TKIs); b) Ph+ CML in CP with the T315I mutation.

The indication for Ph+ CML in CP, previously treated with two or more TKIs 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.

Resources:

Scemblix (asciminib) product information, revised by Novartis Pharmaceuticals Corporation 10-2021. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed November 09, 2021.

SCEMBLIX® (asciminib)

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Chronic Myeloid Leukemia Version 2.2022 – Updated November 15, 2021. Available at https://www.nccn.org. Accessed November 25, 2021.

Hughes TP, Mauro MJ, Cortes LE, et al.: Asciminib in Chronic Myeloid Leukemia after ABL Kinase Inhibitor failure. NEJM 2019 Dec 12; 381 (24): 2315-2326.

ClinicalTrials.gov Identifier NCT02081378. A Phase I multicenter, open-label study of oral ABL001 in patients with Chronic Myelogenous Leukemia (CML) or Philadelphia Chromosome-positive Acute Lymphoblastic Leukemia (Ph+ALL). Last Updated October 22, 2021. Available from: http://clinicaltrials.gov. Accessed November 25, 2021.

ClinicalTrials.gov Identifier NCT03106779. A Phase 3, multicenter, open-label, randomized study of oral ABL001 versus bosutinib in patients with Chronic Myelogenous Leukemia in Chronic Phase (CML-CP), previously treated with 2 or more tyrosine kinase inhibitors. Last Updated November 08, 2021. Available from: http://clinicaltrials.gov. Accessed November 25, 2021.

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.