Scemblix (asciminib)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Scemblix (asciminib) drug policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

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

POLICY

Documentation

The following information is necessary to initiate the prior authorization review:

A. Prior to initiation of therapy for treatment of CML: results of cytogenetic and/or molecular testing for detection of the Ph chromosome or the BCR-ABL gene
B. For members requesting initiation AND continuation of therapy with the requested medication for treatment of T315I-positive CML: results of BCR-ABL1 mutation testing for T315I mutation
C. For members requesting initiation AND continuation of therapy with requested medication for treatment of CML: results of BCR-ABL1 mutation testing for A337T and P465S mutations

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D. For all continuation of therapy requests: submission of medical records (e.g., chart notes, laboratory values, pulmonary function tests, CFQ-R score) documenting clinical benefit from therapy (i.e., no evidence of disease progression)

Criteria for Initial Approval

A. Scemblix (asciminib) may be considered **medically necessary** for the treatment of Philadelphia chromosome positive (Ph+) CML in chronic phase (CP) when either of the following criteria are met:
   1. Member is 18 years of age or older
   2. Member meets either of the following criteria:
      i. Member has T315I mutation positive CML and results of BCR-ABL1 mutation are negative for the following: A337T, P465S, or
      ii. Member has been previously treated with at least two kinase inhibitors (e.g., bosutinib, dasatinib, imatinib, nilotinib) and results of BCR-ABL1 mutation testing are negative for the following: A337T, P465S

Approval is for **12 months.**

Continuation of Therapy

A. Scemblix (asciminib) may be considered **medically necessary** for the continued treatment of Philadelphia chromosome positive (Ph+) CML in chronic phase (CP) when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

Approval is for **12 months.**

Scemblix (asciminib) is considered **not medically necessary** for members who do not meet the criteria set forth above.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits

Medication	Quantity Limit*	FDA-recommended dosing
Scemblix (asciminib) 20 mg tablet	60 tablets per 30 days	Philadelphia chromosome positive chronic myeloid leukemia in chronic phase (Ph+CML in CP): • 80 mg once daily or 40 mg twice daily • with T315I mutation: 200 mg twice daily
Scemblix (asciminib) 40 mg tablet	60 tablets per 30 days*	

*Quantity of 300 tablets per 30 days will be allowed for members who have T315I mutation positive CML

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- N/A

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REFERENCES

1. Scemblix [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; October 2021.

2. NCCN Clinical Practice Guidelines in Oncology® Chronic Myeloid Leukemia (Version 1.2023). © 2022 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed August 9, 2022

*Some content reprinted from CVSHealth

POLICY HISTORY

Policy #: 05.04.53
Original Effective Date: April 25, 2022
Reviewed: October 2022
Revised:
Current Effective Date: TBD

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