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 newly diagnosed Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase (Ph+ CML-CP).
2. Adult patients with previously treated Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase (PH+ CML-CP).
3. Adult patients with Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase (Ph+ CML-CP) with the T315I mutation

Compendial Use

1) Myeloid/lymphoid neoplasms with eosinophilia and ABL1 rearrangement in chronic or blast phase
2) Chronic myeloid leukemia in accelerated phase

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 of therapy with the requested medication for treatment of T315I-positive CML: results of BCR-ABL1 mutation testing for T315I, A337T P465S, M244V and F359V/I/C mutations
C. For members requesting initiation of therapy with the requested medication for treatment of myeloid and/or lymphoid neoplasms with eosinophilia: results of testing or analysis confirming ABL1 rearrangement
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. Chronic Myeloid Leukemia (CML)

Authorization of 12 months may be granted for treatment of Philadelphia chromosome positive (Ph+) CML when any of the following criteria are met:

i. Member has newly diagnosed CML in chronic phase (CP) and the requested medication will be used as a single agent, or
ii. Member has T315I mutation positive CML in chronic phase (CP) and results of BCR-ABL1 mutation testing are negative for the following: A337T, P465S, M244V and F359V/I/C or
iii. Member has CML in chronic phase (CP) that has been previously treated and results of mutation testing are negative for the following: A337T, P465S, M244V and F359V/I/C, or
iv. Member has CML in accelerated phase (AP), has not tested positive for the following mutations: A337T, P465S, M244V and F359V/I/C, and the requested medication will be used as a single agent

B. Myeloid/Lymphoid Neoplasms with Eosinophilia

Authorization of 12 months may be granted for treatment of myeloid and/or lymphoid neoplasms with eosinophilia and ABL1 rearrangement in the chronic phase or blast phase.

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

Other

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): • Initial dose: 80 mg once daily or 40 mg twice daily • First dose reduction: 40 mg once daily or 20 mg twice daily Philadelphia chromosome positive chronic myeloid leukemia in chronic phase (Ph+CML in CP) with the T315I mutation: • Initial dose: 200 mg twice daily • First dose reduction: 160 mg twice daily *Permanently discontinue asciminib if unable to tolerate dose reduction*
Scemblix (asciminib) 40 mg tablet	240 tablets per 30 days	
Scemblix (asciminib) 100 mg tablet	120 tablets per 30 days	

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

REFERENCES

- Scemblix [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; October 2024.
- NCCN Clinical Practice Guidelines in Oncology® Chronic Myeloid Leukemia (Version 2.2025). © 2024 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed November 19, 2024
- The NCCN Drugs and Biologics Compendium©. © 2024 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed November 19, 2024.

*Some content reprinted from CVSHealth

POLICY HISTORY

Policy #: 05.04.53
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