Reference number(s)
5042-A

Specialty Guideline Management Scemblix

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over the counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Scemblix	asciminib

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit 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 (Ph+ CML) in chronic phase (CP).
- Adult patients with previously treated Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase (Ph+ CML-CP).
- Adult patients with Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase (Ph+ CML-CP) with the T315I mutation.

Compendial Use[2]

- Myeloid/lymphoid neoplasms with eosinophilia and ABL1 rearrangement in chronic or blast phase
- Chronic myeloid leukemia in accelerated phase
- Additional therapy for CML patients after hematopoietic stem cell transplant (HSCT)

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All other indications are considered experimental/investigational and not medically necessary.

Documentation

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

- 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
- 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
- For members who have received an HSCT for CML and are requesting initiation of therapy with the requested medication: results of BCR::ABL1 mutation testing for A337T P465S, M244V and F359V/I/C mutations
- 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

Coverage Criteria

Chronic Myeloid Leukemia (CML)[1-3]

Authorization of 7 months may be granted for treatment of Philadelphia chromosome positive (Ph+) CML when any of the following criteria are met:

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

Myeloid/Lymphoid Neoplasms with Eosinophilia[2]

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.

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Continuation of Therapy

CML

Authorization may be granted for continued treatment of CML that has been confirmed by detection of Ph chromosome or BCR::ABL gene by cytogenetic and/ or molecular testing when either of the following criteria are met:

- Authorization of 12 months may be granted when any of the following criteria is met:
  - BCR::ABL1 is less than or equal to 10% and there is no evidence of disease progression or unacceptable toxicity while on the current regimen for members who have been receiving the requested medication for 6 months or greater
  - Member has received HSCT and there is no evidence of unacceptable toxicity or disease progression while on the current regimen
- Authorization of up to 7 months may be granted when the member has completed less than 6 months of therapy with the requested medication.

Myeloid/Lymphoid Neoplasms with Eosinophilia

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.

References

1. Scemblix [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; October 2024.
2. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed April 15, 2025.
3. NCCN Clinical Practice Guidelines in Oncology® Chronic Myeloid Leukemia (Version 3.2025). © 2025 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed April 15, 2025.

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