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

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

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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 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 12 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.

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.

Continuation of Therapy

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

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References

1. Scemblix [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; October 2024.
2. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed November 19, 2024.
3. 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.