Reference number(s)
5042-A

SPECIALTY GUIDELINE MANAGEMENT

SCEMBLIX (asciminib)

POLICY

I. 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 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

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

II. 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 mutation

III. CRITERIA FOR INITIAL APPROVAL

Chronic Myeloid Leukemia (CML)
Authorization of 12 months may be granted for treatment of Philadelphia chromosome positive (Ph+) CML in chronic phase (CP) when either of the following criteria are met:

1. Member has T315I mutation positive CML
2. Member has been previously treated with at least two kinase inhibitors (e.g., bosutinib, dasatinib, imatinib, nilotinib)

IV. CONTINUATION OF THERAPY

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

V. REFERENCES

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