Reference number(s)
2174-A

SPECIALTY GUIDELINE MANAGEMENT

SYNRIBO (omacetaxine mepesuccinate)

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.

A. FDA-Approved Indication
Synribo is indicated for the treatment of adult patients with chronic or accelerated phase chronic myeloid leukemia (CML) with resistance and/or intolerance to two or more tyrosine kinase inhibitors (TKIs).

B. Compendial Use
1. Primary treatment of advanced phase CML for patients with disease progression to accelerated phase
2. Follow-up therapy for CML patients after hematopoietic stem cell transplant (HSCT)

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

II. REQUIRED DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:
Prior to initiation of therapy: results of cytogenetic and/or molecular testing for detection of the Ph chromosome or the BCR-ABL gene

III. CRITERIA FOR INITIAL APPROVAL

Chronic Myeloid Leukemia (CML)
Authorization of 12 months may be granted for treatment of CML confirmed by detection of the Ph chromosome or BCR-ABL gene by cytogenetic and/or molecular testing when all of the following criteria are met:
A. Member meets any of the following:
1. Member has chronic or accelerated phase CML
2. Member has received HSCT for CML
B. Member has experienced resistance or intolerance to two or more tyrosine kinase inhibitors (TKIs) (e.g., bosutinib, dasatinib, imatinib, nilotinib, ponatinib)

IV. CONTINUATION OF THERAPY

Authorization of 12 months 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 there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

V. REFERENCES

1. Synribo [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; November 2019.
2. The NCCN Drugs & Biologics Compendium® © 2021 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed March 30, 2021.
3. NCCN Clinical Practice Guidelines in Oncology® Chronic Myeloid Leukemia (Version 3.2021). © 2021 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed March 30, 2021.