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: 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: Treatment option for posttransplant relapse CML in patients with disease progression due to resistance and/or intolerance to two or more TKIs

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

Chronic myeloid leukemia (CML)
Authorization of 12 months may be granted for members prescribed Synribo for the treatment of CML who have experienced resistance, toxicity, or intolerance to prior therapy with two or more TKIs (e.g., imatinib, dasatinib, nilotinib, bosutinib, ponatinib)

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet ALL initial authorization criteria.

IV. DOSAGE AND ADMINISTRATION

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

V. REFERENCES

1. Synribo [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; April 2014.
2. The NCCN Drugs & Biologics Compendium® © 2016 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed March 3, 2016.