Clinical Policy: Omacetaxine (Synribo)

Reference Number: PA.CP.PHAR.108
Effective Date: 01/18
Last Review Date: 4/18

Coding Implications
Revision Log

Description
The intent of the criteria is to ensure that patients follow selection elements established by Pennsylvania Health and Wellness® clinical policy for omacetaxine mepesuccinate (Synribo®).

FDA Approved Indication(s)
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.

Policy/Criteria
It is the policy of health plans affiliated with Pennsylvania Health and Wellness that Synribo is **medically necessary** when one of the following criteria are met:

I. Initial Approval Criteria

A. Chronic Myeloid Leukemia (must meet all):

1. Diagnosis of chronic myeloid leukemia (CML);
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Dose does not exceed 2.5 mg/m^2 per day.

Approval duration: 6 months

B. Other diagnoses/indications: Refer to PA.CP.PHAR.57 - Global Biopharm Policy

II. Continued Approval

A. All Indications (must meet all):

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care policye (PA.LTSS.PHAR.01) applies;
2. Responding positively to therapy with no disease progression or unacceptable toxicity.
3. If request is for a dose increase, new dose does not exceed 2.5 mg/m^2 per day.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2):

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policye (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.CP.PHAR.57 - Global Biopharm Policy.

Background

Description/Mechanism of Action:
Synribo contains the active ingredient omacetaxine mepesuccinate, a cephalotaxine ester and protein synthesis inhibitor. Omacetaxine mepesuccinate is prepared by a semi-synthetic process from cephalotaxine, an extract from the leaves of Cephalotaxus sp. The mechanism of action of omacetaxine mepesuccinate has not been fully elucidated but includes inhibition of protein synthesis and is independent of direct Bcr-Abl binding. Omacetaxine mepesuccinate binds to the A-site cleft in the peptidyl-transferase center of the large ribosomal subunit from a strain of archaeabacteria. In vitro, omacetaxine mepesuccinate reduced protein levels of the Bcr-Abl oncoprotein and Mcl-1, an anti-apoptotic Bcl-2 family member. Omacetaxine mepesuccinate showed activity in mouse models of wild-type and T315I mutated Bcr-Abl CML.

Formulations:
Synribo: Subcutaneous injectable formulation

- Single-use vial containing 3.5 mg of omacetaxine mepesuccinate as a lyophilized powder

Appendices

Appendix A: Abbreviation Key

CML: chronic myelogenous leukemia
TKI: tyrosine kinase inhibitor

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J9262	Injection, omacetaxine mepesuccinate, 0.01 mg

Reviews, Revisions, and Approvals	Date	Approval Date
Q 2018 annual review: no significant changes; summarized NCCN and FDA approved uses for improved clarity; added specialist involvement in care; references reviewed and updated.	02.13.14	

References

1. Synribo Prescribing Information. North Wales, PA: Teva Pharmaceuticals USA, Inc.; December 2015. Available at http://www.synribohcp.com/pdf/synribo_pi.pdf. Accessed February 2018.
2. Omacetaxine. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available from www.nccn.org. Accessed February 2018.

3. Chronic myelogenous leukemia (Version 1.2016). In: National Comprehensive Cancer Network Guidelines. Available from www.nccn.org. Accessed February 2018.