

## Clinical Policy: Omacetaxine (Synribo)

Reference Number: CP.PHAR.108

Effective Date: 04/13

Last Review Date: 11/16

[Coding Implications](#)  
[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

### Description

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

### Policy/Criteria

It is the policy of health plans affiliated with Centene Corporation® 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. History of resistance or intolerance to  $\geq 2$  tyrosine kinase inhibitors ([TKI]; e.g., Gleevec, Tasigna, Sprycel, Bosulif, Iclusig);
3. Meets a or b:
  - a. FDA approved use:
    - i. CML is in chronic or accelerated phase;
  - b. Off-label NCCN recommended use:
    - i. CML has relapsed post-transplantation.

**Approval duration: 3 months**

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

#### II. Continued Approval

##### A. All Indications (must meet all):

1. Currently receiving medication via Centene benefit or member has previously met all initial approval criteria;
2. Responding positively to therapy with no disease progression or unacceptable toxicity.

**Approval duration: 6 months**

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

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy; or
2. Refer to CP.PHAR.57 - Global Biopharm Policy.

### Background

*Description/Mechanism of Action:*

## CLINICAL POLICY

### Omacetaxine

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 archaeobacteria. 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

#### *FDA Approved Indications:*

Synribo is a cephalotaxine ester/subcutaneous injectable lyophilized powder indicated for:

- Treatment of adult patients with chronic or accelerated phase CML with resistance and/or intolerance to two or more TKI.

## 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
Policy developed	04/13	04/13
Converted to Centene policy template	06/13	06/13
Updated Background, Safety, and References with current information Added Blast Phase to Figure 1	12/13	12/13
Modified background information Added Appendix E Created Figure 2: Synribo Reauthorization algorithm Added "Evidence of myelosuppression?" to Figure 2	12/14	12/14

Reviews, Revisions, and Approvals	Date	Approval Date
Policy converted to new template. Criteria: initial approval period shortened to three months per NCCN monitoring recommendation starting three months post therapy change; documentation requests removed and replaced with attestation requests; denial based on myelosuppression removed; detailed efficacy criteria removed and replaced with general disease progression criteria.	11/15	12/15
Policy converted to new template. Added prescriber and age requirements. Added NCCN recommended use (CML relapse post-transplantation). Removed attestation that member does not have poorly controlled diabetes from initial criteria.	11/16	12/16

**References**

1. Synribo Prescribing Information. North Wales, PA: Teva Pharmaceuticals USA, Inc.; December 2015. Available at [http://www.synribohcp.com/pdf/synribo\\_pi.pdf](http://www.synribohcp.com/pdf/synribo_pi.pdf). Accessed November 11, 2016.
2. Omacetaxine. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available from [www.nccn.org](http://www.nccn.org). Accessed November 11, 2016.
3. Chronic myelogenous leukemia (Version 1.2016). In: National Comprehensive Cancer Network Guidelines. Available from [www.nccn.org](http://www.nccn.org). Accessed November 11, 2016.

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to

applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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**Note: For Medicaid members,** when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

**Note: For Medicare members,** to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at <http://www.cms.gov> for additional information.

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