

## Clinical Policy: Omacetaxine (Synribo)

Reference Number: LA.PHAR.108

Effective Date:

Last Review Date: 04.22

Line of Business: Medicaid

Coding Implications

Revision Log

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

### Description

Omacetaxine (Synribo®) is cephalotaxine ester that inhibits protein synthesis by binding to the A-site in the peptidyl-transferase center of the large ribosomal subunit.

### 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 (TKIs).

### Policy/Criteria

*Prior Authorization is required. Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of Louisiana Healthcare Connections that Synribo is medically necessary when the following criteria are met:

#### I. Initial Approval Criteria

##### A. Chronic Myeloid Leukemia (must meet all):

1. Diagnosis of Ph+ (BCR-ABL1-positive) CML;
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age ≥ 18 years;
4. Request meets one of the following (a or b):
  - a. Member has experienced resistance, toxicity, or intolerance to prior therapy with two or more TKIs (e.g., imatinib, Bosulif®, Sprycel®, Tasigna®, Iclusig®);
  - b. Member has T315I mutation and has received prior treatment with Iclusig and Scemblix®;
5. Request meets one of the following (a or b):\*
  - a. Dose does not exceed 2.5 mg/m<sup>2</sup> per day.
  - b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

\*Prescribed regimen must be FDA-approved or recommended by NCCN

##### Approval duration:

Medicaid - 6 months

Omacetaxine

**B. Other diagnoses/indications**

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): LA.PMN.53 for Medicaid.

**II. Continued Therapy**

**A. Chronic Myeloid Leukemia (must meet all):**

1. Currently receiving medication via Louisiana Healthcare Connections benefit, or documentation supports that member is currently receiving Synribo for CML and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a or b):\*
  - a. New dose does not exceed 2.5 mg/m<sup>2</sup> per day;
  - b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

*\*Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:

Medicaid - 12 months

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

1. Currently receiving medication via Louisiana Healthcare Connections benefit and documentation supports positive response to therapy.  
Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): LA.PMN.53 for Medicaid.

**III. Diagnoses/Indications for which coverage is NOT authorized:**

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – LA.PMN.53 for Medicaid, or evidence of coverage documents.

**IV. Appendices/General Information**

Appendix A: Abbreviation/Acronym Key

CML: chronic myelogenous leukemia

FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may require prior authorization.

## Omacetaxine

<u>Drug Name</u>	<u>Dosing Regimen</u>	<u>Dose Limit/ Maximum Dose</u>
<u>imatinib</u> <u>(Gleevec®)</u>	<u>Adult:</u> • <u>400-600 mg/day PO for chronic phase</u> • <u>600-800 mg/day PO for accelerated phase or blast crisis (800 mg given as 400 BID)</u>	<u>Adult: 800 mg/day</u>
<u>Bosulif®</u> <u>(bosutinib)</u>	<u>400 mg PO QD</u>	<u>600 mg/day</u>
<u>Sprycel®</u> <u>(dasatinib)</u>	<u>Adults:</u> • <u>Chronic phase: 100-140 mg/day PO</u> • <u>Accelerated, myeloid phase, or lymphoid blast phase: 140-180 mg/day PO</u>	<u>Adults: 180 mg/day</u>
<u>Tasigna®</u> <u>(nilotinib)</u>	<u>Adults: 300 mg PO BID</u>	<u>Adults: 600 mg/day</u>
<u>Iclusig®</u> <u>(ponatinib)</u>	<u>Starting dose 45 mg PO QD</u>	<u>45 mg/day</u>
<u>Scemblix®</u> <u>(asciminib)</u>	<u>200 mg PO BID</u>	<u>200 mg/day</u>

Appendix C: Contraindications/Boxed WarningsNone reported

## V. Dosage and Administration

<u>Indication</u>	<u>Dosing Regimen</u>	<u>Maximum Dose</u>
<u>CML</u>	<u>Induction dose: 1.25 mg/m<sup>2</sup>-subcutaneous twice daily for 14 consecutive days of a 28-day cycle</u> <u>Maintenance dose: 1.25 mg/m<sup>2</sup> subcutaneous twice daily for 7 consecutive days of a 28-day cycle</u>	<u>2.5 mg/m<sup>2</sup> per day</u>

## VI. Product Availability

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

## VII. References

1. Synribo Prescribing Information. North Wales, PA: Teva Pharmaceuticals USA, Inc.; May 2021. Available at <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=83a504ef-cf92-467d-9ecf-d251194a3484> . Accessed February 2, 2022.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at [www.nccn.org](http://www.nccn.org). Accessed February 2, 2022.
3. National Comprehensive Cancer Network Guidelines. Chronic Myeloid Leukemia Version 3.2022. Available at [www.nccn.org](http://www.nccn.org). Accessed February 2, 2022.

Coding Implications

## Omacetaxine

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.

<u>HCPCS Codes</u>	<u>Description</u>
<u>J9262</u>	<u>Injection, omacetaxine mepesuccinate, 0.01 mg</u>

<u>Reviews, Revisions, and Approvals</u>	<u>Date</u>	<u>LDH Approval Date</u>
<u>Converted corporate to local policy.</u>	<u>04.22</u>	

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. LHCC 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.

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 LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. 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. LHCC 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

### Omacetaxine

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.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom LHCC has no control or right of control. Providers are not agents or employees of LHCC.

This clinical policy is the property of LHCC. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

©2020 Louisiana Healthcare Connections. All rights reserved. All materials are exclusively owned by Louisiana Healthcare Connections and are protected by United States copyright law and international copyright law. No part of this publication may be reproduced, copied, modified, distributed, displayed, stored in a retrieval system, transmitted in any form or by any means, or otherwise published without the prior written permission of Louisiana Healthcare Connections. You may not alter or remove any trademark, copyright or other notice contained herein. Louisiana Healthcare Connections is a registered trademark exclusively owned by Louisiana Healthcare Connections.