Omacetaxine mepesuccinate (Synribo®)	Place of Service Office Administration Home Infusion Administration Infusion Center Administration Self-Administration HCPCS: **J9262** per 0.01 mg

Condition listed in policy (*see criteria for details*)

- Chronic myeloid leukemia (CML)

AHFS therapeutic class: Antineoplastic

Mechanism of action: Protein synthesis inhibitor

(1) Special Instructions and pertinent Information

If the patient has a prescription drug benefit, please contact Blue Shield Pharmacy Services to obtain a prior authorization.

To submit a request to the Medical Benefit, please submit clinical information for prior authorization review via fax.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Synribo® (omacetaxine) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Chronic myeloid leukemia (CML)

1. Being used as a single-agent therapy, **AND**
2. Must meet one of the following:
    a. Patient has had resistance and/or intolerance to two or more tyrosine kinase inhibitors (TKI), or
    b. Patient has received an allogeneic stem cell transplant, or
    c. Primary treatment for disease that has progressed to accelerated phase, or
    d. Patient has a T315I mutation

Covered Doses

Induction doses: up to 1.25 mg/m^2 SC injection twice daily for 14 consecutive days of 28-day cycles. Cycles should be continued until hematologic response.

Maintenance doses: up to 1.25 mg/m^2 SC injection twice daily for 7 consecutive days of 28-day cycles.

Coverage Period

Indefinitely

ICD-10:

C92.10-C92.12

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for Synribo® (omacetaxine) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How Supplied

3.5 mg (Single-use vial)

Per package insert, patients may self-administer Synribo that has been reconstituted by a health care professional after receiving training on proper handling, storage conditions, administration, disposal, and clean-up of accidental spillage of the product.

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com
- National Comprehensive Cancer Network. Chronic myeloid leukemia (Version 1.2023). Available at http://www.nccn.org.
- Synribo® (omacetaxine mepesuccinate) [Prescribing Information]. Parsippany, PA: Teva Pharmaceuticals USA, Inc.; 5/2021.

(7) Policy Update

Date of last review: 1Q2023

Date of next review: 1Q2024

Changes from previous policy version:

- No clinical change to policy following routine annual review.