MEDICAL MUTUAL®

Drug Policy

Policy:	**201824-CC**	**Initial Effective Date: 09/16/2018**
Code(s):	**HCPCS J9262**	**Annual Review Date:**
SUBJECT:	**Synribo® (omacetaxine mepesuccinate)**	**Last Revised Date:**

Prior approval is required for some or all procedure codes listed in this Corporate Drug Policy.

OVERVIEW

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.[1] Synribo can be administered by someone other than a healthcare professional (e.g., patient or a caregiver), if appropriate.

Synribo is supplied in 8 mL clear glass single-dose vial in individual cartons.[1] Each vial contains 3.5 mg of Synribo for injection. Store unopened vials at 20º to 25ºC (68 to 77ºF); excursions permitted from 15º to 30ºC (59º to 86ºF). Prior to reconstitution, keep product in the original carton to protect from light. Synribo is a cytotoxic agent. Special handling and disposal procedures should be followed.

Guidelines

The National Comprehensive Cancer Network (NCCN) guidelines on Chronic Myeloid Leukemia (version 4.2018) recommends Synribo as a treatment option for patients who have experienced disease progression to accelerated phase CML.[2] It is not an option among patients who present with accelerated phase CML. Synribo is also a treatment option for patients with the T315I mutation.

POLICY STATEMENT

This policy involves the use of Synribo. Prior authorization is recommended for medical benefit coverage of Synribo. Approval is recommended for those who meet the conditions of coverage in the **Criteria**, **Dosing**, **Initial or Extended Approval**, **Duration of Therapy**, and **Labs/Diagnostics** for the diagnosis provided. **Waste Management** applies for all covered conditions. **Conditions Not Recommended for Approval** is listed following the recommended authorization criteria and Waste Management section.

Due to the specialized skills required for evaluation and diagnosis of patients treated with Synribo, as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Synribo to be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy.

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RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Synribo is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. Chronic Myeloid Leukemia (CML).

Criteria. *Patient must meet the following criteria (A, B and C):*

A) Synribo is prescribed by or in consultation with an oncologist; AND

B) The patient is an adult ≥ 18 years of age; AND

C) The patient meets ONE of the following criteria (i or ii):

- **i.** The patient is T315I-positive, OR
- **ii.** The patient has tried two tyrosine kinase inhibitors indicated for use in CML (e.g., Gleevec® [imatinib tablets], Sprycel® [dasatinib tablets], Tasigna® [nilotinib capsules], Bosulif® [bosutinib tablets], Iclusig® [ponatinib tablets]).

Dosing in CML. *Dosing must meet one the following (A or B):*

A) The recommended starting schedule for induction is 1.25 mg/m^2 given subcutaneously (SC) twice daily at approximately 12-hour intervals for 14 consecutive days once every 28 days over a 28-day cycle.[1] Repeat cycles once every 28 days until a hematologic response is achieved.

B) The recommended maintenance schedule is 1.25 mg/m^2 given SC twice daily at approximately 12-hour intervals for 7 consecutive days once every 28 days over a 28 day cycle. Therapy should continue as long is the patient is obtaining benefits.

Initial Approval/Extended Approval.

A) *Initial Approval:* Approve up to 6 months (cycles) of therapy.

B) *Extended Approval:* Approve at 6-month intervals.

Duration of Therapy in CML. Indefinite.

Labs/Diagnostics. None required.

Waste Management for All Indications.

Dosing for Synribo in patients with CML is based on body surface area (mg/m^2). The dose should be calculated and the number of vials needed assessed.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Synribo has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Synribo® injection for subcutaneous use [prescribing information]. North Wales, PS: Teva Pharmaceuticals; June 2017.
2. The NCCN Chronic Myeloid Leukemia Clinical Practice Guidelines in Oncology (Version 4.2018 – January 24, 2018). © 2018 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on July 20, 2018.
3. Cortes J, Digumarti R, Parikh PM, and the omacetaxine 203 Study Group. Phase 2 study of subcutaneous omacetaxine mepesuccinate for chronic-phase chronic myeloid leukemia patients resistant to or intolerant of tyrosine kinase inhibitors. *Am J Hematol*. 2013;88(5):350-354.
4. Cortes J, Lipton JH, Rea Delphine, et al. Phase 2 study of subcutaneous omacetaxine mepesuccinate after TKI failure in patients with chronic-phase CML with T315I mutation. *Blood*. 2012;120(13):2573-2580.
5. Cortes JE, Nicolini FE, Wetzler M, et al. Subcutaneous omacetaxine mepesuccinate in patients with chronic-phase chronic myeloid leukemia previously treated with 2 or more tyrosine kinase inhibitors including imatinib. *Clin Lymphoma Myeloma Leuk*. 2013;13(5):584-591.
6. Khoury HJ, Cortes J, Baccarani M, et al. Omacetaxine mepesuccinate in patients with advanced chronic myeloid leukemia with resistance or intolerance to tyrosine kinase inhibitors. *Leuk Lymphoma*. 2015;56(1):120-127.
7. Cortes JE, Kantarjian HM, Rea D, et al. Final analysis of the efficacy and safety of omacetamine mepesuccinate in patients with chronic- or accelerated-phase chronic myeloid leukemia: results from 24 months of follow-up. *Cancer*. 2015;121:1637-1644.

FOR MEDICAL BENEFIT COVERAGE REQUESTS:

Prior approval is required for HCPCS Codes J9262

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HCPCS Code(s):	
J9262	Injection, omacetaxine mepesuccinate, 0.01 mg