VENTURA COUNTY
HEALTH CARE PLAN

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Oncology (Injectable) – Synribo Utilization Management Medical Policy
- Synribo® (omacetaxine mepesuccinate subcutaneous injection – Teva)

REVIEW DATE: 10/11/2023

OVERVIEW

Synribo is indicated for the treatment of **chronic or accelerated phase chronic myeloid leukemia** (CML) with resistance and/or intolerance to two or more tyrosine kinase inhibitors (TKIs) in adults.[1]

Guidelines

The National Comprehensive Cancer Network (NCCN) guidelines for **CML** (version 1.2024 – August 1, 2023) recommend Synribo as a treatment option for patients with resistance and/or intolerance to two or more TKIs with chronic phase CML that is Philadelphia chromosome or breakpoint cluster gene – Abelson proto-oncogene (BCR-ABL1) positive; as treatment of advanced phase CML for patients with disease progression to accelerated phase CML; and post-allogenic hematopoietic stem cell transplant follow-up therapy.[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

Prior Authorization is recommended for medical benefit coverage of Synribo. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of 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, approval requires Synribo to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indication

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1. **Chronic Myeloid Leukemia**. Approve for 6 months if the patient meets the following (A, B, C and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has Philadelphia chromosome-positive chronic myeloid leukemia (CML); AND
   - **C)** Patient meets one of the following (i or ii):
     - **i.** Patient is T315I-positive, OR
     - **ii.** Patient has tried at least two tyrosine kinase inhibitors indicated for use in CML; AND

Note: Examples include imatinib tablets, Sprycel (dasatinib tablets), Tasigna (nilotinib capsules), Bosulif (bosutinib tablets), and Iclusig (ponatinib tablets).

D) Medication is prescribed by or in consultation with an oncologist.

Dosing. Approve 1.25 mg/m^2 given by subcutaneous injection twice daily for up to 14 days once every 28 days.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Synribo is not recommended in the following situations:

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

REFERENCES

1. Synribo® subcutaneous injection [prescribing information]. North Wales, PS: Teva; May 2021.
2. The NCCN Chronic Myeloid Leukemia Clinical Practice Guidelines in Oncology (version 1.2024 – August 1, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on October 6, 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	10/12/2022
Annual Revision	No criteria changes.	10/11/2023