Medical Drug Clinical Criteria

Subject:	Synribo (omacetaxine mepesuccinate)		
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Overview

This document addresses the use of Synribo (omacetaxine mepesuccinate). Synribo is a protein synthesis inhibitor used to treat chronic myelogenous leukemia (CML). It works by reducing levels of Bcr-Abl and Mcl-1, the proteins responsible for the initiation and progression of CML and causing cell death.

The FDA approved indication for Synribo include use in adults with chronic or accelerated chronic myeloid leukemia with resistance or intolerance to two or more tyrosine kinase inhibitors (TKI). FDA approved TKIs include Gleevec (imatinib), Tasigna (dasatinib), Sprycel (nilotinib), Bosulif (bosutinib), and Iclusig (ponatinib).

The National Comprehensive Cancer Network® (NCCN) provides additional recommendations with a category 2A level of evidence for the use of Synribo when used as a single agent for patients with resistance and/or intolerance to two or more TKIs

- with chronic phase CML (CP-CML) (Philadelphia chromosome or BCR::ABL1 positive)
- as treatment of advanced phase CML for patients with disease progression to accelerated phase (useful in certain circumstances)
- as post-allogeneic hematopoietic stem cell transplant (HCT) follow-up therapy in patients with molecular relapse (BCR::ABL1 transcript positive) following complete cytogenetic response (CCyR)
- as post-allogeneic HCT follow-up therapy in patients with relapse or less than CCyR

Synribo is expected to be discontinued from the drug file on 12/26/2025. The criteria document will remain in place until it is removed from the drug file (Medispan).

Definitions and Measures

Disease Progression: Cancer that continues to grow or spread.

Hematopoietic stem cells: Primitive cells capable of replication and formation into mature blood cells in order to repopulate the bone marrow.

Kinase inhibitor: Type of drug which works by blocking several enzymes that promote cell growth, which has been found to be an effective approach to treat a variety of cancers.

Line of Therapy:

- First-line therapy: The first or primary treatment for the diagnosis, which may include surgery, chemotherapy, radiation therapy or a combination of these therapies.
- Second-line therapy: Treatment given when initial treatment (first-line therapy) is not effective or there is disease progression.
- Third-line therapy: Treatment given when both initial (first-line therapy) and subsequent treatment (second-line therapy) are not effective or there is disease progression.

Relapse or recurrence: After a period of improvement, during which time a disease (for example, cancer) could not be detected, the return of signs and symptoms of illness or disease. For cancer, it may come back to the same place as the original (primary) tumor or to another place in the body.

Clinical Criteria

Synribo (omacetaxine mepesuccinate)

Requests for Synribo (omacetaxine mepesuccinate) may be approved if the following criteria are met:

I. Individual has a diagnosis of chronic or accelerated phase chronic myeloid leukemia (CML) (Label, NCCN 2A); **AND**
II. Individual has resistance and/or intolerance to two or more tyrosine kinase inhibitors (TKI).

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS	
J9262	Injection, omacetaxine mepesuccinate, 0.01 mg
ICD-10 Diagnosis	
C92.10	Chronic myeloid leukemia, BCR/ABL-positive, not having achieved remission
C92.11	Chronic myeloid leukemia, BCR/ABL-positive, in remission
C92.12	Chronic myeloid leukemia, BCR/ABL-positive, in relapse

Document History

Reviewed: 05/16/2025
Document History:

- 05/16/2025 – Annual Review: No changes. Coding Reviewed: No changes.
- 05/17/2024 – Annual Review: No changes. Coding Reviewed: No changes.
- 05/19/2023 – Annual Review: Streamline and update criteria to FDA language. The FDA label is inclusive of the 2A NCCN recommendation in CML. Coding Reviewed: No changes.
- 05/20/2022 – Annual Review: No changes. Coding Reviewed: No changes.
- 05/21/2021 – Annual Review: No changes. Coding Reviewed: No changes.
- 08/21/2020 – Annual Review: Update criteria to clarify use if resistant or intolerant to tyrosine kinase inhibitor (TKI) per NCCN. Coding reviewed: Added HCPCS J9262, Added ICD-10-CM C92.10, C92.11, C92.12
- 11/15/2019 – Annual Review: Moved examples of tyrosine kinase inhibitors to the overview section. Wording and formatting changes.

References

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2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Updated periodically.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2024; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2024 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on March 20, 2024.
    a. Chronic Myeloid Leukemia. V2.2024. December 5, 2023.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.