

Synribo[®] (omacetaxine mepesuccinate) (Subcutaneous)

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I. Length of Authorization

Coverage will be provided for six months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

Synribo 3.5 mg for injection SDV:

- Induction: 28 vials every 28 days (*until hematologic response is achieved, then begin maintenance*)
- Maintenance: 14 vials every 28 days

B. Max Units (per dose and over time) [HCPCS Unit]:

Induction:

- 9,800 billable units every 28 days until hematologic response is achieved, then begin maintenance

Maintenance:

- 4,900 billable units every 28 days

III. Initial Approval Criteria ^{1,2,3}

Coverage is provided in the following conditions:

- Patient is at least 18 years old; **AND**
- Patient's disease is confirmed by either a Philadelphia chromosome-positive (Ph+) or *BCR-ABL1* positive laboratory test result; **AND**

Chronic myelogenous leukemia (CML) †

- Used as single agent therapy for patients resistant, intolerant, or had an inadequate response after at least 3 months of therapy to TWO or more tyrosine kinase inhibitor (TKI) therapies (e.g., bosutinib, imatinib, dasatinib, ponatinib or nilotinib); **AND**
 - Patient has chronic phase CML; **OR**

- Patient has advanced disease that has progressed to accelerated phase; **OR**
- For post-allogeneic stem cell transplant follow-up therapy with molecular relapse (*BCR-ABL1* transcript positive) following complete cytogenetic response (CCyR); **OR**
- For post-allogeneic stem cell transplant follow-up therapy with relapse or those who are not in CCyR; **OR**
- Patient has T315I mutation positive disease

† FDA Approved Indication(s)

IV. Renewal Criteria ^{1,3}

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the criteria identified in Section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: myelosuppression (e.g., severe neutropenia, thrombocytopenia, or anemia), hemorrhage (including cerebral and gastrointestinal), uncontrolled hyperglycemia, etc.; **AND**
- Patient has been adherent to therapy; **AND**
- Treatment response as indicated by one of the following:
 - Patient has *BCR-ABL1* (IS) transcript levels:
 - ≤ 10% at 3 months; **OR**
 - ≤ 10% at 6 months; **OR**
 - ≤ 0.1% or a ≥ 3-log reduction in *BCR-ABL1* mRNA from the standardized baseline, if qPCR (IS) is not available

Note: cytogenetic assessment of response may be used if quantitative RT-PCR (QPCR) using International Scale (IS) for *BCR-ABL1* is not available

V. Dosage/Administration

Indication	Dose
Chronic myelogenous leukemia	<u>Induction Dose:</u> 1.25 mg/m ² administered by subcutaneous injection twice daily for 14 consecutive days of a 28-day cycle. Repeat until a hematologic response is achieved, then begin maintenance.
	<u>Maintenance Dose:</u> 1.25 mg/m ² administered by subcutaneous injection twice daily for 7 consecutive days of a 28-day cycle. Treatment should continue as long as patients are clinically benefiting from therapy.
<ul style="list-style-type: none"> – Synribo should be prepared/reconstituted in a healthcare facility by a healthcare professional – Synribo may be administered by the patient or caregiver with appropriate training and storage of the reconstituted product 	

VI. Billing Code/Availability Information

HCPCS:

- J9262 – Injection, omacetaxine mepesuccinate, 0.01 mg; 1 billing unit = 0.01 mg.

NDC:

- Synribo 3.5 mg single-use vial for injection: 63459-0177-xx

VII. References

1. Synribo [package insert]. North Wales, PA; Teva Pharmaceuticals USA, Inc.; November 2019. Accessed December 2019.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for omacetaxine. National Comprehensive Cancer Network, 2019. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed December 2019.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Chronic Myeloid Leukemia 2.2020. National Comprehensive Cancer Network, 2018. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed December 2019.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
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

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologics. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions

Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC