UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2021 P 1252-4
Program	Prior Authorization/Notification
Medication	Synribo® (omacetaxine)
P&T Approval Date	8/2018, 11/2019, 11/2020, 11/2021
Effective Date	2/1/2022; Oxford only: 2/1/2022

1. Background:

Synribo (omacetaxine) 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 (TKI). The National Cancer Comprehensive Network (NCCN) also recommends the use of Synribo for patients with advanced phase CML with progression to accelerated phase and for patients with relapseddisease after hematopoietic stem cell transplantation with resistance and/or intolerance to two or more tyrosine kinase inhibitors.

Coverage Information:

Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. Coverage Criteria:

A. <u>Patients less than 19 years of age</u>

1. Synribo will be approved based on the following criterion:

a. Patient is less than 19 years of age

Authorization will be issued for 12 months.

B. <u>Chronic Myeloid Leukemia</u>

1. <u>Initial Authorization</u>

a. **Synribo** will be approved based on **<u>all</u>** of the following criteria:

(1) Patient has a history of resistance and/or intolerance to two or more tyrosine kinase inhibitors [e.g., Gleevec (imatinib), Sprycel (dasatinib), Tasigna (nilotinib), Bosulif (bosutinib), Iclusig (ponatinib)]

-AND-

(2) **One** of the following:

(a) Diagnosis of chronic or accelerated phase chronic myelogenous leukemia

-OR-

(b) Diagnosis of advanced phase chronic myelogenous leukemia with progression to accelerated phase

-OR-

(c) Patient has relapsed disease after hematopoietic stem cell transplant

Authorization will be issued for 12 months.

2. Reauthorization

a. Synribo will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Synribo therapy

Authorization will be issued for 12 months.

C. NCCN Recommended Regimens

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Synribo [package insert]. Parsippany, NJ: Teva Pharmaceuticals USA, Inc.; May 2021.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed September 21,2021.

Program	Prior Authorization/Notification - Synribo (omacetaxine)
Change Control	
8/2018	New program.
11/2019	Annual review. Added general NCCN recommendations for use statement. Updated reference.
11/2020	Annual review. Updated references.
11/2021	Annual review. Updated criteria per NCCN and Label that recommendation for all indications is resistance and/or intolerance to two or more tyrosine kinase inhibitors. Updated references.