UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Synribo

Program	Prior Authorization
Medication	Synribo (omacetaxine) injection
Markets in Scope	Arizona, California, Colorado, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	3/2018
Pharmacy and Therapeutics Approval Date	11/2020
Effective Date	12/2020

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 relapsed or refractory disease after hematopoietic stem cell transplantation.

2. Coverage Criteria:

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

1. **<u>Initial Authorization</u>**

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

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

-OR-

(2) **<u>Both</u>** of the following:

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

-AND-

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

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

-OR-

ii. Patient has relapsed or refractory 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.

B. NCCN Recommended Regimens

1. **Initial Authorization**

a. **Synribo** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Authorization will be issued for 12 months.

2. **Reauthorization**

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

(1) Documentation of positive clinical response to Synribo therapy

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]. North Wales, PA. Teva Pharmaceuticals USA, Inc. November 2019.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium). Available at https://www.nccn.org/professionals/drug_compendium/content. Accessed on October 5, 2020.

Program	Prior Authorization
Change Control	
Date	Change
3/2018	New program
8/2018	Revised criteria to align with CML NCCN recommendations.
11/2019	Annual review. Updated references.
11/2020	Annual review. Updated references.