PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Injectable) – Synribo Prior Authorization Policy
- Synribo® (omacetaxine mepesuccinate injection for subcutaneous use – Teva)

REVIEW DATE: 09/09/2020

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] The safety and efficacy of Synribo in pediatric patients have not been established.

Disease Overview

CML is a myeloproliferative neoplasm that comprises 15% of newly-diagnosed adult leukemias with an incidence of 1 to 2 cases per 100,000 adults.[2,3] In 2020, it was estimated that 8,450 patients would be diagnosed in the US, and 1,130 patients would die from the disease.[2] The median age at onset is 67 years; however, CML occurs in all age groups. CML is diagnosed by persistent unexplained leukocytosis with the presence of the Philadelphia chromosome abnormality characterized by a reciprocal translocation between chromosomes 9 and 22 that gives rise to the breakpoint cluster region (*BCR*) Abelson murine leukemia (*ABL*) 1 fusion gene which is believed to play a central role in the initial development of CML. Approximately 50% of patients with CML that are diagnosed in the US are asymptomatic.[3] Diagnosis often occurs following a routine physical examination or blood test.[2,3] CML occurs in three different phases (chronic phase [CP], accelerated phase [AP], or blast phase [BP]) and is usually diagnosed in CP. Common signs and symptoms of CP CML are related to anemia and splenomegaly. These include fatigue, weight loss, malaise, and left upper quadrant pain or fullness. Untreated CP CML will eventually progress to advanced disease in 3 to 5 years. Certain mutations are associated with high rates of disease progression and relapse. The T315I mutation is a commonly noted example, which occurs in about 5% to 15% of cases.

Guidelines

The National Comprehensive Cancer Network (NCCN) guidelines for CML (version 1.2021 – August 28, 2020) recommend Synribo as a treatment option for patients who have experienced disease progression to accelerated phase CML on TKI 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. Synribo is stated as an option for patients with disease that is resistant and/or intolerant to two other TKIs.

POLICY STATEMENT

Prior authorization is recommended for prescription benefit coverage of Synribo. 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

1. **Chronic Myeloid Leukemia (CML).** Approve for 6 months if the patient meets the following criteria (A, B, and C):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient meets one of the following criteria (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).
   - **C)** Medication is prescribed by or in consultation with an oncologist.

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® injection for subcutaneous use [prescribing information]. North Wales, PS: Teva Pharmaceuticals; November 2019.
2. The NCCN Chronic Myeloid Leukemia Clinical Practice Guidelines in Oncology (Version 1.2021 – August 28, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on September 4, 2020.
3. Jabbour E, Kantarjian H. Chronic myeloid leukemia: 2020 update on diagnosis, therapy and monitoring. *Am J Hematol.* 2020;95(6):691-709.