blue of california

omacetaxine solution (SYNRIBO)

Diagnoses Considered for Coverage:

- Chronic myeloid leukemia (CML)

Coverage Criteria:

For diagnosis of chronic myeloid leukemia (CML):

- Meets one of the following:
  - Inadequate response (or patient has had resistance) or intolerable side effects to TWO or more tyrosine kinase inhibitors (TKI) [e.g., imatinib (Gleevec), Tasigna (nilotinib), Sprycel (dasatinib), Bosulif (bosutinib), or Iclusig (ponatinib)], **OR**
  - Patient has received an allogenic stem cell transplant**, OR**
  - Primary treatment for disease that has progressed to accelerated phase, **OR**
  - Patient has a T315L mutation**,**

AND

- Being used as a single agent, **and**
- Dose does not exceed FDA label maximum based upon BSA:
  - **Induction**: up to 1.25 mg/m^2 injection twice daily for 14 consecutive days of
    28-day cycles. Cycles should be continued until hematologic response.
  - **Maintenance**: up to 1.25 mg/m^2 injection twice daily for 7 consecutive days per 28-day cycles.

Coverage Duration: one year

References:

1. Prescribing Information. Synribo. Teva Pharmaceuticals Inc. 5.2021
2. National Comprehensive Cancer Network. Chronic Myeloid Leukemia (v.1.2023). Available at http://www.nccn.org.

Effective Date: 3/29/2023