Synribo® (omacetaxine mepesuccinate) criteria for coverage (Commercial):

Coverage of Synribo® will be authorized when the following apply:

- The patient has a diagnosis of chronic myeloid leukemia (CML) AND
- The patient has previously tried or has a contraindication to at least two of the following:
  Gleevec, Sprycel, or Tasigna OR
- For continuation for therapy: The patient has achieved a hematologic response with Synribo® (defined as an absolute neutrophil count (ANC) ≥ 1.5 x 10^9/L, AND platelets ≥ 100 x 10^9/L, AND no blood blasts; OR bone marrow blasts <5%).

Duration of Authorization:
Initial Therapy:  3 months  
Subsequent Authorizations:  12 months  

**Specialty Medication:** Walgreens Specialty Pharmacy shall be the preferred provider. Authorization Specialist shall attempt to steer requesting provider to Walgreens. Upon initial approval or extension of an approval, complete the Walgreen’s Specialty Referral form and fax to 866-617-6685. Once received, Walgreen’s Specialty will contact the prescriber and member to arrange delivery of the medication.

Question and Answer Guide:

1. Is the request for initial coverage or for continuation of coverage?
   - Initial coverage=proceed to question #2
   - Continuation of coverage=proceed to question #4

2. Does the patient have a diagnosis of chronic myeloid leukemia (CML)?
   - Yes = continue to #3
   - No = deny.  **DENIAL TEXT:** According to our Pharmacy and Therapeutics Committee approved prior authorization guidelines for Synribo, approval requires a diagnosis of chronic myeloid leukemia (CML) and a trial of at least two of the following: Gleevec, Sprycel, or Tasigna.

3. Has the patient previously tried at least two of the following or does the patient have a contraindication to Gleevec, Sprycel, or Tasigna?
   - Yes = approve for 3 fills with a quantity limit of #28 vials per 28 days supply
No = deny. **DENIAL TEXT:** According to our Pharmacy and Therapeutics Committee approved prior authorization guidelines for Synribo, approval requires a diagnosis of chronic myeloid leukemia (CML) and a trial of at least two of the following: Gleevec, Sprycel, or Tasigna.

4. Has the patient achieved a hematologic response (defined as an absolute neutrophil count (ANC) \(\geq 1.5 \times 10^9/L\), AND platelets \(\geq 100 \times 10^9/L\), AND no blood blasts; OR bone marrow blasts <5%)?

[ ] Yes = approve for 12 fills with a quantity limit of #14 vials per 28 days supply
[ ] No = approve for 3 fills with a quantity limit of #28 vials per 28 days supply

Approved: March 7, 2013
Revised: June 24, 2013
Reviewed: January 7, 2014

References:

- Tefferi, A. Overview of the myeloproliferative neoplasms. In: UpToDate, Schrier, SL (Ed), UpToDate, Waltham, MA, 2012.