Synribo (omacetaxine mepesuccinate)

Line(s) of Business: HMO; PPO; QUEST Integration
Akamai Advantage

Original Effective Date: 10/01/2015
Current Effective Date: 01/01/2018
TBD 10/18/2016

POLICY
A. INDICATIONS
The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no contraindications or exclusions to the prescribed therapy.

FDA-Approved Indication
• Chronic myelogenous leukemia
  o Synribo 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 (TKIs).

Compendial Uses
• Treatment option for patients with resistance and/or intolerance to two or more TKIs:
  o For chronic phase
  o For disease progression in accelerated phase
  o For posttransplant relapse

Single agent therapy for:
• Primary treatment of CML disease progression to accelerated phase
• Posttransplant relapse or not in complete response
  o Post allogeneic hematopoietic stem cell transplant (HSCT) follow-up therapy in patients with molecular relapse (BCR-ABL1 transcript positive) following complete cytogenetic response
  o Post allogeneic HSCT follow-up therapy in patients with relapse or those who are not in complete cytogenetic response
• Chronic phase CML in patients with T315I mutation or disease that is resistant and/or intolerant to 2 or more TKIs

B. REQUIRED DOCUMENTATION
The following information is necessary to initiate the prior authorization review:
• Initial therapy
  o Current oncology notes, clinical notes (including previous treatment history and outcome), and any pertinent pathology reports (e.g., cytogenetic testing [conventional or
fluorescence in situ hybridization], molecular testing [quantitative reverse transcriptase polymerase chain reaction]) and/or imaging studies
  - If applicable, results of T315I mutation testing
  - Continuation of therapy
    - Documentation demonstrating lack of disease progression on therapy. This may include clinical notes and objective findings such as laboratory results of bone marrow cytogenetics and/or quantitative reverse transcriptase polymerase chain reaction (quantitative RT-PCR [QPCR]).

C. PRESCRIBER RESTRICTION
  - Synribo must be prescribed by an oncologist or a hematologist.

D. CRITERIA FOR APPROVAL

E. CRITERIA FOR APPROVAL

Chronic Myelogenous Leukemia
Authorization of 6 months may be granted to members with CML who meet any BOTH of the following criteria (1, 2 or 3 below):
1. Member has a diagnosis of chronic phase, accelerated phase CML or posttransplant relapsed CML.
2. Member is receiving follow-up therapy after hematopoietic stem cell transplantation for either of the following:
   a. Molecular relapse (BCR-ABL1 transcript positive) following a previous complete cytogenetic response
   b. Cytogenetic relapse or not in complete cytogenetic response
3. Member has chronic phase CML and either of the following:
   a. Member experienced resistance, toxicity, or intolerance to prior therapy with two or more tyrosine kinase inhibitors (e.g., imatinib, dasatinib, nilotinib, bosutinib, ponatinib), or
   a.b. Positive for the T315I mutation.

F.E. CONTINUATION OF THERAPY

All members, including new members, requesting authorization for therapy must meet ALL initial authorization criteria.

Members who were previously approved for Synribo by HMSA may request reauthorizations after their initial approval. Approvals for an additional 6 months may be granted for members who do not show evidence of disease progression while on Synribo therapy.
1. No previous authorization/precertification:
   - All members (including members currently receiving treatment without prior authorization) must meet criteria for initial approval in section D.
2. Reauthorization:
   - Authorization of 6 months may be granted to members requesting authorization for continuation of therapy if Synribo was previously authorized by HMSA/CVS and there is evidence of a lack of disease progression on therapy.

G.F. DOSAGE AND ADMINISTRATION

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.
**ADMINISTRATIVE GUIDELINES**

Precertification is required. Please refer to the [HMSA medical policy website](http://www.hmsa.com) for the fax form.

**IMPORTANT REMINDER**

The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii’s Patients' Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA’s determination as to medical necessity in a given case, the physician may request that CVS/caremark reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

**REFERENCES**


**Revised May 2016.**

**Document History**

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