Synribo (omacetaxine mepesuccinate)

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

**Original Effective Date:**
10/01/2015

**Current Effective Date:**
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
  - 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:
  - For chronic phase
  - For disease progression in accelerated phase
  - For posttransplant relapse

**B. REQUIRED DOCUMENTATION**
The following information is necessary to initiate the prior authorization review:
- Initial therapy
  - 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
- 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
   1. Chronic Myelogenous Leukemia
      Authorization of 6 months may be granted to members who meet BOTH of the following criteria:
      a. Member has a diagnosis of chronic phase, accelerated phase or posttransplant relapsed CML.
      b. Member experienced resistance, toxicity, or intolerance to prior therapy with two or more tyrosine kinase inhibitors (e.g., imatinib, dasatinib, nilotinib, bosutinib, ponatinib).

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.

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.

G. ADMINISTRATIVE GUIDELINES
   Precertification is required. Please refer to the HMSA medical policy web site for the fax form.

H. 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.

I. REFERENCES