Synribo (omacetaxine mepesuccinate)

Line(s) of Business:  
HMO; PPO; QUEST Integration  
Medicare Advantage  
Original Effective Date:  
10/01/2015  
Current Effective Date:  
01/01/2018

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
Single agent therapy for:
- Primary treatment of CML disease progression to accelerated phase
- Post-transplant relapse or not in complete response
  - Post allogeneic hematopoietic stem cell transplant (HSCT) follow-up therapy in patients with molecular relapse (BCR-ABL1 transcript positive) following complete cytogenetic response
  - 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
  - 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
Chronic Myelogenous Leukemia
Authorization of 6 months may be granted to members with CML who meet any of the following criteria (1, 2 or 3 below):
1. Member has accelerated phase 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. Resistance, toxicity, or intolerance to prior therapy with two or more tyrosine kinase inhibitors (e.g., imatinib, dasatinib, nilotinib, bosutinib, ponatinib), or
   b. Positive for the T315I mutation

E. CONTINUATION OF THERAPY
1. No previous authorization/precertification:
   All members (including new members and member 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.

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/CVS’s determination as to medical necessity in a given case, the physician may request that HMSA reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

I. REFERENCES


Document History

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