

Policy: MBP 102.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Synribo (omacetaxine mepesuccinate)

I. Policy:

Synribo (omacetaxine mepesuccinate)

II. Purpose/Objective:

To provide a policy of coverage regarding Synribo (omacetaxine mepesuccinate)

III. Responsibility:

- A. Medical Directors
- B. Medical Management
- C. Pharmacy Department

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards good medical treatment practiced by the general medical community;
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment

Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
- iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:

Synribo (omacetaxine mepesuccinate) binds to the A-site cleft in the peptidyl-transferase center of the large ribosomal subunit from a strain of archaeobacteria. In vitro, omacetaxine mepesuccinate reduced protein levels of the Bcr-Abl oncoprotein and Mcl-1, an anti-apoptotic Bcl-2 family member. Omacetaxine mepesuccinate showed activity in mouse models of wild-type and T315I mutated Bcr-Abl CML.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Synribo (omacetaxine mepesuccinate) will be considered medically necessary for all lines of business when all of the following criteria are met:

1. Chronic Myeloid Leukemia (CML)
 - Prescribed by a hematologist/oncologist; **AND**
 - Physician documentation of chronic or accelerated phase chronic myeloid leukemia (CML); **AND**
 - Physician documentation of therapeutic failure on, intolerance to, or contraindication to two or more tyrosine kinase inhibitors (eg. Gleevec, Iclusig, Sprycel, Tasigna, Scemblix, or Bosulif)

AUTHORIZATION DURATION: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

Note: For Medicaid (GHP Family), any requests for services that do not meet criteria set in the PARP will be evaluated on a case-by-case basis.

LINE OF BUSINESS:

Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

This policy will be revised as necessary and reviewed no less than annually.

Devised: 1/15/13

Revised: 1/20/15 (formatting, authorization duration, references), 2/28/19 (auth duration), 12/19/22 (LOB carve out, Medicaid PARP statement), 12/18/23 Medicaid business segment, TKI list)

Reviewed: 3/14, 3/16, 3/30/17, 3/29/18, 1/1/20, 1/1/21, 12/21/21