Clinical Policy: Omacetaxine (Synribo)

Reference Number: ERX.SPA.94
Effective Date: 03.01.14
Last Review Date: 05.20
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Omacetaxine (Synribo®) is cephalotaxine ester that inhibits protein synthesis by binding to the A-site in the peptidyl-transferase center of the large ribosomal subunit.

FDA Approved Indication(s)

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.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Synribo is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Chronic Myelogenous Leukemia (must meet all)**:**

1. Diagnosis of Ph+ (BCR-ABL1-positive) CML;
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age ≥ 18 years;
4. Request meets one of the following (a or b):*
   a. Dose does not exceed 2.5 mg/m^2 per day;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Chronic Myelogenous Leukemia (must meet all)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions, or documentation supports that member is currently receiving Synribo for CML and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a or b):*
   a. New dose does not exceed 2.5 mg/m^2 per day;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
CML: chronic myelogenous leukemia
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings
None reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
CML	Induction dose: 1.25 mg/m^2 subcutaneous twice daily for 14 consecutive days of a 28-day cycle Maintenance dose: 1.25 mg/m^2 subcutaneous twice daily for 7 consecutive days of a 28-day cycle	2.5 mg/m^2 per day

VI. Product Availability

Single-use vial: 3.5 mg of omacetaxine mepesuccinate as a lyophilized powder

VII. References

1. Synribo Prescribing Information. North Wales, PA: Teva Pharmaceuticals USA, Inc.; June 2017. Available at http://www.synribohcp.com/pdf/synribo_pi.pdf. Accessed February 5, 2019.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at www.nccn.org. Accessed February 5, 2019.
3. National Comprehensive Cancer Network Guidelines. Chronic Myeloid Leukemia Version 1.2019. Available at www.nccn.org. Accessed February 5, 2019.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	02.14	03.14
Policy converted to new template. Criteria: initial approval period shortened to three months per NCCN monitoring recommendation; documentation requests replaced with attestation requests; detailed efficacy criteria replaced with general disease progression criteria.	07.16	09.16
Converted to new template. Changed approval durations from 3/6 months to 6/12 months Added NCCN recommended use to criteria.	07.01.17	08.17

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Added History of T315I mutation per NCCN compendium		
2Q 2018 annual review: no significant changes; continuity of care statement added; NCCN and FDA approved uses summarized for improved clarity; specialist involvement in care added; approval durations increased to length of benefit; references reviewed and updated.	02.13.18	05.18
2Q 2019 annual review: Ph+ designation added to CML; hematologist added to CML/ALL criteria; references reviewed and updated.	02.19.19	05.19
2Q 2020 annual review: no significant changes; black box warnings removed; references reviewed and updated.	02.11.20	05.20

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.