Clinical Policy Title:	omacetaxine
Policy Number:	RxA.615
Drug(s) Applied:	Synribo®
Original Policy Date:	03/06/2020
Last Review Date:	8/28/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Chronic Myeloid Leukemia (CML) (must meet all)**:**

1. Diagnosis of CML in the chronic and accelerated phase;
2. Request meets one of the following (a or b):
   a. Member has experienced resistance, toxicity, or intolerance to prior therapy with two or more TKIs (e.g., imatinib, Bosulif®, Sprycel®, Tasigna®, Iclusig®) unless contraindicated or clinically significant adverse effects are experienced;
   b. Member has T315I mutation and has received prior treatment with Iclusig and Scemblix®.

Approval Duration

All Lines of Business (except Medicare): 6 months

II. Continued Therapy Approval

A. Chronic Myeloid Leukemia (CML) (must meet all)**:**

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

Approval Duration

All Lines of Business (except Medicare): 12 months

References

1. National Comprehensive Cancer Network Guidelines. Chronic Myeloid Leukemia Version 1.2025. Available at https://www.nccn.org/professionals/physician_gls/pdf/cml.pdf. Accessed August 28, 2024.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: 1. Policy clinical title was updated as "omacetaxine". 2. Lines of business policy applies to all lines of business. 3. Initial approval criteria I.A.1 was updated to add new request.	11/06/2020	12/07/2020

4. Continued therapy criteria II.A.1 was rephrased to “Member is currently receiving medication that has been authorized by RxAdvance…”. 5. References were reviewed and updated.		
Policy was reviewed: 1. References were reviewed and updated.	10/19/2021	12/07/2021
Policy was reviewed: 1. Initial Approval Criteria, I.A.4.b: Updated to include new trial and failure criteria Member has T315I mutation and has received prior treatment with Iclusig® and Scemblix®; 2. Initial Approval Criteria, I.A.1.b: Updated to remove prior follow up therapy criteria "Member is receiving follow-up therapy after hematopoietic stem cell transplantation for either of the following: i. Molecular relapse (BCR-ABL1 transcript positive) following a previous complete cytogenetic response; ii. Cytogenetic relapse or not in complete cytogenetic response; 3. References were reviewed and updated.	8/31/2022	10/19/2022
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. Removed age restrictions. 2. Removed prescriber restrictions. 3. Removed dose restrictions. 4. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days. 5. Removed reauthorization requirement for positive response to therapy. 6. Updated approval duration verbiage. 7. Reference was reviewed and updated.	8/28/2024	9/13/2024