Clinical Policy Title:	bosutinib
Policy Number:	RxA.031
Drug(s) Applied:	Bosulif®
Original Policy Date:	02/07/2020
Last Review Date:	08/28/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

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

1. Diagnosis of Ph+ (BCR-ABL1-positive) CML;
2. Member does not have the following mutations: T315I, V299L, G250E, or F317L.

Approval duration

All Lines of Business (except Medicare): 6 months

B. Acute Lymphoblastic Leukemia (off-label) (must meet all)**:**

1. Diagnosis of Ph+ (BCR-ABL1-positive) acute lymphoblastic leukemia (ALL);
2. Member does not have the following mutations: T315I, V299L, G250E, or F317L.

Approval duration

All Lines of Business (except Medicare): 6 months

C. Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes (off-label) (must meet all)**:**

1. Diagnosis of Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes;
2. The tumor has an ABL1 rearrangement;
3. Request is for treatment in combination with ALL- or AML-type induction chemotherapy followed by allogeneic HCT (if eligible) for lymphoid, myeloid or mixed lineage neoplasms with eosinophilia.

Approval duration

All Lines of Business (except Medicare): 6 months

II. Continued Therapy Approval

A. All Indications in Section I (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.

2. National Comprehensive Cancer Network Guidelines. Acute Lymphoblastic Leukemia Version 2.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/all.pdf. Accessed August 28, 2024.
3. National Comprehensive Cancer Network Guidelines. Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes Version 2.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/mlne.pdf. Accessed August 28, 2024.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy was established	01/2020	02/07/2020
Policy reviewed & updated.	04/30/2020	05/20/2020
Policy was reviewed: 1. Clinical policy title table was updated. 2. Initial and continued therapy age criteria I.A.3 and II.A.3 updated to simplify language. 3. Initial and continued therapy dosing criteria I.A.4, I.B.4, II.A.3 updated to include verbiage “Prescribed regimen must be FDA-approved…”. 4. Continued therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance..." 5. Approval duration section updated for initial and continued therapy to include Medicaid plans. Duration aligned with commercial plans. 6. References were updated.	02/01/2021	03/09/2021
Policy was reviewed: 1. Initial Approval Criteria, I.C: Updated to include approval criteria for indication, Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes (off-label). 2. Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 3. References were reviewed and updated.	11/19/2021	01/17/2022
Policy was reviewed: 1. Initial Approval Criteria, I.A.4 and I.B.3: Updated to include new criteria pertaining to indication Chronic Myelogenous Leukemia, Member does not have the following mutations: T315I, V299L, G250E, or F317L. 2. References were reviewed and updated.	09/28/2022	01/17/2023

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. References were reviewed and updated.	8/28/2024	9/13/2024