Clinical Policy Title:	bosutinib
Policy Number:	RxA.031
Drug(s) Applied:	Bosulif®
Original Policy Date:	02/07/2020
Last Review Date:	10/19/2023
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. Prescribed by or in consultation with an oncologist or hematologist;
3. Age ≥ 18 years;
4. Member does not have the following mutations: T315I, V299L, G250E, or F317L;
5. Request meets one of the following (a or b):
   a. Dose does not exceed 600 mg 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
Commercial: 6 months
Medicaid: 6 months

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

1. Diagnosis of Ph+ (BCR-ABL1-positive) acute lymphoblastic leukemia (ALL);
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Member does not have the following mutations: T315I, V299L, G250E, or F317L;
4. Age ≥ 18 years;
5. Dose is within FDA maximum limit for any FDA-approved indication or 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
Commercial: 6 months
Medicaid: 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. Prescribed by or in consultation with an oncologist or hematologist;
3. Age ≥ 18 years;

4. The tumor has an ABL1 rearrangement;
5. 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;
6. Dose is within FDA maximum limit for any FDA-approved indication or 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
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

A. All Indications in Section I (must meet all)**:**

1. Member is currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy or documentation supports that member is currently receiving bosutinib for a covered indication and has received this drug for at least 30 days;
2. Member is responding positively to therapy (e.g. evidence of hematologic or cytogenetic response);
3. If request is for a dose increase, new dose does not exceed the following (a or b):
   a. Dose does not exceed 600 mg 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
Commercial: 12 months
Medicaid: 12 months

References

1. National Comprehensive Cancer Network Guidelines. Chronic Myeloid Leukemia Version 2.2022. Updated January 13, 2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cml.pdf. Accessed September 28, 2022.
2. National Comprehensive Cancer Network Guidelines. Acute Lymphoblastic Leukemia Version 1.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/all.pdf. Accessed September 28, 2022.
3. National Comprehensive Cancer Network Guidelines. Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes Version 1.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/mlne.pdf. Accessed September 28, 2022.

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	02/01/2021	03/09/2021

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.		
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