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| **Clinical Policy Title:** | bosutinib |
| **Policy Number:** | RxA.31 |
| **Drug(s) Applied:** | Bosulif® |
| **Original Policy Date:** | 02/07/2020 |
| **Last Review Date:** | 03/09/2021 |
| **Line of Business Policy Applies to:** | All lines of business |

## Background

Bosutinib (Bosulif®) is a kinase inhibitor. Bosutinib is indicated for the treatment of adult patients with:

- Newly-diagnosed chronic phase (CP) Philadelphia chromosome-positive chronic myelogenous leukemia (Ph+ CML). This indication is approved under accelerated approval based on molecular and cytogenetic response rates. Continued approval for this indication may be contingent upon verification and confirmation of clinical benefit in an ongoing long-term follow up trial.
- Chronic phase, accelerated phase (AP), or blast phase (BP) Ph+ CML with resistance or intolerance to prior therapy.

## Dosing Information

| Drug Name | Indication | Dosing Regimen | Maximum Dose |
|---|---|---|---|
| bosutinib (Bosulif®) | Newly- diagnosed CP Ph+ CML | 400 mg PO once daily | 600 mg/day |
| | CP, AP, or BP Ph+ CML with resistance or intolerance to prior therapy | 500 mg PO once daily | 600 mg/day |

## Dosage Forms

- Tablets: 100 mg, 400 mg and 500 mg

## Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval 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; and
4. Request meets one of the following (a or b):
   a. Dose does not exceed 600 mg per day; or

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. Age ≥ 18 years; and
4. 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. Currently receiving medication that has been authorized by RxAdvance 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); and
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; or
   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

## III. Appendices

**APPENDIX A: Abbreviation/Acronym Key**
ALL: acute lymphoblastic leukemia
BP: blast phase
AP: accelerated phase
CML: chronic myelogenous leukemia
CP: chronic phase
FDA: Food and Drug Administration
NCCN: National Comprehensive Cancer Network
Ph+: Philadelphia chromosome-positive

**APPENDIX B: Therapeutic Alternatives**
Not applicable.

**APPENDIX C: Contraindications/Boxed Warnings**

- Contraindication(s):
  - Hypersensitivity to bosutinib (anaphylaxis has been reported).

- Boxed Warning(s):
  - None reported.

**APPENDIX D: General Information**

- NCCN Compendium lists bosutinib with a category 1 recommendation for chronic-phase Ph+ (BCR-ABL1-positive) CML as preferred primary treatment; other Ph+ (BCR-ABL1-positive) CML indications are listed as a category 2A recommendation.
- NCCN Compendium lists bosutinib with a category 2A recommendation for the treatment of Ph+ (BCR-ABL1-positive) ALL.

**References**

1. Bosulif® Prescribing Information. New York, NJ: Pfizer Inc.; June 2020. Available at https://www.bosulif.com. Accessed February 1, 2021.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at www.nccn.org. Accessed February 1, 2021.
3. National Comprehensive Cancer Network Guidelines. Chronic Myeloid Leukemia Version 3.2021. Updated January 13, 2021. Available at www.nccn.org. Accessed February 1, 2021.
4. National Comprehensive Cancer Network Guidelines. Acute Lymphoblastic Leukemia Version 2.2020. Available at www.nccn.org. Updated October 23, 2020. Accessed February 1, 2021.
5. Bosutinib. Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI; 2020, April 27. Accessed with subscription at: http://www.micromedexsolutions.com. Accessed February 1, 2021.
6. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed February 1, 2021.

| 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:<br>1. Clinical policy title table was updated.<br>2. Initial and continued therapy age criteria I.A.3 and II.A.3 updated to simplify language.<br>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…”. | 02/01/2021 | 03/09/2021 |

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|---|---|---|
| 4. Continued therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance..."<br>5. Approval duration section updated for initial and continued therapy to include Medicaid plans. Duration aligned with commercial plans.<br>6. Appendix A updated to remove QD as term was expanded.<br>7. References were updated. | | |