Clinical Policy: Bosutinib (Bosulif)

Reference Number: ERX.SPA.61
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

Bosutinib (Bosulif®) is a kinase inhibitor.

FDA Approved Indication(s)

Bosulif 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.

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 Bosulif 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 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 – Length of Benefit
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. 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 – Length of Benefit
Medicaid – 6 months

C. 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. All Indications in Section I (must meet all)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions, or documentation supports that member is currently receiving Bosulif for a covered indication 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 600 mg 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:
Commercial – Length of Benefit
Medicaid – 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

ALL: acute lymphoblastic leukemia
AP: accelerated phase
BP: blast phase
CML: chronic myelogenous leukemia
CP: chronic phase
FDA: Food and Drug Administration
Ph+: Philadelphia chromosome-positive

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: Contraindications/Boxed Warnings

Contraindication(s): hypersensitivity to Bosulif
Boxed warning(s): none reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Newly-diagnosed CP Ph+ CML	400 mg PO QD	600 mg/day
CP, AP, or BP Ph+ CML with resistance or intolerance to prior therapy	500 mg PO QD	600 mg/day

VI. Product Availability

Tablets: 100 mg, 400 mg, 500 mg

VII. References

1. Bosulif Prescribing Information. New York, NJ: Pfizer Inc.; October 2019. Available at https://www.bosulif.com. Accessed February 7, 2020.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at www.nccn.org. Accessed February 7, 2020.
3. National Comprehensive Cancer Network Guidelines. Chronic Myeloid Leukemia Version 3.2020. Available at www.nccn.org. Accessed February 7, 2020.
4. National Comprehensive Cancer Network Guidelines. Acute Lymphoblastic Leukemia Version 1.2020. Available at www.nccn.org. Accessed February 7, 2020.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy converted to new template. Criteria: deleted question about using Bosulif as monotherapy as there are circumstances where Bosulif is used with chemotherapy; removed detailed questions about therapy response due to complexity of monitoring parameters and replaced with general question about disease progression. Removed appendices discussing types of therapy responses and lists of therapeutic options.	07.16	09.16
Converted to new template. Increased approval duration from 3/6 months to 6/12 months.	06.17	08.17
Due to the addition of the new FDA indication for Bosulif in the primary therapy setting the criteria are represented at a high level to encompass both the FDA indications and NCCN recommended uses: AP or BP Ph+ CML primary therapy, post HCT therapy, first- or second-line therapy for the following point mutations (E255K/V, F317L/V/I/C, F359V/C/I, T315A, or Y253H). Preference for imatinib in the primary therapy setting is removed given Bosulif's new FDA labeled use. COC added. Approval durations modified to length of benefit. References reviewed and updated.	01.23.18	02.18
2Q 2018 annual review: off-label ALL added; references reviewed and updated.	02.13.18	05.18
2Q 2019 annual review: no significant changes; hematologist added to CML/ALL criteria; references reviewed and updated.	02.19.19	05.19
2Q 2020 annual review: adult age restriction removed from ALL per NCCN; contraindication added to Appendix C; added Medicaid line of business with 6/12 month approval durations; 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.