

Applicable Drugs: Bosulif (bosutinib)

Preferred: generic bosutinib tablets, Bosulif capsules (brand)

Non-preferred: Bosulif tablets (brand)

Date of Origin: 2/1/2013

Date Last Reviewed / Revised: 7/27/2026

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through IV are met)

- I. Documentation of the following FDA-approved diagnosis AND must meet all criteria listed under the applicable diagnosis:

FDA-Approved Indication(s)

A. Chronic Myelogenous Leukemia (CML)

- i. Documentation Philadelphia chromosome-positive (Ph+) CML and one of the following (a or b):

a) Documentation of accelerated or blast phase.

(1) Documented treatment failure, intolerance to, or contraindication to, one of the following other tyrosine kinase inhibitor (TKI) therapies for CML: dasatinib, imatinib, nilotinib, or ponatinib (Iclusig).

(2) Minimum age requirement: 18 years old.

b) Documentation of chronic phase (CP).

(1) Documented treatment failure, intolerance to, or contraindication to, one of the following other tyrosine kinase inhibitor (TKI) therapies for CML: dasatinib, imatinib, or nilotinib.

(2) Minimum age requirement: 1 year old.

Other Uses With Supportive Evidence

B. Myeloid/Lymphoid Neoplasm with Eosinophilia

C. Acute lymphoblastic leukemia (B-ALL)

- II. Treatment must be prescribed by or in consultation with an oncologist or a hematologist.
- III. Request is for a medication with the appropriate FDA labeling, or its use is supported by current National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1 or 2A.
- IV. Refer to plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- N/A

OTHER CRITERIA

- Capsules are limited to patients who cannot swallow tablets or doses that do not allow for tablet administration.

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Quantity limit of 30 capsules or 30 tablets per 30 days based on dose:
 - Adults with newly diagnosed chronic phase Ph+ CML: 400 mg once daily
 - Adults with chronic, accelerated, or blast phase Ph+ CML with resistance or intolerance to prior therapy: 500 mg once daily
 - Consider dose escalations by increments of 100 mg once daily to a maximum of 600 mg daily in adults who do not reach complete hematologic, cytogenetic, or molecular response and do not have Grade 3 or greater adverse reactions
 - Pediatric patients with newly diagnosed chronic phase Ph+ CML: 300 mg/m² once daily
 - Pediatric patients with chronic phase Ph+ CML with resistance or intolerance to prior therapy: 400 mg/m² once daily
 - Consider dose escalations by increments of 50 mg for those with a BSA < 1.1 m² and 100 mg for those with a BSA ≥ 1.1 m² to a maximum of 600 mg daily in pediatric patients who do not reach sufficient response after 3 months.

APPROVAL LENGTH

- **Authorization:** 1 year
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and does not show evidence of progressive disease.

APPENDIX

- N/A

REFERENCES

1. Bosulif. Prescribing information. Pfizer Inc. 2026. Accessed July 27, 2026.
<http://labeling.pfizer.com/ShowLabeling.aspx?id=884>

2. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Chronic Myeloid Leukemia Version 2.2027. Updated July 10, 2026. Accessed July 27, 2026.
https://www.nccn.org/professionals/physician_gls/pdf/cml.pdf.
3. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes. Version 1.2026. Updated October 3, 2025. Accessed July 27, 2026.
https://www.nccn.org/professionals/physician_gls/pdf/mlne.pdf
4. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Acute Lymphoblastic Leukemia. Version 2.2026. Updated July 24, 2026. Accessed July 27, 2026.
https://www.nccn.org/professionals/physician_gls/pdf/all.pdf

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.