Generic Name: Bosutinib

Therapeutic Class or Brand Name: Bosulif

Applicable Drugs (if Therapeutic Class): N/A

Preferred: N/A

Non-preferred: N/A

Date of Origin: 2/1/2013

Date Last Reviewed / Revised: 11/18/2024

PRIOR AUTHORIZATION CRITERIA

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

I. Documentation of one of the following diagnoses A through C AND must meet all criteria listed under the applicable diagnosis:

FDA-Approved Indication(s)

A. Chronic Myelogenous Leukemia (CML)

i. Documentation that the patient's CML is Philadelphia chromosome-positive (Ph+) 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 (Tasigna), or ponatinib (Iclusig).

(2) Minimum age requirement: 18 years old.

b) Documentation of chronic phase (CP).

(1) Minimum age requirement: 1 year old.

Other Uses With Supportive Evidence

B. Myeloid/Lymphoid Neoplasm with Eosinophilia

i. Presence of ABL1 tumor rearrangement.

ii. Documentation of chronic or blast phase.

iii. Documented treatment failure, intolerance to, or contraindication to imatinib.

iv. Minimum age requirement: 18 years old.

C. Acute lymphoblastic leukemia (B-ALL)

i. Documentation that patient's B-ALL is Philadelphia chromosome-positive (Ph+).

ii. Documentation that the patient does not have any of the following mutations of BCR-ABL1: T315I, V299L, G250E, or F317L.

iii. Documented treatment failure, intolerance to, or contraindication to imatinib and dasatinib.

iv. Minimum age requirement: 15 years old.

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 clinical practice guidelines.

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.

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.
    - Adults with newly diagnosed myeloid/lymphoid neoplasm with eosinophilia: 400 mg once daily
    - Adults with chronic or blast phase myeloid/lymphoid neoplasm with eosinophilia resistant or intolerant to prior therapy: 500 mg daily
    - Acute lymphoblastic leukemia: refer to primary literature for detailed dosing for regimen.

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; 2023. Accessed September 27, 2024. http://labeling.pfizer.com/ShowLabeling.aspx?id=884.
2. NCCN Clinical Practice Guidelines in Oncology. Chronic Myeloid Leukemia V.1.2025. Updated August 8, 2024. Accessed September 27, 2024. https://www.nccn.org/professionals/physician_gls/pdf/cml.pdf.
3. NCCN Clinical Practice Guidelines in Oncology. Myeloid/Lymphoid Neoplasms with Eosinophilia and tyrosine Kinase Fusion Genes V.2.2024. Updated June 19, 2024. Accessed September 27, 2024. https://www.nccn.org/professionals/physician_gls/pdf/mlne.pdf

   NCCN Clinical Practice Guidelines in Oncology. Acute Lymphoblastic Leukemia V.2.2024 Updated July 19, 2024. Accessed September 27, 2024. https://www.nccn.org/professionals/physician_gls/pdf/all.pdf