VENTURA COUNTY
HEALTH CARE PLAN

# PRIOR AUTHORIZATION POLICY

**POLICY:** Oncology – Bosulif Prior Authorization Policy
- Bosulif® (bosutinib tablets – Pfizer)

**REVIEW DATE:** 05/31/2023; selected revision 10/04/2023

---

## OVERVIEW

Bosulif, a tyrosine kinase inhibitor (TKI), is indicated for the following uses:[1]

- **Chronic myelogenous leukemia (CML)**, in chronic phase that is Philadelphia chromosome positive (Ph+) that is newly-diagnosed or resistant or intolerant to prior therapy in adults and pediatric patients ≥ 1 year of age.
- **CML**, Ph+, in accelerated, or blast phase, with resistance or intolerance to prior therapy in adults.

## Guidelines

Bosulif is addressed in guidelines from National Comprehensive Cancer Network (NCCN):

- **Acute Lymphoblastic Leukemia (ALL):** NCCN guidelines (version 2.2023 – July 28, 2023) recommend Bosulif for Ph+ disease in many different clinical circumstances (e.g., induction, consolidation therapy, maintenance, or relapsed or refractory disease) [category 2A].[2] TKIs in combination with other agents (e.g., chemotherapy or corticosteroids) are recommended for induction therapy for Ph+ ALL. TKIs have also been incorporated into consolidation and maintenance therapy, as well as in the relapsed/refractory setting (category 2A). TKI options include: Bosulif, Sprycel® (dasatinib tablets), imatinib, Tasigna® (nilotinib capsules), or Iclusig® (ponatinib tablets) [category 2A]. NCCN panel notes that not all TKIs have been directly studied within the context of each specific regimen and there are limited data for Bosulif in Ph+ ALL. Use of a specific TKI should account for anticipated/prior TKI intolerance and disease-related features. For adults and adolescents, Iclusig has activity against T315I mutations and/or in whom no other TKI is indicated (category 2A).
- **CML:** NCCN guidelines (version 1.2024 – August 1, 2023) recommend Bosulif as a "preferred" primary regimen for newly diagnosed chronic phase Ph+ CML in patients with a low-, intermediate-, or high-risk score (category 1).[3] Bosulif is also recommended as a "preferred" regimen for patients with advanced phase or blast phase CML (category 2A). Bosulif is also recommended as an alternative TKI treatment (after primary treatment with imatinib, Sprycel, or Tasigna (category 2A). Bosulif is also recommended in a variety of other situations, including post-allogeneic hematopoietic stem cell transplantation (HSCT) [category 2A].
- **Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes:** NCCN guidelines (version 2.2023 – July 14, 2023) recommend Bosulif as "other recommended regimens" for patients with *ABL1* rearrangements (category 2A).[4] It is also recommended as treatment in combination with ALL- or acute myeloid leukemia-type induction chemotherapy followed by allogeneic HSCT (if eligible) for lymphoid, myeloid, or mixed lineage neoplasms with eosinophilia and *ABL1* rearrangement in blast phase (category 2A).

## POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Bosulif. All approvals are provided for the duration noted below.

**Automation:** None.

---

## RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Bosulif is recommended in those who meet one of the following criteria:

### FDA-Approved Indication

1. **Chronic Myeloid Leukemia.** Approve for 1 year if the patient meets the following (A and B):
   - **A)** Patient is ≥ 1 year of age; AND
   - **B)** Patient has Philadelphia chromosome-positive chronic myeloid leukemia.

### Other Uses with Supportive Evidence

2. **Acute Lymphoblastic Leukemia.** Approve for 1 year if the patient meets the following (A, B, and C):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has Philadelphia chromosome-positive acute lymphoblastic leukemia; AND
   - **C)** Patient has tried at least one other tyrosine kinase inhibitor for Philadelphia chromosome-positive acute lymphoblastic leukemia.
     Note: Examples include imatinib and Sprycel (dasatinib tablets).

3. **Myeloid/Lymphoid Neoplasms with Eosinophilia.** Approve for 1 year if the patient meets the following (A and B):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** The tumor has an *ABL1* rearrangement.

## CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Bosulif is recommended in those who meet the following criteria:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

## REFERENCES

1. Bosulif® tablets [prescribing information]. New York, NY: Pfizer; September 2023.
2. The NCCN Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (version 2.2023 – July 28, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on October 2, 2023.
3. The NCCN Chronic Myeloid Leukemia Clinical Practice Guidelines in Oncology (version 1.2024 – August 1, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on October 2, 2023.
4. The NCCN Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes Clinical Practice Guidelines in Oncology (version 2.2023 – July 14, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on October 2, 2023.

## HISTORY

| Type of Revision | Summary of Changes | Review Date |
|---|---|---|
| Annual Revision | No criteria changes. | 05/04/2022 |
| Selected Revision | **Chronic Myeloid Leukemia:** Approval duration changed from 3 years to 1 year.<br>**Acute Lymphoblastic Leukemia:** Approval duration changed from 3 years to 1 year.<br>**Myeloid/Lymphoid Neoplasms with Eosinophilia:** Approval duration changed from 3 years to 1 year. | 06/22/2022 |
| Annual Revision | No criteria changes. | 05/31/2023 |
| Selected Revision | The FDA labeled indication of Philadelphia chromosome positive (Ph+) chronic myelogenous leukemia (CML) that is in chronic phase (newly diagnosed or resistant or intolerant to prior therapy) in adults was expanded to include pediatric patients ≥ 1 year of age.<br>**Chronic Myeloid Leukemia:** The criterion for age was changed from "patient is ≥ 18 years of age" to "patient is ≥ 1 year of age" due expanded labeling in the pediatric population. | 10/04/2023 |