

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Bosulif Prior Authorization Policy

- Bosulif® (bosutinib tablets – Pfizer)

REVIEW DATE: 05/04/2022; selected revision 06/22/2022

OVERVIEW

Bosulif, a tyrosine kinase inhibitor (TKI), is indicated for the treatment of adults with:¹

- **Chronic myelogenous leukemia (CML)**, newly diagnosed in chronic phase that is Philadelphia chromosome positive (Ph+).
- **CML, Ph+**, in chronic, accelerated, or blast phase, with resistance or intolerance to prior therapy.

Guidelines

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

- **Acute Lymphoblastic Leukemia (ALL):** The NCCN guidelines for ALL (version 1.2022 – April 4, 2022) [adults] recommend Bosulif as an option for patients with relapsed or refractory ALL (category 2A).²
- **CML:** NCCN guidelines for CML (version 3.2022 – January 27, 2022) state that for patients with chronic phase CML with a low risk score, the primary treatment recommended includes a first-generation TKI (imatinib), or a second-generation TKI (Bosulif, Sprycel® [dasatinib tablets], or Tasigna® [nilotinib capsules] {all category 1}).³ For patients with chronic phase CML with an intermediate or high risk score, a second-generation TKI is preferred (Bosulif [category 1], Sprycel [category 1], or Tasigna [category 1]). A first-generation TKI (imatinib) is an alternative (category 2A). Iclusig® (ponatinib tablets) is an option for patients with a T315I mutation and/or chronic phase CML with resistance or intolerance to at least two prior TKIs or for patients with accelerated-phase CML or blast-phase CML for whom no other TKI is indicated (category 2A). Scemblix® (asciminib tablets) is a treatment option for chronic phase CML in patients with the T315I mutation and/or chronic phase CML with resistance or intolerance to at least two prior TKIs (category 2A).
- **Myeloid/Lymphoid Neoplasms with Eosinophilia:** The NCCN guidelines for myeloid/lymphoid neoplasms with eosinophilia and tyrosine kinase fusion genes (version 1.2022 – April 14, 2022) note that Bosulif is a TKI with activity against *ABL1* rearrangements (category 2A) and it may have a role for use in patients with this condition.⁴

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 criteria (A and B):
 - A) Patient is ≥ 18 years 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; October 2021.
2. The NCCN Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (Version 1.2022 – April 4, 2022). © 2022 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on April 28, 2022.
3. The NCCN Chronic Myeloid Leukemia Clinical Practice Guidelines in Oncology (Version 3.2022 – January 27, 2022). © 2022 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on April 28, 2022.
4. The NCCN Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes Clinical Practice Guidelines in Oncology (version 1.2022 – April 14, 2022). © 2022 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on April 28, 2022.

