PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 05/01/2024; selected revision 06/12/2024

OVERVIEW

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

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

Guidelines

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

- **Acute Lymphoblastic Leukemia (ALL):** NCCN ALL guidelines for adults and adolescents (version 4.2023 – February 5, 2024) recommend Bosulif for Ph+ disease in many different clinical circumstances (e.g., induction, consolidation therapy, maintenance, or relapsed or refractory disease) [category 2A].[2] The guidelines state that the ALL panel considers adolescents to be within the age range of 15-39 years. 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 2.2024 – December 5, 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); an alternative TKI treatment (after primary treatment with imatinib, Sprycel, or Tasigna (category 2A); in a variety of other situations, including post-allogeneic hematopoietic stem cell transplantation (HSCT) [category 2A].
- **Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Gene Fusions:** NCCN guidelines (version 1.2024 – December 21, 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 BOTH of 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 ALL of the following (A, B, and C):
   - **A)** Patient is ≥ 15 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 BOTH of 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 and capsules [prescribing information]. New York, NY: Pfizer; September 2023.
2. The NCCN Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (version 4.2023 – February 5, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on April 29, 2024.
3. The NCCN Chronic Myeloid Leukemia Clinical Practice Guidelines in Oncology (version 2.2024 – December 5, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on April 29, 2024.
4. The NCCN Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Gene Fusion Clinical Practice Guidelines in Oncology (version 1.2024 – December 21, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on April 29, 2024.