UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 1012-13
Program	Prior Authorization/Notification
Medication	Bosulif® (bosutinib)
P&T Approval Date	11/2012, 7/2013, 8/2013, 2/2014, 2/2015, 2/2016, 12/2016, 11/2017, 2/2018, 2/2019, 2/2020, 2/2021, 2/2022, 2/2023
Effective Date	5/1/2023; Oxford only: 5/1/2023

1. Background:

Bosulif® (bosutinib) is a kinase inhibitor indicated for the treatment of adult patients with chronic, accelerated, or blast phase Philadelphia-positive chronic myelogenous leukemia (Ph+ CML) with resistance or intolerance to prior therapy. Bosulif is also indicated for the treatment of newly diagnosed chronic phase Ph+ CML.[1]

The National Comprehensive Cancer Network (NCCN) recommends use of Bosulif in follow-up therapy in CML after primary treatment with imatinib, dasatinib, or nilotinib. NCCN also recommends Bosulif for advanced phase CML, or for CML patients that are post-transplant experiencing a cytogenic or molecular relapse, for Philadelphia-positive acute lymphoblastic leukemia, and for treatment of myeloid/lymphoid neoplasms with eosinophilia and tyrosine kinase fusion genes.[2]

Coverage Information:
Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. Coverage Criteria[a]:

A. <u>Patients less than 19 years of age</u>

1. **Bosulif** will be approved based on the following criterion:

   a. Patient is less than 19 years of age

   Authorization will be issued for 12 months.

B. <u>Chronic Myelogenous/Myeloid Leukemia</u>

1. **<u>Initial Authorization</u>**

   a. **Bosulif** will be approved based on the following criterion:

      (1) Diagnosis of chronic myelogenous / myeloid leukemia

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Bosulif** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Bosulif therapy

Authorization will be issued for 12 months.

C. Philadelphia Chromosome-Positive Acute Lymphoblastic Leukemia

1. **Initial Authorization**

a. **Bosulif** will be approved based on the following criterion:

(1) Diagnosis of Philadelphia chromosome-positive acute lymphoblastic leukemia

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Bosulif** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Bosulif therapy

Authorization will be issued for 12 months

C. Myeloid/Lymphoid Neoplasms

1. **Initial Authorization**

a. **Bosulif** will be approved based on **both** of the following criteria:

(1) Diagnosis of myeloid/lymphoid neoplasms with eosinophilia

- AND –

(2) Presence of ABL1 rearrangement

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Bosulif** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Bosulif therapy

Authorization will be issued for 12 months

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D. NCCN Recommended Regimens

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits and/or step therapy may be in place.

4. References:

1. Bosulif [package insert]. New York, NY: Pfizer, Inc. October 2021.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at https://www.nccn.org. Accessed on December 16, 2022.

Program	Prior Authorization/Notification – Bosulif (bosutinib)
Change Control	
2/2014	Updated coverage criteria to include coverage for post allogeneic HSCT.
9/2014	Administrative change – Tried/Failed exemption for State of New Jersey removed.
2/2015	Annual review. Added coverage for Ph+ALL with mutations. Increased initial authorization to 12 months. Updated background and references.
2/2016	Annual review. Updated background and criteria for NCCN recommendations for expanded CML coverage and removal of tried/failed criteria for ALL. Updated references.
12/2016	Annual review. Changed Gleevec to imatinib mesylate. Removed ALL from off-label coverage criteria per NCCN. Updated background, formatting and references.
11/2017	Annual review. Updated background information and coverage criteria for advanced phase CMLand added criteria for relapsed/refractory Ph+ ALL per NCCN recommendation. Updated references.
2/2018	Updated coverage criteria to include new indication for first line therapy for CML.
2/2019	Annual review. No changes to coverage criteria. Updated reference.

2/2020	Annual review. Added general NCCN recommendations for use criteria. Updated references.
2/2021	Annual review. Added NCCN recommendations for myeloid/lymphoid neoplasms. Updated criteria for Ph+ALL based on NCCN recommendations.
2/2022	Annual review with no changes to coverage criteria. Updated references.
2/2023	Annual review with no changes to coverage criteria. Added state mandate footnote and updated references.