UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Bosulif

Program	Prior Authorization
Medication	Bosulif® (bosutinib)
Markets in Scope	Arizona, California, Colorado, Hawaii, Maryland, Nevada, New Jersey, New York CHIP, New York EPP, Pennsylvania-CHIP, Rhode Island, South Carolina
Issue Date	9/2013
Pharmacy and Therapeutics Approval Date	2/2021
Effective Date	4/2021

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]

2. Coverage Criteria:

A. <u>Chronic Myeloid Leukemia</u>

1. <u>Initial Authorization</u>

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

(1) Diagnosis of chronic myeloid leukemia

-AND-

(2) **<u>One</u>** of the following:

(a) Patient is not a candidate for imatinib as attested by physician

-OR-

(b) Patient is currently on Bosulif therapy

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.

B. 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

D. NCCN Recommended Regimens

1. Initial Authorization

a. **Bosulif** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Authorization will be issued for 12 months.

2. Reauthorization

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

(1) Documentation of positive clinical response to Bosulif therapy

Authorization will be issued for 12 months.

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 may be in place.

4. References:

1. Bosulif [package insert]. New York, NY: Pfizer, Inc. June 2020.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed on December 14, 2020.

Program	Prior Authorization - Bosulif® (bosutinib)
Change Control	
Date	Change
9/19/2013	New guideline.
3/20/2014	Updated Bosulif to allow for "post allogeneic hematopoietic stem cell transplantation (HSCT)" as an alternative to trial/failure to prior therapy for patients with Ph+CML. Background and References sections updated.
6/18/2015	Updated Initial Authorization duration of Bosulif for Philadelphia chromosome-positive chronic myelogenous/myeloid leukemia from 3 months to 12 months.
10/2016	Updated clinical criteria to align with Employer & Individual's notification and updated policy template
12/2016	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 CML and added criteria for relapsed/refractory Ph + ALL per NCCN recommendation. Update references.
2/2018	Updated coverage criteria to include new indication for first line therapy for CML. Added a section for NCCN recommended regimens to account for NCCN updates that occur outside of scheduled policy reviews.
10/2018	Updated criteria requiring consideration of imatinib prior to Bosulif coverage for CML.
2/2019	Annual review. No changes to coverage criteria. Updated references.
2/2020	Annual review. Updated references.
2/2021	Annual review. Added NCCN recommendations for myeloid/lymphoid neoplasms. Updated criteria for Ph+ALL based on NCCN recommendations. Updated references.