UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 3006-16
Program	Step Therapy
Medication	Bosulif® (bosutinib)
P&T Approval Date	8/2013, 2/2014, 2/2015, 2/2016, 12/2016, 11/2017, 2/2018, 2/2019, 2/2020, 2/2021, 2/2022, 4/2022, 4/2023, 4/2024
Effective Date	7/1/2024

1. Background:

Step Therapy programs are utilized to encourage the use of lower cost alternatives for certain therapeutic classes. This program requires a patient trial, or physician consideration of imatinib, and a trial of or contraindication to Tasigna® (nilotinib) before providing coverage for Bosulif (bosutinib) in the setting of Philadelphia chromosome-positive chronic myelogenous/myeloid leukemia (CML).

Bosulif (bosutinib), imatinib, and Tasigna (nilotinib) are kinase inhibitors indicated for the treatment of Philadelphia chromosome-positive CML in chronic phase and recommended by the National Comprehensive Cancer Network (NCCN) for use as preferred primary treatment as a single agents for newly diagnosed chronic phase Philadelphia chromosome-positive CML.

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,b]:

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. **Bosulif** will be approved based on **<u>both</u>** of the following criterion:

   a. Diagnosis of chronic myelogenous / myeloid leukemia

   -AND-

   b. **<u>One</u>** of the following:

(1) **Both** of the following:

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

-AND-

(b) **One** of the following:

i. History of failure, contraindication, or intolerance to Tasigna (nilotinib)

-OR-

ii. Patient has high risk of, or has pre-existing cardiovascular or hepatic disease to a degree that Tasigna (nilotinib) would not be an appropriate option

-OR-

(2) **Both** of the following:

(a) As continuation of therapy

-AND-

(b) Patient has **not** received a manufacturer supplied sample at no cost in prescriber office, or any form of assistance from the Pfizer sponsored Pfizer Oncology Together™ program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Bosulif*

* Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from Pfizer sponsored Pfizer Oncology Together™ program shall be required to meet initial authorization criteria as if patient were new to therapy.

Authorization will be issued for 12 months.

C. Other Indications

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

a. Indication other than chronic myelogenous / myeloid leukemia

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.

[b] Coverage of oncology medications may be approved based on state mandates.

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 Notification may be in place.
   - Coverage of oncology medications may be approved based on state mandates.

4. **References:**

   1. Bosulif [package insert]. New York, NY: Pfizer, Inc. September 2023.
   2. The NCCN Drugs and Biologics Compendium® (NCCN Compendium). Available at cml.pdf (nccn.org). Accessed February 26, 2024.
   3. Tasigna [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation. February 2024.
   4. Gleevec [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; August 2022.

Program	Step Therapy - Bosulif (bosutinib)
Change Control	
8/2013	New step therapy criteria.
2/2014	Updated Coverage Criteria to include coverage for post allogeneic HSCT.
2/2015	Annual review. Added sample pack language. Updated background and references.
2/2016	Annual review. Added Maryland Continuation of Care Guideline. Updated coverage criteria to include coverage for advanced phase CML.
7/2016	Added Indiana and West Virginia coverage information.
11/2016	Added California coverage information.
12/2016	Annual review. Changed Gleevec to imatinib mesylate. Updated background and references.
11/2017	Annual review. Updated sample pack and state mandate verbiage. Updated references.
2/2018	Updated formatting and background information. Updated criteria requiring consideration of both imatinib and Tasigna prior to Bosulif coverage.
2/2019	Annual review. No changes to coverage criteria. Updated reference.
2/2020	Annual review. No changes to coverage criteria. Updated references.
2/2021	Annual review. No changes to coverage criteria. Updated references.
2/2022	Annual review. No changes to coverage criteria. Updated references.
4/2022	Added oncology medications state mandate note.
4/2023	Annual review with no change to clinical coverage criteria. Updated background and references.
4/2024	Annual review with no change to coverage criteria. Updated references.