UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2018 P 1012-8
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
Effective Date	5/1/2018; Oxford only: 5/1/2018

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, and for relapsed or refractory Philadelphia-positive acute lymphoblastic leukemia.[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. <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.

B. Philadelphia Chromosome-Positive Acute Lymphoblastic Leukemia

1. **Initial Authorization**

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

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

-AND-

(2) Disease is relapsed/refractory

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

3. Additional Clinical Rules:

- Supply limits and/or step therapy may be in place.

4. References:

1. Bosulif [package insert]. New York, NY: Pfizer, Inc. December 2017.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed on December 21, 2017, 2017.

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 CML, and 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.