

Commercial/Healthcare Exchange PA Criteria

Effective: November 2, 2016

Prior Authorization: Bosulif

Products Affected: Bosulif (bosutinib monohydrate) oral tablets

Medication Description:

Bosulif is a tyrosine kinase inhibitor indicated for the treatment of adult patients with chronic, accelerated, or blast phase Philadelphia chromosome-positive (Ph+) chronic myelogenous leukemia (CML) with resistance or intolerance to prior therapy.

Bosutinib is a tyrosine kinase inhibitor. Bosutinib inhibits the Bcr-Abl kinase that promotes CML; it is also an inhibitor of Src-family kinases including Src, Lyn, and Hck. Bosutinib inhibited 16 of 18 imatinib-resistant forms of Bcr-Abl expressed in murine myeloid cell lines. Bosutinib did not inhibit the T315I and V299L mutant cells. In mice, treatment with bosutinib reduced the size of CML tumors relative to controls and inhibited growth of murine myeloid tumors expressing several imatinib-resistant forms of Bcr-Abl.

Covered Uses:

1. Newly-diagnosed chronic phase (CP) Philadelphia chromosome-positive chronic myelogenous leukemia (Ph+ CML).
2. Chronic phase, accelerated phase (AP), or blast phase (BP) Ph+ CML with resistance or intolerance to prior therapy.

Exclusion Criteria: Philadelphia chromosome-negative chronic myelogenous leukemia.

Required Medical Information:

1. Diagnosis
2. Philadelphia chromosome status
3. Previous therapies tried

Age Restrictions: 18 years of age and older

Prescriber Restrictions: Prescribed by, or in consultation with, an oncologist.

Coverage Duration: 12 months

Other Criteria:

Philadelphia chromosome-positive CML

- A. Patient has a diagnosis of newly diagnosed Philadelphia chromosome-positive chronic myelogenous leukemia; AND
- B. Patient's disease is chronic phase.

Chronic phase, accelerated phase (AP), or blast phase (BP) Ph+ CML

- A. Patient has a diagnosis of chronic phase, accelerated phase (AP), or blast phase (BP) Philadelphia chromosome-positive chronic myelogenous leukemia; AND
- B. Patient has had resistance or intolerance to prior therapy.

References:

1. Product Information: BOSULIF(R) oral tablets, bosutinib oral tablets. Pfizer Labs (per FDA), New York, NY, 2019.
2. The NCCN Chronic Myelogenous Leukemia Clinical Practice Guidelines in Oncology (Version 1.2016). © 2015 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on August 20, 2016

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	9/13/2016
2	Update	Criteria changed to match Updated FDA Label	Other Criteria	10/03/2018
3	Annual Review	Specified Covered Uses; CCI removed Bosulif from Oncology Policy, adopted EH policy and template	All	1/13/2020