

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	X

Bosulif (bosutinib)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Bosulif (bosutinib)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Bosulif (bosutinib) may be approved if the following criteria are met:

- I. Individual has a diagnosis of Chronic Myeloid Leukemia (CML); **AND**
 - A. Individual has newly-diagnosed chronic phase Philadelphia-positive (Ph+) or BCR-ABL1 positive (test results confirmed) disease; **OR**
 - B. Individual has chronic, accelerated, or blast phase Ph+ disease, with resistance or intolerance to prior treatment (Label, NCCN 2A); **AND**
 - C. Individual does not have any of the following contraindicated mutations:
 1. T315I; **OR**
 2. V299L; **OR**
 3. G250E; **OR**
 4. F317L;
- OR**
- D. Individual has chronic phase Ph+ disease and using Bosulif (bosutinib) as alternative treatment after imatinib, dasatinib, or nilotinib for the following BCR-ABL1 mutation profiles (NCCN 2A):
 1. E255K/V; **OR**
 2. F317L/V/I/C; **OR**
 3. F359V/C/I; **OR**
 4. T315A; **OR**
 5. Y253H; **OR**

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OR

II. Individual has a diagnosis of relapsed/refractory Ph+ Acute Lymphoblastic Leukemia (ALL) (NCCN 2A); **AND**

A. Individual does not have any of the following BCR-ABL1 mutations:

1. T315I; **OR**
2. V299L; **OR**
3. G250E; **OR**
4. F317L; **AND**

B. Individual is using as a single agent; **OR**

C. Individual is using in combination with an induction regimen not previously given.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2019. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2020 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Updated periodically. Accessed on January 23, 2020
 - a. Acute Lymphoblastic Leukemia. V1.2020. Revised January 15, 2020.
 - b. Chronic Myeloid Leukemia. V2.2020. Revised September 25, 2019.
 - c. Pediatric Acute Lymphoblastic Leukemia. V2.2020. Revised November 25, 2019.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.