

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 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**

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

- III. Individual has had a trial and inadequate response or intolerance to generic imatinib. Medication samples/coupons/discount cards are excluded from consideration as a trial.;

OR

- IV. Individual has been receiving and is maintained on a stable dose of Bosulif. Medication samples/coupons/discount cards are excluded from consideration as a trial.;

OR

- V. Individual has resistance, intolerance, contraindication or warning to generic imatinib due to current clinical conditions, including but not limited to pulmonary arterial hypertension, pleural or pericardial effusion, or cardiac abnormalities;

OR

- VI. Individual has intermediate or high Sokal score (0.8 or higher);

OR

- VII. Individual is diagnosed with genetic variants associated with high risk CML.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2024. 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>. Updated periodically.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2024; Updated periodically.
5. Assi R, Kantarjian H, Short NJ, et al. Safety and Efficacy of Blinatumomab in Combination with a Tyrosine Kinase Inhibitor for the Treatment of Relapsed Philadelphia Chromosome-positive leukemia. Clin Lymphoma Myeloma Leuk 2017; 17:897-901
6. Couturier MA, Thomas X, Raffoux E, et al. Blinatumomab+ponatinib for relapsed/refractory Philadelphia chromosome-positive acute lymphoblastic leukemia in adults. Leuk Lymphoma 2021;62:620-629
7. King AC, Pappacena JJ, Tallman MS, et al. Blinatumomab administered concurrently with oral tyrosine kinase inhibitor therapy is a well-tolerated consolidation strategy and eradicates measurable residual disease in adults with Philadelphia chromosome positive acute lymphoblastic leukemia. Leuk Res 2019;79:27-33
8. Short N, Kantarjian HM, Konopleva M, et al. Combination of ponatinib and blinatumomab in Philadelphia chromosome-positive acute lymphoblastic leukemia: Early results from a phase 2 study [abstract] ASCO Meeting abstracts 2021.
9. NCCN Clinical Practice Guidelines in Oncology™. © 2024 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Updated periodically. Accessed on January 3, 2024.
 - a. Acute Lymphoblastic Leukemia. V3.2023. Revised October 9, 2023.
 - b. Chronic Myeloid Leukemia. V2.2024. Revised December 5, 2023.
 - c. Myeloid/Lymphoid Neoplasm with Eosinophilia and Tyrosine Kinase Fusion Genes. V2.2023. Revised July 14, 2023.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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