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**

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;

OR

III. Individual has a diagnosis of B-cell precursor acute lymphocytic leukemia (B-ALL); **AND**
   A. Individual is using in combination with Blincyto (blinatumomab) for one of the following:
      1. Consolidation therapy with persistent or rising minimal residual disease (MRD) following a complete response (CR) to induction therapy**; OR**
      2. Relapsed or refractory disease.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2022. 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.; 2022; 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™. © 2022 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Updated periodically. Accessed on January 4, 2022.
   a. Acute Lymphoblastic Leukemia. V3.2021. Revised December 16, 2021.
   b. Chronic Myeloid Leukemia. V2.2022. Revised November 15, 2021.
   c. Myeloid/Lymphoid Neoplasm with Eosinophilia and Tyrosine Kinase Fusion Genes. V4.2021. Revised July 9, 2021.