Reference number(s)
2171-A

SPECIALTY GUIDELINE MANAGEMENT

BOSULIF (bosutinib)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications[1]
Bosulif is indicated for the treatment of adult patients with:
1. Newly-diagnosed chronic phase Philadelphia chromosome-positive (Ph+) chronic myelogenous leukemia (CML)
2. Chronic, accelerated, or blast phase Ph+ CML with resistance or intolerance to prior therapy.

B. Compendial Uses[2-4]
1. Treatment of patients with advanced phase CML (accelerated phase or blast phase)
2. Follow-up therapy for CML patients after hematopoietic stem cell transplant (HSCT)
3. Therapy for relapsed or refractory Ph+ acute lymphoblastic leukemia (ALL)

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

A. Chronic Myelogenous Leukemia, Chronic Phase (CP-CML)[1-3]
Authorization of 12 months may be granted for members initiating Bosulif for the treatment of CP-CML when diagnosis was confirmed by detection of the Ph chromosome or BCR-ABL gene by cytogenetic and/or molecular testing

B. Chronic Myelogenous Leukemia, Accelerated Phase (AP-CML) or Blast Phase (BP-CML)[1-3]
Authorization of 12 months may be granted for members initiating Bosulif for the treatment of AP-CML or BP-CML when diagnosis was confirmed by detection of the Ph chromosome or BCR-ABL gene by cytogenetic and/or molecular testing.

C. CML, Post-Hematopoietic Stem Cell Transplant (HSCT)[2-3]
Authorization of 12 months may be granted for members who are initiating treatment with Bosulif and have received a HSCT for CML when diagnosis was confirmed by detection of the Ph chromosome or BCR-ABL gene by cytogenetic and/or molecular testing.

D. Ph+ Acute Lymphoblastic Leukemia (ALL)[2,4]
Authorization of 12 months may be granted for members initiating therapy for relapsed/refractory PH+ ALL when diagnosis was confirmed by detection of Ph chromosome or BCR-ABL gene by cytogenetic and/ or molecular testing

© 2018 CVS Caremark. All rights reserved.
This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.

CVS caremark™

Reference number(s)
2171-A

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet ALL initial authorization criteria.

IV. REFERENCES

1. Bosulif [package insert]. New York, NJ: Pfizer Inc.; December 2017.
2. The NCCN Drugs & Biologics Compendium® © 2018 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed March 28, 2018.
3. The NCCN Clinical Practice Guidelines in Oncology® Chronic Myelogenous Leukemia (Version 4.2018). © 2018 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed March 28, 2018.
4. The NCCN Clinical Practice Guidelines in Oncology® Acute Lymphoblastic Leukemia (Version 1.2018). © 2018 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed March 28, 2018.

© 2018 CVS Caremark. All rights reserved.
This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.