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
Bosulif is 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.

B. Compendial Uses
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)

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

II. REQUIRED DOCUMENTATION

The following information is necessary to initiate the prior authorization review:
A. For all members: results of cytogenetic and/or molecular testing for detection of the Ph chromosome or the BCR-ABL gene obtained prior to initiation of therapy
B. For members requesting initiation of Bosulif therapy for the treatment of CML after experiencing resistance to prior tyrosine kinase inhibitor (TKI) therapy: results of T315I mutation testing

III. CRITERIA FOR INITIAL APPROVAL

Chronic Myelogenous Leukemia (CML)
Authorization of 12 months may be granted for members initiating treatment with Bosulif for CML when ALL of the following criteria are met:
1. Diagnosis of CML was confirmed by detection of the Ph chromosome or BCR-ABL gene by cytogenetic and/or molecular testing
2. Member is 18 years of age or older
3. Member meets criteria outlined in Section A, B, or C below

A. CML, Chronic Phase (CP-CML)
Authorization of 12 months may be granted for members initiating Bosulif for the treatment of CP-CML when EITHER of the following criteria is met:
1. Member has experienced resistance to prior therapy with a TKI (e.g., dasatinib, imatinib, nilotinib, ponatinib) AND results of mutational testing are negative for T315I mutation
2. Member has experienced toxicity or intolerance to prior therapy with a TKI (e.g., dasatinib, imatinib, nilotinib, ponatinib)

B. CML, Accelerated Phase (AP-CML) or Blast Phase (BP-CML)
Authorization of 12 months may be granted for members initiating Bosulif for the treatment of AP- CML or BP-CML who meet ANY of the following criteria:
1. Member has not received prior therapy with a TKI
2. Member experienced toxicity or intolerance to prior therapy with a TKI
3. Member has experienced resistance to prior therapy with a TKI AND results of mutational testing are negative for T315I mutation

C. CML, Post-Hematopoietic Stem Cell Transplant (HSCT)
Authorization of 12 months may be granted for members who are initiating treatment with Bosulif and have received a HSCT for CML

IV. CONTINUATION OF THERAPY

Chronic Myelogenous Leukemia (CML)
Authorization of up to 12 months may be granted for members continuing treatment with Bosulif for CML when ALL of the following criteria are met:
1. Diagnosis of CML was confirmed by detection of the Ph chromosome or BCR-ABL gene by cytogenetic and/or molecular testing
2. Member is 18 years of age or older
3. Member meets criteria outlined in Section A or B below

A. CML, Chronic Phase (CP-CML)
Authorization of up to 12 months may be granted for members in CP-CML who have experienced resistance, toxicity, or intolerance to prior therapy with a TKI (e.g., dasatinib, imatinib, nilotinib, ponatinib) when EITHER of the following criteria is met:
1. Authorization of up to 12 months for members who have been receiving Bosulif for < 12 months
2. Authorization of 12 months for members who have been receiving Bosulif for ≥ 12 months and do not show evidence of disease progression

B. CML, Accelerated Phase (AP-CML), Blast Phase (BP-CML), and Post-Hematopoietic Stem Cell Transplant (HSCT)
Authorization of 12 months may be granted for members continuing Bosulif for the treatment of AP- CML, BP-CML, and for members who have received a HSCT for CML.

V. DOSAGE AND ADMINISTRATION

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The following dosing limits apply: 600mg per day.

VI. REFERENCES

1. Bosulif [package insert]. New York, NJ: Pfizer Inc.; April 2016.
2. The NCCN Drugs & Biologics Compendium® © 2016 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed April 12, 2016.
3. The NCCN Clinical Practice Guidelines in Oncology® Chronic Myelogenous Leukemia (Version 1.2016). © 2016 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed March 3, 2016.