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
Adult patients with:
1. Newly-diagnosed chronic phase (CP) Philadelphia chromosome-positive chronic myelogenous leukemia (Ph+ CML)
2. Chronic phase, accelerated phase (AP), or blast phase (BP) Ph+ CML with resistance or intolerance to prior therapy

B. Compendial Uses
1. Primary 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. REQUIRED DOCUMENTATION

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

III. CRITERIA FOR INITIAL APPROVAL

A. Chronic Myeloid Leukemia (CML)
Authorization of 6 months may be granted for treatment of CML that has been confirmed by detection of the Ph chromosome or BCR-ABL gene by cytogenetic and/or molecular testing when any of the following criteria are met:
1. Member has not received prior therapy with a TKI (e.g., dasatinib, imatinib, nilotinib, ponatinib)
2. Member experienced toxicity or intolerance to prior therapy with a TKI
3. Member experienced resistance to prior therapy with a TKI and results of mutational testing are negative for T315I mutation
4. Member has received HSCT for CML

B. Ph+ Acute Lymphoblastic Leukemia (ALL)/Lymphoblastic Lymphoma (LL)

Authorization of 12 months may be granted for treatment of relapsed or refractory Ph+ ALL or LL that has been confirmed by detection of Ph chromosome or BCR-ABL gene by cytogenetic and/ or molecular testing when results of mutational testing are negative for T315I mutation.

IV. CONTINUATION OF THERAPY

A. CML

Authorization of 12 months may be granted for continued treatment of CML that has been confirmed by detection of Ph chromosome or BCR-ABL gene by cytogenetic and/ or molecular testing when either of the following criteria are met:

1. BCR-ABL1 ≤ 10% for members who have been receiving Bosulif for ≤ 12 months
2. No evidence of disease progression for members who have been receiving Bosulif for > 12 months
3. Member has received HSCT

B. Ph+ ALL/LL

Authorization of 12 months may be granted for continued treatment of Ph+ ALL or LL that has been confirmed by detection of Ph chromosome or BCR-ABL gene by cytogenetic and/ or molecular testing in members who have not experienced disease progression or an unacceptable toxicity.

V. REFERENCES

1. Bosulif [package insert]. New York, NJ: Pfizer Inc.; October 2018.
2. The NCCN Drugs & Biologics Compendium® © 2019 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed April 16, 2019.
3. NCCN Clinical Practice Guidelines in Oncology® Chronic Myeloid Leukemia (Version 1.2019). © 2019 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed April 16, 2019.
4. NCCN Clinical Practice Guidelines in Oncology® Acute Lymphoblastic Leukemia (Version 1.2019). © 2019 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed April 17, 2019.