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. Component of a treatment induction regimen, consolidation therapy regimen, or maintenance therapy regimen for Ph+ acute lymphoblastic leukemia (ALL)
4. Therapy for relapsed or refractory Ph+ acute lymphoblastic leukemia (ALL)
5. Maintenance therapy for Ph+ ALL patients after hematopoietic stem cell transplant (HSCT)
6. Myeloid/lymphoid neoplasms with eosinophilia and ABL1 rearrangement in chronic phase
7. Lymphoid, myeloid or mixed lineage neoplasms with eosinophilia and ABL1 rearrangement in blast phase

All other indications are considered experimental/investigational and not medically necessary.

II. REQUIRED DOCUMENTATION

The following information is necessary to initiate the prior authorization review:
A. Prior to initiation of therapy for treatment of CML or Ph+ ALL/LL: results of cytogenetic and/or molecular testing for detection of the Ph chromosome or the BCR-ABL gene
B. For members requesting initiation of therapy with the requested medication for treatment of CML or Ph+ ALL/LL after experiencing resistance to prior tyrosine kinase inhibitor (TKI) therapy: results of BCR-ABL1 mutation testing including T315I, G250E, V299L, F317L mutations
C. For members requesting initiation of therapy with the requested medication for treatment of myeloid and/or lymphoid neoplasms with eosinophilia: results of testing or analysis confirming ABL1 rearrangement

III. CRITERIA FOR INITIAL APPROVAL

A. Chronic Myeloid Leukemia (CML)

Authorization of 7 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 tyrosine kinase inhibitor (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 BCR-ABL1 mutation testing are negative for all of the following mutations: T315I, G250E, V299L, and F317L
4. Member has received HSCT for CML and results of BCR-ABL1 mutation testing are negative for all of the following mutations: T315I, G250E, V299L, and F317L

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

Authorization of 12 months may be granted for treatment Ph+ ALL or LL that has been confirmed by detection of 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 intolerance or toxicity to prior therapy with a TKI
3. Member experienced resistance to prior therapy with a TKI and results of BCR-ABL1 mutation testing are negative for all of the following mutations: T315I, G250E, V299L, and F317L
4. Member has received HSCT for ALL/LL and results of BCR-ABL1 mutation testing are negative for all of the following mutations: T315I, G250E, V299L, and F317L

C. Myeloid/Lymphoid Neoplasms with Eosinophilia

Authorization of 12 months may be granted for treatment of myeloid and/or lymphoid neoplasms with eosinophilia and ABL1 rearrangement in the chronic phase or blast phase.

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. Authorization of 12 months may be granted when any of the following criteria is met:
   a. BCR-ABL1 is less than or equal to 10% for members who have been receiving treatment with the requested medication for less than or equal to 12 months.
   b. No evidence of disease progression or unacceptable toxicity while on the current regimen for members who have been receiving the requested medication for greater than 12 months
   c. Member has received HSCT when there is no evidence of unacceptable toxicity or disease progression while on the current regimen
2. Authorization of up to 7 months may be granted when the member has completed less than 6 months of therapy with the requested medication.

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 when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

C. Myeloid/Lymphoid Neoplasms with Eosinophilia

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

V. REFERENCES

1. Bosulif [package insert]. New York, NY: Pfizer Inc.; October 2019.
2. The NCCN Drugs & Biologics Compendium® © 2020 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed August 18, 2020.
3. NCCN Clinical Practice Guidelines in Oncology® Chronic Myeloid Leukemia (Version 3.2020). © 2020 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed March 30, 2020.
4. NCCN Clinical Practice Guidelines in Oncology® Acute Lymphoblastic Leukemia (Version 1.2020). © 2020 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed March 30, 2020.