Clinical Policy: Bosutinib (Bosulif)

Reference Number: PA.CP.PHAR.105
Effective Date: 01/18
Last Review Date: 04/18

Revision Log

Description
The intent of the criteria is to ensure that patients follow selection elements established by Pennsylvania Health and Wellness® clinical policy for bosutinib (Bosulif®).

FDA Approved Indication(s)
Bosulif is indicated for the treatment of adult patients with:

- Newly-diagnosed chronic phase (CP) Philadelphia chromosome-positive chronic myelogenous leukemia (Ph+ CML). This indication is approved under accelerated approval based on molecular and cytogenetic response rates. Continued approval for this indication may be contingent upon verification and confirmation of clinical benefit in an ongoing long-term follow up trial
- Chronic phase, accelerated phase (AP), or blast phase (BP) Ph+ CML with resistance or intolerance to prior therapy

Policy/Criteria
It is the policy of health plans affiliated with Pennsylvania Health and Wellness that bosutinib (Bosulif) is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Chronic Myelogenous Leukemia (must meet all)**:**

1. Diagnosis of Ph+ or BCR-ABL1+ chronic myelogenous leukemia (CML);
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Prescribed dose of Bosulif does not exceed 600 mg daily;

Approval duration: 3 months

B. Other diagnoses/indications: Refer to PA.CP.PHAR.57 – Global Biopharm Policy.

II. Continued Approval

A. Chronic Myelogenous Leukemia (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. Prescribed dose does not exceed 600 mg once daily;

Approval duration: 6 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.CP.PHAR.57 - Global Biopharm Policy.

Background

Description/Mechanism of Action:

Bosutinib is a tyrosine kinase inhibitor. Bosutinib inhibits the Bcr-Abl kinase that promotes CML; it is also an inhibitor of Src-family kinases including Src, Lyn, and Hck. Bosutinib inhibited 16 of 18 imatinib-resistant forms of Bcr-Abl expressed in murine myeloid cell lines. Bosutinib did not inhibit the T315I and V299L mutant cells. In mice, treatment with bosutinib reduced the size of CML tumors relative to controls and inhibited growth of murine myeloid tumors expressing several imatinib-resistant forms of Bcr-Abl.

Formulations:

Bosulif is supplied as tablets in two strengths:

- 100 mg yellow, oval, biconvex, film-coated tablet, debossed with "Pfizer" on one side and "100" on the other, available in bottles of 120;
- 500 mg red, oval, biconvex, film-coated tablet, debossed with "Pfizer" on one side and "500" on the other, available in bottles of 30.

Appendices

Appendix A: Abbreviation Key

CML: chronic myelogenous leukemia
FDA: Food and Drug Administration
NCCN: National Comprehensive Cancer Network
Ph+: Philadelphia chromosome positive
TKI: tyrosine kinase inhibitor
ULN: upper limit of normal

Reviews, Revisions, and Approvals	Date	Approval Date
Specialist added; ages added; references reviewed and updated.	01.23.18	

References

1. Bosulif Prescribing Information. New York, NJ: Pfizer Inc.; December 2017. Available at www.bosulif.com. Accessed January 2018
2. National Comprehensive Cancer Network. Chronic Myeloid Leukemia Version 3.2018. Available at www.nccn.org. Accessed January 2018.
3. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at http://www.nccn.org/professionals/drug_compendium. Accessed January 2018.