OVERVIEW:

Bosulif® (bosutinib) is an oral tyrosine kinase inhibitor (TKI) indicated for the treatment of adult patients with chronic, accelerated, or blast phase (CP, AP, or BP, respectively) Philadelphia chromosome-positive (Ph+) chronic myelogenous leukemia (CML) with resistance or intolerance to prior therapy. Approved alternative therapies include: Gleevec® (imatinib tablets), Sprycel® (dasatinib tablets), and Tasigna® (nilotinib capsules). Bosulif inhibits the BCR-ABL kinase that promotes CML; it is also an inhibitor of Src-family kinase, including Src, Lyn, and Hck. Bosulif inhibited 16 of 18 imatinib-resistant forms of BCR-ABL expressed in murine myeloid cell lines. Treatment with Bosulif has shown to reduce the size of CML tumors in mice, and inhibit the growth of tumors several imatinib-resistant forms of Bcr-Abl. Bosulif treatment should continue until disease progression or patient intolerance.

POLICY STATEMENT: In order to be considered for coverage, this drug must be prescribed by or in consultation with a hematologist or oncologist.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Bosulif is recommended in those who meet the following criteria:

1. **Adult patients with Chronic Myelogenous Leukemia (CML) that is Philadelphia chromosome positive (Ph+) with resistance or intolerance to prior therapy.**
   Approve in patients who meet the following criteria, have tried one of the following (a,b, and/or c):
   a. Gleevec® (imatinib tablets)
   b. Sprycel® (dasatinib tablets)
   c. Tasigna® (nilotinib capsules)

2. **Patients with another indication that is not listed but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation.**
   Prescriber will provide specific diagnosis for documentation.
   Approve.

3. **Patient has been started on Bosulif.**
   Approve for an indication or condition addressed as an approval in this document.

Approval Duration: 365 days (1 year)
References