

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Bosulif® (bosutinib tablets – Pfizer)

DATE REVIEWED: 03/20/2019

OVERVIEW

Bosulif, a tyrosine kinase inhibitor (TKI), is indicated for the treatment of adult patients with: newly-diagnosed chronic phase Philadelphia chromosome-positive (Ph+) chronic myelogenous leukemia (CML).¹ This indication was 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. Bosulif is also indicated for the treatment of adult patients with chronic phase (CP), accelerated phase (AP), or blast phase (BP) Ph+ CML with resistance or intolerance to prior therapy. Currently, there are four other TKIs approved for the treatment of Ph+ CML: Gleevec® (imatinib tablets, generic), Sprycel® (dasatinib tablets), Tasigna® (nilotinib capsules), and Iclusig® (ponatinib tablets).²⁻⁵ These agents are indicated for the treatment of Ph+ CML in various phases; some TKIs are indicated after resistance or intolerance to prior therapy. Iclusig is approved for patients with T315I-positive CML and in adult patients with CML for whom no other TKI therapy is indicated.⁵ Sprycel, Gleevec and Iclusig are also indicated for use in patients with Ph+ acute lymphoblastic leukemia (ALL).^{2-3,5}

Guidelines

The National Comprehensive Cancer Network (NCCN) guidelines for CML (version 1.2019 – August 1, 2018) state that for patients with CP CML with a low-risk score, the primary treatment recommended includes a first-generation TKI (Gleevec or generic imatinib 400 mg QD [Category 1]), or a second-generation TKI (Bosulif 400 mg QD [Category 1], Sprycel 100 mg QD [Category 1], or Tasigna 300 mg BID [Category 1]).⁶ For patients with CP CML with an intermediate- or high-risk score, a second-generation TKI is preferred (Bosulif 400 mg QD [Category 1], Sprycel 100 mg QD [Category 1], or Tasigna 300 mg BID [Category 1]). A first-generation TKI (Gleevec or generic imatinib 400 mg QD) is an alternative [Category 2A]. Iclusig is an option for patients with a T315I mutation and for with disease that has not responded to multiple TKIs or in whom another TKI is not indicated.⁶ The NCCN guidelines for ALL (version 1.2018 – March 12, 2018) recommend Bosulif as an option for patients with relapsed or refractory ALL and for use in specific mutations.⁷

POLICY STATEMENT

Prior authorization is recommended for prescription benefit coverage of Bosulif. All approvals are provided for 3 years in duration.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indications

- 1. Chronic Myeloid Leukemia (CML) That is Philadelphia Chromosome Positive (Ph+).**
Approve for 3 years.

Other Uses with Supportive Evidence

- 2. Acute Lymphoblastic Leukemia (ALL) That is Philadelphia Chromosome Positive (Ph+).**
Approve for 3 years if the patient has tried one other tyrosine kinase inhibitor (TKI) for Ph+ ALL (e.g., Gleevec® [imatinib tablets], Sprycel® [dasatinib tablets]).

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Bosulif has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. Rationale for non-coverage for these specific conditions is provided below. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.)

- 1. Breast Cancer.** The efficacy of Bosulif in patients with locally advanced or metastatic breast cancer previously treated with one to three chemotherapy regimens was evaluated in one small Phase II study (n = 73).⁸ Multiple other agents are indicated for the treatment of breast cancer. More data are needed to further define the place in therapy of Bosulif for the treatment of breast cancer, and which subset of patients (e.g., hormone-receptor positive) may receive the most benefit from Bosulif.
- 2.** Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Bosulif® tablets [prescribing information]. New York, NY: Pfizer Inc; October 2018.
2. Gleevec® tablets [prescribing information]. East Hanover, NJ: Novartis; July 2018.
3. Sprycel® tablets [prescribing information]. Princeton, NJ: Bristol-Myers Squibb; December 2018.
4. Tasisign® capsules [prescribing information]. East Hanover, NJ: Novartis; July 2018.
5. Iclusig® tablets [prescribing information]. Cambridge, MA: Ariad Pharmaceuticals; October 2018.
6. The NCCN Chronic Myeloid Leukemia Clinical Practice Guidelines in Oncology (Version 1.2019 – August 1, 2018). © 2018 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on March 12, 2019.
7. The NCCN Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (Version 1.2018 – March 12, 2018). © 2018 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on March 12, 2019.
8. Campone M, Bondarenko I, Brinca S, et al. Phase II study of single-agent bosutinib, a Src/Abl tyrosine kinase inhibitor, in patients with locally advanced or metastatic breast cancer pretreated with chemotherapy. *Ann Oncol*. 2012;23:610-617.

History

Type of Revision	Summary of Changes*	TAC Approval Date
Annual revision	No criteria changes.	03/01/2017
Annual revision	For the indication in CML, changed the criteria to approve the request for 3 years. Previously, use of Bosulif required a trial of one TKI inhibitor indicated for Ph+ CML. Criteria added to approve Bosulif in patients with ALL that is Philadelphia Chromosome Positive (Ph+) if the patient has tried one other TKI for Ph+ ALL (e.g., Gleevec® [imatinib tablets], Sprycel® [dasatinib tablets]). Also, removed the criteria allowing for approval if the patient has been started on Bosulif for an indication or condition addressed as an approval in the Recommended Authorization section (FDA-approved indications or other uses with supportive evidence).	03/07/2018
Annual revision	No criteria changes.	03/20/2019

* For a further summary of criteria changes, refer to respective TAC minutes available at: <http://esidepartments/sites/Dep043/Committees/TAC/Forms/AllItems.aspx>; TAC – Therapeutic Assessment Committee; ALL – Acute lymphoblastic leukemia; NCCN – National Comprehensive Cancer Network; Chronic myelogenous leukemia; TKI(s) – Tyrosine kinase inhibitor(s); Ph+ CML – Philadelphia chromosome positive.