

## PRIOR AUTHORIZATION POLICY

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

**DATE REVIEWED:** 04/01/2020

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### OVERVIEW

Bosulif, a tyrosine kinase inhibitor (TKI), is indicated for the treatment of adults with: newly diagnosed chronic phase Philadelphia chromosome-positive (Ph+) chronic myelogenous leukemia (CML).<sup>1</sup> 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 adults 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), Tassigna® (nilotinib capsules), and Iclusig® (ponatinib tablets).<sup>2-5</sup> 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.<sup>5</sup> Sprycel, Gleevec and Iclusig are also indicated for use in patients with Ph+ acute lymphoblastic leukemia (ALL).<sup>2,3,5</sup>

### Guidelines

The National Comprehensive Cancer Network (NCCN) guidelines for CML (version 3.2020 – January 30, 2020) 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 Tassigna 300 mg BID [Category 1]).<sup>6</sup> 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 Tassigna 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.<sup>6</sup> The NCCN guidelines for ALL (adult and adolescent young adults) [version 1.2020 – January 15, 2020] recommend Bosulif as an option for patients with relapsed or refractory ALL.<sup>7</sup>

### 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:

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### **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 at least one other tyrosine kinase inhibitor (TKI) for Ph+ ALL.

Note: Examples include Gleevec® (imatinib tablets) and 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. 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 2019.
  2. Gleevec® tablets [prescribing information]. East Hanover, NJ: Novartis; July 2018.
  3. Sprycel® tablets [prescribing information]. Princeton, NJ: Bristol-Myers Squibb; December 2018.
  4. Tasigna® capsules [prescribing information]. East Hanover, NJ: Novartis; September 2019.
  5. Iclusig® tablets [prescribing information]. Cambridge, MA: Ariad Pharmaceuticals; January 2020.
  6. The NCCN Chronic Myeloid Leukemia Clinical Practice Guidelines in Oncology (Version 3.2020 – January 30, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on March 17, 2020.
  7. The NCCN Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (Version 1.2020 – January 15, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on March 17, 2020.
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