BlueCross BlueShield Federal Employee Program

BOSULIF
(bosutinib)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Bosulif (bosutinib) is a tyrosine kinase inhibitor indicated for the treatment of chronic myelogenous leukemia (CML). Bosulif is intended for patients with Philadelphia chromosome positive CML (Ph+ CML) who are newly-diagnosed or resistant to or who cannot tolerate other therapies, including imatinib. Bosulif inhibits the BCR-ABL kinase, an enzyme that promotes chronic myelogenous leukemia (CML) (1-2).

Regulatory Status

FDA-approved indications: Bosulif is a kinase inhibitor indicated for the treatment of: (1)

1. Adult and pediatric patients 1 year of age and older with chronic phase Ph+ chronic myelogenous leukemia (CML), newly-diagnosed or resistant or intolerant to prior therapy.
2. Adult patients with accelerated, or blast phase Ph+ chronic myelogenous leukemia (CML) with resistance or intolerance to prior therapy.

Off-Label Uses: (2-4)

1. Follow-up therapy for CML patients after hematopoietic stem cell transplant (HSCT)
2. Relapsed or refractory Ph+ acute lymphoblastic leukemia (ALL)

Bosulif has warnings and precautions regarding gastrointestinal toxicity, myelosuppression, hepatic toxicity, fluid retention and embryo-fetal toxicity. Patients should be monitored and managed using standards of care. Therapy should be interrupted, the dose reduced or discontinued as necessary (1).

Liver enzymes should be monitored at least monthly for the first 3 months and as needed Thrombocytopenia, anemia and neutropenia can occur; therefore, a complete blood count should be performed weekly for the first month and then monthly or as clinically indicated (1).

The safety and efficacy of Bosulif in patients less than 1 year of age have not been established (1).

Summary

Bosulif (bosutinib) is a kinase inhibitor that inhibits the BCR-ABL kinase, an enzyme that promotes chronic myelogenous leukemia (CML). In studies, 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. Bosulif has warnings and precautions regarding gastrointestinal toxicity, myelosuppression, hepatic toxicity, fluid retention and embryo-fetal toxicity. (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Bosulif while maintaining optimal therapeutic outcomes.

References

1. Bosulif [package insert]. New York, NY: Pfizer Labs; December 2024.
2. NCCN Drugs & Biologics Compendium® Bosutinib 2025. National Comprehensive Cancer Network, Inc. Accessed on January 13, 2025.
3. NCCN Clinical Practice Guidelines in Oncology® Chronic Myeloid Leukemia (CML) (Version 3.2025). National Comprehensive Cancer Network, Inc. November 2024. Accessed on January 13, 2025.
4. NCCN Clinical Practice Guidelines in Oncology® Acute Lymphoblastic Leukemia (Version 3. 2024). National Comprehensive Cancer Network, Inc. December 2024. Accessed on January 13, 2025.