PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Bosulif Prior Authorization Policy
- Bosulif® (bosutinib tablets and capsules – Pfizer)

REVIEW DATE: 05/01/2024; selected revision 06/12/2024

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Bosulif, a tyrosine kinase inhibitor (TKI), is indicated for the following uses:[1]
- **Chronic myelogenous leukemia (CML)**, Philadelphia chromosome positive (Ph+), in chronic phase in adults and pediatric patients ≥ 1 year of age who are newly-diagnosed or resistant or intolerant to prior therapy.
- **CML**, Ph+, in accelerated, or blast phase, in adults with resistance or intolerance to prior therapy.

Guidelines

Bosulif is addressed in guidelines from National Comprehensive Cancer Network (NCCN):
- **Acute Lymphoblastic Leukemia (ALL):** NCCN ALL guidelines for adults and adolescents (version 4.2023 – February 5, 2024) recommend Bosulif for Ph+ disease in many different clinical circumstances (e.g., induction, consolidation therapy, maintenance, or relapsed or refractory disease) [category 2A].[2] The guidelines state that the ALL panel considers adolescents to be within the age range of 15-39 years. TKIs in combination with other agents (e.g., chemotherapy or corticosteroids) are recommended for induction therapy for Ph+ ALL. TKIs have also been incorporated into consolidation and maintenance therapy, as well as in the relapsed/refractory setting (category 2A). TKI

options include: Bosulif, Sprycel® (dasatinib tablets), imatinib, Tasigna® (nilotinib capsules), or Iclusig® (ponatinib tablets) [category 2A]. NCCN panel notes that not all TKIs have been directly studied within the context of each specific regimen and there are limited data for Bosulif in Ph+ ALL. Use of a specific TKI should account for anticipated/prior TKI intolerance and disease-related features. For adults and adolescents, Iclusig has activity against T315I mutations and/or in whom no other TKI is indicated (category 2A).

- **CML:** NCCN guidelines (version 2.2024 – December 5, 2023) recommend Bosulif as a "preferred" primary regimen for newly diagnosed chronic phase Ph+ CML in patients with a low, intermediate-, or high-risk score (category 1).[3] Bosulif is also recommended as a: "preferred" regimen for patients with advanced phase or blast phase CML (category 2A); an alternative TKI treatment (after primary treatment with imatinib, Sprycel, or Tasigna (category 2A); in a variety of other situations, including post-allogeneic hematopoietic stem cell transplantation (HSCT) [category 2A].
- **Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Gene Fusions:** NCCN guidelines (version 1.2024 – December 21, 2023) recommend Bosulif as "other recommended regimens" for patients with *ABL1* rearrangements (category 2A).[4] It is also recommended as treatment in combination with ALL- or acute myeloid leukemia-type induction chemotherapy followed by allogeneic HSCT (if eligible) for lymphoid, myeloid, or mixed lineage neoplasms with eosinophilia and *ABL1* rearrangement in blast phase (category 2A).

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Bosulif. All approvals are provided for the duration noted below.

- **Bosulif® (bosutinib tablets and capsules (Pfizer)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indication

1. **Chronic Myeloid Leukemia.** Approve for 1 year if the patient meets BOTH of the following (A and B):
   A) Patient is ≥ 1 year of age; AND
   B) Patient has Philadelphia chromosome-positive chronic myeloid leukemia.

Other Uses with Supportive Evidence

2. **Acute Lymphoblastic Leukemia.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
   A) Patient is ≥ 15 years of age; AND

B) Patient has Philadelphia chromosome-positive acute lymphoblastic leukemia; AND
C) Patient has tried at least one other tyrosine kinase inhibitor for Philadelphia chromosome-positive acute lymphoblastic leukemia.
Note: Examples include imatinib and Sprycel (dasatinib tablets).

3. **Myeloid/Lymphoid Neoplasms with Eosinophilia.** Approve for 1 year if the patient meets BOTH of the following (A and B):
   A) Patient is ≥ 18 years of age; AND
   B) The tumor has an *ABL1* rearrangement.

CONDITIONS NOT COVERED

- **Bosulif® (bosutinib tablets and capsules (Pfizer)**

is(are) considered experimental, investigational or unproven for ANY other use(s); criteria will be updated as new published data are available.

REFERENCES

1. Bosulif® tablets and capsules [prescribing information]. New York, NY: Pfizer; September 2023.
2. The NCCN Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (version 4.2023 – February 5, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on April 29, 2024.
3. The NCCN Chronic Myeloid Leukemia Clinical Practice Guidelines in Oncology (version 2.2024 – December 5, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on April 29, 2024.
4. The NCCN Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Gene Fusion Clinical Practice Guidelines in Oncology (version 1.2024 – December 21, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on April 29, 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	05/31/2023
Selected Revision	The FDA labeled indication of Philadelphia chromosome positive (Ph+) chronic myelogenous leukemia (CML) that is in chronic phase (newly diagnosed or resistant or intolerant to prior therapy) in adults was expanded to include pediatric patients ≥ 1 year of age. **Chronic Myeloid Leukemia:** The criterion for age was changed from "patient is ≥ 18 years of age" to "patient is ≥ 1 year of age" due expanded labeling in the pediatric population.	10/04/2023
Selected Revision	Added new formulation of capsule to the policy with same criteria as tablets.	02/07/2024
Annual Revision	No criteria changes.	05/01/2024
Selected Revision	**Acute Lymphoblastic Leukemia:** The age requirement was changed from ≥18 years of age to ≥ 15 years of age.	06/12/2024