PREFERRED SPECIALTY MANAGEMENT POLICY

POLICY: Oncology (Oral) – Bosutinib Preferred Specialty Management Policy
- Bosulif® (bosutinib tablets and capsules – Pfizer, generic)

REVIEW DATE: 07/29/2026

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 WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. 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

Bosutinib, 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.

POLICY STATEMENT

This Preferred Specialty Management program has been developed to encourage the use of the Preferred Product. For all medications (Preferred and Non-Preferred), the patient is required to meet the standard *Oncology (Oral) – Bosutinib Prior Authorization Policy* criteria. The program also directs the patient to try the Preferred Product prior to the approval of the Non-Preferred Product. Requests for

the Non-Preferred Product will also be reviewed using the exception criteria (below). If the patient meets the standard *Oncology (Oral) – Bosutinib Prior Authorization Policy* criteria but has not tried a Preferred Product, approval for the Preferred Product will be authorized. All approvals are provided for the duration noted below.

Note: Bosulif 50 mg capsules are not targeted in this policy.

Documentation: Documentation is required as noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart notes, prescription claims records, prescription receipts, and/or other information. All documentation must include patient-specific identifying information.

Preferred Product: generic bosutinib tablets
Non-Preferred Product: Bosulif tablets and Bosulif 100 mg capsules

***Oncology (Oral) – Bosutinib Preferred Specialty Management Policy* non-preferred product(s) is(are) covered as medically necessary when the following non-preferred product exception criteria is(are) met. Any other exception is considered not medically necessary.**

NON-PREFERRED PRODUCT EXCEPTION CRITERIA

Non-Preferred Product	Exception Criteria
Bosulif tablets	**1.** Approve for 1 year if the patient meets BOTH of the following (A and B): **A)** Patient meets the standard *Oncology (Oral) – Bosutinib Prior Authorization Policy* criteria; AND **B)** Patient meets BOTH of the following (i and ii): **i.** Patient has tried generic bosutinib tablets **[documentation required]**; AND **ii.** Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the Non-Preferred and Preferred product which, according to the prescriber, would result in a significant allergy or serious adverse reaction **[documentation required]**. **2.** For a patient who has met the *Oncology (Oral) – Bosutinib Prior Authorization Policy* criteria, but has not met exception criteria (1B) for brand Bosulif tablets: approve generic bosutinib tablets.

Bosulif 100 mg capsules	**1.** Approve for 1 year if the patient meets BOTH of the following (A and B): **A)** Patient meets the standard *Oncology (Oral) – Bosutinib Prior Authorization Policy* criteria; AND **B)** Patient meets ONE of the following (i or ii): **i.** Patient meets BOTH of the following (a and b): **a)** Patient has tried generic bosutinib tablets **[documentation required]**; AND **b)** Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the Non-Preferred and Preferred product which, according to the prescriber, would result in a significant allergy or serious adverse reaction **[documentation required];** OR **ii.** Patient cannot swallow whole tablets or capsules or has difficulty swallowing whole tablets or capsules; OR **2.** For a patient who has met the *Oncology (Oral) – Bosutinib Prior Authorization Policy* criteria, but has not met exception criteria (1B) for brand Bosulif 100 mg capsules: approve generic bosutinib tablets.

REFERENCES

1. Bosulif® tablets and capsules [prescribing information]. New York, NY: Pfizer; March 2026.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	07/29/2026