DRUG QUANTITY MANAGEMENT POLICY – PER RX

POLICY: Oncology – Bosulif Drug Quantity Management Policy – Per Rx
- Bosulif® (bosutinib tablets – Pfizer)

REVIEW DATE: 11/01/2023

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. 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 treatment of adults with[1]:
- **Chronic myelogenous leukemia (CML)**, in chronic phase that is Philadelphia chromosome positive (Ph+) and is newly-diagnosed or resistant or intolerant to prior therapy in adults and pediatric patients ≥ 1 year of age.
- **CML**, Ph+, in accelerated, or blast phase, with resistance or intolerance to prior therapy in adults.

Dosing

Adult Dosing

The recommended initial dose of Bosulif for the treatment of newly-diagnosed, chronic phase, Ph+ CML is 400 mg once daily (QD).[1] For chronic, accelerated, or blast phase Ph+ CML with resistance or intolerance to prior therapy, the dose is 500 mg QD.

Pediatric Dosing

The recommended dose of Bosulif in pediatric patients with newly-diagnosed, chronic phase, Ph+ CML is 300 mg/m^2 QD.[1] For chronic phase Ph+ CML that is resistant or intolerant to prior therapy, the dose is 400 mg/m^2 QD. Dosing based on BSA is in

Table 1. As appropriate, the desired dose can be attained by combining different strengths of Bosulif tablets or capsules.

Table 1. Dosing of Bosulif for Pediatric Patients.[1]

BSA	Newly-Diagnosed Recommended Once Daily Dose	Resistant or Intolerant Recommended Once Daily Dose
< 0.55 m^2	150 mg	200 mg
0.55 m^2 to < 0.63 m^2	200 mg	250 mg
0.63 m^2 to < 0.75 m^2	200 mg	300 mg
0.75 m^2 to < 0.9 m^2	250 mg	350 mg
0.9 m^2 to < 1.1 m^2	300 mg	400 mg
≥ 1.1 m^2	400 mg*	500 mg*

BSA – Body surface area; * Maximum starting dose.

For patients who do not achieve or maintain a hematologic, cytogenetic, or molecular response and who do not have Grade 3 or higher adverse reactions, the dose may be escalated in increments of 100 mg per day to a maximum of 600 mg QD. In pediatric patients with a BSA < 1.1 m^2 and an insufficient response after 3 months, consider increasing the dose by 50 mg increments up to a maximum of 100 mg above the starting dose. For pediatric patients with a BSA ≥ 1.1 m^2, dose increases for insufficient response should be done according to the adult recommendations, in 100 mg increments up to a maximum of 600 mg QD.

Dose Adjustments
To manage potential adverse events, Bosulif may need to be temporarily discontinued and potentially restarted at a reduced dose.[1] The dose may also need to be reduced in patients with renal or hepatic failure.

Availability
Bosulif is available as 100 mg, 400 mg and 500 mg tablets.[1] The 100 mg tablets are available in bottles of 120 tablets each, while the 400 mg and 500 mg tablets in bottles of 30 tablets each. It is also available as 50 mg capsules (bottles of 30) and 100 mg capsules (bottles of 150).

The tablets are to be swallowed whole and should not be crushed, chewed, broken, or cut.[1] Continue treatment until disease progression or intolerance to therapy. Capsules may be swallowed whole or opened and the contents mixed with applesauce or yogurt.

POLICY STATEMENT
This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of Bosulif. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined

by the Criteria below. All approvals are provided for 1 year in duration, unless otherwise noted.

Drug Quantity Limits

Product	Strength and Form	Retail Maximum Quantity per Rx	Home Delivery Maximum Quantity per Rx
Bosulif® (bosutinib tablets)	100 mg tablets	90 tablets	270 tablets
	400 mg tablets	30 tablets	90 tablets
	500 mg tablets	30 tablets	90 tablets
	50 mg capsules	30 capsules	90 capsules
	100 mg capsules	90 capsules	270 capsules

Oncology – Bosulif Drug Quantity Management Policy – Per Rx product(s) is(are) covered as medically necessary when the following criteria is(are) met. Any other exception is considered not medically necessary.

CRITERIA

Bosulif 50 mg capsules

1. If the patient is taking a dose that does not correspond to a commercially-available dosage form (that is, the dose requires multiple same strength tablets be used OR would otherwise require two or more strengths to be used), approve the requested quantity, not to exceed 210 capsules per dispensing at retail or 630 capsules per dispensing at home delivery.

Bosulif 100 mg tablets and 100 mg capsules

1. If the patient is taking a dose that does not correspond to a commercially-available dosage form (that is, the dose requires multiple same strength tablets be used OR would otherwise require two or more strengths to be used), approve the requested quantity, not to exceed 180 tablets or capsules per dispensing at retail or 540 tablets or capsules per dispensing at home delivery.

Bosulif 400 mg tablets

No exceptions.

Bosulif 500 mg tablets

No exceptions.

REFERENCES

1. Bosulif® tablets [prescribing information]. New York, NY: Pfizer; September 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	Approval duration was changed from 3 years to 1 year. No changes to criteria.	11/09/2022
Early Annual Revision	**Bosulif 50 mg capsules:** Quantity limits of 30 capsules per dispensing at retail or 90 capsules per dispensing at home delivery were added to the policy. Added an exception to approve the requested quantity not to exceed 210 capsules per dispensing at retail or 630 capsules per dispensing at home delivery if the patient is taking a dose that does not correspond to a commercially-available dosage form (that is, the dose requires multiple same strength tablets be used OR would otherwise require two or more strengths to be used). **Bosulif 100 mg capsules:** Quantity limits of 90 capsules per dispensing at retail or 270 capsules per dispensing at home delivery were added to the policy. Added an exception to approve the requested quantity not to exceed 180 capsules per dispensing at retail or 540 capsules per dispensing at home delivery if the patient is taking a dose that does not correspond to a commercially-available dosage form (that is, the dose requires multiple same strength tablets be used OR would otherwise require two or more strengths to be used).	11/01/2023