DRUG QUANTITY MANAGEMENT POLICY – PER RX

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

REVIEW DATE: 11/09/2022

OVERVIEW

Bosulif, a tyrosine kinase inhibitor (TKI), is indicated for the treatment of adults with[1]:
- **Chronic myelogenous leukemia (CML)**, newly diagnosed in chronic phase that is Philadelphia chromosome positive (Ph+).
- **CML**, Ph+, in chronic, accelerated, or blast phase, with resistance or intolerance to prior therapy.

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 is 500 mg QD. 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. The recommended dose is taken orally QD with food. The tablet is to be swallowed whole and should not be broken or cut. Continue treatment until disease progression or intolerance to therapy. To manage potential adverse events, Bosulif may need to be temporarily discontinued and potentially restarted at a reduced dose. Doses < 300 mg/day have been used, but efficacy has not been established.

Availability

Bosulif is available as 100 mg, 400 mg and 500 mg tablets.[1]

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.

Automation: None.

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

CRITERIA

Bosulif 100 mg tablets

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 per dispensing at retail or 540 tablets per dispensing at home delivery.

Bosulif 400 mg tablets

No overrides recommended.

Bosulif 500 mg tablets

No overrides recommended.

REFERENCES

1. Bosulif® tablets [prescribing information]. New York, NY: Pfizer; May 2021.