

DRUG QUANTITY MANAGEMENT POLICY – PER RX

POLICY: Oncology – Calquence Drug Quantity Management Policy – Per Rx

- Calquence® (acalabrutinib capsules and tablets – AstraZeneca)

REVIEW DATE: 06/15/2022; selected revision 08/31/2022

OVERVIEW

Calquence, a Bruton tyrosine kinase (BTK) inhibitor, is indicated in adults for the following uses:^{1,2}

- **Chronic lymphocytic leukemia (CLL) or small lymphocytic leukemia (SLL).**
- **Mantle cell lymphoma (MCL),** in patients who have received at least one prior therapy.

Dosing

Monotherapy

The recommended dose of Calquence for treatment of MCL, CLL, or SLL, is 100 mg orally every 12 hours until disease progression or unacceptable toxicity.¹ Error! Reference source not found.

Combination with Obinutuzumab

For the treatment of CLL or SLL in previously untreated patients, the recommended dose of Calquence is 100 mg orally every 12 hours until disease progression or unacceptable toxicity.¹ Each treatment cycle is 28 days. Calquence should be started at Cycle 1 and obinutuzumab at Cycle 2, for a total of 6 cycles.

The dose may need to be reduced or withheld due to adverse events, hematological toxicities or drug interactions with cytochrome P450 (CYP)3A inhibitors.¹ CYP3A inducers may decrease Calquence plasma concentrations, therefore a dose of 200 mg every 12 hours is recommended, as tolerated, in patients taking strong CYP3A4 inducers (e.g., apalutamide, carbamazepine, enzalutamide, mitotane, phenytoin, rifampin, St. John's wort).

Availability

Calquence is available in 100 mg capsules and tablets supplied in bottles of 60.¹

POLICY STATEMENT

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of Calquence. 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.

Automation: None.

Drug Quantity Limits

Product	Strength and Form	Retail Maximum Quantity per Rx	Home Delivery Maximum Quantity per Rx
Calquence® (acalabrutinib capsules)	100 mg capsules	60 capsules	180 capsules
	100 mg tablets	60 tablets	180 tablets

CRITERIA

06/15/2022

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1. If the patient is taking a strong cytochrome P450 (CYP)3A inducer, approve 120 capsules or tablets per dispensing at retail and 360 capsules or tablets per dispensing at home delivery.

Note: Examples of CYP3A inducers include, but are not limited to, apalutamide, carbamazepine, enzalutamide, mitotane, phenytoin, rifampin, and St. John's wort.

REFERENCES

1. Calquence® capsules [prescribing information]. Wilmington, DE: AstraZeneca; March 2022.