Drug Quantity Management – Per Rx
Oncology – Calquence® (acalabrutinib capsules)

Table of Contents

Product Identifier(s)

Effective 1/1/23 to 3/21/23: 109078

Effective 3/22/23: 61472

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.

National Formulary Medical Necessity

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.

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

Cigna covers quantities as medically necessary when the following criteria are met:

1. If the individual 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.

Conditions Not Covered

Any other exception is considered not medically necessary.

Background

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]

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]

References

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

Revision History

Type of Revision	Summary of Changes	Approval Date
Annual Revision	The duration of approval was changed from 3 years to 1 year. In the override criteria, reference to "CYP3A4" was updated to state "CYP3A".	06/15/2022
Selected Revision	Policy was updated to reflect the existing quantity limits when a product is obtained via home delivery. Calquence 100 mg tablets were added to the policy.	08/31/2022