



STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ACALABRUTINIB

Generic	Brand	HICL	GCN	Exception/Other
ACALABRUTINIB	CALQUENCE	44607		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of mantle cell lymphoma (MCL) and meet **ALL** of the following criteria?
 - The patient is 18 years of age or older
 - The patient has received at least one prior therapy for mantle cell lymphoma (MCL)

If yes, **approve for 12 months by HICL with a quantity limit of #60 capsules per 30 days.**
If no, do not approve.

DENIAL TEXT: The guideline named **ACALABRUTINIB (Calquence)** requires a diagnosis of mantle cell lymphoma (MCL) and the following criteria must also be met:

- The patient is 18 years of age or older
- The patient has received at least one prior therapy for mantle cell lymphoma (MCL)

RATIONALE

To promote appropriate utilization of Calquence based on FDA approved indication.

FDA APPROVED INDICATIONS

Calquence is a kinase inhibitor indicated for the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy.

This indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

DOSING AND ADMINISTRATION

The recommended dose of Calquence is 100 mg taken orally approximately every twelve hours until disease progression or unacceptable toxicity.

Patients should swallow capsule whole with water. Patients should not open, break or chew the capsules. Calquence may be taken with or without food. If a dose of Calquence is missed by more than 3 hours, it should be skipped and the next dose should be taken at its regularly scheduled time. Extra capsules of Calquence should not be taken to make up for a missed dose.

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REFERENCES

- Calquence [Prescribing Information]. AstraZeneca Pharmaceuticals: Wilmington, DE; October 2017.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 04/01/18

Created: 02/18

Client Approval: 02/18

P&T Approval: 01/18