UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Calquence

Program	Prior Authorization
Medication	Calquence® (acalabrutinib)
Markets in Scope	Arizona, California, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania CHIP, Rhode Island, South Carolina
Issue Date	12/2017
Pharmacy and Therapeutics Approval Date	4/2020
Effective Date	6/2020

1. Background:

Calquence® (acalabrutinib) is a kinase inhibitor indicated for the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy. It is also approved for the treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).[1]

2. Coverage Criteria:

A. Mantle Cell Lymphoma (MCL)

1. Initial Authorization

a. **Calquence** will be approved based on the following criteria:

(1) **Both** of the following:

(a) Diagnosis of mantle cell lymphoma (MCL)

-AND-

(b) Patient has received at least one prior therapy for MCL [e.g., Rituxan (rituximab)]

Authorization will be issued for 12 months.

2. Reauthorization

a. **Calquence** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Calquence therapy

Authorization will be issued for 12 months.

B. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma

1. Initial Authorization

a. **Calquence** will be approved based on the following criteria:

(1) Diagnosis of chronic lymphocytic leukemia/small lymphocytic lymphoma

Authorization will be issued for 12 months.

2. Reauthorization

a. **Calquence** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Calquence therapy

Authorization will be issued for 12 months.

C. NCCN Recommended Regimens

1. Initial Authorization

a. **Calquence** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Authorization will be issued for 12 months.

2. Reauthorization

a. **Calquence** will be approved based on the following criterion:

(1) Documentation of positive clinical response to Calquence therapy

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Calquence [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP. November 2019.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed March 4, 2020.

Program	Prior Authorization
Change Control	
Date	Change
12/2017	New program
11/2018	Added criteria for Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma and NCCN Recommended Regimen review criteria. Updated background and references.
12/2019	Annual review. Updated references.
4/2020	Revised criteria to align with FDA label change for CLL/SLL. Updated background and references.