UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 1237-8
Program	Prior Authorization/Notification
Medication	Calquence® (acalabrutinib)
P&T Approval Date	12/2017, 12/2018, 12/2019, 4/2020, 5/2021, 5/2022, 5/2023, 5/2024
Effective Date	8/1/2024

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. 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. It is also approved for the treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).[1]

The National Comprehensive Cancer Network (NCCN) recommends the use of Calquence for the treatment of B-cell lymphomas, including splenic and nodal marginal zone lymphoma, extranodal marginal zone lymphoma (EMZL) of the stomach, extranodal marginal zone lymphoma of nongastric sites (noncutaneous), and Waldenström macroglobulinemia/lymphoplasmacytic lymphoma.[2]

Coverage Information:

Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. Coverage Criteria[a]:

A. Patients less than 19 years of age

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

   a. Patient is less than 19 years of age

   Authorization will be issued for 12 months.

B. 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.

C. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma

1. **Initial Authorization**

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

(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.

D. B-Cell Lymphomas

1. **Initial Authorization**

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

(1) Diagnosis of **one** of the following:

(a) Nodal Marginal Zone Lymphoma
(b) Extranodal Marginal Zone Lymphoma (EMZL) of the stomach
(c) Splenic Marginal Zone Lymphoma
(d) Extranodal Marginal Zone Lymphoma of Nongastric Sites (Non-cutaneous)

-AND-

(2) Disease is recurrent, relapsed, refractory, or progressive

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.

E. Waldenström Macroglobulinemia / Lymphoplasmacytic Lymphoma

1. **Initial Authorization**

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

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

(a) Diagnosis of Waldenström Macroglobulinemia / Lymphoplasmacytic Lymphoma

-AND-

(b) **One** of the following:

i. Patient did not respond to primary therapy
ii. Disease is relapsed or progressive

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.

F. NCCN Recommended Regimens

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

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. August 2022.
   2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at https://www.nccn.org/professionals/drug_compendium/content/. Accessed March 21, 2024.

Program	Prior Authorization/Notification – Calquence (acalabrutinib)
Change Control	
12/2017	New program
12/2018	Annual review. Added criteria for Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma.
12/2019	Annual review. No changes to coverage criteria.
4/2020	Updated criteria to reflect FDA label change for CLL/SLL. Added NCCN recommended regimens standard language.
5/2021	Annual review. Added criteria for B-cell lymphomas and Waldenström Macroglobulinemia according to NCCN guidelines.
5/2022	Annual review with no change to clinical criteria. Updated background and reference.
5/2023	Annual review. Changed classification of Gastric MALT lymphoma to Extranodal marginal zone lymphoma (EMZL) of the stomach and Nongastric MALT Lymphoma (Noncutaneous) to Extranodal Marginal Zone Lymphoma of Nongastric Sites (Noncutaneous) per NCCN guidelines. Added state mandate. Removed Imbruvica criteria. Updated background and references.
5/2024	Annual review with no change to clinical criteria. Updated reference.