UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

| | |
|---|---|
| Program Number | 2018 P 1237-2 |
| Program | Prior Authorization/Notification |
| Medication | Calquence® (acalabrutinib) |
| P&T Approval Date | 12/2017, 12/2018 |
| Effective Date | 2/1/2019;<br>Oxford only: 2/1/2019 |

**1. Background:**

Calquence® (acalabrutinib) is a kinase inhibitor indicated for the treatment of patients with mantle cell lymphoma (MCL) who have received at least one prior therapy.[1]

The National Comprehensive Cancer Network (NCCN) also recommends Calquence for the treatment of relapsed or refractory Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma as a single agent in patients without BTK C481S mutations.[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. <u>Patients less than 19 years of age</u>**

**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. <u>Mantle Cell Lymphoma (MCL)</u>**

**1. <u>Initial Authorization</u>**

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

(1) **<u>Both</u>** 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 criteria:

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

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

**-AND-**

(b) Disease is relapsed or refractory

**-AND-**

(c) Confirmed documentation of no BTK C481S mutation

**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.**

**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 2017.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed September 13, 2018.


| 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. |