CareSource

PHARMACY POLICY STATEMENT **Indiana Medicaid**	
DRUG NAME	Calquence (acalabrutinib)
BILLING CODE	Must use valid NDC for self-administered product
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) QUANTITY LIMIT— 60 caps for 30 days
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Calquence (acalabrutinib) is a **non-preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

MANTLE CELL LYMPHOMA (MCL)

For **initial** authorization:

1. Member 18 years of age or older; AND
2. Member has pathologically confirmed MCL, with documentation of monoclonal B cells that have a chromosome translocation t(11;14)(q13;q32) and/or overexpress cyclin D1; AND
3. Member must try at least one first-line treatment (e.g., bendamustine + rituximab, RCOP, VR-CAP, etc.); AND
4. Member was not treated with BTK inhibitors (e.g., Imbruvica); AND
5. Member does not have significant cardiovascular disease such as uncontrolled or symptomatic arrhythmias, congestive heart failure, or myocardial infarction, or any Class 3 or 4 cardiac disease as defined by the New York Heart Association Functional Classification, or corrected QT interval (QTc) > 480 msec; AND
6. Member does not have malabsorption syndrome, disease significantly affecting gastrointestinal function, or resection of the stomach or small bowel or ulcerative colitis, symptomatic inflammatory bowel disease, or partial or complete bowel obstruction.
7. **Dosage allowed:** 100 mg taken orally approximately every 12 hours until disease progression or unacceptable toxicity.

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:

1. Member does not have disease progression or unacceptable toxicity (chart notes required).

If member meets all the reauthorization requirements above, the medication will be approved for an additional 6 months.

CareSource considers Calquence (acalabrutinib) not medically necessary for the treatment of the diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
11/08/2017	New policy for Calquence created.

References:

1. Calquence [package insert]. Wilmington, DE: AstraZeneca; Oct 2017.
2. ClinicalTrials.gov web site. Bethesda, MD. U.S. National Institutes of Health. Identifier NCT02213926, An Open-label, Phase 2 Study of ACP-196 (Acalabrutinib) in Subjects With Mantle Cell Lymphoma; August 01, 2017. Available at: https://clinicaltrials.gov/ct2/show/NCT02213926?term=02213926&rank=1.
3. NCCN Guidelines for Patients. Mantle Cell Lymphoma, 2017. Available at: https://www.nccn.org/patients/guidelines/nhl-mantle/files/assets/common/downloads/files/mantlecell.pdf.

Effective date: 03/01/2018
Revised date: 11/08/2017