Calquence

Description

Calquence (acalabrutinib)

Background
Calquence is a kinase inhibitor that is used to treat adults with mantle cell lymphoma or relapsed or refractory chronic lymphocytic leukemia (CLL) /small lymphocytic lymphoma (SLL) who have received at least one prior therapy. Mantle cell lymphoma is a rare and fast-growing type of non-Hodgkin lymphoma. Mantle cell lymphoma is a cancer of the lymph system, which is part of the body’s immune system and is made up of lymph tissue, lymph nodes, the spleen, thymus, tonsils and bone marrow. By the time mantle cell lymphoma is diagnosed, it usually has spread to the lymph nodes, bone marrow and other organs. Calquence is a kinase inhibitor that works by blocking an enzyme needed by the cancer to multiply and spread (1-2).

Regulatory Status
FDA-approved indication: 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 (1).

Off-Label Uses: (2)
1. Chronic Lymphocytic Leukemia (CLL) /Small Lymphocytic Lymphoma(SLL) – should not be used for ibrutinib refractory CLL/SLL in patients with BTK C481S mutations

Patients have a chance of Grade 3 or higher bleeding events (subdural hematoma, gastrointestinal bleeding, and hematuria). Calquence may increase the risk of hemorrhage in patients receiving antiplatelet or anticoagulant therapies. Consider the benefit-risk of withholding
Calquence for at least 3 to 7 days pre and post-surgery depending upon the type of surgery and the risk of bleeding (1).
Significant adverse reactions may occur with Calquence therapy including fatal and non-fatal infections, atrial fibrillation, atrial flutter, cytopenias, myelosuppression and primary malignancies including skin cancers. Patients should have the following monitored while on Calquence therapy: fever, infections, complete blood counts, and hydration (1).

Based on findings in animals, Calquence may cause fetal harm when administered to a pregnant woman (1).

The safety and effectiveness of Calquence in pediatric patients has not been established (1).

**Related policies**

Imbruvica

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**Policy**

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*

Calquence may be considered *medically necessary* in patients who are 18 years of age or older with mantle cell lymphoma (MCL) or relapsed or refractory chronic lymphocytic leukemia (CLL) /small lymphocytic lymphoma (SLL) and if the conditions indicated below are met.

Calquence is considered *investigational* in patients who are less than 18 years of age and for all other indications.

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**Prior-Approval Requirements**

**Age**

18 years of age and older

**Diagnosis**

Patient must have **ONE** of the following:

1. Mantle cell lymphoma (MCL)
   a. Patient has received at least one prior therapy
2. Relapsed or refractory chronic lymphocytic leukemia (CLL) /small lymphocytic lymphoma (SLL)
   a. NO prior therapy with ibrutinib (Imbruvica) in patients with BTK C481S mutations

   AND ALL of the following for BOTH indications:
   a. Used as a single agent
   b. Prescriber agrees to do a baseline CBC and monitor monthly during therapy
   c. Prescriber agrees to monitor for malignancies
   d. Prescriber agrees to monitor for bleeding

Prior – Approval Renewal Requirements

Age       18 years of age and older

Diagnosis

Patient must have the following:

1. Mantle cell lymphoma (MCL)
2. Relapsed or refractory chronic lymphocytic leukemia (CLL) /small lymphocytic lymphoma (SLL)

   AND ALL of the following for BOTH indications:
   a. Used as a single agent
   b. Prescriber agrees to monitor CBC monthly during therapy
   c. Prescriber agrees to monitor for malignancies
   d. Prescriber agrees to monitor for bleeding
   e. NO disease progression or unacceptable toxicity

Policy Guidelines

Pre - PA Allowance
None

Prior - Approval Limits
**Section:** Prescription Drugs  
**Effective Date:** July 1, 2019  
**Subsection:** Antineoplastic Agents  
**Original Policy Date:** November 17, 2017  
**Subject:** Calquence  
**Page:** 4 of 5

### Quantity
100 mg  
180 capsules per 90 days

### Duration
12 months

**Prior – Approval Renewal Limits**
Same as above

### Rationale

**Summary**
Calquence is an orally administered kinase inhibitor indicated for the treatment of patients with mantle cell lymphoma (MCL) or relapsed or refractory chronic lymphocytic leukemia (CLL) /small lymphocytic lymphoma (SLL). Current warnings include the possibility for hemorrhage, myelosuppression and primary malignancies including skin cancers. The safety and effectiveness of Calquence in pediatric patients has not been established (1).

Prior approval is required to ensure the safe, clinically appropriate and cost effective use of Calquence while maintaining optimal therapeutic outcomes.

**References**

**Policy History**

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<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>November 2017</td>
<td>New addition to PA</td>
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<tr>
<td>March 2018</td>
<td>Annual editorial review and reference update</td>
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<tr>
<td></td>
<td>Addition of relapsed or refractory chronic lymphocytic leukemia (CLL) /small lymphocytic lymphoma (SLL) with no prior therapy with ibrutinib (Imbruvica) in patients with BTK C481S mutations per SME</td>
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<td>Addition of the following requirements: used as a single agent, prescriber agrees to do a baseline CBC and monitor monthly during therapy, prescriber agrees to monitor for malignancies, and prescriber agrees to monitor for bleeding per SME</td>
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<tr>
<td>June 2018</td>
<td>Annual review</td>
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This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 20, 2019 and is effective on July 1, 2019.