**PRIOR AUTHORIZATION POLICY**

**POLICY:** Oncology – Calquence® (acalabrutinib capsules – AstraZeneca)

**TAC APPROVAL DATE:** 06/05/2019

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**OVERVIEW**

Calquence is a Bruton tyrosine kinase (BTK) inhibitor indicated for the treatment of adult patients with mantle cell lymphoma who have received at least one prior therapy. The recommended dose is 100 mg taken approximately once every 12 hours (Q12H).

**Disease Overview**

Mantle cell lymphoma is a rare and fast-growing type of non-Hodgkin lymphoma (NHL). It accounts for approximately 6% of cases of newly-diagnosed NHL. The median age at diagnosis is 68 years of age and it is more common in males. Mantle cell lymphoma is a cancer involving the lymphatic system which is part of the immune system comprised of lymph tissue, lymph nodes, the spleen, thymus, tonsils, and bone marrow. Approximately one-third of patients with mantle cell lymphoma present with high levels of lactate dehydrogenase (LDH).

**Clinical Efficacy**

The efficacy of Calquence was established in one open-label, Phase II study involving patients with mantle cell lymphoma who had received at least one prior therapy (n = 124). The median age at diagnosis was 68 years; 80% of patients were male and 74% of patients were Caucasian. Patients had received a median of two prior regimens (range, 1 to 5); 18% of patients had undergone a prior stem cell transplantation. The median follow-up was 15.2 months. The overall response rate was approximately 80%.

**Guidelines**

The National Comprehensive Cancer Network (NCCN) guidelines for B-cell lymphomas (version 3.2019 – May 6, 2019) provide recommendations for patients with mantle cell lymphoma. Various agents and chemotherapy regimens are recommended, many of which are given intravenously (IV) and involve Rituxan® (rituxumab injection for IV use) therapy. Calquence is recommended as a preferred agent as second-line therapy.

The NCCN guidelines for CLL/small lymphocytic lymphoma (SLL) [version 5.2019 – May 23, 2019] added Calquence as an option for relapsed/refractory therapy among patients with and without deletion 17p (TP53 mutation). Data are available with Calquence. CLL and SLL are different manifestations of the same diseases which are managed in the same way.

**Other Uses with Supportive Evidence**

**POLICY STATEMENT**

Prior authorization is recommended for prescription benefit coverage of Calquence. All approvals are provided for the duration noted below.
**RECOMMENDED AUTHORIZATION CRITERIA**

Coverage of Calquence is recommended in those who meet the following criteria:

**FDA-Approved Indications**

1. **Mantle Cell Lymphoma.** Approve for 3 years.

**Other Uses with Supportive Evidence**

2. **Chronic Lymphocytic Leukemia (CLL).** Approve for 3 years if the patient has tried one prior therapy (e.g., Imbruvica® [ibrutinib capsules or tablets]; chlorambucil plus Gazyva® [obinutuzumab intravenous injection]; chlorambucil plus Arzerra® [ofatumumab injection for intravenous use]; Treanda® [bendamustine injection for intravenous use] with or without rituximab; chlorambucil plus rituximab; high-dose methylprednisolone [HDMP] plus rituximab; Arzerra; Gazyva; rituximab; chlorambucil; Campath® [alemtuzumab injection for intravenous use] with or without rituximab; FCR [fludarabine, cyclophosphamide and rituximab]; FR [fludarabine plus rituximab]; PCR [pentostatin, cyclophosphamide, rituximab]; Zydelig® [idelalisib tablets] with or without rituximab; Venclexta® [venetoclax tablets] with or without rituximab; Venclexta plus Gazyva; or Copiktra™ [duvelisib capsules]).

3. **Small Lymphocytic Lymphoma (SLL).** Approve for 3 years if the patient has tried one prior therapy (e.g., Imbruvica® [ibrutinib capsules or tablets]; chlorambucil plus Gazyva® [obinutuzumab intravenous injection]; chlorambucil plus Arzerra® [ofatumumab injection for intravenous use]; Treanda® [bendamustine injection for intravenous use] with or without rituximab; chlorambucil plus rituximab; high-dose methylprednisolone [HDMP] plus rituximab; Arzerra; Gazyva; rituximab; chlorambucil; Campath® [alemtuzumab injection for intravenous use] with or without rituximab; FCR [fludarabine, cyclophosphamide and rituximab]; FR [fludarabine plus rituximab]; PCR [pentostatin, cyclophosphamide, rituximab]; Zydelig® [idelalisib tablets] with or without rituximab; or Venclexta® [venetoclax tablets] with or without rituximab; Venclexta plus Gazyva; or Copiktra™ [duvelisib capsules]).

**CONDITIONS NOT RECOMMENDED FOR APPROVAL**

Calquence has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. Rationale for non-coverage for these specific conditions is provided below. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.)

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.
REFERENCES

HISTORY

<table>
<thead>
<tr>
<th>Type of Revision</th>
<th>Summary of Changes*</th>
<th>TAC Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>New Policy</td>
<td>-</td>
<td>11/01/2017</td>
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<tr>
<td>Early Annual revision</td>
<td>Changed the criteria for Calquence regarding mantle cell lymphoma from requiring a trial of one other therapy to approve the requests. Criteria added in other uses with supportive evidence section to approve Calquence for chronic lymphocytic leukemia and small lymphocytic lymphoma if the patient has tried one other therapy (as recommended in NCCN guidelines).</td>
<td>05/16/2018</td>
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<tr>
<td>Annual revision</td>
<td>For clarity, the reference to Rituxan when listing previous required therapies was changed to “rituximab”. Also, the following changes were also made: 1. Chronic Lymphocytic Leukemia: Venclexta plus Gazyva and Copiktra were added to the list of examples of agents that count toward the requirement of a trial of one prior therapy. 2. Small Lymphocytic Lymphoma: Venclexta plus Gazyva and Copiktra were added to the list of examples of agents that count toward the requirement of a trial of one prior therapy.</td>
<td>06/05/2019</td>
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* For a further summary of criteria changes, refer to respective TAC minutes available at: http://esidepartments/sites/Dep043/Committees/TAC/Forms/AllItems.aspx; TAC – Therapeutic Assessment Committee; NCCN – National Comprehensive Cancer Network.