

Specialty Guideline Management

Calquence

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

| Brand Name | Generic Name |
|------------|---------------|
| Calquence | acalabrutinib |

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications

Mantle Cell Lymphoma

- Calquence is indicated for the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy.
- Calquence in combination with bendamustine and rituximab is indicated for the treatment of adult patients with previously untreated mantle cell lymphoma (MCL) who are ineligible for autologous hematopoietic stem cell transplant (HSCT).

Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma

Calquence is indicated for the treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).

Compendial Uses

- Waldenström Macroglobulinemia/Lymphoplasmacytic Lymphoma

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| Reference number(s) |
| 2397-A |

- Gastric MALT Lymphoma (Extranodal Marginal Zone Lymphoma of the Stomach)/Non-gastric MALT Lymphoma (Extranodal Marginal Zone Lymphoma of Nongastric Sites)
- Nodal Marginal Zone Lymphoma
- Splenic Marginal Zone Lymphoma
- CLL/SLL
- Mantle Cell Lymphoma

All other indications are considered experimental/investigational and not medically necessary.

Coverage Criteria

Mantle Cell Lymphoma

Authorization of 12 months may be granted for treatment of mantle cell lymphoma when any of the following criteria are met:

- The requested medication will be used as a single agent for subsequent therapy.
- The requested medication will be used in combination with rituximab for induction therapy.
- The requested medication will be used in combination with rituximab as pre-treatment to limit the number of cycles of induction therapy with RHyperCVAD (rituximab, cyclophosphamide, vincristine, doxorubicin and dexamethasone) regimen.
- The requested medication will be used in combination with bendamustine and rituximab for previously untreated disease and the member is ineligible for transplant.

Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL)

Authorization of 12 months may be granted for treatment of CLL/SLL as a single agent or in combination with obinutuzumab.

Waldenström Macroglobulinemia/Lymphoplasmacytic Lymphoma

Authorization of 12 months may be granted for subsequent treatment of Waldenström Macroglobulinemia /Lymphoplasmacytic Lymphoma as a single agent.

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| Reference number(s) |
| 2397-A |

Gastric MALT Lymphoma (Extranodal Marginal Zone Lymphoma of the Stomach)/Non-gastric MALT Lymphoma (Extranodal Marginal Zone Lymphoma of Nongastric Sites)/Nodal Marginal Zone Lymphoma/Splenic Marginal Zone Lymphoma

Authorization of 12 months may be granted for treatment of gastric MALT lymphoma (extranodal marginal zone lymphoma of the stomach), non-gastric MALT lymphoma (extranodal marginal zone lymphoma of nongastric sites), nodal marginal zone lymphoma and splenic marginal zone lymphoma when used as subsequent therapy.

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

References

1. Calquence [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; January 2025.
2. The NCCN Drugs & Biologics Compendium[®] © 2024 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed May 29, 2024.
3. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines): B-Cell Lymphomas. Version 2.2024. Accessed May 29, 2024. https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf.