Reference number(s)
2397-A

SPECIALTY GUIDELINE MANAGEMENT

CALQUENCE (acalabrutinib)

POLICY

I. 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.

A. FDA-Approved Indications
1. 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.
2. 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).

B. Compendial Uses
1. Waldenström Macroglobulinemia/Lymphoplasmacytic Lymphoma
2. Gastric MALT Lymphoma (Extranodal Marginal Zone Lymphoma of the Stomach)/Non-gastric MALT Lymphoma (Extranodal Marginal Zone Lymphoma of Nongastric Sites)
3. Nodal Marginal Zone Lymphoma
4. Splenic Marginal Zone Lymphoma
5. CLL/SLL
6. Mantle Cell Lymphoma

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

II. CRITERIA FOR INITIAL APPROVAL

A. Mantle cell lymphoma
Authorization of 12 months may be granted for treatment of mantle cell lymphoma when any of the following criteria are met:
1. The requested medication will be used as a single agent for subsequent therapy.
2. The requested medication will be used in combination with rituximab for induction therapy.
3. 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.

B. 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.

C. Waldenström Macroglobulinemia/Lymphoplasmacytic Lymphoma

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

D. 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.

III. CONTINUATION OF THERAPY

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

IV. REFERENCES

1. Calquence [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; August 2022.
2. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed January 22, 2024.