

Calquence (acalabrutinib)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Calquence (acalabrutinib)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Calquence (acalabrutinib) may be approved if the following criteria are met:

- I. Individual has a diagnosis of one of the following B-cell Lymphoma types:
 - A. Zone lymphoma, including extranodal marginal zone lymphoma of the stomach, extranodal marginal zone lymphoma of nongastric sites (noncutaneous), nodal marginal zone lymphoma, and splenic marginal zone lymphoma (NCCN 2A); **AND**
 - B. Individual is using as second-line and subsequent therapy for relapsed, refractory, or progressive disease;

OR

- C. Individual has a diagnosis of mantle cell lymphoma (Label, NCCN 2A); **AND**
- D. Meets one of the following:
 1. Individual has received at least one prior therapy;

OR

2. Individual has previously untreated mantle cell lymphoma (Label); **AND**
3. Individual is ineligible for autologous hematopoietic stem cell transplantation (HSCT); **AND**
4. Individual is using in combination with bendamustine and rituximab;

OR

- II. Individual has a diagnosis of Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL) with or without del(17p)/TP53 mutation (Label, NCCN 1, NCCN 2A); **AND**
- III. Individual is using in one of the following ways:
 - A. Individual is using as a single agent; **AND**
 - B. Individual is not using in refractory CLL/SLL with BTK C481S mutation post ibrutinib therapy (NCCN 2A); **OR**
 - C. As first line therapy in combination with obinutuzumab;

OR

- IV. Individual has a diagnosis of Waldenstrom Macroglobulinemia (NCCN 2A); **AND**
- A. Individual is using as alternative therapy for previously treated disease; **AND**
 - B. Individual has had no prior Bruton Kinase inhibitor therapy; **AND**
 - C. Individual is using as a single-agent.

Key References:

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Updated periodically.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2025; Updated periodically.
4. NCCN Clinical Practice Guidelines in Oncology™. © 2025 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on January 17, 2025.
 - a. B-Cell Lymphomas. V1.2025. Revised December 2024.
 - b. Chronic Lymphocytic Lymphoma/Small Lymphocytic Lymphoma. V1.2025. Revised October 1, 2024.
 - c. Waldenström Macroglobulinemia/ Lymphoplasmacytic Lymphoma. V2.2025. Revised December 18, 2024.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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