

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 marginal 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; **AND**
- II. Individual is using as second-line and subsequent therapy for relapsed, refractory, or progressive disease;

OR

- III. Individual has a diagnosis of mantle cell lymphoma (Label, NCCN 2A); **AND**
- IV. Individual has received at least one prior therapy; **AND**
- V. Individual is using as a single agent;

OR

- III. Individual has a diagnosis of Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL) with or without del(17p)/TP53 mutation (NCCN 1, NCCN 2A); **AND**
 - IV. 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;

V.

OR

- VI. 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. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2024. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Updated periodically.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2024; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2024 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on January 10, 2024.
 - a. B-Cell Lymphomas. V6.2023. Revised October 10, 2023.
 - b. Chronic Lymphocytic Lymphoma/Small Lymphocytic Lymphoma. V1.2024. Revised November 3, 2023.
 - c. Waldenström Macroglobulinemia/ Lymphoplasmacytic Lymphoma. V2.2024. Revised December 5, 2023.

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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