

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 mantle cell lymphoma (Label, NCCN 2A); **AND**
- II. Individual has received at least one prior therapy*;

OR

- III. Individual has a diagnosis of Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL) with or without del(17p)/TP53 mutation (Label, NCCN 1); **AND**
- IV. Individual is not using in refractory CLL/SLL with BTK C481S mutation post ibrutinib therapy (NCCN 2A).

***Note:** The most common prior therapies in clinical trials included CHOP (cyclophosphamide, doxorubicin, vincristine, and prednisone) based and cytarabine therapy. This list is not inclusive of all possible prior therapies.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2021. 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>. Accessed: January 8, 2021.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2021; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2021 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on January 8, 2021.
 - a. B-Cell Lymphomas. V4.2020. Revised August 13, 2020.
 - b. Chronic Lymphocytic Lymphoma/Small Lymphocytic Lymphoma. V2.2021. Revised December 3, 2020.
 - c. Waldenström Macroglobulinemia/ Lymphoplasmacytic Lymphoma. V1.2021. Revised September 1, 2020.

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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