

Brukinsa (zanubrutinib)

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

Medications	Quantity Limit
Brukinsa (zanubrutinib)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Brukinsa (zanubrutinib) may be approved if the following criteria are met:

- I. Individual is 18 years of age or older; **AND**
- II. Individual has no prior BTK inhibitor usage; **AND**
- III. Individual has an ECOG score of 0-2; **AND**
- IV. Individual has a diagnosis of mantle cell lymphoma (MCL); **AND**
- V. Individual has received at least one prior therapy;

OR

- VI. Individual is 18 years of age or older; **AND**
- VII. Individual has no prior BTK inhibitor usage; **AND**
- VIII. Individual has an ECOG score of 0-2; **AND**
- IX. Individual has a diagnosis of Waldenström's Macroglobulinemia;

OR

- X. Individual is 18 years of age or older; **AND**
- XI. Individual has a diagnosis of relapsed or refractory marginal zone lymphoma (including Splenic Marginal Zone Lymphoma, Nongastric and Gastric MALT Lymphoma, and Nodal Marginal Zone Lymphoma) (Label, NCCN 2A); **AND**
- XII. Individual has no prior BTK inhibitor usage; **AND**
- XIII. Individual has an ECOG score of 0-2; **AND**
- XIV. Individual has prior treatment with at least one CD-20 directed regimen;

OR

- XV. Individual is 18 years of age or older (Label, NCCN 1, 2A); **AND**
- XVI. Individual has no prior BTK inhibitor usage; **AND**
- XVII. Individual is using as a single agent; **AND**
- XVIII. Individual has an ECOG score of 0-2; **AND**
- XIX. Individual has a diagnosis of one of the following:
 - A. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL); **OR**
 - B. CLL/SLL with 17p deletion.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2023. 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 17, 2023.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology TM. © 2022 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on January 17, 2023.
 - a. B cell Lymphomas. V5.2022. Revised July 12, 2022.
 - b. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma. V1.2023. Revised August 30, 2022.
 - c. Waldenström's Macroglobulinemia/ Lymphoplasmacytic Lymphoma V1.2023. Revised July 6, 2022.
6. Tam CS, Robak T, Ghia P, et al. Zanubrutinib monotherapy for patients with treatment naïve chronic lymphocytic leukemia and 17p deletion. *Haematologica*. 2020;Online ahead of print:10.3324/haematol.2020.259432. Published 2020 Oct 13. doi:10.3324/haematol.2020.259432 Available at: <https://haematologica.org/article/view/haematol.2020.259432>. Accessed January 17, 2023.
7. Xu W, Yang S, Zhou K, et al. Treatment of relapsed/refractory chronic lymphocytic leukemia/small lymphocytic lymphoma with the BTK inhibitor zanubrutinib: phase 2, single-arm, multicenter study. *J Hematol Oncol*. 2020;13(1):48. Published 2020 May 11. doi:10.1186/s13045-020-00884-4 Available at: <https://jhoonline.biomedcentral.com/track/pdf/10.1186/s13045-020-00884-4.pdf>. Accessed January 17, 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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