UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 1306-5
Program	Prior Authorization/Notification
Medication	Brukinsa® (zanubrutinib)
P&T Approval Date	1/2020, 1/2021, 10/2021, 10/2022, 10/2023
Effective Date	1/1/2024

1. **Background:**
Brukinsa (zanubrutinib) is a kinase inhibitor indicated for the treatment of patients with mantle cell lymphoma (MCL) who have received at least one prior therapy and relapsed or refractory marginal zone lymphoma (MZL) who have received at least one anti-CD20-based regimen. These indications are approved under accelerated approval based on overall response rate. Continued approval for these indications may be contingent upon verification and description of clinical benefit in a confirmatory trial. Brukinsa is also indicated for the treatment of Waldenström's macroglobulinemia (WM) and Chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL). NCCN recommends Brukinsa as second-line and subsequent therapy for extranodal marginal zone lymphoma (EMZL) of the stomach or extranodal marginal zone lymphoma of nongastric sites (noncutaneous) , nodal marginal zone, or splenic marginal zone lymphomas.

Coverage Information:
Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. **Coverage Criteria[a]:**

A. Patients less than 19 years of age

1. **Brukinsa** will be approved based on the following criterion:

   a. Patient is less than 19 years of age

   Authorization will be issued for 12 months.

B. B-Cell Lymphomas

1. **Initial Authorization**

   a. **Brukinsa** will be approved based on the **one** of the following criteria:

   (1) Diagnosis of mantle cell lymphoma (MCL)

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-OR-

(2) **All** of the following:

(a) Diagnosis of marginal zone lymphoma

-AND-

(b) Disease is relapsed, refractory, or progressive

-AND-

(c) Patient has received at least one anti-CD20-based regimen (e.g., rituximab, obinutuzumab)

-OR-

(3) **All** of the following:

(a) Diagnosis of **one** of the following:

i. Extranodal marginal zone lymphoma (EMZL) of the stomach
ii. Extranodal marginal zone lymphoma of nongastric sites (noncutaneous)

-AND-

(b) Disease is relapsed, refractory, or progressive

-AND-

(c) Patient has received at least one anti-CD20-based regimen (e.g., rituximab, obinutuzumab)

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Brukinsa** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Brukinsa therapy

Authorization will be issued for 12 months.

C. Waldenström's Macroglobulinemia (WM)

1. **Initial Authorization**

a. **Brukinsa** will be approved based on the following criterion:

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(1) Diagnosis of Waldenström's macroglobulinemia (WM)

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Brukinsa** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Brukinsa therapy

Authorization will be issued for 12 months.

D. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL)

1. **Initial Authorization**

a. **Brukinsa** will be approved based on the following criteria:

(1) Diagnosis of Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL)

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Brukinsa** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Brukinsa therapy

Authorization will be issued for 12 months.

E. NCCN Recommended Regimens

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

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- Supply limits may be in place.

4. References:

1. Brukinsa® [package insert]. BeiGene, Ltd., San Mateo, CA, April 2023.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed August 29, 2023.

Program	Prior Authorization/Notification – Brukinsa® (zanubrutinib)
Change Control	
1/2020	New program.
1/2021	Annual review. Background updated to reflect package insert. No changes to coverage criteria. References updated.
10/2021	Clinical coverage criteria added for Waldenström's Macroglobulinemia, Marginal Zone Lymphoma and Chronic Lymphocytic Leukemia/Small Lymphocytic. Clinical coverage criteria updated for other B-Cell Lymphomas. Updated background and references.
10/2022	Annual review. Updates made to B-Cell Lymphoma and CLL/SLL criteria based on NCCN recommendations. Updated background and reference. Added state mandate footnote.
10/2023	Annual review. Updates made to B-Cell Lymphoma criteria based on NCCN recommendations. Updated background and reference.

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