UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Brukinsa

Program	Prior Authorization
Medication	Brukinsa™ (zanubrutinib)
Markets in Scope	Arizona, California, Colorado, Hawaii, Maryland, New Jersey, Nevada, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	1/2020
Pharmacy and Therapeutics Approval Date	1/2021
Effective Date	3/2021

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.

This indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

2. Coverage Criteria:

A. <u>Mantle Cell Lymphoma</u>

1. **<u>Initial Authorization</u>**

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

      (1) Diagnosis of mantle cell lymphoma (MCL)

      -AND-

      (2) Patient has received at least one prior therapy for MCL

   Authorization will be issued for 12 months.

2. **<u>Reauthorization</u>**

   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.

B. NCCN Recommended Regimens

1. **Initial Authorization**

a. **Brukinsa** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Authorization will be issued for 12 months.

2. **Reauthorization**

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

(1) Documentation of positive clinical response to Brukinsa therapy

Authorization will be issued for 12 months.

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.
- Supply limits may be in place.

4. References:

1. Brukinsa™ [package insert]. BeiGene, Ltd., San Mateo, CA, November 2019.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed November 18, 2020.

Program	Prior Authorization
Change Control	
Date	Change
1/2020	New program
1/2021	Annual review. No changes to coverage criteria. Updated references