Mass General Brigham
Health Plan

Brukinsa (zanubrutinib)
Effective 09/01/2022

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☒ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit (NLX)		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Specialty Medications**		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

Overview

Zanubrutinib is a highly selective Bruton tyrosine kinase (BTK) inhibitor. Zanubrutinib forms a covalent bond with a cysteine residue in the BTK active site to inhibit BTK activity. BTK is a signaling molecule of the B-cell antigen receptor and cytokine receptor pathways. BTK signals activation of pathways necessary for B-cell proliferation, trafficking, chemotaxis, and adhesion. Zanubrutinib inhibits malignant B-cell proliferation and reduces tumor growth.

Coverage Guidelines

Authorization may be reviewed for members new to the plan who are currently receiving treatment with Brukinsa excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Authorization may be granted for members when all the following criteria are met, and documentation is provided:

1. The member is ≥ 18 years of age
2. The member is using Brukinsa for the treatment of mantle cell lymphoma
3. The member has had 1 prior therapy for mantle cell lymphoma (see appendix)
4. Provider specialty is oncology/hematology, or the medication is being prescribed in consultation with oncologist or hematologist
5. Appropriate dosing

Continuation of Therapy

Reauthorization requires physician documentation of improvement of member's condition.

Limitations

1. Initial approvals and reauthorizations will be for 12 months.
2. The following quantity limits apply:

Brukinsa 80mg	120 capsules per 30 days

Appendix:

The NCCN Guidelines for the treatment of B-Cell Lymphomas (section on MCL) note that first-line therapy for patients with MCL is radiation therapy alone or radiation therapy in combination with chemo-immunotherapy. Examples of acceptable induction chemo-immunotherapy regimens (both aggressive and less aggressive) are listed below. Please note this list is **not** all inclusive.

a. Rituximab, dexamethasone, and cytarabine (RDHA) plus platinum (cisplatin, carboplatin, or oxaliplatin)
b. Alternating RCHOP and rituximab, dexamethasone, cisplatin and cytarabine (RDHAP)
c. Rituximab plus cyclophosphamide, vincristine, doxorubicin, and prednisone (maxi-CHOP) alternating with rituximab plus high dose cytarabine (NORDIC regimen)
d. Cyclophosphamide, vincristine, doxorubicin and dexamethasone alternating with high-dose methotrexate and cytarabine (HyperCVAD) and rituximab
e. Bendamustine and rituximab
f. Bortezomib, rituximab, cyclophosphamide, doxorubicin, and prednisone (VR-CAP)
g. Rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone (RCHOP)
h. Lenalidomide plus rituximab
i. Modified HyperCVAD and rituximab

References

1. Brukinsa (zanubrutinib) [prescribing information]. San Mateo, CA: BeiGene USA Inc; November 2019.
2. Song Y, Zhou K, Zou D, et al. Safety and activity of the investigational Bruton tyrosine kinase inhibitor zanubrutinib (BGB-3111) in patients with mantle cell lymphoma from a phase 2 trial. *Blood*. 2018;132(suppl 1):S132. [Abstract 132 from ASH 20187 Annual meeting].
3. Tam CS, Trotman J, Opat S, et al. Phase 1 study of the selective BTK inhibitor zanubrutinib in B-cell malignancies and safety and efficacy evaluation in CLL. *Blood*. 2019;134(11):851-859.[PubMed 31340982]

Review History

07/22/2020 – Reviewed at P&T. Effective 09/01/2020
11/5/2020 – Effective 1/1/21 Updated to be in compliance with the Masshealth partial unified formulary requirements; Added appropriate dosing and appendix
07/20/22 – Reviewed and updated for July P&T. Separated out Masshealth from Comm/Exch policy. Effective 09/1/22.