

Pharmacy Policy

Pepaxto/Blenrep

Policy Number: 9.723

Version Number: 1.0

Version Effective Date: 9/1/2021

Product Applicability <input type="checkbox"/> All Plan⁺ Products	
Well Sense Health Plan	Boston Medical Center HealthNet Plan
<input type="checkbox"/> New Hampshire Medicaid	<input type="checkbox"/> MassHealth - MCO
	<input type="checkbox"/> MassHealth - ACO
	<input checked="" type="checkbox"/> Qualified Health Plans/ConnectorCare/Employer Choice Direct
	<input type="checkbox"/> Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

Prior Authorization Policy

Products Affected:

- Pepaxto® (melphalan flufenamide injection 20mg)
- Blenrep (Belantamab Mafodotin-blmf) injection 100mg/ml)

The Plan may authorize coverage of the above products for members meeting the following criteria:

Covered Use	All FDA approved indications not otherwise excluded
Exclusion Criteria	None

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Required Medical Information	<p><u>Pepaxto:</u></p> <ol style="list-style-type: none"> 1. Diagnosis of relapsed or refractory multiple myeloma; AND 2. Member has received 4 prior lines of therapy with disease refractory to at least 1 proteasome inhibitor, 1 immunomodulatory agent, and 1 CD38-directed monoclonal antibody <p><u>Blenrep:</u></p> <ol style="list-style-type: none"> 1. Diagnosis of relapsed or refractory multiple myeloma; AND 2. Member must have received at least 4 prior therapies including an anti-CD 38 monoclonal antibody, a protease inhibitor, and an immunomodulatory agent, AND 3. Member and provider must be enrolled in the Blenrep REMs Program.
Age Restriction	Member is 18 years of age or older
Prescriber Restriction	Prescribed by or in consultation with an oncologist.
Coverage Duration	12 months
Quantity Limit	None
Other criteria	<p><u>Reauthorization Criteria:</u></p> <ol style="list-style-type: none"> 1. Member has met initial criteria; AND 2. Member has had stabilization of disease and/or no progression of disease.

Applicable coding:

Code	Medication
J3490; J9999	Pepaxto® (melphalan flufenamide injection 20mg)[Unclassified drugs; Not otherwise classified, antineoplastic drugs]
J9999	Belantamab Mafodotin-blmf for injection, for Intravenous use (Blenrep™) [Not otherwise classified, antineoplastic drugs]

Clinical Background Information and References

1. Blenrep (belantamab mafodotin) [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; August 2020. Accessed March 2021

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2. Pepaxto (melphalan flufenamide) [prescribing information]. Waltham, MA: Oncopeptides Inc; February 2021. Accessed March 2021.
3. UpToDate. [Belantamab mafodotin drug information]. Topic 129194 Version 30.0. Accessed March 2021.
4. UpToDate. [Melphalan flufenamide drug information]. Topic 130900 Version 23.0. Accessed March 2021.

Original Approval Date	Original Effective Date	Policy Owner	Approved by
5/13/2021	9/1/2021	Pharmacy Department	P&T Committee

Policy Revisions History			
Review Date	Summary of Revisions	Revision Effective Date	Approved by
5/13/2021	Policy created	9/1/2021	P&T Committee

Next Review Date

5/2022

Other Applicable Policies

Reference to Applicable Laws and Regulations, If Any

Disclaimer Information

Medical Policies are the Plan’s guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member’s benefit document, and when appropriate, coordinates with the Member’s health care Providers to consider the individual Member’s health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan’s service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member’s benefit document, take precedence over these guidelines. Policies are reviewed and updated

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on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.

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