Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 02/01/2023**
Policy Number: PA.CP.PHAR.469	**Effective Date: 10/2020** **Revision Date: 01/2023**
Policy Name: Belantamab Mafodotin-blmf (Blenrep)	

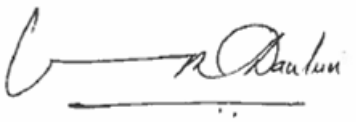
Type of Submission – Check all that apply:

- ☐ **New Policy**
- ✓ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ☐ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

RT4: added disclaimer about FDA and manufacturer withdrawal; added requirement for prescriber attestation to all criteria sets; added Appendix D.

Name of Authorized Individual (Please type or print): **Venkateswara R. Davuluri, MD**	**Signature of Authorized Individual:** 

Clinical Policy: Belantamab Mafodotin-blmf (Blenrep)

Reference Number: PA.CP.PHAR.469
Effective Date: 10/2020
Last Review Date: 01/2023

Coding Implications
Revision Log

Description
Belantamab mafodotin-blmf (Blenrep®/™) is an anti-B-cell maturation antigen (BCMA) monoclonal antibody and microtubule inhibitor conjugate.

FDA Approved Indication(s)
Blenrep is indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least 4 prior lines of therapy, including an anti-CD38 antibody, a proteasome inhibitor, and an immunomodulatory agent.

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

***GlaxoSmithKline (GSK), the manufacturer of Blenrep, voluntarily withdrew Blenrep after post-market data from the DREAMM-3 Phase 3 trial revealed Blenrep did not meet the requirements of the FDA Accelerated Approval regulation. The FDA withdrew its approval for the product (*see Appendix D*).**

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with PA Health & Wellness® that Blenrep is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Multiple Myeloma (must meet all)**:**

1. Provider attestation of acknowledgement of FDA's request for withdrawal of product due to failure to demonstrate superior progression-free survival (PFS) compared to Pomalyst (pomalidomide) in combination with low-dose dexamethasone (PomDex);
2. Diagnosis of multiple myeloma;
3. Prescribed by or in consultation with an oncologist or hematologist;
4. Age ≥ 18 years;
5. Blenrep is prescribed as monotherapy;
6. Member has received ≥ 4 prior lines of therapy (*see Appendix B for examples*) that include all of the following (a, b, and c):
    a. One proteasome inhibitor (e.g., bortezomib, Kyprolis®, Ninlaro®);
    b. One immunomodulatory agent (e.g., Revlimid®, pomalidomide, Thalomid®);
    c. One anti-CD38 antibody (e.g., Darzalex®/Darzalex Faspro™, Sarclisa®);
    **Prior authorization may be required*
7. Request meets one of the following (a or b):
    a. Dose does not exceed 2.5 mg/kg every 3 weeks;

b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

II. Continued Therapy

A. Multiple Myeloma (must meet all)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Provider attestation of acknowledgement of FDA's request for withdrawal of product due to failure to demonstrate superior PFS compared to Pomalyst (pomalidomide) in combination with low-dose dexamethasone (PomDex);
3. Member is responding positively to therapy;
4. Dose is ≥ 1.9 mg/kg every 3 weeks;
5. If request is for a dose increase, request meets one of the following (a or b):
   a. New dose does not exceed 2.5 mg/kg every 3 weeks;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – PA.CP.PMN.53

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

BCMA: B-cell maturation antigen
FDA: Food and Drug Administration
GSK: GlaxoSmithKline
PFS: progression free survival

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
bortezomib/Revlimid® (lenalidomide)/dexamethasone	Varies	Varies
bortezomib/cyclophosphamide/dexamethasone	Varies	Varies
bortezomib/doxorubicin (or liposomal doxorubicin)/ dexamethasone	Varies	Varies
Kyprolis® (carfilzomib) Revlimid® (lenalidomide)/ dexamethasone	Varies	Varies
Kyprolis® (carfilzomib)/cyclophosphamide/ dexamethasone	Varies	Varies
Kyprolis® (carfilzomib – weekly or twice weekly)/ dexamethasone	Varies	Varies
Ninlaro® (ixazomib)/Revlimid® (lenalidomide)/ dexamethasone	Varies	Varies
Ninlaro® (ixazomib)/dexamethasone	Varies	Varies
Ninlaro® (ixazomib)/pomalidomide/dexamethasone	Varies	Varies
bortezomib/dexamethasone	Varies	Varies
bortezomib/Thalomid® (thalidomide)/dexamethasone	Varies	Varies
cyclophosphamide/Revlimid® (lenalidomide)/ dexamethasone	Varies	Varies
Revlimid® (lenalidomide)/dexamethasone	Varies	Varies
VTD-PACE (dexamethasone/Thalomid® (thalidomide)/ cisplatin/doxorubicin/cyclophosphamide/etoposide/ bortezomib)	Varies	Varies
Revlimid® (lenalidomide)/low-dose dexamethasone	Varies	Varies
Darzalex® (daratumumab) or Darzalex Faspro™ (daratumumab/hyaluronidase-fihj)/bortezomib/ melphan/prednisone	Varies	Varies
Darzalex® (daratumumab) or Darzalex Faspro™ (daratumumab/hyaluronidase-fihj)/ bortezomib/dexamethasone	Varies	Varies
Darzalex® (daratumumab) or Darzalex Faspro™ (daratumumab/hyaluronidase-fihj)/Revlimid® (lenalidomide)/dexamethasone	Varies	Varies
Darzalex® (daratumumab) or Darzalex Faspro™ (daratumumab/hyaluronidase-fihj)	Varies	Varies
Darzalex® (daratumumab) or Darzalex Faspro™ (daratumumab/hyaluronidase-fihj)/pomalidomide/ dexamethasone	Varies	Varies
Empliciti® (elotuzumab)/Revlimid® (lenalidomide)/ dexamethasone	Varies	Varies
Empliciti® (elotuzumab)/bortezomib/dexamethasone	Varies	Varies

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Empliciti® (elotuzumab)/pomalidomide/dexamethasone	Varies	Varies
bendamustine/bortezomib/dexamethasone	Varies	Varies
bendamustine/Revlimid® (lenalidomide)/ dexamethasone	Varies	Varies
panobinostat/bortezomib/dexamethasone	Varies	Varies
panobinostat/Kyprolis® (carfilzomib)	Varies	Varies
panobinostat/Revlimid® (lenalidomide)/dexamethasone	Varies	Varies
pomalidomide/cyclophosphamide/dexamethasone	Varies	Varies
pomalidomide/dexamethasone	Varies	Varies
pomalidomide/bortezomib/dexamethasone	Varies	Varies
pomalidomide/Kyprolis® (carfilzomib)/dexamethasone	Varies	Varies
Sarclisa® (isatuximab-irfc)/pomalidomide/ dexamethasone	Varies	Varies

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): none reported
- Boxed warning(s): ocular toxicity
  - In clinical studies, Blenrep caused changes in the corneal epithelium resulting in changes in vision, including severe vision loss and corneal ulcer, and symptoms, such as blurred vision and dry eyes. Because of these risks, Blenrep is only available through a restricted program, called the Blenrep REMS.

Appendix D: Withdrawal from Market

- GSK, the manufacture of Blenrep, voluntarily withdrew Blenrep after post-market data from the DREAMM-3 Phase 3 trial revealed Blenrep did not meet the requirements of the FDA Accelerated Approval regulation.
  - Blenrep did not meet its primary endpoint of superior PFS compared to pomalidomide and dexamethasone (PomDex) for relapsed or refractory multiple myeloma.
  - The hazard ratio for PFS was 1.03 (95% CI: 0.72, 1.47). However, the observed median PFS was longer for Blenrep vs PomDex (11.2 vs 7 months).
- GSK has stopped new patient enrollment (as of November 22, 2022) into the Blenrep REMS.
- GSK recommends prescribers discuss the individual risk vs benefits to decide ongoing care.
- For enrolled patients deriving clinical benefits, Blenrep will continue to be available until GSK launces compassionate use program.
  - Details on compassionate use program will be provided directly to REMS enrolled prescriber.
- GSK recommends patients currently being treated with Blenrep should consult their healthcare providers.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Multiple myeloma	2.5 mg/kg* IV infusion every 3 weeks until disease progression or unacceptable toxicity	2.5 mg/kg/dose

**If dose reduction to < 1.9 mg/kg is required, discontinue therapy.*

VI. Product Availability

Lyophilized powder in a single-dose vial for reconstitution and further dilution for injection: 100 mg

VII. References

1. Blenrep Prescribing Information. Research Triangle Park, NC: GlaxoSmithKline; February 2022. Available at: www.blenrep.com. Accessed December 14, 2022.
2. Lonial S, Lee HC, Badros A, et al. Belantamab mafodotin for relapsed or refractory multiple myeloma (DREAMM-2): a two-arm, randomised, open-label, phase 2 study. Lancet Oncology. 2020; 21(2): 207-221.
3. National Comprehensive Cancer Network. Multiple Myeloma Version 4.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf. Accessed January 25, 2022.
4. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed January 25, 2022.
5. GSK provides an update on Blenrep (belantamab mafodotin-blmf) US marketing authorisation. November 22, 2022. Available at https://www.gsk.com/en-gb/media/press-releases/gsk-provides-update-on-blenrep-us-marketing-authorisation/. Accessed December 14, 2022.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
C9069	Injection, belantamab mafodontin-blmf, 0.5 mg
J9037	Injection, belantamab mafodontin-blmf, 0.5 mg

Reviews, Revisions, and Approvals	Date
Policy created	10/2020
2Q 2021 annual review: no significant changes; added non-specific HCPCS code as no drug-specific codes are currently available; references reviewed and updated.	04/2021
2Q 2022 annual review: updated HCPCS codes; references reviewed and updated.	04/2022

Reviews, Revisions, and Approvals	Date
RT4: added disclaimer about FDA and manufacturer withdrawal; added requirement for prescriber attestation to all criteria sets; added Appendix D.	01/2023