RXADVANCE
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Southborough, MA 01772

Clinical Policy Title:	Belantamab Mafodotin-blmf
Policy Number:	RxA.660
Drug(s) Applied:	Blenrep ™
Original Policy Date:	10/15/2020
Last Review Date:	12/07/2020
Line of Business Policy Applies to:	All lines of business

Background

Blenrep is a B-cell maturation antigen (BCMA)-directed antibody and microtubule inhibitor conjugate indicated for the treatment of adult patients with relapsed or refractory multiple myeloma (RRMM) who have received at least 4 prior therapies including an anti-CD38 monoclonal 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).

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
Belantamab Mafodotin-blmf (Blenrep)	Relapsed/Refractory Multiple Myeloma	2.5 mg/kg as an intravenous infusion over approximately 30 minutes once every 3 weeks.	Varies

Dosage Forms

- For injection: 100 mg as a lyophilized powder in a single-dose vial for reconstitution and further dilution.

Clinical Policy

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

I. Initial Approval Criteria

A. Multiple Myeloma (must meet all):

1. Diagnosis of RRMM;
2. Age ≥ 18 years old;
3. Member has received at least four prior chemotherapies, including an antiCD38 monoclonal antibody, a proteasome inhibitor, and an immunomodulatory agent;
4. Prescribed by or in consultation with an hematologist or oncologist;
5. Request meets one of the following (a or b)*:
    a. Dose does not exceed 2.5 mg/kg of actual body weight;
    b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label

use (prescriber must submit supporting evidence).
* Prescribed regimen must be FDA-approved or recommended by NCCN.

Approval Duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

A. Multiple Myeloma (must meet all):

1. Member is currently receiving the medication that has been authorized by RxAdvance, or documentation supports that member is currently receiving Blenrep for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If the request is for dose increase, request meets one of the following (a or b)*:
   a. Dose does not exceed 2.5 mg/kg of actual body weight;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).
   * Prescribed regimen must be FDA-approved or recommended by NCCN.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
BCMA: B-cell maturation antigen
FDA: Food and Drug Administration
NCCN: National Comprehensive Cancer Network
RRMM: Relapsed or Refractory Multiple Myeloma

APPENDIX B: Therapeutic Alternatives
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements

Drug Name	Dosing Regimen	Dose Limit/Maximum Dose
Proteasome Inhibitors		
Velcade (bortezomib)	varies	varies
Kyprolis®(carfilzomib)	varies	varies
Ninlaro® (ixazomib)	varies	varies
Immunomodulatory Drugs		
Revlimid® (lenalidomide)	varies	varies
Pomalyst (pomalidomide)	varies	varies
XPO1 inhibitor		
Selinexor (Xpovio)	varies	varies

Anti-CD38 monoclonal antibody		
Darzalex® (daratumumab)	varies	varies
Sarclisa (isatuximab)	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.

- Boxed Warning(s):
  - Ocular toxicity

APPENDIX D: General Information

- Perform ophthalmic examinations (visual acuity and slit lamp) at baseline within 3 weeks prior to the first dose, at least 1 week after the previous dose and within 2 weeks prior to the next dose, and promptly during treatment for any worsening symptoms;
- Use preservative-free lubricant eye drops at least 4 times a day starting with the first infusion and continuing until end of treatment and avoid contact lenses.
- Blenrep is administered in outpatient infusion centres.
- Blenrep is available only through a restricted program called BLENREP REMS.

References

1. Blenrep Prescribing Information GlaxoSmithKline; August 2020. Available at: https://www.blenrep.com/ . Accessed October 6, 2020.
2. NCCN Clinical practice guidelines of oncology, Multiple Myeloma, version 2.2021; Sep 9, 2020. Available at https://www.nccn.org/professionals/physician_gls/pdf/myeloma_blocks.pdf Accessed on October 6, 2020.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	10/15/2020	12/07/2020