PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Injectable) – Blenrep Prior Authorization Policy
- Blenrep™ (belantamab mafodotin-blmf intravenous infusion – GlaxoSmithKline)

REVIEW DATE: 09/28/2022; selected revision 01/18/2023

OVERVIEW

Blenrep, a B-cell maturation antigen-directed antibody and microtubule inhibitor conjugate, is indicated for treatment of adults with relapsed or refractory **multiple myeloma**, in those who have received at least four prior therapies, including an anti-CD38 monoclonal antibody, a proteasome inhibitor, and an immunomodulatory drug. The FDA granted accelerated approval to Blenrep in August 2020, based on overall response rate from an open-label, Phase II study. Because the primary endpoint (progression-free survival) was not met in the confirmatory Phase III study, the manufacturer has initiated the process of removing Blenrep from the market. In November 2022, the manufacturer announced that no new patients would be allowed enrollment in the Blenrep REMS program.

Guidelines

National Comprehensive Cancer Network (NCCN) guidelines for multiple myeloma (version 3.2023 – December 8, 2022) recommend various regimens as primary therapy (transplant eligible and non-transplant candidates), maintenance therapy, and previously treated multiple myeloma.[2] The choice of regimen takes into account patient factors as well as response and tolerability to previous regimens. Triplet regimens (e.g., with a proteasome inhibitor, immunomodulatory drug, and corticosteroid) are standard therapy for multiple myeloma. Blenrep is listed as useful in certain circumstances if available through the compassionate use program, and after at least four prior therapies (including an anti-CD38 monoclonal antibody, proteasome inhibitor, and an immunomodulatory drug).

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Blenrep. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Blenrep as well as the monitoring required for adverse events and long-term efficacy, approval requires Blenrep to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Blenrep is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Multiple Myeloma.** Approve for 1 year if the patient meets ALL of the following (A, B, C, D, and E):
   - **A)** Patient is currently receiving Blenrep; AND
   - **B)** Patient is ≥ 18 years of age; AND
   - **C)** Patient has tried at least four systemic regimens; AND
   - **D)** Among the previous regimens tried, the patient has received at least one drug from each of the following classes (i, ii, and iii):

i. Proteasome inhibitor; AND
Note: Examples include Velcade (bortezomib injection), Kyprolis (carfilzomib infusion), Ninlaro (ixazomib capsules).

ii. Immunomodulatory drug; AND
Note: Examples include Revlimid (lenalidomide capsules), Pomalyst (pomalidomide capsules), Thalomid (thalidomide capsules).

iii. Anti-CD38 monoclonal antibody; AND
Note: Examples include Darzalex (daratumumab infusion), Darzalex Faspro (daratumumab and hyaluronidase-fihj subcutaneous injection), or Sarclisa (isatuximab-irfc infusion).

E) The medication will be prescribed by or in consultation with an oncologist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Blenrep is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Blenrep™ intravenous infusion [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; February 2022.
2. The NCCN Multiple Myeloma Clinical Practice Guidelines in Oncology (version 3.2023 – December 8, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 13, 2023.