

SUMMARY

belantamab mafodotin

**BLNREP 100 mg,
powder for solution for dilution for infusion
Reassessment**

Original French opinion adopted by the Transparency Committee on
25 October 2023

The legally binding text is the original French opinion version

Transparency Committee's Conclusions**Clinical Benefit**

- Multiple myeloma is severe, life-threatening haemopathy. Despite the emergence of new treatments, multiple myeloma is still considered as incurable. Patients alternate between relapsing and remitting phases; the latter becoming shorter and shorter over time.
- BLNREP (belantamab mafodotin) is a specific curative multiple myeloma treatment.
- The efficacy/adverse effects ratio is poorly defined considering the findings of the non-comparative phase II study (DREAMM-2) and the lack of evidence of superiority of BLNREP (belantamab mafodotin) versus the association of pomalidomide and low-dose dexamethasone, in a randomised, open-label phase III study (DREAMM-3), in terms of progression-free survival (primary outcome measure: HR = 1.03 (CI_{95%} [0.72; 1.47]; p = NS).

There are therapeutic alternatives (See Section 5.2 Clinically relevant comparators) to BLNREP (belantamab mafodotin) treatment.

→ Public health benefit

In view of:

- the seriousness of the condition, especially for heavily pre-treated patients,
- its incidence,
- the partially met medical need,
- the lack of response to the identified need with:
 - the lack of evidence of an additional impact on morbidity-mortality and on quality of life,
 - the lack of additional impact on the delivery of care.

BLNREP (belantamab mafodotin) is unlikely to have an additional impact on public health.

Considering all of these elements, the Committee deems that the clinical benefit of **BLENREP** (belantamab mafodotin) 100 mg, powder for solution for dilution for infusion, is insufficient in the MA indication to justify public funding.

The Committee disapproves continued inclusion of **BLENREP** (belantamab mafodotin) 100 mg, powder for solution for dilution for infusion, in the list of covered drugs for inpatients in the indication and at the dosages of the MA.

BLENREP 100 mg, 25 October 2023

All our publications can be found on www.has-sante.fr