

SUMMARY

velmanase alfa

LAMZEDE 10 mg

powder for solution for infusion

Modification of the listing conditions

Adopted by the Transparency Committee on 11 December 2024

Summary of opinion**Favourable opinion:**

- for reimbursement in the non-hospital setting,
- for maintenance of reimbursement in the hospital setting with the new CIP code,

in the enzyme replacement therapy of non-neurological manifestations in patients with mild to moderate alpha-mannosidosis.

Transparency Committee's conclusions**Clinical Benefit**

Inclusion in the list for non-hospital use does not modify the Committee's previous conclusions. The Transparency Committee considers that the clinical benefit of LAMZEDE 10 mg (velmanase alfa) powder for solution for infusion is substantial to justify public funding in the MA indication.

The Committee issues a favourable opinion:

- for inclusion in the list of covered drugs for outpatients in the indication and at the MA dosages,
- for maintenance of inclusion in the list of covered drugs for inpatients in the indication and at the MA dosages with the new CIP code.

➔ **Recommended reimbursement rate for inclusion in the list of covered drugs for outpatients: 65%**

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Clinical Added Value

Inclusion in the list for non-hospital use does not modify the Committee's previous conclusions. The Transparency Committee considers that LAMZEDE 10 mg (velmanase alfa) powder for solution for infusion provides a minor clinical added value (CAV IV) in the management of non-neurological manifestations in patients with mild to moderate alpha-mannosidosis.