OPINION RELATIVE TO MEDICINAL PRODUCTS

Honey bee (Apis mellifera) venom and wasp (Vespula spp) venom

ALUTARD 100 SQ-U/ml, 1000 SQ-U/ml, 10 000 SQ-U/ml, 100 000 SQ-U/ml,

Suspension injectable

First assessment

Adopted by the Transparency Committee on 29 June 2022

SUMMARY

The legally binding text is the original French opinion version

- **Allergies**
- **Sectors: Retail and hospital**

Key points

Favourable opinion for reimbursement in the treatment of patients with a history of systemic reactions to honey bee *(Apis mellifera)* and wasp *(Vespula spp)* venom.

What therapeutic improvement?

No clinical added value compared to ALYOSTAL (honey bee *(Apis Mellifera)* and wasp *(Vespula spp)* venom) in the treatment of patients with a history of systemic reactions to honey bee *(Apis mellifera)* and wasp *(Vespula spp)* venom.

Role in the care pathway?

According to the European Academy of Allergy and Clinical Immunology (EAACI), venom immunotherapy is indicated in venom-allergic children and adults to prevent further moderate-to-severe systemic sting reactions. Venom immunotherapy is also recommended in adults with only generalised skin reactions as it results in significant improvements in quality of life compared to carrying an adrenaline autoinjector.

Management

The management of insect venom allergy includes:

- minimisation of the risk of further stings,
- access to training in the use of self-administered adrenaline,
- allergy immunotherapy, which is the only preventive treatment for Hymenoptera venom allergy. It reduces mortality and morbidity in the event of further stings. Its efficacy is around 95% for wasps and 80% for bees. The indications for desensitisation depend on the severity of the initial reaction, the risk of recurrence and patients' risk factors.

Role of the medicinal product in the care pathway

Like all allergy immunotherapies, ALUTARD (honey bee *(Apis mellifera)* and wasp *(Vespula spp)* venom) is the first-line treatment in patients with a documented history of generalised and/or systemic IgE-mediated allergic reactions due to sensitisation to honey bee *(Apis mellifera)* or wasp *(Vespula spp)* venom. It should be specified that the proprietary medicinal product ALUTARD (honey bee *(Apis mellifera)* and wasp *(Vespula spp)* venom) is a preparation adsorbed on aluminium, and is consequently a medicinal product with a more delayed effect and is not suitable for ultra-rush protocols, which are those most commonly used by French allergy specialists. Conversely, aqueous forms like ALYOSTAL (honey bee *(Apis mellifera)* and wasp *(Vespula spp)* venom) are rapidly absorbed and are therefore more appropriate for this protocol.

Committee's conclusions

Considering all of this information and further to debate and voting, the Committee considers:

Clinical benefit

Allergy to honey bee *(Apis mellifera)* venom

- Hypersensitivity reactions to honey bee venom can be life-threatening, either immediately or following complications.
- The proprietary medicinal product ALUTARD (honey bee *(Apis mellifera)* and wasp *(Vespula spp)* venom) is a curative medicinal product.
- The efficacy/adverse effects ratio is high.
- There are medicinal therapeutic alternatives.
- Allergy immunotherapies are the first-line treatment in patients with a history of systemic reactions to honey bee *(Apis mellifera)* venom.

Allergy to wasp *(Vespula spp)* venom

- Hypersensitivity reactions to wasp venom can be life-threatening, either immediately or following complications.
- The proprietary medicinal product ALUTARD (honey bee *(Apis mellifera)* and wasp *(Vespula spp)* venom) is a curative medicinal product.
- The efficacy/adverse effects ratio is high.
- There are medicinal therapeutic alternatives.
- Allergy immunotherapies are the first-line treatment in patients with a history of systemic reactions to wasp *(Vespula spp)* venom.

➔ Public health benefit

Considering:

- the potential seriousness of the condition, which can be life-threatening in some patients,
- the medical need currently partially met by the only other proprietary medicinal product available, and given recent supply tensions,
- the partial response to the identified need, taking into account:
  - an additional impact expected on morbidity and mortality in view of the accepted efficacy of allergy immunotherapies,
  - the absence of any demonstrated additional impact on the organisation of care,

ALUTARD (honey bee *(Apis mellifera)* and wasp *(Vespula spp)* venom) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of ALUTARD (honey bee *(Apis mellifera)* and wasp *(Vespula spp)* venom) is substantial in the MA indications.

The Committee issues a favourable opinion for inclusion in both the hospital formulary list and the retail formulary list of reimbursed proprietary medicinal products approved for use in the MA indications and dosages.

Recommended reimbursement rate: 65%

Clinical Added Value

Considering:

- The efficacy of this allergy immunotherapy, ranging from 78.6 to 100% depending on the studies for honey bee venom and 88 to 100% for wasp venom, based on non-comparative data derived from a review of the literature,
- Demonstration of a reduction in systemic reactions in two comparative randomised trials versus proprietary medicinal products with an aqueous formulation,

But taking into account:

- The presence of aluminium in the formulation of ALUTARD (honey bee *(Apis mellifera)* and wasp *(Vespula spp)* venom), making it a delayed form that cannot be used for the performance of ultra-rush protocols, currently the most commonly practised in France.

The Committee considers that ALUTARD (honey bee *(Apis mellifera)* and wasp *(Vespula spp)* venom) provides no clinical added value (CAV V) in the care pathway.