

**NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE**

**Health Technology Appraisal**

**Pharmalgen for the treatment of venom allergy**

**Draft scope (Pre-referral)**

**Draft remit/appraisal objective**

To appraise the clinical and cost effectiveness of pharmalgen for the treatment of bee and wasp venom allergy within its licensed indication.

**Background**

Bee venom and wasp venom contain allergens that typically produce an intense, burning pain followed by erythema (redness) and a small area of oedema (swelling) at the site of the sting which usually subsides within a few hours. A small number of people (less than 0.5% of the population) may experience a severe, generalised allergic reaction known as anaphylaxis. Anaphylaxis can be severe and potentially fatal. Anaphylaxis reactions are of rapid onset (typically up to 15 minutes from the sting) and of variable presentation. Initial features are usually cutaneous followed by hypotension, with light-headedness, fainting or collapse. Some people develop respiratory symptoms due to either asthma or laryngeal oedema. However, a few people have little or no warning before collapsing and losing consciousness. Less common features are conjunctivitis, rhinitis and gastrointestinal reactions.

Bee sting allergy occurs mainly in beekeepers, their relatives or neighbours, that is, in those exposed to bees and frequently stung. In contrast, wasp venom allergy, which is much more common than bee venom allergy in the UK, occurs with random occasional stings.

In 2000, it was estimated that 25% of all UK deaths from anaphylaxis are due to reactions to hymenoptera stings. Every year in the UK there are 2–9 deaths due to anaphylaxis from bee or wasp stings. Wasp stings in the UK cause twice as many anaphylactic deaths as bee stings.

Anaphylaxis can be treated with an injection of adrenaline. Individuals who are aware that they are allergic to stings often carry their own adrenaline injections kits (adrenalin auto-injectors) for use in an emergency. In addition, antihistamines may be used to treat mild reactions. Immunotherapy (desensitisation), available at a few centres in the UK, seeks to address the underlying cause of anaphylaxis and consists of a course of injections of venom into the patient.

**The technology**

Bee and wasp venoms (Pharmalgen, ALK-Abello) involve the administration of increasing doses of allergen, which over time desensitises a person with an allergy by altering their immune system. It is administered by subcutaneous

injection. Treatment is carried out in two phases: the initial phase and the maintenance phase, and can last up to 3 years.

Pharmalgen Bee Venom has a UK marketing authorisation for the diagnosis and treatment of IgE-mediated allergy to bee venom. Pharmalgen Wasp Venom is licensed in the UK for the diagnosis and treatment of IgE-mediated allergy to wasp venom<sup>1</sup>.

<b>Intervention(s)</b>	Pharmalgen for the treatment of bee and wasp venom allergy
<b>Population(s)</b>	People with a history of anaphylaxis to: <ul style="list-style-type: none"> <li>• wasp venom</li> <li>• bee venom</li> </ul>
<b>Comparators</b>	<ul style="list-style-type: none"> <li>• no immunotherapy</li> </ul>
<b>Outcomes</b>	The outcome measures to be considered include: <ul style="list-style-type: none"> <li>• anaphylactic episodes</li> <li>• local and systemic sting reaction</li> <li>• mortality</li> <li>• adverse effects of treatment</li> <li>• health-related quality of life.</li> </ul>
<b>Economic analysis</b>	<p>The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year.</p> <p>The reference case stipulates that the time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared.</p> <p>Costs will be considered from an NHS and Personal Social Services perspective.</p>
<b>Other considerations</b>	Guidance will only be issued in accordance with the marketing authorisation
<b>Related NICE recommendations</b>	None

<sup>1</sup> NICE is not intending to look at the use of pharmalgen in the diagnosis of allergy to bee and wasp venom

**Questions for consultation**

Have the most appropriate comparators for the treatment of bee and wasp venom allergy been included in the scope?

Are there any subgroups of patients in whom the technology is expected to be more clinically effective and cost effective or other groups that should be examined separately?

Are there any issues that require special attention in light of the duty to have due regard to the need to eliminate unlawful discrimination and promote equality?

NICE intends to appraise this technology through its Multiple Technology Appraisal (MTA) Process. We welcome comments on the appropriateness of appraising this topic through this process. (Information on the Institute's Technology Appraisal processes is available at [http://www.nice.org.uk/aboutnice/howwework/devnicetech/technologyappraisalprocessguides/technology\\_appraisal\\_process\\_guides.jsp](http://www.nice.org.uk/aboutnice/howwework/devnicetech/technologyappraisalprocessguides/technology_appraisal_process_guides.jsp))