NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Health Technology Appraisal

Pharmalgen for the treatment of venom allergy

Final Scope

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 chemicals 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 type I allergic reaction known as anaphylaxis. Type I reactions (that is, immediate hypersensitivity reactions) involve immunoglobulin E (IgE)–mediated release of histamine. Anaphylaxis can be severe and potentially fatal. Anaphylactic reactions are of variable presentation and typically of rapid onset (within 15 minutes from the sting), although they may occur up to one hour after the sting. Initial symptoms 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. The enzyme tryptase is generally markedly elevated in cases of sting-induced severe anaphylaxis and baseline levels of tryptase may predict the severity of response in people with bee or wasp venom allergy. Less common allergic reactions are conjunctivitis, rhinitis and gastrointestinal reactions. People with allergies to bee and wasp venom may experience a decreased quality of life as a result of anxiety associated with the possibility of future stings and subsequent allergic reactions.

Bee venom 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.

Estimates of the prevalence of anaphylaxis vary widely. In 2000, it was estimated that 25% of all UK deaths from anaphylaxis were 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 deaths due to anaphylaxis as bee stings.

Anaphylaxis can be treated with an injection of adrenaline. Individuals who are aware that they are allergic to venom often carry their own adrenaline

injections kits (adrenaline 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.

The technology

Bee and wasp venom immunotherapies (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 (also known as 'updosing') and the maintenance phase, which lasts 3 to 5 years.

Pharmalgen Bee Venom has a UK marketing authorisation for the diagnosis and treatment of IgE-mediated allergy to bee venom. Pharmalgen Wasp Venom has a UK marketing authorisation for the diagnosis and treatment of IgE-mediated allergy to wasp venom[1].

Intervention(s)	Pharmalgen for the treatment of bee and wasp venom allergy
Population(s)	People with a history of type 1 IgE-mediated systemic allergic reactions to: • wasp venom • bee venom
Comparators	Standard care without venom immunotherapy, including: ○ advice on the avoidance of bee and wasp venom, ○ high-dose antihistamines, ○ adrenaline auto-injector prescription and training

[1] NICE will not be looking at the use of pharmalgen in the diagnosis of allergy to bee and wasp venom

Outcomes	The outcome measures to be considered include: • number and severity of type 1 IgE-mediated, systemic allergic reactions • anxiety related to possibility of future allergic reactions • mortality • adverse effects of treatment • health-related quality of life.
Economic analysis	The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year. 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. Costs will be considered from an NHS and Personal Social Services perspective.
Other considerations	Guidance will only be issued in accordance with the marketing authorisation. If the evidence allows, consideration will be given to subgroups of people according to their: • risk of future stings (as determined, for example, by occupational exposure). • risk of severe allergic reactions to future stings (as determined by such factors as baseline tryptase levels and co-morbidities). If the evidence allows, the appraisal will consider separately people who have a contraindication to adrenaline. If the evidence allows, the appraisal will consider children separately.
Related NICE recommendations	None