

## Standard Operating Procedure

### Administration of sub-cutaneous immunotherapy (SCIT)

Venom immunotherapy (VIT) is indicated for all adults and children who have experienced a severe systemic reaction to a sting and a proportion of adult patients who have had a moderate systemic reaction to a sting<sup>(1-3)</sup>. Severe venom allergy is potentially life threatening. VIT has been shown to be effective in 95% of patients with wasp venom allergy and approximately 80% of bee venom allergic individuals<sup>(1,2)</sup>. The BSACI has published guidelines for the investigation and management of venom allergy <http://www.bsaci.org/guidelines/venom-allergy><sup>(1)</sup>

Grass / tree pollen immunotherapy is recommended for patients who, despite allergen avoidance and a supervised trial of maximal pharmacotherapy, still have uncontrolled symptoms of seasonal allergic rhinitis.<sup>(4-6)</sup> Immunotherapy has been shown to be clinically effective, and is the only treatment option that can modify the IgE-mediated allergic response and induce long-term remission<sup>(7)</sup>.

Subcutaneous immunotherapy (SCIT) has been shown to be effective in reducing the symptoms and medications required in patients with grass-pollen related seasonal allergic rhinitis<sup>(4,6)</sup>. The BSACI has produced guidelines for the use of immunotherapy in patients with allergic rhinoconjunctivitis (<http://www.bsaci.org/guidelines/allergic-rhinitis>)<sup>(7)</sup>.

Product	UK Licence	Considerations
<b>Bee and Wasp Venom subcutaneous injection vaccines</b>		
<b>Pharmalgen</b> ( <i>ALK Abello</i> )	Yes (insert age)	12 week up-dosing followed by three years of monthly maintenance treatment  Up-dosing can be shortened by using a rush protocol
<b>Grass and Tree Pollen subcutaneous injection vaccines</b>		
<b>Pollinex</b> ( <i>Allergy Therapeutics</i> ) ➤ Trees (Alder, Hazel & Birch) ➤ Grasses & Rye (13 species)	Yes  (from 6 years)	6 injections pre-seasonally, repeated for three years
<b>Pollinex Quattro</b> ( <i>Allergy Therapeutics</i> ) ➤ 12 species of grass and rye	No	Four injections pre-seasonally, repeated for 3 years

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<b>Allergovit (Allergopharma)</b> <ul style="list-style-type: none"> <li>➤ Grass (6 species of grass)</li> <li>➤ Tree (3 species of tree)</li> </ul>	No	7 injections pre-seasonally, repeated for three years.
<b>Alutard SQ (ALK Abello)</b> <ul style="list-style-type: none"> <li>➤ Grass (6 species of grass)</li> </ul>	No	15 up-dosing injections must be completed outside pollen season.  Maintenance injections every 4-8 weeks continue for 3 years.  During the pollen season down dosing should be considered
<b>House Dust Mite subcutaneous injection vaccines</b>		
<b>Tyrosin (Allergy Therapeutics)</b>	No	7 up-dosing injections  Maintenance injections every 4-8 weeks continue for 3 years
<b>Alutard (ALK Abello)</b>	No	15 up-dosing injections  Maintenance injections every 4-8 weeks continue for 3 years

**How to administer SCIT**

- Sub-cutaneous immunotherapy should be initiated in a clinical area that has sufficient space for direct observation of patients following injections, resuscitation facilities and clinical staff experienced in the administration of immunotherapy and equipped to recognize and manage anaphylaxis.
- SCIT should be performed in the immediate (or adjacent) availability of a doctor.
- Informed consent should be obtained by patient or in the case of a child, a carer with parental responsibility and assent given by the child.
- Patients should be advised that they must be well on the day of administration and if they have asthma this should be well controlled (FEV1 >80%).
- Wash hands prior to procedure and adhere to local Trust's Infection Control Policy.

<b>PROCEDURE<sup>(1,2,6,7,9)</sup></b>	<b>RATIONALE</b>
Check patients' name and DOB to confirm that SCIT is being administered to the correct patient	To ensure the patient receives the correct treatment

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Assess the patient's clinical status i.e. that they are well	SCIT should not be administered if the patient has an inter-current infection or exacerbation of asthma. Newly diagnosed medical conditions should be documented, assessed and a decision made about continuing treatment.
Check and record baseline observations prior to commencing SCIT, including peak flow, blood pressure and pulse. Confirm peak flow is within patient's usual range ( $\geq 80\%$ usual / predicted).	To ensure patient is medically stable in order to reduce the risk of a severe or systemic reaction.
Confirm that the patient is not pregnant or breast feeding.	SCIT should not be initiated in patients who are pregnant, due to the risk of anaphylaxis. A senior clinician should carefully consider, and discuss the risk / benefit before continuing maintenance treatment in patients who become pregnant during their course of treatment. Due to the lack of evidence and the potential risk of sensitization of the infant immunotherapy should not be initiated whilst a woman is breast feeding.
Assess the patient's response to the previous dose	To assess if the dosage requires adjustment. Dose adjustments following a reaction to a previous dose of immunotherapy should be discussed with the prescriber.
Review any changes in the patient's current medication including any recent vaccinations	To ensure that the patient is not taking any contraindicated medication. Immunotherapy should not be given within 7 days of another vaccination.
Document if patient has taken an antihistamine prior to injection	To allow for accurate assessment of the patient's response to treatment
For VIT, ask if patient has had a live sting since last injection and document response and any treatment required.	Assess response to treatment and consider if dose modification is required.
Document the time interval from the previous dose	To assess if the dose requires adjustment in line with product dosing protocol.
Checking of injectable drugs should be in line with local Trust drug administration policy. SCIT dose should be checked by a second clinician for product, dose and expiry prior to injection. Using aseptic technique and a 1ml syringe draw up the allergen dose and check expiry date prior to administration. Needle should be changed to a	To ensure administration of correct allergen and dose within expiry date

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new orange 25g needle before administration.	
Administer dose via a subcutaneous injection into the outer aspect of the upper arm. Care should be taken to avoid intravascular injection by drawing back the plunger prior to injection and at intervals during the injection.	
Dispose of sharps safely in line with local guidelines.	To prevent needlestick injury and in line with local infection control policy
Document dose, batch number and expiry date of allergen administered	For governance and to enable tracking of batch in the event of an adverse reaction
Document site of administration	To allow for accurate assessment of patient's response
Monitor patient for any sign of an allergic reaction for 60 minutes following administration of SCIT.	An allergic reaction can occur following administration of SCIT
Reassure patient if they experience symptoms such as pain, mild swelling and redness at injection site.	These are common side effects and can be modified by use of antihistamines, topical ice packs or paracetamol if required.
Promptly treat any adverse allergic reaction or side effects of SCIT	Maintain safety of patient
Reassess the patient prior to discharge and document pulse, blood pressure, peak flow and any local reaction to the injection.	To ensure the patient has not had an allergic reaction and is fit for discharge.
Arrange the next appointment with the patient	To ensure continuity of treatment
Advise patient to avoid strenuous exercise, alcohol, saunas for the rest of the day	These activities increase blood flow to the injection site and may result in larger local reactions.
Ensure the patient and/or family have the following information on discharge; <ul style="list-style-type: none"> <li>• How to recognise and manage an allergic reaction</li> <li>• How to manage a local injection site reaction</li> <li>• Advise the patient to ensure they have immediate access to a non-sedating antihistamine.</li> <li>• Contact details should they require ongoing support</li> <li>• Advice about continuing to carry adrenaline autoinjector(s)</li> </ul>	To ensure the patient and family are supported and aware of how to overcome any problems with their treatment.  To treat side effects of SCIT.

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<p>Follow up patient as appropriate.</p> <p>For venom patients advise about management of future sting reactions and provide contact details for them to report future response to a sting.</p> <p>For pollen immunotherapy, document hayfever severity annually on a global visual analogue scale 0-10 in response to the question “how bad was your hayfever this year?” This should be recorded before the start of treatment and annually after each pollen season</p> <p>The BRIT registry has validated quality of life questionnaires for clinicians to use for patients with venom allergy and rhinoconjunctivitis.</p>	<p>To monitor effects of immunotherapy.</p>
<p>Invite patient to join BSACI registry for immunotherapy (BRIT) Link below.</p> <p><a href="http://brit.e-dendrite.com/">http://brit.e-dendrite.com/</a></p>	

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