

ASTHMA & ALLERGY ASSOCIATES PA

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Ronald E. Weiner, M.D.

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IMMUNOTHERAPY GUIDELINES

Dear Provider,

Our patient, _____, DOB _____ desires to receive allergy shots at your facility. Please review and sign Guidelines and return by fax ASAP.

1. The patient's immunotherapy (allergy shot) extract ("serum") contains the tree-grass-weed pollens, indoor-outdoor mold spores, animal dander and/or house dust components (EG., dust mite and cockroach) to which the patient's skin tests and history suggested the patient may be allergic to.
2. The immunotherapy injections are being given to help improve the patient's allergic rhinitis (seasonal or perennial), **recurrent-chronic sinusitis, allergic conjunctivitis** and/or **allergic asthma**.
3. The immunotherapy injections will be given perennially (year round) and not seasonally or pre-seasonally.
4. The immunotherapy injections will usually be given **once a week initially** while the patient is in the "**build-up**" phase (i.e. while the immunotherapy injection dosage and/or concentration is being increased).
5. After a **maintenance dose** has been reached (typically in a few to several months) the patient will usually get the **injections less and less frequently** such that the interval between injections may increase to every 2, then every 3, then every 4 weeks. You will be notified by our office as to when these changes may occur.
6. The **duration** of immunotherapy will vary from patient to patient but most patients will get the injections for **3 to 5 years**.
7. The **onset of benefit** of immunotherapy injections varies from patient to patient but it will usually take a **few to several months** and **peak benefit** may not be seen for **3 to 4 years**. If no benefit is seen after the first 15-18 months then we may recommend that immunotherapy be discontinued.
8. The immunotherapy injections will usually be made up in **four concentrations**. The **1st (weakest)** bottle to be used will have a **green cap** and will be a **1:1000 concentration**. The **2nd** bottle will have a **blue cap** and will be **1:100**. The **3rd** bottle will have a **yellow cap** and be 1:10. The **4th (strongest)** will have a **red cap** and will be a 1:1 concentration. The bottles will be sent to your office sequentially. When the last shot of one bottle has been given then call our office to have the next bottle sent. **Extracts should be refrigerated**.

9. PRIOR TO EACH INJECTION:

- Ask the patient if they are having **problems with asthma, taking prednisone, or are ill**. If so, do not give the injections and instruct the patient to call our office for help. Do not give immunotherapy injections to patients on Beta-blocker medications. These block effect of epinephrine when treating systemic reactions. Do not give shots if patient has peak flows below 80% of their personal best. Peak flows are to be measured before each allergy shot. If so, do not give the injections and instruct the patient to call our office for help.
- Ask to see the patient's epinephrine autoinjector(**Epi-pen, Auvi-Q, Adrenacllick**). If they can't show it to you then they are required to wait in the office 60 minutes instead of 30 minutes. The patient has been instructed to keep the epinephrine autoinjector on hand for the first 60 minutes after the shot.
- Ask the patient if they had a **generalized reaction** within a few hours after their last injection. By this we mean itchy skin, hives, chest tightness, coughing, wheezing, dyspnea, runny nose, nasal congestion, or sneezing that they weren't having before the shot.
- Ask the patient about any **local reactions** to their last shot starting the day of the shot. By local reactions we mean swelling, redness, warmth, discomfort, and itching at the shots site. Local reactions are categorized into 3 types: **1)** not bothersome and well tolerated, **2)** bothersome but tolerable, and **3)** not only bothersome but also poorly tolerated. With a **type 1** local reaction continue to advance the dose per protocol during the buildup phase or continue the dose as is during the maintenance phase. With a **type 2** local reaction keep the dose the same during both the buildup phase and the maintenance phase. With a **type 3** local reaction reduce the dose one step in both the buildup and maintenance phases. Allow the patient to have considerable input into repeating or reducing a dose at their discretion based on their perception of how well the last shot was or wasn't tolerated.
- **Show the patient** (or the patient's parent) **their extract bottle checking name and DOB** so that the patient may verify that the bottle is the correct one and reduce the risk of the inadvertent administration of an immunotherapy extract of one patient to another patient.
- Make sure that a **physician or licensed APRN/PA is in the office** and will be so for the next **30** minutes after the shot (or **60** minutes if the patient is waiting **60** minutes without an Epi-Pen).
- Make sure that 1:1000 **epinephrine** and **oxygen** are immediately available for the treatment of generalized (systemic) reactions to the injection.

10. Cleanse the skin at the proposed injection site with **isopropyl alcohol** before the injection.

11. Use a **1cc(ml) tuberculin or insulin syringe (25 or 27 gauge needle)** and administer the injection subcutaneously in the proximal arm, posterolaterally. Always pull back on the plunger of the syringe before injecting to ensure that blood doesn't appear in the syringe (which could result in possible inadvertent intravascular administration of the extract). Obviously, if blood does appear in the syringe on aspiration then the needle needs to be repositioned.

12. The protocol for administration of the immunotherapy is presented in the chart below. Obviously, deviations from the proposed protocol may need to be made for generalized and local reactions (as detailed above) or for missed injections. **Doses are in ml(cc).**

COLOR	GREEN	BLUE	YELLOW	RED (maintenance/undiluted)*
CONCENTRATION	1:1000 v/v	1:100 v/v	1:10 v/v	1:1 v/v
SHOT #1	0.05	0.05	0.05	0.05
SHOT #2	0.10	0.10	0.07	0.07
SHOT #3	0.20	0.20	0.10	0.10
SHOT #4	0.35	0.35	0.15	0.15
SHOT #5	0.50	0.50	0.25	0.25
SHOT #6			0.35	0.35
SHOT #7			0.50	0.50

*For final concentration of each allergen in the maintenance extract see our immunotherapy recipe order(s) which are available upon request.

13. Once a dose of 0.50 ml of the Red (1:1) bottle has been reached, then this will be regarded as a **maintenance dose** and this will be the dose administered shot after shot. Sometimes patients are unable to tolerate this dose or even lower doses after repeated tries dose may lead to lower a lower maintenance dose. Once the red-capped bottle is nearly empty then call or fax our office to order more.

14. Always keep the patient under **observation** for at least **30 minutes** after each shot as the majority of severe generalized reactions to immunotherapy injections will start in the first 30 minutes after the injection. If you notice that the patient after one warning continues to leave sooner than the required 30 minute waiting period, then refuse to give anymore injections until the patient has contacted our office.

15. The **treatment of a mild generalized reaction** to an immunotherapy infection (eg. dermal pruritus, urticaria, rhinitis and conjunctivitis) might consist of just a **liquid antihistamine** (for quicker absorption) such as Benadryl (even if the patient already had an antihistamine that morning). Obviously, if the patient is an adult who drove to the office, caution should be exercised in allowing the patient to drive home. If the patient is symptomatic enough to need **IM Benadryl** (1 mg/kg up to a maximum of 50 mg) then they are symptomatic enough to need Adrenalin.

If the patient is having **asthma symptoms** then the patient could be given **2-4 puffs of a bronchodilator metered dose inhaler** (eg. Proventil, Ventolin, ProAir, etc.) Very rarely will a patient too young to use a metered dose inhaler with a spacer device (eg. Aerochamber, etc.) be placed on immunotherapy injections but in such an event one could use a **nebulized bronchodilator**. If an older child or adult is having enough asthma that you think they need a nebulized bronchodilators then they need Adrenalin. A repeat PEFR could document response to therapy.

With more bothersome persistent symptoms then one should give 1:1000 **Adrenalin** 0.01 ml/kg body weight IM in the lateral thigh (up to a maximum of 0.50 ml). This could be repeated if necessary in 10-15 minutes. Very rarely would repeat doses of Adrenalin, administration of **oxygen** or need for **intravascular fluid** be needed.

Any generalized reactions should result in a phone call to our office regarding further instructions before administration of the next shot.

16. If the patient is late for a shot, please make the following adjustments:

During build-up phase

- 1 to 14 days since last shot: advance as usual to the next step in protocol
- 15 to 30 days since last shot: repeat previous dose
- 31 days or more since last shot: call our office

During maintenance phase:

- 15-60 days since last shots: repeat previous dose
- 61 or more days since last shot: call our office

Please notify Asthma & Allergy Association 3 weeks before allergy extract supply expires or is all used. Send a copy of the allergy shot administration record when re-ordering extract.

Do not allow patient to transport extract to another medical facility without the written consent of Asthma & Allergy Associates PA.

17. Drs. Weiner and Frick would like to sincerely thank you for having read these guidelines and assisting the patient and us in the administration of these immunotherapy injections. Obviously, if you have any other questions about the administration of the injections, please do not hesitate to call us. Please fax or mail this signed consent to our office. Thanks again,

Ronald E. Weiner, M.D.

Warren E. Frick, M.D.

Provider Name _____

Provider Address _____

Provider Signature _____

Provider Phone _____

Date _____

August 2018