
HOME-BASED ALLERGY IMMUNOTHERAPY

Timarron Family Medicine

Criteria for Patients Initiating Subcutaneous Immunotherapy

Please initial next to each statement indicating you understand the following:

- _____ Able to use an Epi-Pen; Prescribe a 2-pack when possible
- _____ Ready access to an Epi-Pen during the day of SCIT
- _____ Able to contact emergency responders (call “911”) if you have a severe allergic reaction.
- _____ Trained to identify and treat local vs. systemic reactions.
- _____ The presence of a trained “partner” when SCIT is administered
- _____ Able to perform a pre-injection health screen
- _____ Asthma must be well-controlled
- _____ Asthma must be mild and intermittent
- _____ Peak flow measurements prior to injection
- _____ If prescribed a beta-blocker medication patient will inform nurse
- _____ Able to avoid exertion or strenuous exercise 2 hours before and after injections
- _____ Training on proper subcutaneous immunotherapy technique
- _____ Maintain regular treatment appointments
- _____ Able to contact healthcare provider as questions arise
- _____ No other health conditions that might be a contraindication to at-home treatment including (but not limited to): cardiovascular disorders; uncontrolled hypertension; an uncontrolled seizure disorder; with a history of anaphylaxis to aeroallergens; with Mast cell disorders, hyper-IgE syndrome, or significant immunodeficiency disorders; or to those with moderate to severe COPD; or to those who are initiating therapy during pregnancy; or to those with moderate to severe systemic disorders; or to those with oxygen dependent cardiopulmonary disorders

DOSING PROTOCOL

First Dose

The first dose of each new vial in the patient's treatment set(s) will be administered in the office. After the first injection patient will have to be monitored for 30 minutes to ensure that the next highest strength of extract is tolerated well. During this time we will review the dose recording sheets, train on injection protocols or reaction management, and address any concerns or questions the patient may have about their treatment.

Dosing Frequency

The at-home protocol will allow the patient to self-administer 2 injections per week. Keep in mind you need to have another adult present for at least 20min post injection. This frequency allows the dose advancement to proceed steadily and cautiously while also promoting patient compliance. It is suggested that the patient allow 72 hours between injections, although a 48-hour interval is likely acceptable. If injections are administered within a shorter period, there is a theoretical risk of compounding the exposure of allergen and triggering a reaction, and it may be difficult to determine if a reaction is due to the single dose administered, delayed from the previous dose, or an accumulation of allergen following doses administered within a short window of time.

Dose Advancement

The at-home immunotherapy build-up phase of treatment proceeds with 2 injections administered every week for 10 weeks. A total of 20 doses will be administered from each vial with a total volume of approximately 4 milliliters drawn from the vial. The schedule calls for each dose to be repeated once, so the patient will administer each dose 2 times. The step-wise increase with repeated dosing at each level allows for the patient to advance in their treatment cautiously and ensure that each dose is tolerated before advancing to the next higher dose.

Just as in the in-office program, there are 5 titration vials in the build-up treatment set. The practice will prepare the vials in the same manner as if they are to be given in the office, but the patient will only receive one (1) vial at a time to take home. The patient will schedule an appointment to pick up each new vial and receive the first dose in the office. The following tables illustrate the dosing schedule.

PATIENT MANAGEMENT

One of the most critical aspects of an at-home immunotherapy treatment program is the ability to effectively communicate with a patient about the specific instructions related to self-administered injections. In particular, it is critical that your patients fully understand how to recognize an adverse reaction should it occur and how to seek medical help, if needed, including the administration of epinephrine or calling 911.

It is also important to work with your patients and help them understand that the best chance for treatment success depends on remaining compliant with treatment. Many patients report that the primary reason they stopped immunotherapy is due to a lack of symptoms, so patients should understand that treatment must continue even when they are feeling well and when allergic symptoms are not bothersome. The following patient training checklists will aid you in providing additional information to support your at-home treatment program and ensure that your patients are knowledgeable and capable of self-administering their allergy injections.

Injection Protocols

- ☐ Patient understands treatment schedule
- ☐ Patient understands proper storage of vials
- ☐ Patient understands allergy injection protocol
- ☐ Patient withdraws all proper dosages
- ☐ Patient can fill out Dose Recording Log
- ☐ Patient received prescription for syringes

Allergy Safety & Emergency Protocols

- ☐ Patient can perform preinjection health screen
- ☐ Patient understands the signs & symptoms of anaphylaxis
- ☐ Patient understands treatment protocols for allergy reactions
- ☐ Patient watched Epi auto injector video
- ☐ Patient received training on Epi auto. injector trainer
- ☐ Patient knows how to safely dispose of syringes

Precautions

- Always educate an allergy partner who can help recognize adverse allergic reactions and help administer rescue medications if needed.
- Verify the brand of epinephrine auto-injector prescribed and ensure training is specific to the brand.
- Verify proper storage of epinephrine auto-injector.
- Prescription vials must be kept refrigerated for optimum potency. However, studies have shown that vial potency is not appreciably affected if vials are left out of refrigeration for brief periods of time (< 1 hour). If vials are exposed to heat or freeze, they should be replaced immediately.
- Do not administer an injection with a fever >99.5, if wheezing or following a Peak Flow reading less than 80% of personal best.
- Do not administer an injection if patient is prescribed a beta-blocker medication.
- Have patient check with provider if on new medications or if a new medical condition occurs.
- Do not dose on the same day a vaccine is administered.
- Dose adjustments may be based on missed days or adverse reactions (see example chart below).

Dose Adjustments

The at-home protocol for subcutaneous immunotherapy allows for patients to adjust their dose based on non-compliance or adverse reactions. However, the provider will provide guidance on dose adjustments (or whether to continue at-home immunotherapy), if a patient has an extended lapse in treatment or experiences a large-local or severe reaction. The table below summarizes the general guidance on dose adjustments for a few scenarios, but other situations may arise that require a modification in the dosing schedule.

Guideline for Dose Adjustments

Missed Treatment

Up to 7 days since last injection...
8-14 days since last injection...
>14 days since last injection...

Dose Adjustment

None – proceed with schedule Repeat last tolerated dose
Consult with allergy provider before proceeding

Adverse Reactions

Mild local reaction <2cm in size; quickly resolves...
Large local reaction 2. 10cm; resolves with medication...
Systemic reaction or use of Epi-Pen...

Dose Adjustment

Repeat last tolerated dose
Consult with allergy provider before proceeding
Do not continue allergy shots; schedule appointment

Injection Recording Form

The at-home protocol for subcutaneous immunotherapy requires that the patient capture information about each injection that is self-administered. The patient will keep an injection log with each treatment vial and return to every appointment with the recording form filled out. An example dose recording form is shown in the Appendix, which shows the following information that should be entered by the patient:

- Enter the date of injection.
 - Select “Pass” or “Fail” on the self-administered health screen (patient should never administer an allergy injection if answering “Yes” to the health screen questions though missed injections due to a failed health screen should still be recorded).
 - The location of the injection (e.g. arm, abdomen)
 - Enter initials of person administering the injection (this may not always be self-administered)
 - Any comments or observations following the injection – it is especially important to document and allergic symptoms at the injection site or elsewhere in the body. Patient should describe the reaction (e.g. mild swelling, redness, itching, etc), the size (in cm or in relation to something comparable like coin size palm size etc), and duration, and any medications taken to resolve the reaction.
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Consent for allergy injections given outside Allergy clinic

I, _____, acknowledge that Timarron Family Medicine has given me instructions on shots given outside of the clinic for at-home use. I acknowledge that the risks of immunotherapy (shots) has been discussed with me. I understand that these risks include but are not limited to local reactions and even death. I understand that I am to wait 30 minutes in the presence of an adult after administering my shot.

I agree to have my epinephrine with me in case of a life-threatening reaction. I acknowledge that I have received instructions on its use and administration. I further understand that I must periodically check that my epinephrine is not expired and will call the office for a renewal if needed.

I understand that it is my responsibility to maintain follow up appointments with my Timarron Family Medicine Provider. Failure to do so may result in a delay of serum renewal. I understand when I have finished my current vial I am to bring the vial, epinephrine pen and my injection log with me to my follow up appointment at the clinic..

By signing this form, I accept full responsibility for receiving my allergy injections outside of Timarron Family Medicine and release Timarron Family Medicine from any liability or responsibility for any reactions or conditions.

_____	_____	_____
Patient’s Name (Print)/ DOB	Signature of Patient / Parent/Guardian	Date

_____	_____	_____
Witness name	Witness Signature	Date

Staff initials- Copy of signed form given to patient: _____ Syringes _____ Epinephrine _____

Consent for allergy shots given outside of an Allergy office

Instructions for take-out injection immunotherapy

- Refrigerate all allergy immunotherapy serum extract. Do not freeze.
- Use a disposable 1cc syringe with 30g needle (insulin syringe). Inject at a 45-90 degree angle below the skin layer into the fat on the back of the arm approximately halfway between the elbow and the shoulder. Never give into the muscle.
- Increase or maintain dose as directed.
- Always question the patient before injection. The following are reasons not to proceed with shot:
 - Any significant local or system reactions from the last injection
 - An acute illness or fever or having asthma symptoms
 - Strenuous exercise within the last 2 hours
 - If the patient is on weekly shots and it has been longer than 21 days since the last injection, please contact our office for proper instructions.

Information on injection immunotherapy

Immunotherapy may have to be discontinued for patients that are prescribed beta-blockers (a common medication used to treat high blood pressure or glaucoma).

The most common local reaction is redness at the injection site and minor swelling. While this is uncomfortable, it is not dangerous (unless greater than the size of the palm of your hand).

- Please do not scratch or rub injection site.
- Ice, benadryl, or cortisone cream may be applied for comfort measures.
- An antihistamine such as (zyrtec, xyzal, allegra, etc.) prior to injections may be beneficial.
- If swelling does not go away in 24 hours, please call our allergy department.

Systemic reactions, although exceedingly rare, can occur (swelling of face/hands/feet, difficulty breathing, tight feeling in the chest or wheezing). If this should occur, use your epinephrine as instructed and call 911.