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IMMUNOTHERAPY POLICIES & PROCEDURES

Injection Administration Instructions:

1. Injections are to be recorded by dose, date, reactions and location.
2. Prior to each injection an inquiry will be made regarding reactions to previous injections and general state of health. Periodically check medications that might contraindicate immunotherapy (beta-blockers) and make sure patients are aware of the beta-blocker warning.
3. Treatment should be initiated at the dilution from the physician's orders at a dosage of 0.05 cc. At regular intervals the dosage and dilution will be increased. Build-up treatment is administered at typically once a week in accordance with the scheduled dosage summarized below.

First dose	0.05 cc indicated dilution
Second dose	0.10 cc indicated dilution
Third dose	0.20 cc indicated dilution
Fourth dose	0.30 cc indicated dilution
Fifth dose	0.40 cc indicated dilution
Sixth dose*	0.50 cc indicated dilution

*Sixth dose given only for 10-fold dilution and undiluted vials.

4. Once a dilution is complete, change to the next higher concentration and repeats the dosage schedule. Dilutions start at 1,000-fold (or 10,000-fold depending on the patient) and are increased 10 fold to a final undiluted vial. In the build-up phase injections can be given every 48 hours (up to three times per week).
5. Most patients will reach a maintenance dose of 0.50 cc of the undiluted vial. If this maintenance dose can not be reached, please contact the allergist at our office for further instructions. If doing well after 6 weeks of weekly maintenance dose (0.5 cc of undiluted vial) injections, patients can try to increase the interval of their injections to every 2 weeks. Patients, who have been on maintenance dose injections every 2 weeks for 6 weeks and are doing well, may receive their maintenance injections every 3 weeks. Patients, who have been on maintenance injections every 3 weeks for 6 weeks and are doing well, may take maintenance injections every 4 weeks (monthly) and stay at this injection interval [Summary for building up to monthly injections: If patient is doing well at weekly injections, give allergy shots at every other week for 3 intervals, then every three weeks for 2 intervals and then continue at every four weeks]. Only increase allergy injections if patient is doing well. Some patients prefer to keep more frequent schedules (example: injections every week or every other week).
6. All patients must remain under observation for 20-30 minutes following injections to observe and then record local or generalized reactions (severe reactions commonly begin within this period of time).
7. Allergen immunotherapy must be administered by trained technicians or nursing staff, with a physician in attendance. Unusual reactions to immunotherapy or modifications from the regime described above needs to be discussed with the physician.
8. It must be remembered that some patients may benefit by a weaker dose, but, most patients must complete the schedule before maximum results are obtained.
9. Each bottle contains more than the amount called for by the schedule. This is to cover any wastage or added doses that may be required.

Recommended Technique for Immunotherapy

1. Antigens should be stored under refrigeration at a temperature 37°F to 43°F.
2. A separate disposable tuberculin syringe and needle must be used for each injection.
3. Extract should not be given superficially (intradermally) as it will cause burning and we suggest you apply pressure with cotton after the injection is given to prevent leakage.
4. Injections should be given **subcutaneously** in the outer aspect of the upper arm, midway between the shoulder and elbow. Avoid blood vessels and be sure to draw back to ensure that you are not in a blood vessel before administering the injection. Alternate arms are used for the series of injections. Do not massage the area.

5. Prior to each injection an inquiry should be made regarding delayed or immediate reactions following the last injections and also the patient's present state of health. If any questions arise as to the advisability of an injection, withhold it and consult with this office or physician.
6. An emergency kit with adrenaline (1:1000), IV fluids, tourniquet, steroids, antihistamine, oxygen, etc. should be readily available to treat systemic reactions.
7. To avoid potential serious reactions, error on the conservative side of therapy, when a question arises, contact the allergist at our office.
8. For those with asthma or breathing problems, a spirometry or peak flow should be performed before giving the injections to ensure that the patient is not having breathing difficulties. For patients in the build-up, spirometry or peak flow can be done weekly unless his/her condition dictates it be done more frequently.

What to do if you miss an injection?

There have been no studies that have investigated the effect of dosage modification for gaps in immunotherapy injection intervals. Below is a suggested approach to modification of doses of allergen immunotherapy because of gaps between treatment during the build-up and maintenance phase

Build-up phase (time intervals from last injection). **Day 0 = time from last injection**

- o 0 to 14 days, continue as scheduled
- o 15 to 20 days, reduce by 1 dose.
- o 21 to 28 days, reduce by 2 doses.
- o 29 to 35 days, reduce by 4 doses
- o >36 days, contact physician for orders

Then increase the dose for each injection as directed on the immunotherapy schedule until therapeutic maintenance dose is reached.

Maintenance phase (remember time intervals can be at 2, 3, or 4 week intervals based on the patient's maintenance schedule). **Day 0 = time from missed scheduled injection (for example if shots are every 14 days then day 0 starts at day 14 from last injection).**

- o 0 to 7 days, repeat last dose.
- o 8 to 15 days, reduce dose by 2 doses.
- o 16 to 24 days, reduce dose by 4 doses.
- o >25 days, contact physician for orders.

Then increase the dose for each injection visit as directed on the immunotherapy schedule until therapeutic maintenance dose is reached. Then the patient can work-up to their regularly scheduled maintenance interval as above (i.e to injections every 2 to 4 weeks).

Local reactions

Management of local reactions: recent literature suggests that individual local reactions do not predict systemic reactions. However, one study found that the rate of large local reactions, defined as ≥ 25 mm was almost 4 times higher (35.2% vs 8.9% of all visits and 19.5% vs 5.3% of all injections; $P < .001$ for each) among patients who subsequently experienced a systemic reaction compared with those who had never experienced a systemic reaction. For patient comfort dosage adjustments should be considered if large local reactions develop.

Guidelines for administration of allergy injection based on reaction size

- Negative: Swelling (as in a welt NOT the redness) < 25 mm (quarter size) - progress according to schedule.
- Swelling 26-40 mm (quarter to golf ball size) – repeat same dose
- Swelling persisting more than 24 hours or over 40 mm (larger than golf ball) - return to the last dosage which caused no reaction.

If reduced dose is tolerated, increase dose each injection visit as directed on the immunotherapy schedule until therapeutic maintenance dose is reached. If local reactions persist, patient should be seen in our office with dosage sheet or contact the allergist at our office.

Systemic Reactions

A systemic or constitutional reaction usually occurs within 20-30 minutes and may consist of an increase in the allergic symptoms for which the injections are being given. In addition hypotension, respiratory, cardiovascular, GI or GU symptoms, flushing, hives or CNS symptoms may occur. If a patient feels any of these symptoms, they should immediately let the technician know so that adrenalin (epinephrine) or other medications may be administered under physicians order. These systemic reactions generally occur within the 20 minute waiting period, but rarely there may be delayed reactions occurring 30 minutes to 18 hours after the injection. If a delayed reaction occurs, it is imperative that the patient inform the allergy technician prior to the next injection. All systemic reactions should be reported to this office so that further recommendations regarding immunotherapy may be made.

If any questions should arise which are not answered or explained fully in the above statements, please contact our office as we are here to help in any and every way possible. For full detailed information, please refer to the Immunotherapy: Practice Parameters published by the Joint Council of Allergy, Asthma, and Immunology (JCAAI).

Additional Considerations:

Refrigeration: If vaccine is exposed to extreme heat or cold or if serum becomes cloudy, do not administer and notify the office.

Expiration date: Allergen vaccines have an expiration date and should be replaced after this date.

Pregnant: If the patient becomes pregnant, do not administer any further injections. Have her schedule an appointment with our office and bring vials and all dosage sheets for this visit.

Wheezing: do not give allergy shots if the patient is having asthma symptoms.

Asthmatic patients: Peak flow measurements or another form of breathing test should be done prior to all injections if indicated or if patient is symptomatic. If the peak flow measurement is **less than 70%** of the patient's baseline, the allergy injection should **not be given until the patient is further evaluated by physician.**

Exercise: **No exercise** for at least **4 hours** after receiving allergy injection.