Referring Allergist Agreement

Your patient ________________________________ is requesting that the University of Mary Washington Student Health Center (UMWSHC) administer allergy extracts provided by your office. Consistent with our policies we ask that you, as the prescribing and referring Allergy/Immunology physician, review our Allergy Immunotherapy Policy and Procedures and Provider Management of Anaphylaxis and Systemic Reactions and return a signed copy of this referral agreement.

I agree that:

- I will provide allergen immunotherapy extract in adequately labeled vials for administration at UMWSHC.
- The allergen immunotherapy extracts will be prepared by individuals experienced and trained in handling allergenic products.
- I will provide maintenance concentrate that contains therapeutically effective dosing individually formulated but consistent with current guidelines as outlined within the Allergy Joint Task Force’s Allergen Immunotherapy: A practice parameter third update, 2010.
- If necessary, I will provide adequately labeled vials of serial dilutions of the maintenance concentrate should the patient still be undergoing the build-up phase of immunotherapy.
- I acknowledge that “off the board and into the syringe” method of allergen immunotherapy preparation and administration poses risk of cross-contamination. UMWSHC will therefore not employ this method of immunotherapy for any of its patients.
- I will provide detailed directions regarding dosage schedule for build-up phase and/or maintenance, and instructions on adjustments that might be necessary under the following circumstances:
  - The use of new vials.
  - If the constituents of the allergen immunotherapy extract have changed; these include changes in the lot, manufacturer, vaccine type (e.g., aqueous, glycerinated, standardized), and component allergens and their respective concentrations in the extract.
  - During seasonal exposure to allergens that are in the patient’s allergen vaccine, to which the patient is very sensitive.
  - If the patient has missed injections.
  - When reactions occur to the allergen immunotherapy extract.
- I will continue to be responsible for the management of this patient’s immunotherapy and for the modification of doses during therapy.
- I will reevaluate this patient at least every 6 to 12 months.
- I will be available by phone to the nurses and providers at UWMSHC should questions or problems arise with this patient’s immunotherapy.

Allergy injections are associated with some widely recognized risks. While most adverse reactions are local, there is a low risk of severe systemic reactions even with appropriately administered allergen immunotherapy; life-threatening and fatal reactions do occur. These systemic reactions, though rare, are unpredictable and may occur with the first injection or after a long series of injections, with no previous warning. I have read the UMW Allergy Immunotherapy Policy and Procedures and agree that they provide adequately for the care and safety of my patient.

Printed name ________________________________ Signature ________________________________ Date ________________________________
Allergy Immunotherapy Policy and Procedures

Administration of Extracts Under Protocols from Allergists Not Privileged at the University of Mary Washington Student Health Center

Purpose:
Allergy immunotherapy is used to alter the immunologic response in allergic patients. The extracts used are individually prepared solutions supplied by allergists not privileged at the University Of Mary Washington Student Health Center (UMWSHC). It is the intent of UMWSHC to provide to patients the service of administering these extracts under protocols written and provided by outside allergists.

Policy:

- Patients requesting administration of immunotherapy extracts will complete a consent and request form titled Allergy Shot Clinic Informed Consent.
- Allergists not privileged at UMWSHC will complete a referral agreement indicating they have reviewed UMWSHC procedures for administering extracts and protocols for treating reactions and agree that they are acceptable for care of their patient. They further agree to be available to UMWSHC nurses for questions related to patient care and dosage adjustment.
- Referring Allergists will provide:
  1. Allergen Extract for injection
  2. Detailed protocols for dosing and dose adjustments including schedules for: escalation and maintenance dosing, the use of new vials, during seasonal exposures, if the constituents of the allergen immunotherapy extract have changed, missed doses, and when reactions occur,
- Protocols from referring Allergists will be reviewed and approved by the UMWSHC Consulting Provider (Physician or Nurse Practitioner) to insure that the protocol is consistent with current standards of care and consistent with the current capabilities of UMWSHC. If the protocol does not meet these criteria, the patient will be given an appropriate referral, either to the original Allergist or to an Allergist in the community.
- The referring Allergist is responsible for the management of the individual immunotherapy and modification of dosing schedules. UMWSHC will periodically send updated treatment history back to the referring Allergist if outlined per the protocol provided by the referring Allergist.
- Administration of immunotherapy extract will be performed by a licensed UMWSHC RN. The patient will not see a UMWSHC provider as part of routine immunotherapy injection visits.
- RN encounter notes will be reviewed as indicated by the UMWSHC consulting provider.
- Allergen immunotherapy will not be administered unless an UMWSHC attending provider (Physician or Nurse Practitioner) is present and readily accessible in the office.
- Treatment of reactions will be done under UMWSHC protocol.
- UMWSHC will provide the service of storing allergen extracts for patients between injections as described in the following procedures. UMWSHC is not liable for the compromise in the integrity of the medication due to handling before UMWSHC receives the medication or for loss or compromise of integrity due to power outage, storage equipment failure, or catastrophic event.
- Consents and referral agreements expire at the end of each academic year (July 31st).

UMWSHC expects the referring Allergist to reevaluate the patient at least annually.
Procedures

Allergy Clinic Visit

The patient is seen by an RN who is privileged to administer immunotherapy extract. The patient must have:

- Referral agreement signed by the referring Allergist.
- “Request and Consent for Administration of Allergy Immunotherapy” signed by the patient.
- Protocols for dosing and dose adjustment form from the referring Allergist and approved by the UMWSHC consulting Provider.
- Allergen extract from the referring Allergist.

Storage of Extract

- The extract is to be stored in containers clearly indicating the patients name and labeled to identify the contents of the vial.
- The extract is to be stored, refrigerated and kept between 3°C and 6°C (37.4°F and 42.8°F).
- If the extract is exposed to heat or frozen, UMWSHC will contact the referring Allergist for instructions and document the contact and instructions.

Administration of Extract

- A UMWSHC attending provider (physician or nurse practitioner) must be present in the office and readily available during the entire allergy injection and observation period before extract can be administered.
- Injections are given subcutaneously using a 1-mL syringe with a 27 gauge half-inch non-removable needle.
- Injections should be given in the posterior portion of the middle third of the upper arm at the junction of the deltoid and triceps muscles.
- The syringe should be aspirated to check for blood return in the syringe before injecting. If blood is present, the solution should not be injected and the syringe removed and discarded in an appropriate container.
- The patient must remain and be observed for 30 minutes after an injection. (The onset of most anaphylactic reactions occurs within 30 minutes following injection.)

Dosage and Dose Adjustment

- Dose changes are indicated 1) during escalation and maintenance dosing, 2) the use of new vials, 3) during seasonal exposures, 4) if the constituents of the allergen immunotherapy extract have changed, 5) missed doses, and 6) if reactions have occurred. Detailed dose and dose adjustment for the above mentioned scenarios are per the schedule provided by the referring Allergist.
- Any questions or clarifications should be made to the referring Allergist.

Contraindications

- Injections should be postponed if the patient is ill, febrile, has symptomatic asthma, or has sunburn or irritation at the injection site.
- Injections should not be given to patients taking beta-blockers or monoamine oxidase inhibitors (MAOI’s).
- Caution advised- appropriately revised dosage schedules must be obtained from the referring Allergist in order to continue injections during pregnancy.
Documentation
Every visit is to be charted in the UMWSHC allergy chart documenting the following information:

1. Current health status (document recent illnesses); include statement attesting to whether patient’s asthma is stable or not (e.g. albuterol usage in week prior to injection, nocturnal symptoms, hospitalizations or ER visits, compliance with medications).
2. Temperature (if clinically appropriate).
3. Record if patient felt any reaction occurred with most previous injection (local swelling, local itching, wheezing, hives, delayed reaction, systemic, large local, etc.)
5. Patient’s Baseline Peak Flow listed for reference (if patient is asthmatic).
6. Pre-injection Peak Flow if clinical concern for possible asthma symptoms or exacerbation (e.g. if Albuterol use in the last week, recent asthma flare, or recent illness).
7. Post-injection Peak Flow (if systemic reaction symptoms occur)
8. Missed or late dose
9. Protocol reference for next dose
10. Injection information (extract, concentration, volume, location of injection)
11. Documentation that patient was observed for 30 minutes or that patient left early
12. Inspection and description of injection site after 30 minutes (e.g. negative, inflammation, swelling, wheal and flare size in mm of longest diameter, etc.)
13. Reaction, if any, due to injection (local or systemic)
14. Post injection treatment (e.g. ice, topical steroid, oral antihistamines, resuscitation, etc.)
   - The treatment record provided by the referring Allergist is to be completed for each visit and kept in a separate Allergy Clinic chart.
   - Any time the treatment record is sent to the referring Allergist, a note should be placed in the allergy chart and a copy of the treatment record sent should be placed into the allergy chart.

Treatment of Local Reactions by the RN

- Usually no treatment is required for local reactions other than application of an ice pack and adjustment of future doses.
- For Local reactions greater than 2 inches, topical steroids may be applied.
- For local itching, redness and large swelling, an oral antihistamine such as diphenhydramine 50mg may be given.

Immediate Treatment of Systemic Reactions by the RN

- If a systemic reaction is suspected, assess airway, breathing, and circulation. A provider should be summoned urgently.
- The RN can administer a dose of 0.3 mL epinephrine 1:1000 intramuscularly or subcutaneously into the Deltoid near the injection site.

Provider management of systemic reactions is per the protocol Provider Management of Anaphylaxis and Systemic Reactions.
Provider Management of Anaphylaxis and Systemic Reactions

Definition

Anaphylaxis is an acute systemic allergic reaction following antigen exposure in a sensitized person and is considered a medical emergency. Anaphylactoid reactions are thought to reflect a release of inflammatory mediators by non-immunologic mechanisms. Most reactions will occur within 5 – 30 minutes following administration of a specific antigen, but may be prolonged or may be recurrent (biphasic) within 8 to 12 hours (J Allergy Clin Immunology, Sept 2002).

Manifestations

- **General** - Patients often report sudden anxiety, morbid fear and a sense that “something is very wrong.” Palpitation may occur as well as dizziness or “graying out”.
- **Cutaneous Reactions** - intense itching; especially of scalp, palms and groin areas; erythema +/- hives
- **Laryngeal Edema** - may be experienced as a “lump” in the throat, hoarseness or stridor
- **Angioedema** - sensed as fullness, numbness or other awareness of the swollen part.
- **Lower Airways** - feeling of tightness in the chest, cough or wheezing; shortness of breath
- **Gastrointestinal/Visceral** - nausea, vomiting, or diarrhea; abdominal and uterine cramping
- **Cardiovascular** - lightheadedness, palpitations, hypotension with or without syncope and/or cardiac arrhythmias

Assessment

The identification of an anaphylactic reaction depends largely upon an accurate history revealing the onset of one or more of the following:

- **Cutaneous reactions** – diffuse or localized erythema, pruritis, urticaria and/or angioedema
- **Upper airway** - laryngeal edema with possible dysphoria, stridor; rhinitis symptoms
- **Lower Airway bronchospasm** - respiratory distress, cough, wheeze, dyspnea
- **Cardiovascular system** – hypotension with or without syncope possibly progressing to vascular collapse, cardiac arrhythmias, cardiac arrest
- **Gastrointestinal system** – gastrointestinal spasm and edema leading to nausea, vomiting and/or diarrhea

Plan

**Local Reactions** - Usually no treatment is required other than application of ice pack and adjustment of dosage for subsequent allergy shots. If an unusually large reaction is noted before patient leaves the office, a tablet or capsule of an antihistamine such as Benadryl, Claritin, or Zyrtec may be given.

**Mild Systemic Reactions** - (itching of palms, scalp, roof of mouth or groin areas, mild hay fever or asthma): Administer aqueous epinephrine 1:1000 dilution 1 mg/ml.), 0.2 -0.5 ml, (0.01 mg/kg in children; maximum dose, 0.3 mg dosage) intramuscularly (*preferably initially into the arm that received the allergy shot), every 5 minutes, as necessary, to control symptoms and blood pressure. Diphenhydramine 25 to 50 mg. may be given (parenterally). Consider giving an oral corticosteroid (e.g. prednisone (0.5 mg./kg.) to prevent recurrent and protracted reactions.
Severe Systemic Reactions - (anaphylactic shock, hypotension with or without lightheadedness, bronchospasm, worsening angioedema with or without laryngeal edema, visceral spasm):

1. If a suspected offending antigen is being given, immediately stop administration; if feasible apply tourniquet above the implicated injection site.
2. The nurse should immediately contact the provider.
3. For a severe reaction, the nurse may administer one dose of aqueous epinephrine 1:1000 dilution (1 mg/ml.), 0.2 – 0.5 ml, (0.01 mg/kg in children; maximum dose, 0.3 mg. dosage) intramuscularly into the arm (deltoid) prior to arrival of provider.
4. The provider will perform an initial assessment as above and will consider anaphylaxis as well as other possible diagnoses (hypoglycemia, vasovagal reaction, seizure, PE, myocardial dysfunction, etc.). If assessment is consistent with anaphylaxis, proceed as follows:
5. Administer aqueous epinephrine 1:1000 dilution (1 mg./ml.), 0.2 - 0.5 ml (0.01 mg/kg in children, maximum dose, 0.3 mg. dosage) intramuscularly into the arm every 5 minutes as necessary and assess response.
6. Place patient in recumbent position if hypotensive.
7. Initiate oxygen at 2-4 liters/minute per nasal cannula or mask for patients in respiratory distress. Monitor pulse oximetry at frequent intervals. Monitor airway closely.

For Inadequate Clinical Response – Call 911

- Immediately for laryngeal/pharyngeal edema
- Immediately for significant hypotension
- Immediately for cardiac arrhythmia
- For respiratory distress not responsive to epinephrine
- For symptoms that recur or worsen during observation after treatment

For Good Clinical Response

- Observation – length of time and setting individualized depending on severity of reaction.
- Administer diphenhydramine 25 to 50 mg. orally every 4 - 6 hours as needed.
- Consider hospital admission for 24 hour observation for patients who have manifested significant systemic reactions.
- If the patient is being discharged home after a significant systemic reaction:
- Prescribe an Epi-pen auto injector. Instruct patient on the use of Epi-pen and discuss the possibility of recurrent/biphasic reactions, the signs and symptoms thereof, and self treatment.
- The patient should not be alone for the first 24 hours after the reaction.
- Consider giving an oral corticosteroid (e.g. prednisone 0.5 gm./kg.) to prevent recurrent or protracted reactions.