Allergy & Asthma Specialists

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Immunotherapy - "Allergy Shots"

Allergen immunotherapy (also known as "allergy shots") is the repeated administration of specific allergens to patients with allergy-related conditions (such as insect allergy, hay fever and asthma) for the purpose of providing protection against their allergic symptoms and inflammatory reactions associated with exposure to these allergens. Immunotherapy should be used as part of a comprehensive allergy management plan that includes attempts to control allergy symptoms with appropriate environmental modifications and medical therapies. Immunotherapy is the only potential cure for allergic rhinitis and insect hypersensitivity. It is not a cure for asthma, but in those patients with asthma triggered significantly by allergens, it can result in improvement in the asthma as well. There is now also an FDA indication for atopic dermatitis.

Allergen immunotherapy has been practiced since the early part of the 20th century. Our understanding of how it works is constantly evolving, and although more is understood today than 80 years ago, the precise mechanism(s) for the observed clinical effects has yet to be determined. We do know that giving allergy shots modifies the patient's immune system in such a way as to decrease sensitivity to the specific substances to which the individual is allergic. The following are theories that have been partially supported by clinical and scientific data.

- "Blocking Antibody"- The immune system responds to immunotherapy by producing a protein which binds with the allergen, blocking the allergy antibody from doing so, and thus not allowing an allergic reaction to occur.
- "Decrease in IgE (allergy antibody)"- Studies have shown that there is a gradual decrease (after an initial increase) in allergy antibody levels due to allergy shots.
- "Modulation of Cells That Play a Role in Allergic Reactions"- Immunotherapy decreases the release of certain chemicals from specific white blood cells. These chemicals would normally play a large role in the allergic reactions and would also "call in" other types of cells to the site of the allergic reaction. If left unchecked, these other types of cells would contribute to prolonging the allergic reaction.
- "Increase in Suppressor Cell Activity"- Some cells of the immune system are responsible for suppressing or controlling immunologic reactions. This is to prevent the reactions from actually damaging the host (patient). Allergy shots increase the activity of these suppressor cells.
- Several other mechanisms have been proposed and are also being studied.

Types of Immunotherapy

Traditional Immunotherapy: These injections begin at a very diluted concentration (to minimize the possibility of an allergic reaction) and gradually build up to maintenance level. Patients start by receiving 1 to 2 injections a week for about 9 months. Once maintenance levels have been obtained and maintained for a period of time, the frequency of injections is gradually tapered. Administration of high doses of allergen is the ultimate goal for this type of schedule. It may take 6 to 12 months to achieve this goal.

Rush Immunotherapy (RIT): We also provide rush immunotherapy for appropriate patients. This method involves the administration of several injections over the course of one day to reach maintenance levels in a brief period of time. The patient is evaluated in the clinic one week prior to RIT, and baseline lung function testing is performed. The patient is given pretreatment with antihistamines, prednisone, and leukotriene antagonists starting 3 days prior to RIT. The patient must be prepared to stay in the clinic from 8am-12pm and 1pm-5pm on the day of RIT. After the rush protocol is completed, the patient will receive weekly injections for 8-10 weeks before starting to receive less frequent injections. The protocol has been demonstrated to be as safe and efficacious for insect allergy as standard protocols. However, there is a slight increase in frequency of adverse reactions when using pollens and house dust mites. These patients will see results from immunotherapy sooner than those who undergo traditional immunotherapy.

These techniques of immunotherapy have been scientifically studied and proven. There are other techniques that are still unproven. These include the administration of allergens sublingually (under the tongue) and neutralization-provocation therapy. These techniques are also different from the process of rapid desensitization, which is sometimes used in a controlled environment to prevent a reaction to a substance (such as penicillin) to which the patient is known to be allergic.

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Duration of Immunotherapy: The optimal duration of immunotherapy for inhalant allergens has yet to be determined. For most patients that have a good response, 4 to 5 years of therapy is recommended by most allergists. Continuation of immunotherapy for 4 to 5 years is still recommended in patients who undergo rush immunotherapy despite more quickly reaching a maintenance dose. It is believed that benefit from a brief course of immunotherapy may be rapidly lost, whereas benefit from a longer course may persist after injections are discontinued. The time frame for a patient to respond varies from person to person. Some will notice a response within 6 to 8 months. Others may take up to 18 months to respond. In general, if there is not an adequate response by 2 years of therapy, the use of this treatment modality in that patient should be reassessed. In patients who have had a good response after 4 to 5 years of therapy, a trial period off of immunotherapy should be undertaken. A few patients will have an exacerbation of symptoms once the allergy shots have been discontinued. In these cases, it may be desirable to continue the immunotherapy for a much longer period of time. These decisions must be made on a case-by-case basis. Allergy shots for insect allergy may be safely discontinued after 5 to 7 years of therapy in many, but not all, patients, especially those sensitive to fire ants. This decision should be made on an individual basis.

Conditions for Which Allergy Shots Have Been Shown to be Effective

- *Allergic Rhinitis*

Also commonly known as hay fever, patients with this condition often suffer severe nasal (and possible eye and throat) reactions when exposed to pollens or other air borne allergens to which they are sensitive. Well-designed scientific studies have been shown that immunotherapy is beneficial in the treatment of allergic rhinitis due to tree pollen, grass pollen, weed pollen, mold spores, dust mites, and animal allergens (e.g., cat and dog).

- *Asthma*

Well-designed clinical studies have demonstrated the efficacy of allergen immunotherapy in patients with pollen-induced and mold-induced asthma. Some studies have also shown a benefit in patients with animal-induced or dust mite induced asthma.

- *Insect Allergy*

Allergen immunotherapy should be considered in patients who have had reactions to insects after exposure to these allergens (such as through inhalation or injection). The efficacy of immunotherapy in patients allergic to the stings of honeybees, yellow jackets, hornets, wasps, and imported fire ants has been well documented.

- *Atopic Dermatitis/Eczema*

The FDA had recently approved the use of immunotherapy for atopic dermatitis/eczema.

Conditions for Which Allergen Immunotherapy Has Not Proven Effective.

- *Food Allergy*

There are no well-designed studies which have shown immunotherapy to be effective in patients with life threatening food allergy. However, this is an area of active research, and with time, this treatment modality may be available to patients with food allergies.

- *Urticaria, and Candida Infections*

Thus far, the use of immunotherapy in these conditions remains unclear. The data that is available at this time is conflicting.

Who Should Receive Allergy Shots?

Patients being considered for immunotherapy should undergo an appropriate evaluation by an allergist. This evaluation should include a clinical history correlated with specific allergens to which the patient is sensitive on allergy testing. Patients with allergic rhinitis, asthma, and/or insect sensitivity may be considered candidates. Factors to be taken into consideration when making this decision include severity and duration of symptoms (and the effect they have on the patient's quality of life), and response to environmental avoidance measures and conventional medications. Unacceptable adverse reactions to conventional medications may also be taken into consideration. Other medical conditions the patient may have or other medications they may require can affect the decision-making process.

Patients who have completed immunotherapy in the past, but are again experiencing symptoms may require reevaluation with consideration for an additional course of immunotherapy.

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Age of the patient plays a role in deciding whether to use immunotherapy or not. Most allergists do not recommend allergy shots for allergic rhinitis or asthma in children under 5 years of age. However, some studies have shown it to be effective in this age group and this decision should be individualized for each child. In fact, there are studies supporting immunotherapy in younger children as a means of preventing the development of asthma and new allergic sensitivities. In children, (regardless of age) who have experienced life-threatening allergic reactions to insect stings, the benefits of allergy shots may outweigh the risks. Most allergists do not recommend allergen immunotherapy for most patients over the age of 70. However, this too should be decided on a case-by-case basis based on the patient's prior history, co-existing medical conditions and response to conservative management of their allergies.

****The following should be read carefully****

This is an explanation of the possible risks associated with immunotherapy (allergy shots) and will serve as an acknowledgement that you have been informed and understand that there may be adverse reactions to allergy shots. Included in the information below is a description of certain conditions that patients may have which may keep them from being candidates for allergy shots. Your signature in the appropriate place will also indicate that you do **NOT** currently have one of these conditions. We strongly advise you that if, in the future, you develop one of these conditions or are diagnosed with **ANY** new medical problem while you are on allergy shots, you can contact our office before the next injection to discuss this with us. It's recommended that you should not participate in any strenuous activity 2 hours before or 2 hours after allergy shots because of increased risk of reaction.

Conditions Which May Prohibit Patients from Receiving Allergy Shots

- Patients who are receiving a type of medication known as beta-adrenergic blocking agents should generally not receive allergen immunotherapy. This type of medication is often used to control high blood pressure, migraine headaches, certain types of tremors, and other medical conditions. If you are being treated for one of these conditions and are unsure if you are taking a beta-adrenergic-blocking agent, please discuss this with us. If one of these medications is prescribed for you after you begin allergy shots, you must contact us ***before*** your next injection. In rare circumstances, the decision to proceed with immunotherapy despite the use of these medicines may be made.
- Alternatives to allergen immunotherapy should be considered in patients with any of the following problems:
    1. Patients with markedly decreased lung function
    2. Patients with poorly controlled asthma
    3. Patients with unstable angina (chest pain related to heart conditions)
    4. Patients who have recently experienced a myocardial infarction ("heart attack") or significant arrhythmias (irregular heart rate and/or rhythm)
    5. Patients with uncontrolled hypertension (high blood pressure)
    6. Patients with failure of a major organ system (such as a kidney failure)
- Pregnancy will affect the management of immunotherapy. If you are now pregnant, please let us know before beginning allergy shots. If you become pregnant while taking allergy shots, you must let us know before your next injection.

Adverse Reactions (Also Known as Risks) of Immunotherapy (Allergy Shots)

The following is a description of the different types of reactions that may occur as a result of receiving allergy shots. It is important for you to realize that all forms of medical therapy, including allergy shots, can produce adverse reactions. There is always some degree of risk associated with medical therapies that must be weighed against the benefits to be obtained. **It is your responsibility to bring to our attention any problems that you may have as a result of your allergy injections.**

Local Reactions: These reactions are defined as occurring in the immediate vicinity of the allergy injection site and are the most common type of reaction associated with allergy shots. These reactions can be classified by size and by the time it takes for them to develop. These reactions may consist of only localized pain, redness and swelling of various sizes.

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Large local reactions may involve the majority of the upper arm, extending up towards the shoulder and down to the elbow. These large reactions can be uncomfortable and adjustment of the extract dosage should be considered. Local reactions may occur within 30 minutes of the injection (during the period of time you are being observed in the doctor's office) or may develop several hours later and persist for a day or two. In general, these reactions are not serious and there is not a correlation between these reactions and the possibility of having a more serious systemic reaction (described below). If the reaction is unusually large or painful, you may need to call us for advice on symptomatic treatment of these reactions. In any case, please bring the occurrence of these reactions to our attention so that we may make any necessary adjustments in extract dosage.

Systemic Reactions: These reactions are defined as focal (involving one area of the body) or generalized (involving several areas of the body) symptoms occurring away from or distant from the site of injection. These reactions are more likely to occur during the build-up phase and in patients with asthma. However, they can occur at any time and in any patient. Symptoms that occur occasionally include hives (welts) and itching, hay fever-like symptoms (such as sneezing; nasal congestion and/or drainage; eye symptoms such as redness, itching, watering, and swelling of the eye lids), asthma symptoms (cough, shortness of breath, chest tightness, and/or wheeze) and are more serious than the local reactions described above. These symptoms should receive our immediate attention. **Again, if these occur, please notify us promptly of their development.**

Extremely rare systemic reactions that may occur include severe breathing difficulties (such as narrowing and spasm of the upper and/or lower airway); generalized hives accompanied by marked swelling of the face, hands, feet, tongue, throat, and/or genitalia; cardiac (heart) abnormalities (chest pain, irregular heartbeat, sudden drops in blood pressure) and even death have been reported in association with allergy shots. The possibility of any of these types of reactions is extremely unlikely***. In most instances, these types of reactions occur within 30 minutes of the allergy injection. It is for this reason that you are required to wait 30 minutes in the physician's office after receiving your injection.***

It is your responsibility to wait the appropriate period of time in the physician's office after each injection so that the doctor will be available to treat any serious adverse reactions that may occur. Patients with extreme sensitivities or complaining medical conditions may be required to wait longer than these prescribed times.

Allergy Shots Must Be Given in a Medical Facility

This is the policy of our practice, and the vast majority of allergy practices in this country, that all allergy shots *must* be given at a medical facility with a physician present who has been trained in the treatment of allergic reactions. **This is for your protection.** Although the risk of severe allergic reactions is very rare, the possibility that they may occur precludes us from allowing patients to administer injections to themselves or their children at home. Patients receiving injections for insect allergy must receive their injections in our office. This is due to the complexity of making up and administering these injections. All other injections may be given in our office or any physicians' office that is convenient for you. Please indicate on the form below where you plan to receive your injections.

Patients receiving **Rush Immunotherapy** are at a slightly increased risk for systemic reaction, both during the day of the rush protocol and the next several weeks while the patient is on weekly injections. Patients are required to take the prescribed pretreatment medications for 3 days prior to the day of rush immunotherapy. Patients are required to stay in the office from 8am to 12pm and 1pm to 5pm on the day of rush immunotherapy. The patient will receive multiple injections at 30 minutes to one-hour intervals throughout the course of the day with frequent clinical monitoring. Immunotherapy, hypo sensitization, or allergy injections should be administered at a medical facility with a medical physician present since occasional reactions may require immediate therapy. I am aware that these reactions may consist of any or all of the following symptoms: itchy eyes, nose, or throat; nasal congestion; runny nose; tightness in the throat or chest; coughing, increased wheezing; lightheadedness; faintness; nausea and vomiting; hives; and shock, the last under extreme conditions.

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****IN SUMMARY, PLEASE READ CAREFULLY BEFORE SIGNING****

ALLERGEN IMMUNOTHERAPY is designed to decrease your sensitivity to your allergens identified during your skin testing. Immunotherapy works like a vaccine to increase your immunity or tolerance to allergens.

The allergy shot process is comprised of a build-up phase and a maintenance phase of subcutaneous administration of increasing quantities of purified natural allergen extracts. Immunotherapy begins with the weakest dilution at silver, and the concentration increases as the vials go from green to blue to yellow and finally to red. During the buildup phase injections may be one to two times every 7-10 days. During the buildup phase if greater than 10 days has passed between shots either the previous dose may have to be repeated, or a lower dose will be given so as to minimize the likelihood of a systemic reaction. After this dose the regular build-up will continue. This phase typically lasts between 3-6 months and is determined by the frequency of the injections. The goal of the buildup phase is to reach the effective therapeutic dose. This dose may vary from patient to patient and is determined by how sensitive you are to the allergen extract and your immune responses during the buildup phase. In the maintenance phase the goal is to increase the time between shots to every 2-4 weeks. This will be determined by your symptoms and in consultation with your physician. When new vials are made the level of antigen is very high and thus you will have a short build up phase before going back to your regular schedule. The recommended time for the maintenance phase is between 3-5 years. Immunotherapy has been shown to prevent the development of new allergies and, in children, it can prevent the progression of the allergic disease from allergic rhinitis to asthma. Allergen immunotherapy can lead to the long-lasting relief of allergy.

You will be required to wait at least 30 minutes in the office after you receive your shot. No exceptions. If you do leave you are leaving against medical advice and we may not be able to administer your immunotherapy in the future.

Patient responses vary depending on the initial severity of their symptoms but most patients show decreased, minimal to no allergy symptoms. Decreased symptoms can be observed during the buildup phase but are typically seen a few months after being on the maintenance dose. If you are very sensitive to the allergy shots and have very large local reactions then you may be switched to a sensitive build up schedule that requires repeating each dose before advancement to minimize local and or systemic reactions.

Allergen extracts are completely natural and do not typically have side effects. However, there are two types of adverse reactions that can occur with allergen immunotherapy i.e., Local and Systemic reactions. Systemic reactions typically occur within 30 minutes of your shot administration and hence patients are required to wait in the clinic for 30 minutes after their allergy shot.

LOCAL REACTIONS are common and are usually restricted to a small area around the injection site. They include redness, slight swelling and itching. They can be treated with cold packs and topical Benadryl or Hydrocortisone creams along with an antihistamine by mouth. These reactions are more likely to occur as you reach the maintenance dose. Redness, itching and bruising at the injection site are all normal. These symptoms should go away within 4-8 hours after receiving the shot. If the local reaction lasts longer than 24 hours and is very bothersome then please inform the staff prior to your next shot as it may require to change your build up regimen to a sensitive protocol. Red raised wheals larger than a 50-cent piece occurring within 30 - 60 minutes should be reported to our office so we can adjust the dose accordingly. If the wheal occurs over an hour after injection, you may proceed to next scheduled dose. If swelling remains from previous injection, postpone the next injection until the swelling has subsided.

If you should have an exaggeration of your allergy symptoms (such as nasal congestion, runny nose or wheezing) in the afternoon or night of your allergy injection, take your antihistamine. Report this to the person giving you your next shot.

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SYSTEMIC REACTIONS are less frequent than local reactions. They are typically mild and include symptoms like sneezing, nasal congestion and hives. They quickly respond to antihistamines.
Anaphylaxis is a serious systemic reaction and possible symptoms include the above plus dizziness, wheezing, throat swelling or chest tightness. This requires rapid treatment with intramuscular epinephrine and the staff is trained to respond to such reactions. If you have any serious systemic reactions after you leave our office then you should call **911** or proceed to the nearest ER. Also notify our office prior as soon as possible and let the staff know again prior to your next shot. If you have a severe allergic reaction, you should seek medical attention immediately at the nearest emergency facility. Also notify us the next day so we can adjust your vial accordingly. You should **NOT** receive another allergy shot until you speak with our office. These systemic reactions can occur at any time whether building or at maintenance without previous warning.

It is crucial to let the doctor know if you become pregnant as this will require adjustment to your immunotherapy.

If you start any new medications especially beta blockers it is very important to let the nurse know before your shot is administered. Beta blockers interfere with medications used to treat a systemic reaction and you will need to see the doctor before immunotherapy can be initiated or continued.

When you should **NOT** get an allergy shot: If you have a fever greater than 100 degrees Fahrenheit. Please wait 48 hours after you are fever free before getting an allergy shot. If you are having any breathing difficulties such as asthma exacerbation, or have had to use your rescue inhaler within 48 hours, or an illness such as influenza or pneumonia. Patients who are in respiratory distress (wheezing, coughing, chest tightness, or shortness of breath) should **NOT** receive allergy injections. If you are experiencing any problems with breathing, you should call our office for an appointment with a physician. If you have a cold or sinus infection you may get a shot if you don't have a fever or breathing difficulties, which may be wheezing or chest tightness. If you are unsure if you can have an allergy shot please call our office. **If you received an immunization or vaccination such as flu, MMR, tetanus, etc., you should NOT get an allergy shot the same day, as it would be difficult to distinguish which one caused a reaction if one were to occur.**

EXERCISE. There should be **NO** strenuous exercise or overheating for 2 hours before and/or 2 hours after your allergy injection. Increased blood flow can promote faster release of allergens from the shot into the blood stream.

Reactions, though unusual, can be serious but rarely fatal. I understand that I am required to wait in the medical facility in which I receive the injections for at least 30 minutes after I receive each injection.

Patient signature: _____Date: _____

Witness: _____Date: _____

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The Allergy Shot Process and Understanding Your Financial Commitment

This information is provided to educate you about the logistics of providing allergy shots to you, to inform you of the financial obligations associated with allergy shots, and to assist you in obtaining your insurance carrier's benefits on all procedures involved in allergy shots. The following information DOES NOT apply to venom injections. IMPORTANT - Our office cannot guarantee payment from your insurance company. We can only provide you with the information your insurance company provides to us. Your insurance company will make the final decision on payments. (Please note, any cost estimate examples listed in this consent are just that, *ESTIMATES ONLY*. Prices are subject to change at any time and are at the sole discretion of the insurance company and their fee policies).

Our allergy extract nurse will mix a treatment set of 5 vials for each extract prescription you will receive (between 1 and 4 prescriptions per patient depending on the extent of your environmental allergies; therefore 5, 10, 15 or 20 vials in your initial treatment set). Each treatment set contains 4 "build-up" vials and 1 maintenance vial. All 5, 10, 15 or 20 vials in the initial treatment set have to be prepared on the same day. Each vial contains 5 to 15 doses (average is 10) and is billed based on the number of doses we plan to use out of each vial. For example, if you will be receiving 1 allergy shot at each visit, you or your insurance carrier will be billed for 5 vials, for an **approximate** total of **$850**; 2 injections at each visit, 10 vials, **$1,700**; 3 injections at each visit, 15 vials, **$2550**; 4 injections at each visit, 20 vials, **$3400**. There is also a vaccine administration fee that we (or the administering M.D. if taken out of our office) will assess for each shot given weekly.

Allergy extracts contain proteins that weaken over time and therefore, an expiration date is applied to each vial based on the manufacturers' specifications. ***It is very important that you adhere to your allergy shot schedule so that you will utilize all of your vials before they reach their expiration date. If you are not receiving your shots/immunotherapy regularly, the vials will expire resulting in a new vial having to be made and additional charge to you and your insurance carrier, if you wish to continue. We cannot refund fees previously collected for vials already prepared which expire because they are unused.*** Patients who are "building-up" their dose to maintenance should receive injections 1 to 2 times per week. This is usually accomplished over 5-to-9-month period. Once a maintenance dose is reached, injections may be gradually decreased in frequency over time to every 2 to 6 weeks.

After completion of the 5th set of vials (which is the first maintenance vial) from the initial treatment set, our extract nurse will only mix 1 maintenance vial for each extract prescription that you are receiving; therefore, you or your insurance will be billed for **$170** each of these new maintenance vials. If you receive 2 shots, you or your insurance carrier will be billed for 2 vials or **$340**. If you receive 3 shots per visit, you will be billed for 3 vials or **$510**; 4 injections at each visit, 20 vials, **$680**. You or your insurance carrier will be billed for each maintenance vial used for the duration of the immunotherapy program, which will be for a period of 3 to 5 years.

- ☐ If you are choosing to use the **Traditional schedule for immunotherapy**, our administration charges for each day you receive immunotherapy is $30 for each injection visit. (***Prices are subject to change***. Revised Oct 2023)
- ☐ If you are choosing to use the **Rush schedule for immunotherapy**, the charge for this procedure ranges from **$1000 to $1400,** depending on the total hours that the procedure takes. Once you complete the Rush procedure, you will receive allergy shots according to a schedule set for you. Our administration charges each day you receive immunotherapy is **$30** for each injection visit. On the date of your Rush procedure, there will be additional charges for an office visit (**with the applicable co-pay**) and breathing test, if needed. In addition, if you were to have a systemic reaction during this procedure, additional fees will be assessed based on treatments needed to reverse the reaction.

***Your vials will be mixed once you sign this consent form and you will be responsible for payment of these vials, even if you change your mind afterwards and decide not to start your allergy shots.** We give you ample opportunity to contact your insurance company to determine your benefits and prefer that you do so before giving the consent form. Again, **specific questions regarding your insurance benefits should be directed to your insurance company.** As stated in our financial policy, patients must pay the amounts that the insurance company states are their responsibility at each doctor's office visit and/or each visit for allergy injections. All claims will be filed with your insurance company initially, if you direct us to do so. The balance of the allowed amount after insurance has been paid, will then be billed to you.

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My signature below indicates that I have read the patient information sheets on immunotherapy and understand them. This signature also indicates my affirmation that I do not have any of the medical conditions described above as contraindications for immunotherapy. If one or more of these conditions is diagnosed by another physician while I am receiving immunotherapy, I will notify Dr. James and Dr. Raby's office before I receive any further allergy injections. The opportunity has been answered to my satisfaction. I understand that every precaution consistent with the best medical practice will be carried out to protect me against such reaction.

NOTIFICATION OF NON-COVERED SERVICES

As your physician, I want to provide you with the best care possible. There are services that I feel are necessary for the treatment of your condition and maintenance of good health that may not be covered by your insurance plan. Your policy may have limitations on the number of covered services; therefore, you are expected to pay for those services in full.

Let me reassure you that I will order only the test and treatments that I feel are necessary for your treatment and care. If you have any questions about whether or not a particular service is covered by your health insurance plan, please call your insurance plan or you can contact someone in our office to assist you. Thank you for your understanding.

Patient Name (Printed) D.O.B.

Patient Signature (Parent Signature, if Patient is a Minor) Date

Witness Signature Date