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Food Allergy - Xolair Protocol and Consent

1. **Please be aware that you are responsible for your Xolair refills and medication being at the office that you wish to receive your injections in. It is your responsibility to call your pharmacy company for refills when necessary and to notify us if we need to contact the insurance company about refills/approval. Please ask the nurse for list of pharmacies.**
2. You will be given a prescription for an epinephrine autoinjector (ie EpiPen, AuviQ, etc.) and instructed on its use to counteract a potential anaphylactic reaction from your injection. You will need to physically show to the nurse before your medication is mixed. **If you do not have an epinephrine autoinjector on your person you will not be able to receive your injection.** This is in accordance to the Practice Parameters set for the by the Academy of Allergy, Asthma and Immunology.
3. You will be required to wait in our office for 2 hours for the first 3 injections. You will be required to wait 30 minutes for each subsequent injection.
4. **An office visit with the physician you see in our practice is required every 3-4 months to evaluate how your injections are going.** Your Xolair injection should be scheduled during our injection hours; however, it should not be scheduled at peak hours in the evening.
5. As with all injections, you cannot be given an injection at the time of illness or fever. Please call the office to reschedule your appointment.

CONSENT FOR ADMINISTRATION OF IMMUNOTHERAPY

Authorization of Treatment

My physician at Princeton Allergy and Asthma has informed me of the recent FDA findings on **Anaphylaxis** to Xolair.

Before receiving Xolair, please tell Princeton Allergy about all of your medical conditions, including if you:

- Have or have had a parasitic (helminth) infection
- Have a latex allergy or any other allergy
- Have or have had cancer
- Are taking oral or inhaled corticosteroid medicines. Do not stop taking your corticosteroid medicines unless instructed by your physician. This may cause other symptoms that were controlled by the corticosteroid medicine to come back.
- Have sudden breathing problems (bronchospasm)
- Have ever had a severe allergic reaction called anaphylaxis
- If you are pregnant, planning to become pregnant or breast-feeding, Xolair should not be given.
- Tell your physician about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.
- Do not stop taking your other asthma medicines unless instructed to do so by your physician.

XOLAIR can cause serious side effects, including:

- Allergic (hypersensitivity) reactions. Serious allergic reactions can happen after you get your XOLAIR injection. Allergic reactions can sometimes happen hours or days after you get a dose of XOLAIR. Tell your healthcare provider or get emergency help right away if you have any of the following symptoms of an allergic reaction:
 - Fever
 - Muscle aches
 - Breathing problems, chest pain
 - Rash
- Herpes zoster infections that can cause shingles have happened in people who received XOLAIR

The most common side effects in the study of XOLAIR for IgE-mediated food allergies were injection site reactions (pain, redness, swelling, itching or a burning feeling at the injection site) and fever. Other common side effects of XOLAIR include: headache, dizziness, skin rash, ear pain, arm or leg or joint pain, and weakness (fatigue).

Additional side effects may be viewed online.

- I have been given written information describing anaphylaxis and its signs and symptoms.
- I am aware that a reaction to Xolair may be delayed.
- I have been educated on the need to carry Benadryl and an epinephrine autoinjector to each injection, and to use my epinephrine autoinjector with the first signs or symptoms of anaphylaxis and to call 911.
- I have been given verbal and/or written information on Xolair regarding its efficacy and safety. I will not hold Princeton Allergy and Asthma responsible for any complications that may occur as a result of this drug.

Please be sure to verify that we have received your medication 2-3 days prior to your Xolair appointment. If we have not yet received it, please contact your pharmacy.

Please note: If you do not keep regular follow-up visits with your physician every 4 months, we will not be able to renew your XOLAIR prescription.

Please be aware that you will be charged for a Nurse Visit and administration of injection at each visit. You will be responsible for any copays, deductibles and coinsurance.

Printed Name of Patient: _____ Date: _____

Patient/Parent Signature: _____ Date: _____

Witness: _____ Date: _____

FOR OFFICE USE ONLY:

I certify that I have counseled this patient and/or authorized legal guardian concerning the information in this consent for therapy and that it appears to me that the signee understands the nature, risks, and benefits of the proposed treatment plan.

Physician: _____ Date: _____

3/26/24