



NORTH TEXAS ALLERGY & ASTHMA ASSOCIATES

Locations throughout Dallas – Specializing in personalized care since 1927
Main: (214) 369-1901 ~ Fax: (214) 369-1905

INFORMED CONSENT FOR OMALIZUMAB (XOLAIR)

TO THE PATIENT: You have the right, as a patient, parent, or legal guardian, to be informed about the condition and the recommended medical or diagnostic procedure to be used, so that you may make the decision whether to undergo the procedure after knowing the risks and hazards involved. This disclosure is not meant to frighten or alarm you; it is simply an effort to make you better informed, so you may give or withhold your consent to the procedures recommended to you.

I (we) am (are) of sound mental and physical condition, and I (we) am (are) able to give informed consent. I (we) acknowledge that I (we) am (are) fully aware of the care, treatment, and/or services that I (we) am (are) going to receive that is subject to of this consent form. I (we) voluntarily request North Texas Allergy & Asthma Associates (“NTAAA”) staff physicians, and other health care providers as they may deem necessary, to perform the following medical and/or diagnostic procedures, and I (we) voluntarily consent and authorize these treatments/procedures as deemed necessary upon examination.

Treatment/Procedure to be performed: Omalizumab (Xolair)

My (our) physician has prescribed Xolair subcutaneous injection therapy for patients 6 and older with moderate to severe allergic asthma or for patients 12 and older with Chronic Idiopathic Urticaria. Xolair is not used to treat sudden breathing problems and additional information is available online (www.xolair.com). Xolair is given in 1 or more injections every 2 or 4 weeks.

I (we) understand the risks and benefits that I (we) can reasonably expect from administration of Xolair. It may result in complications of hypersensitivity (allergic) reactions such as angioedema (swelling), bronchospasm (wheezing), low blood pressure, hives, other rashes, or even death. These generally have occurred within hours of administration, but in some instances can be delayed. Anaphylaxis has occurred as early as after the first dose, but also has occurred beyond 1 year after beginning regularly administered treatment. **Because of this allergic reaction risk, we will provide you with a prescription for Epinephrine and ask that you bring this device with you to every Xolair appointment.** I also understand that, as with every procedure, there is a possibility of unexpected complications. Possible side effects of Xolair include: cancer, inflammation of your blood vessels, fever, muscle aches, rash, parasitic infection, and heart & circulation problems. The most common side effects of Xolair include: pain, dizziness, fatigue, rash, bone fractures, cold symptoms, abdominal pain, nausea, and vomiting. Please inform us of any side effect that bothers you or does not go away. I (we) understand that I (we) may contact the physician’s office if I (we) have any further questions. Before starting Xolair, please tell the physician if you are or plan to be pregnant or breast feed.

I (we) understand that as a patient taking Xolair, my physician may stop certain medications (Beta-Blockers because of the inability to treat an allergic reaction or MAO Inhibitors which may cause high blood pressure when adrenalin or other medications are administered). Furthermore, I (we) understand that it is required for me to wait **AT LEAST 30 to 120 MINUTES** after each injection (typically - 120 minutes is for the first 3 injections, 30 minutes is for future injections if approved by the doctor). If I (we) leave early, I (we) understand that it is against medical advice and will hold my treating physician, NTAAA, and their staff free of any liability. I (we) understand that any time Xolair is given; there is a rare chance of nicking a tiny blood vessel causing a bruise, numbness or pain. If swelling is over a size of a quarter (2 inches) at the site of injection, I (we) will notify the staff before receiving my next injection. I (we) will inform the physician if we develop an allergic reaction to Xolair or any other ingredient in Xolair.

Potential Reactions during the injection:

- IMMEDIATE REACTIONS: The risks of an immediate allergic reaction include: Itching, rash, swelling, chest pain/tightness, shortness of breath, wheezing, abdominal pain, nausea, vomiting, diarrhea, palpitations, dizziness, confusion, shock and rarely death.
- DELAYED REACTIONS: Can include: rash, itching, liver or kidney involvement, fevers, chills, joint pains, and ulcerations.
- OTHER: There is a risk of other types of allergic reactions as a result of side effects of the medication, food or chemical. Non-allergic drug side effects may occur and depend on the drug. Common side effects include nausea, mild diarrhea, headaches, and acid reflux.

I (we) have completed this form with accurate information. I (we) have been given an opportunity to ask questions about my condition and treatment, alternative forms of treatment, risks of non-treatment, the procedures to be used, and the risks and hazards involved of the procedure, and I (we) believe that (we) have sufficient information to give this informed consent. I (we) acknowledge that this disclosure and informed consent has been fully explained to me, that I (we) have read it or have had it read to me and that I (we) understand its contents. I (we) have had all my (our) questions, if any, answered to my (our) satisfaction, and I (we) consent to this treatment/procedure.

Date: _____ Time: _____ Patient Name: _____ Signature: _____

Date: _____ Time: _____ Doctor Name: _____ Signature: _____

Date: _____ Time: _____ Witness Name: _____ Signature: _____

IF A MINOR, PLEASE COMPLETE THIS SECTION (Parent or legal guardian):

Relationship: _____ Name: _____ Signature: _____