Cape Fear Otolaryngology

Ear, nose, throat and allergy

CONSENT FOR ADMINISTRATION OF DUPIXENT (dupilumab)

What is DUPIXENT?

DUPIXENT is an injectable prescription medicine used to:

- Treat moderate to severe atopic dermatitis in patients 18 years of age and older who continue to have symptoms that are not controlled by topical prescription therapies
- It is not used to treat other allergic conditions
- Other forms of allergic acute bronchospasm, or status asthmaticus

Who should not receive DUPIXENT?

Do not receive DUPIXENT if you:

- Are allergic to dupilumab or any of its excipients

What should I tell my health care provider before receiving DUPIXENT?

Before receiving DUPIXENT, tell your health care provider about all your medical conditions, including if you:

- Have any other allergies (such as food allergy or seasonal allergies)
- Have a history of asthma
- Have ever had a severe allergic reaction called anaphylaxis
- Have or have had a parasitic infection
- Have or have had cancer
- Are pregnant or plan to become pregnant; it is not known if DUPIXENT may harm your unborn baby
- Are breastfeeding or plan to breastfeed; it is not known if DUPIXENT passes into your breast milk

How should I receive DUPIXENT?

- DUPIXENT should be given by your health care provider in a health care setting
- DUPIXENT is given in 1 or more injections under the skin (subcutaneous), 1 time every 2 weeks
- You may not see improvement in your symptoms right away after DUPIXENT treatment

Initials _____

What are the possible side effects of DUPIXENT?

DUPIXENT may cause serious effects, including:

- Anaphylaxis: A severe allergic reaction called anaphylaxis can happen when you receive DUPIXENT. The reaction can occur after the first dose or after many doses. It may also occur right after a DUPIXENT injection or days later. Anaphylaxis is a life-threatening condition and can lead to death. Go to the nearest emergency room right away if you have any of these symptoms of an allergic reaction:
  - Wheezing, shortness of breath, cough, chest tightness, or trouble breathing
  - Low blood pressure, dizziness, fainting, rapid or weak heartbeat, anxiety, or feeling of "impending doom"
  - Flushing, itching, hives, or feeling warm
  - Swelling of the throat or tongue, throat tightness, hoarse voice, or trouble swallowing
  - Anaphylactic shock is a potential complication. It is a serious event characterized by acute asthma, vascular collapse (low blood pressure), unconsciousness, and potentially death
- Conjunctivitis
- Keratitis
- Safety and efficiency of DUPIXENT have not been established in the treatment of asthma. Do not adjust or stop your asthma treatments, even if you are feeling better, without consulting your doctor
- Parasitic infection. Some people who are at a high risk for parasite (worm) infections get a parasite infection after receiving DUPIXENT. Your health care provider can test your stool to check if you have a parasite infection. It is unknown if DUPIXENT will influence the immune response against helminth infections.

These are not all the possible side effects of DUPIXENT.

The above reactions are unpredictable and may occur with the first injection or after a long series of injections, with no previous warning. All generalized reactions require immediate evaluation and medical intervention.

- Appropriate advice and treatment will always be available from our office staff at the time of any adverse reaction

OBSERVATION PERIOD FOLLOWING ADMINSTRATION: All patients receiving DUPIXENT should wait in the clinic area for 2 hours after the first 2 injections, and then 30 minutes after each subsequent injection.

- If you have a reaction, you may be advised to remain in the clinic longer for medical observation and treatment. If a generalized reaction occurs after you have left the clinic area, you should immediately return to the clinic or go to the nearest emergency medical facility.

ATTACHMENTS: I acknowledge that I have received the three attachments on DUPIXENT entitled:

A. ANAPHYLAXIS: RECOGNITION & MANAGEMENT GUIDELINES
B. ANAPHYLAXIS EMERGENCY ACTION PLAN
C. INSTRUCTIONS ON THE USE OF AN EPIPEN

Initials: _____

Consent for Administration of DUPIXENT, Authorization for Treatment

The following points regarding DUPIXENT were reviews and discussed in great detail:

- The nature and purpose of the Dupixent treatment program
- The risks of the treatment, including the possibility of an allergic reaction as well as the risk that the treatment program may not accomplish the desired objectives
- The possible outcome of the treatment
- The available alternative medical treatment
- The prognosis if the program is not followed
- The need for regular therapy and follow-up, including the need to evaluate my atopic dermatitis by keeping records of my medication use, symptoms, and need for unscheduled care
- Risk of anaphylaxis and epinephrine use, with proper demonstration of epinephrine auto injector
- Office policies regarding DUPIXENT (e.g., calling ahead for mixing and scheduled office visit required prior to administration if experiencing increase in symptoms)
- Patients of DUPIXENT should have an office visit with the prescribing allergist every 6 months
- You will need to bring your EpiPen with you for each administration of DUPIXENT

I have read the information in this consent form and understand it. The opportunity has been provided for me to ask questions regarding the potential risks of DUPIXENT, and these questions have been answered to my satisfaction. I understand that precautions consistent with the best medical practice will be carried out to protect me from adverse reactions to DUPIXENT. I do hereby give consent for the patient designated below to be given DUPIXENT over an extended period of time and at specific intervals, as prescribed. I further hereby give authorization and consent for treatment, by Dr. Mansfield and his staff, of any reactions that may occur as a result of DUPIXENT.

I have read and fully understand this form:

Printed name of DUPIXENT patient: _____

Patient signature (or legal guardian): _____ Date signed: _____

Witness signature: _____ Date signed: _____

FOR OFFICE USE ONLY: I certify that I have counseled this patient and/or legal guardian concerning the information in the CONSENT for DUPIXENT and that it appears to me that the signee understands the nature, risks, and benefits of the proposed treatment plan.

Cape Fear Otolaryngology Staff: _____ Date signed: _____