# OMALIZUMAB THERAPY PROTOCOL

## PURPOSE

Omalizumab (Xolair) is a recombinant DNA derived monoclonal antibody which inhibits IgE binding to the high affinity IgE receptor on mast cells and basophils. By inhibiting the binding of IgE, activation and release of allergic response mediators decreases.

## POLICY STATEMENTS

Omalizumab is currently non-formulary. Patient's supply is from the outpatient pharmacy.

Adminsitration of omalizumab requires a prescriber's order that specifies dosage, frequency of administration, and indication. The order must also include an order for management of anaphylaxis.

Omalizumab is given by subcutaneous injection and is administered in a hospital or clinic setting, by a nurse or physician.

The dose and frequency is dependent on the patient's serum IgE level and weight prior to start of therapy.

Patient must remain in the clinical area and be observed for signs and symptoms of anaphylaxis for 120 minutes following omalizumab injection.

## INDICATIONS

- Patients with cystic fibrosis who have severe persistent Allergic Bronchopulmonary Aspergillosis (ABPA), have elevated serum IgE, and may have eosinophilia, chest X-ray changes, and whose symptoms are inadequately controlled with inhaled and systemic corticosteroids and antifungal agent
- Patients with moderate to severe persistent asthma who have a positive skin test or in vitro reactivity to a perennial aeroallergen, and whose symptoms are inadequately controlled with inhaled corticosteroids.

## CONTRAINDICATIONS

Patients with known hypersensitivity to omalizumab or any component of the formulation (histidine, polysorbate 20, sucrose).

## PRECAUTIONS

- Anaphylaxis, presenting as angioedema of the throat or tongue, bronchospasm, hypotension, syncope, and/or urticaria has been reported to occur after administration of omalizumab.
- Anaphylaxis can occur as early as after the first dose, but has also been reported to occur beyond 1 year of beginning treatment. Most reactions occur within the first 2 hours post injection, but some reported to occur beyond 2 hours post injection.
- Patients should be observed closely for an appropriate period of time after omalizumab administration, and health care providers should be prepared to manage anaphylaxis that can be life threatening.
- Discontinuation of therapy would be advised if patient develops rare, but severe cases of Churg-Strauss syndrome, hypereosinophilic syndrome, and serum sickness.

## ADVERSE REACTIONS AND INTERVENTIONS

- Injection site reaction (45%) – bruising, redness, warmth, burning, stinging, itching, hive formation, pain, indurations, mass and inflammation. Occurs within 1 hour post injection, and last for less than 8 days. Tends to decrease in frequency with additional dosing.
- Central Nervous System – pain (7%), fatigue (3%), dizziness (3%)
- Dermatologic – dermatitis (2%), pruritis (2%)
- Neuromuscular/Skeletal – arthralgia (8%), leg pain (4%), arm pain (2%), fracture (2%)
- Otic – Earache (2%)
- Anaphylaxis (0.2%)

## EQUIPMENT

a. Swirler (provided by Novartis)


b. Omalizumab (Xolair®) 150 mg vial(s)
c. Sterile water preservative free for injection vial(s)
d. 2 x 3 mL syringes
e. 2 x 1 inch, blunt needles for reconstitution
f. 1 x 25 gauge needle (for subcutaneous injection)
g. Chlorhexidine/alcohol swabs
h. Drugs for anaphylaxis as per prescriber's orders (epinephrine, diphenhydramine)
   - **Epinephrine 1:1000 (1 mg/mL) injection** – 0.01 mg/kg intramuscularly up to a maximum of 0.5 mg. May repeat every 15 minutes for 3-4 doses.
   - **Diphenhydramine 50 mg/mL injection** – 1 – 2 mg/kg/dose IV slowly over 5 minutes, rate not greater than 25 mg/min (Maximum 50 mg/dose, 300 mg/24 hours for pediatrics; 100 mg/dose, 400 mg/24 hours for adults)

| PROCEDURE | *Rationale* |
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| 1. **REVIEW** prescriber's order for omalizumab and drugs for management of anaphylaxis. | *Medication orders that meet safe prescribing practices promote patient safety.* |
| 2. **ENSURE** emergency equipment is functioning and rescue drugs are readily available and **CALCULATE** appropriate doses/volumes. | *Immediate interventions can be provided in case of anaphylaxis.* |
| 3. **ASSEMBLE** equipment. | *Facilitates completion of task in timely manner.* |
| 4. **PERFORM** hand hygiene. | *Routine infection control practices; reduces transmission of microorganisms.* |
| 5. **PREPARE** omalizumab powder for injection:<br>a. Each 150 mg vial is reconstituted with 1.4 mL of sterile water for injection yielding concentration of 125 mg/mL<br>b. Place vial into swirler to dissolve powder. DO NOT SHAKE. Some vials may take longer than 20 minutes to dissolve completely.<br>c. Inspect vial to ensure there are no visible gel-like particles in the solution. If vial has not dissolved completely in 40 minutes – do not use the content of this vial. | *Once reconstituted, vial(s) stable for*<br>• *4 hours at room temperature OR*<br>• *8 hours under refrigeration.*<br>*Swirler machine used to help reconstitute omalizumab vial.* |
| 6. **IDENTIFY** patient and **EXPLAIN** procedure. **ENSURE** patient/family understand signs and symptoms of adverse reactions that require immediate reporting (i.e. anaphylaxis). | *Failure to correctly identify patients prior to procedures may result in errors.*<br>*Reduces child and family's anxiety. Evaluates and reinforces understanding of previously taught* |

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| | *information and confirms consent for medication administration.* |
| 6. **PERFORM** pre-treatment assessment:<br>a. heart rate (HR)<br>b. blood pressure (BP)<br>c. temperature (T)<br>d. respiratory rate (RR)<br>e. oxygen saturation ($SpO_2$)<br>f. breathing pattern<br>g. breath sounds<br>h. cognitive ability to understand and follow instructions | *Establishes baseline assessment.* |
| 7. **PLACE** patient in a comfortable position, preferably sitting or lying down on side depending on subcutaneous injection site preferred. | |
| 8. **ADMINISTER** omalizumab subcutaneously to patient.<br><br>**NOTE:** Solution is viscous, the injection may take up to 5 to 10 seconds to administer | *No more than 150 mg (1.2 mL) per injection site. For patients requiring more than 1 injection per administration, it is important to choose a different injection site for each injection.* |
| 9. **REASSESS** patient every 30 minutes during the treatment for up to 2 hours post administration.<br>a. heart rate (HR)<br>b. blood pressure (BP)<br>c. temperature (T)<br>d. respiratory rate (RR)<br>e. oxygen saturation ($SpO_2$)<br>f. breathing pattern<br>g. breath sounds<br>h. cognitive ability to understand and follow instructions | *To evaluate effectiveness of treatment and detect any adverse effects of medication.* |
| 10. **MONITOR** for potential signs and symptoms of anaphylaxis for at least 2 hours post injection including, but not limited to:<br>○ Shortness of breath (shallow irregular breath), wheezing cough, tightness in chest<br>○ Hives, rash, itching cool clammy skin and any changes in the skin's appearance<br>○ Swelling of the throat or tongue, eyelids, hands, feet and (in men) genitals<br>○ Faintness, lightheadedness, feeling of imminent fainting<br>○ Restlessness<br>○ Decreased level of consciousness<br>○ Flushed appearance<br>○ Cyanosis<br>○ Cool clammy skin<br>○ The patient may tell you that they feel dizzy or confused<br>○ Nausea, vomiting, cramping/abdominal pain, diarrhea<br>○ Pain | *Anaphylaxis requires immediate intervention as may become life-threatening if not treated.* |

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| ○ Rhinorrhea, nasal congestion, sneezing<br>○ Bleeding or unusual bruising<br>○ Headache<br>○ Injection site reaction (pain, redness, swelling, itching) | |
| 11. **MONITOR** efficacy of treatment as follows:<br>• **For ABPA treatment:**<br>At baseline and at every 3 months after start of omalizumab injections:<br>○ Bloodwork including CBC for eosinophils, Aspergillus Fumigatus RAST, Aspergillus Precipitins<br>○ Chest X-ray<br>○ Pulmonary function test with exhaled NO<br>○ Sputum culture<br>At every month<br>○ Pulmonary function test<br>• **For Asthma treatment:**<br>At every asthma clinic visit<br>○ Asthma control<br>○ Pulmonary function test (if able to perform test)<br>○ Frequency of exacerbations<br>○ Ability to wean other asthma medications | *Determines efficacy of treatment.* |

## DOCUMENTATION

**DOCUMENT** in appropriate record(s):

- date and time
- omalizumab dose administered and volume of diluent
- assessments of HR, BP, T, RR, $SpO_2$, breathing pattern, breath sounds
- patient response to procedure
- unexpected outcomes and related treatment
- any patient/family education
- any other pertinent actions or observations

## REFERENCES

Dosing from BC Children's Hospital – Pediatric Drug Dosage Guidelines. 6th edition, 2012.

Lexicomp Inc. **Omalizumab Drug Information**. Accessed June 2013.

Novartis. **Omalizumab Prescribing Information**. Last revised February 2010.