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**Biologics in the Treatment of Asthma**

**Why the need for biologics?**

Asthma is a complex disease that has a large impact on quality of life. Current treatments are usually effective for individuals with mild to moderate disease; however, more severe asthma is often not fully controlled with currently available inhaled medications. The need for additional and different therapeutic approaches in patients with severe disease, especially for those who become dependent on systemic steroids, has sparked research to identify molecules that contribute to asthma. Many of these molecules have been identified as potential targets for therapy. Multiple antibodies have been developed in attempts to reduce cytokines (proteins used in cellular signaling) known to fuel allergic-type responses and inflammation.

The goal in starting any of these medications is to reduce asthma exacerbations, decrease the need for oral corticosteroids, and prevent hospitalizations for asthma-related issues.

**Anti-IgE monoclonal antibody**

**XOLAIR® (omalizumab)** is a monoclonal antibody directed against IgE, and acts to prevent its ability to function with multiple cell types. It is given as a **subcutaneous** injection every 2 to 4 weeks by a healthcare provider. The dose is dependent on the patient’s baseline weight and IgE level prior to treatment. This medication is currently approved in patients 6 years of age or older whose asthma symptoms are not controlled by inhaled corticosteroids. A skin or blood test is performed to see if you have allergies to year-round allergens.

The most commonly reported adverse events in patients 12+ years of age include injection site reactions, joint pain, dizziness, fatigue, fracture, arm pain, itching, and earache.

The most commonly reported adverse events in patients 6 – 12 years of age include cold-like symptoms, headache, fever, abdominal pain, strep throat, ear infections, and nosebleeds.

Anaphylaxis (a severe allergic reaction involving hypotension, fainting, wheezing, hives, and/or swelling of the tongue and/or throat) has been rarely reported with this medication. For this reason, you will need to be monitored in the office for a specified period of time following each dose.

There is also a black box warning for malignancies, but in studies examining the patients on Xolair and those not treated with Xolair, the prevalence of cancer between the 2 groups was similar.

**Anti-IL-5 monoclonal antibodies**

IL-5 is a cytokine that is involved in the development of eosinophils. Eosinophils are a type of white blood cell that are a normal part of the body's immune system. Too many eosinophils may lead to inflammation in the lungs that can cause severe asthma attacks. Anti-IL-5 monoclonal antibodies reduce the number of eosinophils in the blood, but the exact mechanism of action is not fully understood. A simple blood test may be done to measure the number of eosinophils in your blood. In clinical studies, an eosinophil count helped identify patients whose asthma was more likely to respond to treatment with this type of monoclonal antibody.

There are currently 2 anti-IL-5 monoclonal antibodies that are FDA-approved as add-on therapy for the treatment of moderate to severe asthma in patients 18+ years of age:

**NUCALA® (mepolizumab)** is given as a single **subcutaneous** (under the skin) injection by a healthcare provider, once every 4 weeks.

**CINQAIR® (reslizumab)** is given as a single **intravenous** injection by a healthcare provider, once every 4 weeks. It takes about 20 to 50 minutes to receive the full dose of CINQAIR.

The most commonly reported adverse events with Nucala include cold-like symptoms, upper respiratory infection, worsening or exacerbation of asthma, headache, bronchitis, and sinusitis. Other side effects include back pain, joint pain, mouth/throat pain, and injection site reaction.

The most commonly reported adverse events with Cinqair include mouth/throat pain, elevated levels of CPK (a muscle enzyme), and muscle aches.

Anaphylaxis has been rarely reported with Cinqair. For this reason, you will need to be monitored in the office for a specified period of time following each dose.

**Anti-IL5 alpha receptor antibody**

**FASENRA® (benralizumab)** is a monoclonal antibody that binds directly to the IL-5 alpha receptor on an eosinophil and uniquely attracts certain immune cells to induce programmed cell death of eosinophils, which have been implicated in increased asthma severity and symptoms that can lead to decreased lung function and increased risk of exacerbations. It is given as a **subcutaneous** injection that is administered every 4 weeks for the first 3 doses, then once every 8 weeks thereafter.

The most commonly reported adverse events with Fasenra include headache and fever.