Xolair® (omalizumab) – Updated dosing

- On April 12, 2021, Genentech announced the FDA approval of Xolair (omalizumab) prefilled syringe for self-injection across all its approved indications.
    - Xolair prefilled syringe was previously approved for administration by a healthcare professional only.
- Xolair is approved for:
    - Adults and pediatric patients 6 years of age and older 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.
    - Add-on maintenance treatment of nasal polyps in adult patients 18 years of age and older with inadequate response to nasal corticosteroids.
    - Treatment of adults and adolescents 12 years of age and older with chronic idiopathic urticaria who remain symptomatic despite H1 antihistamine treatment.
- Before starting self-injection with Xolair prefilled syringe, the patient must have no prior history of anaphylaxis and be closely observed by a healthcare provider for at least three injections with no hypersensitivity (allergic reactions).
- After Xolair therapy has been initiated and safely established in a healthcare setting, a healthcare provider may determine whether self-injection with Xolair prefilled syringe by the patient or a caregiver is appropriate.
    - The healthcare provider must train the patient or caregiver on the correct subcutaneous injection technique, how to recognize the signs and symptoms of anaphylaxis and how to treat anaphylaxis appropriately, before the first self-injection outside a healthcare setting.
- Xolair is also available as a lyophilized powder for injection. This formulation should only be prepared and injected by a healthcare provider.
- For complete dosing and administration recommendations, refer to the Xolair drug label.
- Xolair carries a boxed warning for anaphylaxis.