Xolair® (omalizumab) – New indication

- On December 1, 2020, Genentech announced the FDA approval of Xolair (omalizumab), for add-on maintenance treatment of nasal polyps in adult patients 18 years of age and older with inadequate response to nasal corticosteroids.

- Xolair is also approved for:

  — 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.
  — Adults and adolescents 12 years of age and older with chronic idiopathic urticaria (CIU) who remain symptomatic despite H1 antihistamine treatment. Xolair is not indicated for treatment of other forms of urticaria.

- Nasal polyps affect 13 million people in the U.S. Nasal polyps present as noncancerous lesions on the lining of the nasal sinuses or nasal cavity associated with irritation and inflammation, which can block normal airflow. Nasal polyps may co-occur with other respiratory conditions, such as allergies and asthma.

- The approval of Xolair for the new indication was based on two, randomized, double blind, placebo-controlled clinical studies in 265 patients with nasal polyps with inadequate response to nasal corticosteroids. The co-primary endpoints in the studies were nasal polyp score (NPS) and average daily nasal congestion score (NCS) at week 24. Refer to the Xolair drug label for detailed definitions for these endpoints.

  — In studies 1 and 2, the mean change from baseline in NPS at week 24 for Xolair compared to placebo were -1.1 vs. 0.1 (treatment difference: -1.1, 95% CI: -1.6, -0.7; $p < 0.0001$) and -0.9 vs. -0.3 (treatment difference: -0.6, 95% CI: -1.1, -0.1; $p = 0.0140$), respectively.
  — In studies 1 and 2, the mean change from baseline in NCS at week 24 for Xolair compared to placebo were -0.9 vs. -0.4 (treatment difference: -0.6, 95% CI: -0.8, -0.3; $p = 0.0004$) and -0.7 vs. -0.2 (treatment difference: -0.5, 95% CI: -0.8, -0.2; $p = 0.0017$).

- Xolair carries a boxed warning for anaphylaxis.

- The most common adverse reactions (≥ 3%) with Xolair use for nasal polyps were headache, injection site reaction, arthralgia, upper abdominal pain, and dizziness.

- The recommended dose of Xolair for the treatment of nasal polyps is 75 mg to 600 mg subcutaneously every 2 or 4 weeks based on serum total IgE level (IU/mL) measure before the start of treatment and by body weight. The need for continued therapy should be periodically reassessed based upon the patient's disease severity and level of symptom control.

  — Xolair should be administered by a healthcare professional.
  — For patients with both asthma and nasal polyps, dosing determination should be based on the primary diagnosis for which Xolair is being prescribed.

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— Refer to the Xolair drug label for additional dosing and administration recommendations, including for treatment of asthma and CIU.

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