Xolair® (omalizumab) – New indication

- On February 16, 2024, Novartis announced the FDA approval of Xolair (omalizumab), for the reduction of allergic reactions (Type I), including anaphylaxis, that may occur with accidental exposure to one or more foods in adult and pediatric patients aged 1 year and older with IgE-mediated food allergy.
    - Xolair is to be used in conjunction with food allergen avoidance.
    - Xolair is not indicated for the emergency treatment of allergic reactions, including anaphylaxis.
- Xolair is also approved for the treatment of asthma, chronic rhinosinusitis with nasal polyps, and chronic spontaneous urticaria.
- Xolair is the first FDA-approved drug to reduce allergic reactions in people with one or more food allergies.
- The approval of Xolair for the new indication was based on a randomized, double-blind, placebo-controlled study in patients who were allergic to peanut and at least two other foods, including milk, egg, wheat, cashew, hazelnut, or walnut (ie, studied foods). Patients were randomized to Xolair or placebo for 16 to 20 weeks. The efficacy analysis included 165 pediatric patients. The primary endpoint was the percentage of patients who were able to consume a single dose of ≥ 600 mg of peanut protein without dose-limiting symptoms (eg, moderate to severe skin, respiratory or gastrointestinal symptoms) during a double-blind placebo-controlled food challenge (DBPCFC). The secondary endpoints were the percentage of patients who were able to consume a single dose of ≥ 1000 mg of cashew, milk, or egg protein without dose-limiting symptoms during DBPCFC.
    - Xolair treatment led to a statistically higher response rate than placebo for the primary and secondary endpoints (see table below).

Food, challenge dose	Response rate		Treatment difference (95% CI)
	Xolair	Placebo	
Peanut, ≥ 600 mg	68%	5%	63% (50, 73)
Peanut, ≥ 1000 mg	65%	0%	65% (56, 74)
Cashew, ≥ 1000 mg	42%	3%	39% (20, 53)
Milk, ≥ 1000 mg	66%	11%	55% (29, 73)
Egg, ≥ 1000 mg	67%	0%	67% (49, 80)

    - The effectiveness of Xolair in adults is supported by the adequate and well-controlled trial of Xolair in pediatric patients, disease similarity in pediatric and adult patients, and pharmacokinetic similarity.
    - While efficacy cannot be established from uncontrolled, open-label studies, for 38 pediatric patients who continued Xolair for 24 to 28 weeks in an open-label extension, the percentage of patients who were able to consume ≥ 600 mg of peanut protein and ≥ 1000 mg of egg, milk, and/or cashew protein without moderate to severe dose-limiting symptoms was maintained.
- Xolair carries a boxed warning for anaphylaxis.

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- The most common adverse reactions (≥ 3%) with Xolair use were injection site reactions and pyrexia.

- The recommended dose of Xolair for IgE-mediated food allergy is 75 mg to 600 mg by subcutaneous injection every 2 or 4 weeks based on serum total IgE level (IU/mL), measured before the start of treatment, and by body weight. Refer to the Xolair drug label for complete dosage recommendations.

    — The appropriate duration of therapy for IgE-mediated food allergy has not been evaluated. The need for continued therapy should be periodically reassessed.
    — Xolair therapy should be initiated in a healthcare setting and once therapy has been safely established, the healthcare provider may determine whether self-administration of Xolair prefilled syringe or autoinjector by the patient or caregiver is appropriate, based on careful assessment of risk for anaphylaxis and mitigation strategies.

- Refer to the Xolair drug label for dosing for its other indications.

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