# FDA Approves Interchangeable Biosimilar to Xolair

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This is a developing story.

The FDA has approved omalizumab-igec (Omlyco; Celltrion), the first interchangeable biosimilar to omalizumab (Xoliar; Genentech).

Omalizumab-igec is indicated for the treatment of:

- Moderate to severe persistent asthma among individuals greater than 6 years of age whose asthma symptoms are not well controlled with inhaled corticosteroids (ICS)
- Chronic rhinosinusitis with nasal polyps among individuals aged 18 years and older with inadequate response to nasal corticosteroids when used as add-on maintenance treatment
- Food allergy among individuals 1 years of age and older
- Chronic spontaneous urticaria (CSU) among individuals aged 12 years of age and older whose hives are not controlled with H1 antihistamine treatment

Omalizumab-igec is designed to attach to immunoglobulin E (IgE), which is produced at high levels among individuals with allergies, triggering an allergic response to an allergen. The biosimilar blocks IgE from binding to its receptors. Although omalizumab-igec is administered subcutaneously for all indications, it requires different dosing instructions for each indication.

Pharmacists play a crucial role in the subcutaneous injection process of omalizumab-igec, particularly in ensuring patient safety and adherence. In addition to verifying the prescription, pharmacists assess for potential drug interactions and educate patients on proper injection technique, including site selection and rotation. In some settings, pharmacists may administer the injections themselves, particularly during initial doses or when patients require close monitoring. Moreover, they are vital in managing adverse reactions, providing ongoing support, and coordinating with physicians to optimize treatment outcomes, ultimately contributing to improved allergy management for patients.

**REFERENCE**

Omalizumab-igec (Omlyclo). [package insert]. Celltroin; 2025. https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/761399s000lbl.pdf. Accessed March 7, 2025.

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