



MN008-T205
9900 Bren Road East
Minnetonka, MN 55343

September 30, 2021

Rick Slawny, Executive Director
American College of Allergy, Asthma & Immunology
85 West Algonquin Road, Suite 550
Arlington Heights, IL 60005

Re: Your inquiry about the UnitedHealthcare coverage policy for Xolair

Dear Mr. Slawny:

Thank you for contacting us about the UnitedHealthcare® announced coverage change for Xolair®, effective Oct. 1, 2021. This change is specific to UnitedHealthcare commercial plans. Coverage policies under UnitedHealthcare Medicare Advantage and UnitedHealthcare Community Plans may differ.

You have shared concerns regarding the commercial policy requirement to shift in-office administration of Xolair by a health care professional to self-administration at home when clinically appropriate.

We appreciate your insights and want to give you some background information.

Medical and drug policy development

Clinicians with subject matter expertise help us develop our medical and drug policies, as do materials and insights we receive from clinical experts. We review each submission with great care and consideration because they contribute to the overall quality and integrity of our medical policy review and development process.

Our current drug policy

We take the safety of our plan members very seriously and carefully weigh all the evidence before making any decisions. On April 12, 2021, the Food and Drug Administration (FDA) approved the self-administration of Xolair pre-filled syringe once therapy has been safely established in a health care setting and the health care provider has determined self-administration by the patient or caregiver is appropriate.

Based on this FDA approval of the self-administered Xolair product and published safety data, our Pharmacy and Therapeutics Committee has determined that the Xolair pre-filled syringe can be safely self-administered by a patient or caregiver once therapy has been safely established in a health care setting and the health care provider has determined self-administration of the Xolair pre-filled syringe by the patient or caregiver is appropriate. If self-administration of the Xolair pre-filled syringe by the patient or caregiver has been determined to not be appropriate, the current Xolair drug policy allows coverage of health care

provider-administered Xolair with provider attestation and supporting documentation that self-administration is not appropriate. We understand your concerns and value your feedback. Our policy does not require members to self-administer Xolair should they not be a suitable candidate for self-administration. Based on your feedback we are evaluating revisions to our policy, which we hope will clarify this.

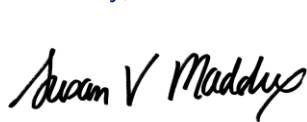
The following published safety data was reviewed when drafting our Xolair drug policy:

1. Denman, S., El-Shanaway, T., Carne, E., et al. Multicentre Experience of Home Omalizumab Treatment for Chronic Spontaneous Urticaria. *Eur J Hosp Pharm* 2019. E-pub Date: 15 July 2019. doi: 10.1136/ejhpharm-2019-001914.
2. Denman, S., Ford, K., Toolan, J., et al. Home Self-Administration of Omalizumab for Chronic Spontaneous Urticaria. *Br J Dermatol* 2016;175: 1405-1407. doi:10.1111/bjd.15074.
3. Ghazanfar, M.N., Thomsen, S.F. Home Self-Administration of Omalizumab. *J Dermatol Treat* 2018;29:2, 196, DOI: 10.1080/09546634.2017.1341611 7.
4. Lieberman, P.L., Umetsu, D.T., Carrigan, G.J., Rahmaoui, A. Anaphylactic Reactions Associated With Omalizumab Administration: Analysis of a Case-Control Study. *J Allergy Clin Immunol.* 2016; 138:913–915.e2.
5. Lieberman, P.L., Jones, I., Rajwanshi, R., et al. Anaphylaxis-Associated With Omalizumab Administration: Risk Factors and Patient Characteristics. *J Allergy Clin Immunol.* 2017;Volume 140, Issue 6, 1734 – 1736.e4.
6. Liebhaber, M., Dyer, Z. Home Therapy With Subcutaneous Anti-Immunoglobulin-E Antibody Omalizumab in 25 Patients With Immunoglobulin-E-Mediated (Allergic) Asthma. *J Asthma* 2007;44:3, 195-196, DOI: 10.1080/02770900701209749.
7. Menzella, F., Ferrari, E., Ferrucci, S.M., et al. Self-Administration of Omalizumab: Why Not? A Literature Review and Expert Opinion. *Expert Opinion on Biological Therapy*, DOI: 10.1080/14712598.2021.1882990.
8. Timmermann, H., Mailänder, C. Home Self-Administration of Biologics – a German Survey Among Omalizumab-Treated Patients with Severe Asthma and Their Treating Physicians. *Pneumologie* 2020 74:2 (103-111).
9. Xolair® [package insert]. Genentech, Inc. and Novartis Pharmaceuticals Corporation; South San Francisco, CA. and East Hanover, NJ. 2021.

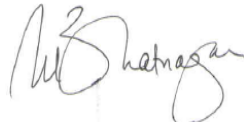
We welcome your feedback

We appreciate you taking the time to contact us and hope this information is helpful to you. If you have further questions, please contact us medical_policy_inquiries@uhc.com.

Sincerely,



Susan V. Maddux, PharmD
Chief Pharmacy Officer



Upasana Bhatnagar, MD
Chairperson, UnitedHealthcare
Pharmacy & Therapeutics Committee

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