CENTENE Corporation	
CLINICAL POLICY	
Department: Medical Management	**Document Name:** Xolair®
Page: 1 of 9	**Reference Number:** NH.PHAR.125
Effective Date: 10/08	**Replaces Document:**
Retired:	**Reviewed:** 08/09, 03/17
Specialist Review: Allergist 09/08, 08/10, IM-PD, 02/14	**Revised:** 09/10, 09/11, 10/12, 12/13, 02/14, 06/14, 7/15, 7/16, 2/17
`Product Type: All	**Committee Approval:** 10/08, 08/09, 09/10, 10/11, 11/12, 12/13, 03/14, 06/14

IMPORTANT REMINDER

This Clinical Policy has been developed by appropriately experienced and licensed health care professionals based on a thorough review and consideration of generally accepted standards of medical practice, peer-reviewed medical literature, government agency/program approval status, and other indicia of medical necessity.

The purpose of this Clinical Policy is to provide a guide to medical necessity. Benefit determinations should be based in all cases on the applicable contract provisions governing plan benefits ("Benefit Plan Contract") and applicable state and federal requirements, as well as applicable plan-level administrative policies and procedures. To the extent there are any conflicts between this Clinical Policy and the Benefit Plan Contract provisions, the Benefit Plan Contract provisions will control.

Clinical policies are intended to be reflective of current scientific research and clinical thinking. This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.

Subject:

Medical necessity criteria for Xolair® (omalizumab)

Description:

The intent of the criteria is to ensure that patients follow selection elements established by Centene medical policy Xolair.

FDA-Approved Indication

Xolair (omalizumab) is indicated for adults and adolescents (≥6 years of age) 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.[1] Xolair has been shown to decrease the incidence of asthma exacerbations in these patients.[1]

Xolair is also indicated for chronic idiopathic urticaria in adults and adolescents (≥ 12 years of age) who remain symptomatic despite H1 antihistamine treatment.

Important Limitations of Use:[1]

Xolair is not indicated for treatment of other allergic conditions or other forms of urticaria.
Xolair is not indicated for the relief of acute bronchospasm or status asthmaticus.
Xolair is not indicated for use in pediatric patients less than 6 years of age.

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Policy/Criteria:
It is the policy of Health Plans affiliated with Centene Corporation that Xolair® is **medically necessary** for members who meet the following algorithm criteria:

Figure 1: Xolair Initial Asthma Algorithm
Figure 2: Xolair Re-authorization Asthma Algorithm
Figure 3: Xolair Initial Urticaria Algorithm
Figure 4: Xolair Re-authorization Urticaria Algorithm

Figure 1: Xolair Initial Asthma Algorithm

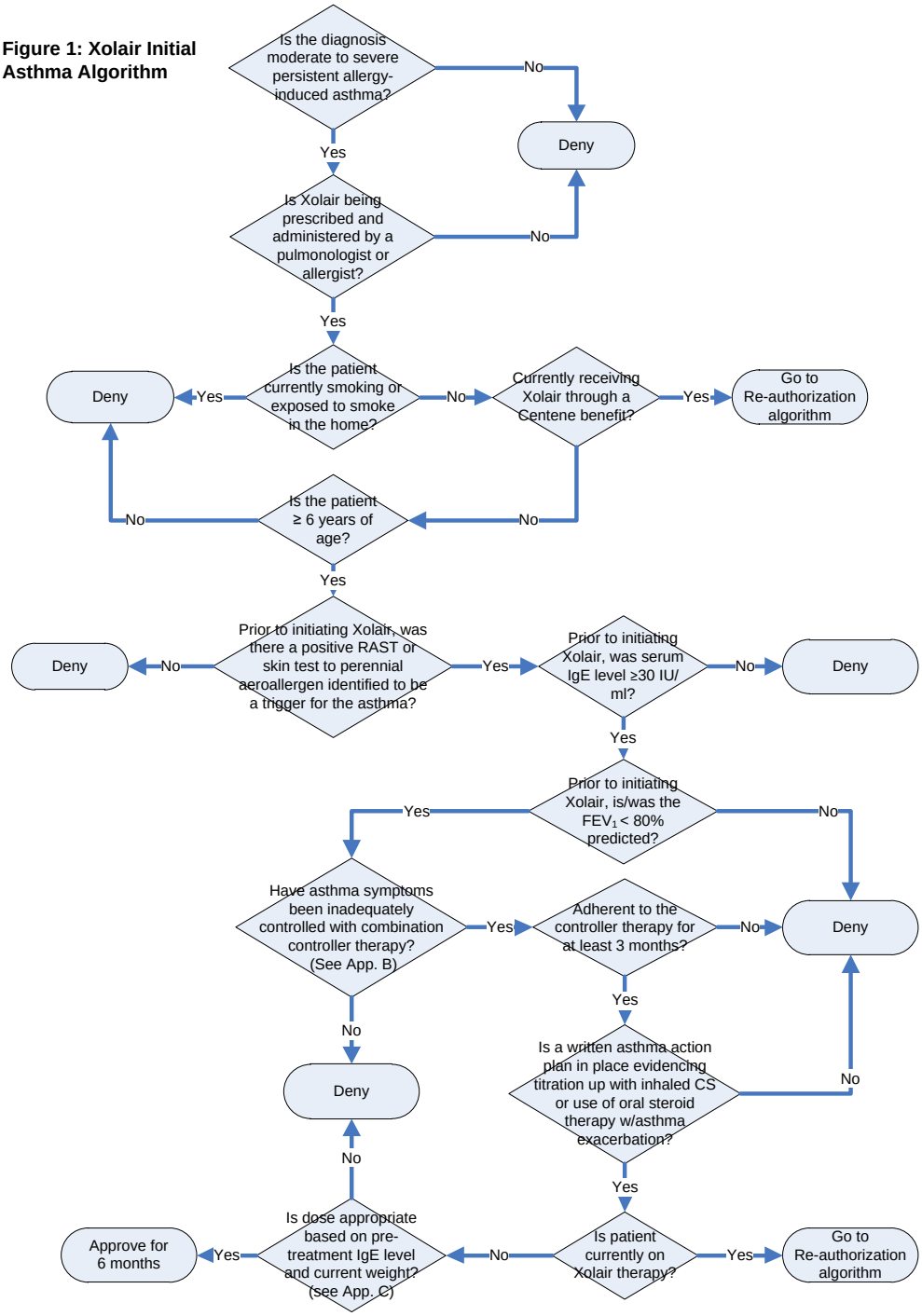


Figure 2: Xolair Re-authorization Asthma Algorithm

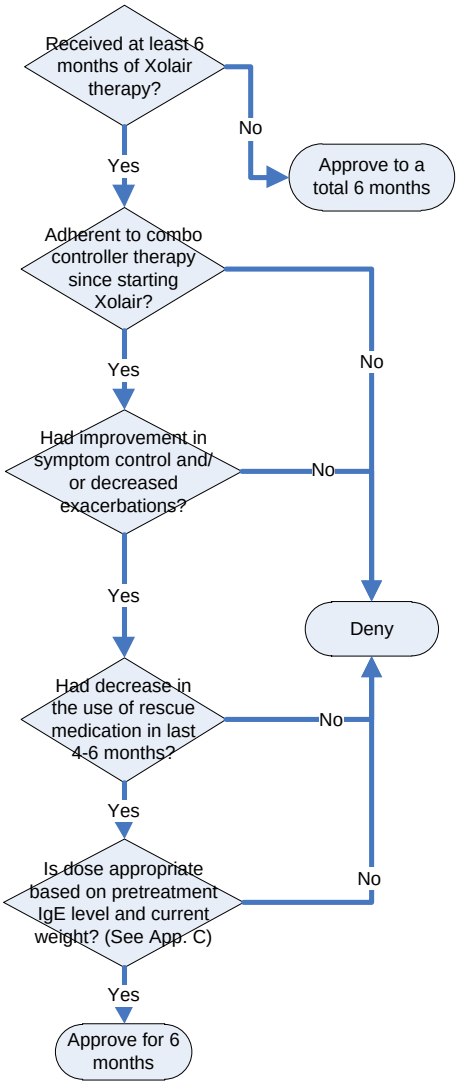


Figure 3: Xolair Initial Urticaria Algorithm

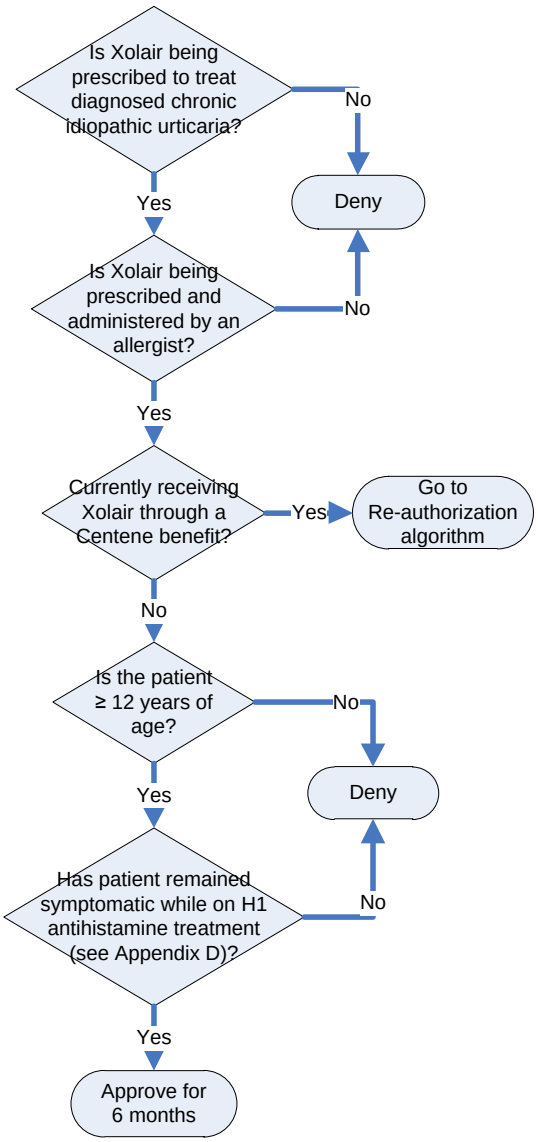
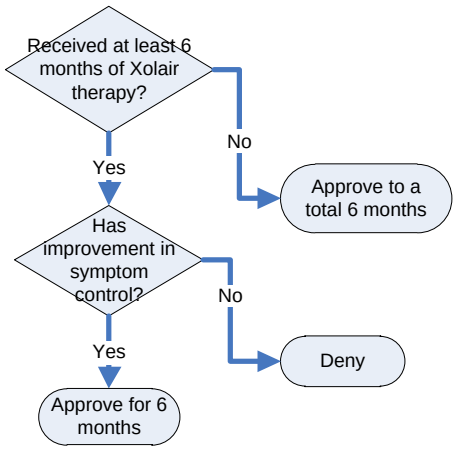


Figure 4: Xolair Re-authorization Urticaria Algorithm



Background

Xolair is an injectable medication given subcutaneously for moderate to severe persistent asthma that is triggered by year-round environmental allergens. It is a recombinant humanized monoclonal anti-IgE antibody that selectively binds to IgE, which inhibits free IgE from binding to mast cell receptors, thereby preventing activation and subsequent release of cellular mediators. The FDA approved its use in 2003 for patients with moderate to severe persistent allergy-related asthma who are sub-optimally controlled with inhaled steroid treatments.[2]

CIU is defined as itchy hives that last for at least 6 weeks, with or without angioedema, and that have no apparent external triggers. CIU can have burdensome symptoms including swelling, severe itch, pain, and discomfort that generally has a prolonged duration of 1-5 years and has a detrimental effect on patients' emotional and physical health-related quality of life.[7] Despite H1-antihistamine therapy, about 50% of patients still have an inadequate response and experience symptoms. Xolair is the first biologic medicine approved by the FDA for CIU since non-sedating H1-antihistamines. The dosing of Xolair in CIU patients is not dependent on serum IgE (free or total) level or body weight.[1]

Appendices

Appendix A: Abbreviation Key

FEV_1: forced expiratory volume in 1 Second
CS: corticosteroids

CIU: chronic idiopathic urticaria

Appendix B: Examples of combination controller therapy

- High dose inhaled corticosteroids **plus** long acting beta 2 agonists (ie. arformoterol (Brovana®), formoterol (Foradil®, salmeterol (Serevent®))

  or
- Combination inhaled corticosteroids and beta 2 agonists (ie. fluticasone/salmeterol (Advair®), budesonide/formoterol (Symbicort®))

  and/or
- Leukotriene modifiers (ie. Singulair, Accolate, Zyflo)

Appendix C: Dosing Tables

Table 1 – Every 4 Week Dosing (in millimgrams)

Pre-treatment Serum IgE (IU/mL)	*Body weight - pounds (kilograms)*			
	66-132 (30-60)	*>132-154 (>60-70)*	*>154-198 (>70-90)*	*>198-330 (>90-150)*
≥ 30 – 100	**150**	**150**	**150**	**300**
> 100 – 200	300	300	300	
> 200 – 300	**300**			
> 300	See Table 2			

Table 2 – Every 2 Week Dosing (in milligrams)

Pre-treatment Serum IgE (IU/mL)	*Body weight - pounds (kilograms)*			
	66-132 (30-60)	*>132-154 (>60-70)*	*>154-198 (>70-90)*	*>198-330 (>90-150)*
≥ 30 – 100	See Table 1			
> 100 – 200				**225**
> 200 – 300		**225**	**225**	**300**
> 300 – 400	**225**	**225**	**300**	
> 400 – 500	**300**	**300**	**375**	
> 500 – 600	**375**	**375**	**DO NOT USE**	
> 600 – 700	**375**			

Note: Total IgE levels are elevated during treatment and remain elevated for up to one year after the discontinuation of treatment. Therefore, re-testing of IgE levels during Xolair treatment cannot be used as a guide for dose determination.

Appendix D: Examples of H1- Antihistamines Used for CIU[6,7]

First-Generation	**Second-Generation**

Diphenhydramine (Benadryl) Hydroxyzine (Vistaril, Atarax)	Fexofenadine (Allegra) Cetirizine (Zyrtec) Levocetirizine (Xyzal) Desloratidine (Clarinex) Loratadine (Claritin)

References:

1. National Heart, Lung and Blood Institute and the National Asthma Education and Prevention Program.: Guidelines for the Management and Control of Asthma. Expert Panel Report 3, 2007. http://www.nhlbi.nih.gov/guidelines/asthma/asthgdln.pdf
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7. Maurer, MD, M. et al. Omalizumab for the Treatment of Chronic Idiopathic or Spontaneous Urticaria. March 2013. New England Journal of Medicine; 368: 924-935. http://www.nejm.org/doi/full/10.1056/NEJMoa1215372. Accessed on April 1, 2014.

Revision Log	Date:
References updated. Removed "Available Dosing" section.	08/10
Converting to Caremark SGM criteria for Xolair.	09/11
Changed baseline serum IgE level from >30 to ≥30 IU/mL	10/12
Converted to Centene policy template	08/13
Added questions regarding dosing to algorithms and Appendix C dosing tables	12/13
Removed peak flow meter reading improvement from reauthorization algorithm	02/14
Added indication for urticaria	06/14
Removed adverse reactions to Xolair results in denial in figure 2 and 4	07/15
Changed policy number from NH. Phar.01 to NH.PHAR.125	07/16
Changed age on asthma indication to match FDA guidelines of ≥6 years of age. Also updated FDA indication section of policy for the same reason.	2/17
Annual Review, No Changes	03/17

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