



SmartPA

Clinical Edit Criteria

Drug/Drug Class: **Respiratory Monoclonal Antibodies Clinical Edit
(formerly Xolair® Clinical Edit)**

Date: **August 2, 2017**

Revised:

Prepared by: MO HealthNet

New Criteria

Revision of Existing Criteria

Executive Summary

Purpose: Ensure appropriate utilization and control of Xolair® (omalizumab), Nucala® (mepolizumab) and Cinqair® (reslizumab).

Respiratory Monoclonal Antibodies are indicated in the treatment of moderate to severe persistent asthma in adults and adolescents with perennial allergic asthma not controlled with inhaled corticosteroids OR as add-on maintenance treatment of patients with severe asthma, with an eosinophilic phenotype. They are not indicated for acute bronchospasm or status asthmaticus.

**Why was this
Issue
Selected:**

Xolair® shows efficacy in reduction of exacerbations in asthma patients with IgE-mediated diseases. Xolair® is also indicated for chronic idiopathic urticaria.

Nucala® is an interleukin-5 antagonist that reduces the production and survival of eosinophils (a cell type associated with inflammation and an important component of the pathogenesis of asthma). Cinqair® (reslizumab) is the newest entrant into this category with indications similar to Nucala®.

MHD will ensure that participants have appropriate access to these medications and will monitor utilization.

	Drug	Package Size	Cost per Vial
Program-specific information:	Xolair [®] is supplied as a lyophilized sterile powder for injection.	150mg/vial	\$1,022.489 WAC
	Cinqair [®] is supplied as a preservative-free, sterile, clear to slightly hazy/opalescent, colorless to slightly yellow solution in single-use vials	100 mg/10 mL vial	\$835.000 WAC
	Nucala [®] is supplied as a lyophilized sterile powder for injection.	100mg/vial	\$2,574.094 WAC

Setting & Population:

Xolair[®]: Adults and adolescents with moderate to severe perennial allergic asthma or chronic idiopathic urticaria

Nucala[®]: Adults and adolescents with severe asthma with an eosinophilic phenotype

Cinqair[®]: Adults with severe asthma with an eosinophilic phenotype

Type of Criteria:

Increased risk of ADE Non-Preferred Agent

Appropriate Indications

Data Sources: Only administrative databases Databases + Prescriber-supplied

Setting & Population

- Drug class for review: Respiratory Monoclonal Antibodies (Xolair[®] / Nucala[®] / Cinqair[®])
- Age range: 6 years of age and older for Xolair for moderate to severe persistent asthma
- Age range: 12 years of age and older for Xolair for chronic idiopathic urticaria
- Age range: 12 years and older for Nucala for severe asthma
- Age range: 18 years and older for Cinqair for severe asthma
- Gender: Male and female

Approval Criteria

- 1) Omalizumab, mepolizumab and reslizumab must be prescribed by a specialist (e.g., allergist, immunologist, pulmonologist) – for initial treatment only (1st dose).
- 2) In order to be approved for omalizumab for moderate to severe persistent asthma, a patient must meet all three of the below criteria (i.e. asthma diagnosis, prescription drug claim history indicating inadequately controlled asthma, and skin testing or RAST or in vitro reactivity at least one perennial aeroallergen).
- 3) In order to be approved for mepolizumab and reslizumab for severe asthma, a patient must also have documentation of eosinophilic phenotype and the drug is an add-on maintenance treatment.
- 4) Documented inadequate or poor asthma symptom control as defined below in the last 45 days.
- 5) In order to be approved for omalizumab for chronic idiopathic urticaria must meet both criteria (i.e. diagnosis of chronic idiopathic urticarial, and remain symptomatic after being treated with H1 antihistamine therapy for past 60 out of 90 days).

Approval Diagnoses			
Condition	Inferred Drugs	Date Range	
<i>Omalizumab, mepolizumab and reslizumab</i>			
Asthma	N/A	360 days	
Inadequately controlled asthma	<ul style="list-style-type: none"> • Inhaled corticosteroids and • Short-acting beta₂ agonists (excessive use – defined as minimum of 3 inhalers) 	45 days 60 days	
	<ul style="list-style-type: none"> • Inhaled corticosteroids and • Short-term steroid use 	45 days 45 days	
	<ul style="list-style-type: none"> • Inhaled corticosteroids and • Emergency room visit 	45 days 45 days	
	<i>Omalizumab only</i>		
	Chronic Idiopathic Urticaria	N/A	360 days
Inadequately controlled chronic idiopathic Urticaria	<ul style="list-style-type: none"> • H1 antihistamines 	60 out of 90 days	
<i>Mepolizumab and reslizumab</i>			
Eosinophilic Phenotype			

Denial Criteria

- Absence of approval criteria
- Age < 6 years of age for Xolair® for moderate to severe persistent asthma
- Age < 12 years of age for Xolair® for chronic idiopathic urticaria
- Age < 12 years of age for Nucala® for severe asthma
- Age < 18 years of age for Cinqair® for severe asthma

References

1. Genentech, Inc. Prescribing Information for Xolair® (Omalizumab), June 2017.
2. Drug Facts and Comparisons On-line, 2017.
3. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2017.
4. USPDI, Micromedex; 2017.
5. GlaxoSmithKline. Prescribing Information for Nucala® (Mepolizumab), February 2017.
6. Teva Respiratory. Prescribing Information for Cinqair® (Reslizumab), May 2016