



## Drug and Biologic Coverage Criteria

including bradykinin-related angioedema and interleukin-1-associated urticarial syndromes (auto-inflammatory disorders, urticarial vasculitis)

AND

3. Prescribers attests that possible conditions or triggers for urticaria are being maximally managed without improvement  
AND
4. Documented baseline score from an objective clinical evaluation tool within the past 30 days [e.g., Urticaria Control Test (UCT), Urticaria Activity Score (UAS7), Angioedema Activity Score (AAS), Dermatology Life Quality Index (DLQI), Angioedema Quality of Life (AE-QoL), or Chronic Urticaria Quality of Life Questionnaire (CU-Q2oL)] [DOCUMENTATION REQUIRED]  
AND
5. Documentation that member continues to experience hives associated with itching despite adequate, adherent trials (minimum 4 weeks) of ALL of the following treatments (See Appendix 6) (*Reference: AAAAI/ACAAI guideline on diagnosis and management acute and chronic urticaria [J Allergy Clin Immunol 2014 May;133(5):1270] see BACKGROUND*) [DOCUMENTATION REQUIRED of trial/failure with dates of therapy]:
  - (a) Two different H1-antihistamines at the maximally tolerated doses (up to 4 times standard daily dose), unless medically contraindicated as monotherapy  
*MOLINA REVIEWER NOTE: If denying for prior utilization at high doses, please enter override for antihistamine quantity limits*  
AND
  - (b) One H1-antihistamine IN COMBINATION with leukotriene receptor antagonist (LTRA) at the maximally tolerated doses (up to 4 times standard daily dose), unless medically contraindicated  
AND
  - (c) One H1-antihistamine at the maximally tolerated doses (up to 4 times standard daily dose) in combination with ANY of the following: H2-Antihistamines OR an anti-inflammatory agent (e.g., dapsone, hydroxychloroquine, sulfasalazine) OR an immunosuppressant agent (e.g., cyclosporine, mycophenolate), unless medically contraindicated  
AND
6. Prescriber attests or clinical reviewer has found that Xolair (omalizumab) is not prescribed for concurrent use with any of the following: Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)], OR Anti-interleukin 5 therapy [e.g., Nucala (mepolizumab), Cinqair (reslizumab), Fasenna (benralizumab)], OR Anti-TSLP Tezspire (tezepelumab-ekko)

## B. MODERATE-TO-SEVERE PERSISTENT ALLERGIC ASTHMA:

1. Documented diagnosis of moderate to severe persistent asthma  
AND
2. Prescriber attests or clinical reviewer has found that Xolair (omalizumab) is NOT being used as monotherapy for asthma (must be prescribed as add-on maintenance to be used in combination with other medications for long-term control of asthma)  
AND
3. Documented pre-treatment serum total IgE levels (measured prior to start of treatment) greater than or equal to 30 IU/mL and less than or equal to 1500 IU/mL [DOCUMENTATION REQUIRED]  
AND
4. Documentation member has experienced exacerbation(s) or hospitalization(s), within the last 12 months as evidenced by any of the following [DOCUMENTATION REQUIRED]:
  - i. Two or more exacerbations requiring treatment with systemic corticosteroid (intramuscular, intravenous, or oral) despite the use of high-dose inhaled corticosteroids in the past 12 months OR
  - ii. One or more exacerbation requiring hospitalization in the past 12 months OR
  - iii. Two-fold increase or greater in the dose of systemic corticosteroid treatment for asthma exacerbations OR
  - iv. Asthma worsens upon tapering of oral corticosteroid therapy OR

## Drug and Biologic Coverage Criteria

- v. Mechanical ventilation in the past 12 months OR
- vi. Poor symptom control indicated by Asthma Control Questionnaire (ACQ) score consistently greater than 1.5 or Asthma Control Test (ACT) score consistently less than 20 OR
- vii. Forced expiratory volume in 1 second (FEV1) < 80% predicted OR
- viii. FEV1/forced vital capacity (FVC) < 0.80

AND

5. Documentation of adherence to ONE of the following regimens of at least 3 months (within the past 90 days) and symptoms inadequately controlled (as documented in criteria above):
  - (a) Medium or High dose ICS- LABA combination product AND one additional asthma controller medication (LAMA, LTRA, Low dose azithromycin), preferably a LAMA- per GINA 2024 guideline
  - OR
  - (b) Medium or High dose ICS- LABA combination product AND oral corticosteroids [see appendix for product classes]

*MOLINA REVIEWER NOTE: Verify pharmacy claims for compliance with the combination therapy above within the last 90 days. For new members to Molina Healthcare, confirm medication use in medical chart history. Non-compliance, which can be documented by review of the prescription fill history, would not constitute therapeutic failure.*

AND

6. Prescriber attestation that IF member is a smoker, the member has been counseled regarding the benefits of smoking cessation and/or connected with a program to support smoking cessation
- AND
7. Prescriber attestation that the member's underlying conditions or triggers for asthma or pulmonary disease are being maximally managed
- AND
8. Prescriber attests or clinical reviewer has found that Xolair (omalizumab) is not prescribed for concurrent use with any of the following: Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)], OR Anti-interleukin 5 therapy [e.g., Nucala (mepolizumab), Cinqair (reslizumab), Fasenra (benralizumab)], OR Anti- TSLP Tezspire (tezepelumab-ekko)

### C. CHRONIC RHINOSINUSITIS WITH NASAL POLYPS:

1. Documented diagnosis of chronic rhinosinusitis with nasal polyposis
- AND
2. Prescriber attests that member has a history of sino-nasal surgery or is not eligible for surgery
- AND
3. Documentation member has experienced an inadequate response (after 3 consistent months of use) or serious side effects to one of the following medications unless contraindicated: preferred formulary/PDL intranasal steroids OR preferred formulary/PDL oral corticosteroids
- AND
4. Documentation member is concurrently receiving treatment with one of the following agents: Intranasal steroids, Oral corticosteroids, Nasal saline irrigations, Antibiotics, or antileukotriene agents (i.e., not to be used as monotherapy)
- AND
5. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal (e.g., nasal congestion, loss of smell, sino-nasal symptoms) [DOCUMENTATION REQUIRED]
- AND
6. Prescriber attests or clinical reviewer has found that Xolair (omalizumab) is NOT prescribed for concurrent use with any of the following: Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)], OR Anti- interleukin 5 therapy [e.g., Nucala (mepolizumab), Cinqair (reslizumab), Fasenra (benralizumab)], OR Anti-TSLP Tezspire (Tezepelumab-ekko)

### D. FOOD ALLERGIES:

1. Documented diagnosis of food allergy (e.g., peanut, milk, egg, wheat, cashew, hazelnut, walnut)

## Drug and Biologic Coverage Criteria

AND

2. Documentation of confirmation of an IgE mediated food allergy from a positive skin test or specific IgE or total serum IgE  
AND
3. Documented pre-treatment serum total IgE levels (measured prior to start of treatment)  
[DOCUMENTATION REQUIRED]  
AND
4. Documentation of baseline systemic allergic reactions requiring treatment and member has a history of at least 1 systemic allergic reaction requiring hospitalization, an ER visit, or use of injectable epinephrine  
NOTE: Continuation of therapy request requires follow-up documentation as evidence of positive benefit from therapy  
AND
5. Prescriber attests that member will use Xolair in conjunction with an allergen avoidant diet  
AND
6. Member has a current prescription for epinephrine and access to an epinephrine autoinjector while using Xolair (Review Rx history)  
AND
7. Prescriber attests or clinical reviewer has found member has NOT experienced severe or life-threatening episode of anaphylaxis or anaphylactic shock to the member specific foods (i.e., neurological compromise, intubation)  
AND
8. Documentation of medical justification which supports necessity for immunotherapy despite avoidance diet (e.g., member has a severe allergy that can be triggered by smell)  
AND
9. Prescriber attests or clinical reviewer has found that Xolair (omalizumab) is not prescribed for concurrent use with any of the following: Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)], OR Anti-interleukin 5 therapy [e.g., Nucala (mepolizumab), Cinqair (reslizumab), Fasenra (benralizumab)], OR Anti-TSLP Tezspire (Tezepelumab-ekko)

### CONTINUATION OF THERAPY:

#### A. FOR ALL INDICATIONS:

1. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation  
AND
2. Prescriber attests to or clinical reviewer has found no evidence of ANY of the following: Intolerable adverse effects or unacceptable toxicity from the drug [e.g. symptoms of anaphylaxis (bronchospasm, hypotension, syncope, urticaria, and/or angioedema), malignancy, symptoms similar to serum sickness (fever, arthralgia, and rash); parasitic (helminth) infection, eosinophilic conditions (e.g. vasculitic rash, worsening pulmonary symptoms, cardiac complications, and/ or neuropathy, especially upon reduction of oral corticosteroids]  
AND
3. Prescriber attests or clinical reviewer has found that Xolair (omalizumab) is not prescribed for concurrent use with any of the following: Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)], OR Anti-interleukin 5 therapy [e.g., Nucala (mepolizumab), Cinqair (reslizumab), Fasenra (benralizumab)] OR Anti-TSLP Tezspire (Tezepelumab-ekko)

#### B. CHRONIC SPONTANEOUS URTICARIA:

1. Clinical improvement as documented by improvement from baseline using objective clinical evaluation tools [e.g., Urticaria Control Test (UCT), Urticaria Activity Score (UAS7), Angioedema Activity Score (AAS), Dermatology Life Quality Index (DLQI), Angioedema Quality of Life (AE-QoL), or Chronic Urticaria Quality of Life Questionnaire (CU- Q2oL)]. [DOCUMENTATION REQUIRED]

## Drug and Biologic Coverage Criteria

### C. MODERATE-TO-SEVERE PERSISTENT ALLERGIC ASTHMA:

1. Documentation that Xolair (omalizumab) therapy has resulted in clinical improvement as documented by ONE or more of the following from baseline [DOCUMENTATION REQUIRED]:
  - a. Improvement in lung function (increase in percent predicted FEV1 or PEF)
  - b. Decreased utilization of rescue medications
  - c. Decreased frequency of exacerbations (defined as worsening of asthma that requires increase in inhaled corticosteroid dose or treatment with systemic corticosteroids)
  - d. Decreased frequency of unscheduled clinic, urgent care or emergency department visits
  - e. Reduction in reported symptoms: chest tightness, coughing, shortness of breath, nocturnal waking wheezing, sustained improvement in Asthma Control Test (ACT) scores
  - f. Decreased or stopped oral treatments (including oral corticosteroids and other add on medications, if applicable), or reduced ICS- LABA dose (to at least moderate)
  - g. Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing/heavy breathing, coughing, chest tightness or heaviness shortness of breath, sleep disturbance, night waking, fatigue, or asthmatic symptoms upon awakening)

MOLINA REVIEWER NOTE: For members with unclear response after initial use, see Background (GINA 2024).

AND

2. Documentation member is currently treated and is compliant with standard therapy (e.g., inhaled corticosteroids, long-acting beta-2 agonist (LABA), leukotriene receptor antagonist (LTRA), long-acting muscarinic antagonist (LAMA)) within the past 90 days

### D. NASAL POLYPS:

1. Documentation of positive clinical response as demonstrated by low disease activity and/or improvements in the condition's signs and symptoms (e.g., nasal congestion, loss of smell, sino-nasal symptoms) [DOCUMENTATION REQUIRED]  
AND
2. Prescriber attests or clinical reviewer has found that member continues on standard therapy (intranasal steroids, oral corticosteroids, nasal saline irrigations, antibiotics, or antileukotriene agents)

### E. FOOD ALLERGIES:

1. Documentation of member re-assessment for this condition to determine if continuation of treatment with requested medication is medically necessary  
AND
2. Documentation of positive response to treatment as documented by at least ONE of the following compared to pre-treatment to evaluate effectiveness:
  - a. Reduction in severe allergic reactions
  - b. Reduction in epinephrine use
  - c. Reduction in physician/clinic visits due to food allergy (physician office/ER visits/hospitalizations)
  - d. Improvement in quality of life or productivity

### DURATION OF APPROVAL:

Initial authorization: 6 months, Continuation of therapy: 12 months

### PRESCRIBER REQUIREMENTS:

Prescribed by, or in consultation with, a board-certified asthma specialist (allergist, immunologist, pulmonologist), or physician experienced in the management of asthma, allergist, immunologist, dermatologist, or otorhinolaryngologist. [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

### AGE RESTRICTIONS:

Chronic spontaneous urticaria: 12 years of age and older

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## Drug and Biologic Coverage Criteria

Asthma: 6 years of age and older

Nasal polyposis: 18 years of age and older

Food allergy: 1 year of age and older

### QUANTITY:

*Options for dosing quantity limits:*

Dose (75mg) = 1 x 75mg syringe ONLY

Dose (150mg) = 1 x 150mg syringe OR 150mg vial

Dose (225mg) = 1 x 75mg syringe + 1x 150mg syringe ONLY

Dose (300mg) = 2 x 150mg syringe OR 2 x 150mg vials

Dose (375mg) = 1 x 75mg syringe + 2 x 150mg syringe/vial Dose (450mg) = 3 x 150mg syringe OR 3 x 150mg vial

Dose (525mg) = 1 x 75mg syringe + 3 x 150mg syringe/vial

Dose (600mg) = 4 x 150mg syringe/vial

For Chronic Spontaneous Urticaria: MAX 300 mg every 4 weeks (dosing not dependent on serum IgE or body weight)

For Asthma: MAX 375 mg every 2 weeks, with dosing determined by serum IgE level (IU/mL) measured before the start of treatment, and body weight

For Nasal polyps: MAX 600 mg every 2 weeks, with dosing determined by serum IgE level (IU/mL) measured before the start of treatment, and body weight

For Food allergies: MAX 600 mg every 2 weeks, with dosing determined by serum IgE level (IU/mL) measured before the start of treatment, and body weight

**Maximum Quantity Limits** – Based on FDA labeled indication, weight, and IgE level

### PLACE OF ADMINISTRATION:

The recommendation is that injectable medications in this policy will be for pharmacy or medical benefit coverage and the subcutaneous injectable products administered in a place of service that is a non- hospital facility-based location as per the Molina Health Care Site of Care program.

**Note:** Site of Care Utilization Management Policy applies for Xolair (omalizumab). For information on site of care, see [Specialty Medication Administration Site of Care Coverage Criteria \(molinamarketplace.com\)](https://www.molinamarketplace.com)

## DRUG INFORMATION

### ROUTE OF ADMINISTRATION:

Subcutaneous

### DRUG CLASS:

Anti-IgE Monoclonal Antibody

### FDA-APPROVED USES:

Indicated for:

- Moderate to severe persistent asthma in adults and pediatric patients 6 years of age and older with a positive skin test or in vitro reactivity to a perennial aeroallergen and symptoms that are inadequately controlled with inhaled corticosteroids

*Limitations of use: Not indicated for acute bronchospasm or status asthmaticus*

- Chronic rhinosinusitis with nasal polyps (CRSwNP) in adult patients 18 years of age and older with inadequate response to nasal corticosteroids, as add-on maintenance treatment
- IgE-mediated food allergy in adult and pediatric patients aged 1 year and older for the reduction of allergic reactions (Type I), including anaphylaxis, that may occur with accidental exposure to one or more foods. To be used in conjunction with food allergen avoidance

*Limitations of use: Not indicated for the emergency treatment of allergic reactions, including anaphylaxis*

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## Drug and Biologic Coverage Criteria

- Chronic spontaneous urticaria (CSU) in adults and adolescents 12 years of age and older who remain symptomatic despite H1 antihistamine treatment

*Limitations of use: Not indicated for other forms of urticaria*

### COMPENDIAL APPROVED OFF-LABELED USES:

None

## APPENDIX

### APPENDIX 1:

Controller medications: suppress the inflammatory causes of asthma to provide clinical control over the long term, whereas reliever medications relieve bronchoconstriction quickly. Controller medications include inhaled glucocorticoids, long-acting beta-agonists (LABAs) and Leukotriene receptor antagonists (LTRA). Theophylline (Theo-24, Uniphyl, TheoChron ER, generics) is also a controller agent, however, it is not as efficacious as LABAs and not recommended for treatment.

#### Anticholinergic (LAMA)

Tiotropium bromide monohydrate (Spiriva Respimat)

#### Inhaled Corticosteroids (ICS) (list not all inclusive):

*Beclomethasone dipropionate (QVAR)*

*Fluticasone furoate (Arnuity Ellipta)*

*Budesonide DPI (Pulmicort Flexhaler)*

*Fluticasone propionate (Flovent Diskus)*

*Budesonide nebulas (Pulmicort Respules)*

*Fluticasone propionate (Flovent HFA)*

*Ciclesonide (Alvesco)*

*Fluticasone propionate (ArmonAir Digihaler)*

*Flunisolide (Aerospan)*

*Mometasone furoate (Asmanex Twisthaler)*

*Mometasone furoate (Asmanex HFA\*)*

*\*HFA: hydrofluoroalkane propellant metered dose inhaler*

*\*DPI: dry powder inhaler*

#### Combination Long-Acting Bronchodilator and Corticosteroid (ICS+ LABA) (list not all inclusive):

*Budesonide/formoterol fumarate dihydrate (Symbicort)*

*Fluticasone propionate/salmeterol (Advair Diskus/ Adair HFA/ AirDuo/ AirDuo RespiClick/Wixela Inhub)*

*Fluticasone furoate/vilanterol (Breo Ellipta)*

*Mometasone furoate/formoterol fumarate dihydrate (Dulera)*

#### Combination Anticholinergic and Corticosteroid and long-acting bronchodilator (ICS+ LAMA+ LABA)

*Fluticasone/umeclidinium/vilanterol (Trelegy Elipta)*

*Budesonide/glycopyrrolate/formoterol (Breztri Aerosphere)*

#### Leukotriene receptor antagonist (LTRA) (list not all inclusive):

*Montelukast (Singulair), Zafirlukast (Accolate), Zileuton (Zyflo)*

### APPENDIX 2:

- FEV1 (forced expiratory volume in 1 second): A measure of airway obstruction determined using spirometry. Individual FEV1 values are compared to predicted values based on age, height, sex and race.
- PEF (peak expiratory flow): PEF is often described as a percent of personal best measurement. Personal best PEF is the highest PEF value attained after 2 to 3 weeks of testing when asthma is in good control.

### APPENDIX 3: Managing Asthma in Adults and Adolescents 12+ Years

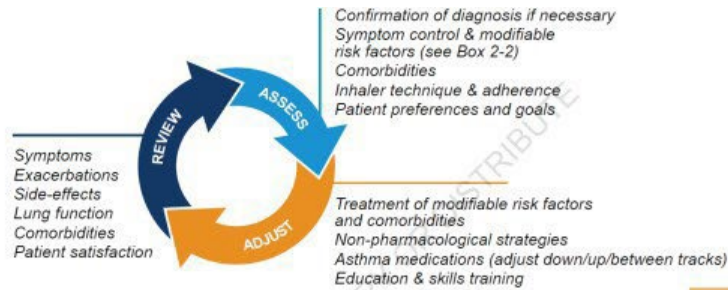
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# Drug and Biologic Coverage Criteria

## GINA 2023 – Adults & adolescents 12+ years

**Personalized asthma management**  
Assess, Adjust, Review  
for individual patient needs



**TRACK 1: PREFERRED CONTROLLER and RELIEVER**  
Using ICS-formoterol as the reliever\* reduces the risk of exacerbations compared with using a SABA reliever, and is a simpler regimen

<b>STEPS 1 – 2</b> As-needed-only low dose ICS-formoterol	<b>STEP 3</b> Low dose maintenance ICS-formoterol	<b>STEP 4</b> Medium dose maintenance ICS-formoterol	<b>STEP 5</b> Add-on LAMA Refer for assessment of phenotype. Consider high dose maintenance ICS-formoterol, ± anti-IgE, anti-IL5/5R, anti-IL4R $\alpha$ , anti-TSLP
<b>RELIEVER: As-needed low-dose ICS-formoterol*</b>			

See GII severe asthma

**TRACK 2: Alternative CONTROLLER and RELIEVER**  
Before considering a regimen with SABA reliever, check if the patient is likely to adhere to daily controller treatment

<b>STEP 1</b> Take ICS whenever SABA taken*	<b>STEP 2</b> Low dose maintenance ICS	<b>STEP 3</b> Low dose maintenance ICS-LABA	<b>STEP 4</b> Medium/high dose maintenance ICS-LABA	<b>STEP 5</b> Add-on LAMA Refer for assessment of phenotype. Consider high dose maintenance ICS-LABA, ± anti-IgE, anti-IL5/5R, anti-IL4R $\alpha$ , anti-TSLP
<b>RELIEVER: as-needed ICS-SABA*, or as-needed SABA</b>				

Other controller options (limited indications, or less evidence for efficacy or safety – see text)

Low dose ICS whenever SABA taken*, or daily LTRA, or add HDM SLIT	Medium dose ICS, or add LTRA, or add HDM SLIT	Add LAMA or LTRA or HDM SLIT, or switch to high dose ICS	Add azithromycin (adults) or LTRA. As last resort consider adding low dose OCS but consider side-effects
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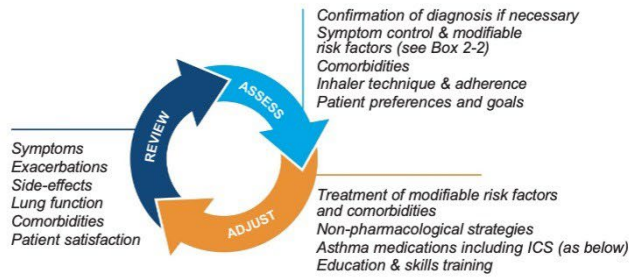
\*Anti-inflammatory reliever (AIR)



# Drug and Biologic Coverage Criteria

## GINA 2024 – Adults & adolescents 12+ years

**Personalized asthma management**  
Assess, Adjust, Review  
for individual patient needs



### TRACK 1: PREFERRED CONTROLLER and RELIEVER

Using ICS-formoterol as the reliever\* reduces the risk of exacerbations compared with using a SABA reliever, and is a simpler regimen

#### STEPS 1 – 2

As-needed-only low dose ICS-formoterol

#### STEP 3

Low dose maintenance ICS-formoterol

#### STEP 4

Medium dose maintenance ICS-formoterol

#### STEP 5

Add-on LAMA  
Refer for assessment of phenotype. Consider high dose maintenance ICS-formoterol, ± anti-IgE, anti-IL5/5R, anti-IL4Rα, anti-TSLP

RELIEVER: As-needed low-dose ICS-formoterol\*

See GINA severe asthma guide

### TRACK 2: Alternative CONTROLLER and RELIEVER

Before considering a regimen with SABA reliever, check if the patient is likely to adhere to daily controller treatment

#### STEP 1

Take ICS whenever SABA taken\*

#### STEP 2

Low dose maintenance ICS

#### STEP 3

Low dose maintenance ICS-LABA

#### STEP 4

Medium/high dose maintenance ICS-LABA

#### STEP 5

Add-on LAMA  
Refer for assessment of phenotype. Consider high dose maintenance ICS-LABA, ± anti-IgE, anti-IL5/5R, anti-IL4Rα, anti-TSLP

RELIEVER: As-needed ICS-SABA\*, or as-needed SABA

Other controller options (limited indications, or less evidence for efficacy or safety – see text)

Low dose ICS whenever SABA taken*, or daily LTRA <sup>1</sup> , or add HDM SLIT	Medium dose ICS, or add LTRA <sup>1</sup> , or add HDM SLIT	Add LAMA or add LTRA <sup>1</sup> or add HDM SLIT, or switch to high dose ICS-only	Add azithromycin (adults) or add LTRA <sup>1</sup> . As last resort consider adding low dose OCS but consider side-effects
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\*Anti-inflammatory reliever; <sup>1</sup>advise about risk of neuropsychiatric adverse effects

GINA 2024 Box 4-6

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ABBREVIATIONS: BUD-FORM: budesonide-formoterol; ICS: inhaled corticosteroid; LABA: long-acting beta2-agonist; LTRA: Leukotriene Receptor Antagonist; MART: maintenance and reliever therapy with ICS-formoterol; OCS: oral corticosteroids; SABA: short-acting beta2-agonist; SLIT: sublingual immunotherapy  
REFERENCE: Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2024. Available from: www.ginasthma.org

Managing Asthma in Children 6-11 Years

GINA 2024 – Children 6–11 years



**Personalized asthma management:**

Assess, Adjust, Review

Symptoms  
Exacerbations  
Side-effects  
Lung function  
Comorbidities  
Child and parent/  
caregiver satisfaction



Confirmation of diagnosis if necessary  
Symptom control & modifiable  
risk factors (see Box 2-2)  
Comorbidities  
Inhaler technique & adherence  
Child and parent/caregiver preferences and goals

Treatment of modifiable risk factors  
& comorbidities  
Non-pharmacological strategies  
Asthma medications including ICS  
Education & skills training

**Asthma medication options:**

Adjust treatment up and down for individual child's needs

**PREFERRED CONTROLLER**

to prevent exacerbations and control symptoms

Other controller options (limited indications, or less evidence for efficacy or safety)

**RELIEVER**

<p><b>STEP 1</b></p> <p>Low dose ICS taken whenever SABA taken*</p>	<p><b>STEP 2</b></p> <p>Daily low dose inhaled corticosteroid (ICS) (see table of ICS dose ranges for children)</p>	<p><b>STEP 3</b></p> <p>Low dose ICS-LABA, OR medium dose ICS, OR very low dose ICS-formoterol maintenance and reliever therapy (MART)</p>	<p><b>STEP 4</b></p> <p>Refer for expert advice, OR medium dose ICS-LABA, OR low dose ICS-formoterol maintenance and reliever therapy (MART)</p>	<p><b>STEP 5</b></p> <p>Refer for phenotypic assessment ± higher dose ICS-LABA or add-on therapy, e.g. anti-IgE, anti-IL4Rα, anti-IL5</p>
	<p>Daily leukotriene receptor antagonist (LTRA<sup>†</sup>), or low dose ICS taken whenever SABA taken*</p>	<p>Low dose ICS + LTRA<sup>†</sup></p>	<p>Add tiotropium or add LTRA<sup>†</sup></p>	<p>As last resort, consider add-on low dose OCS, but consider side-effects</p>
<p>As-needed SABA (or ICS-formoterol reliever* in MART in Steps 3 and 4)</p>				

\*Anti-inflammatory reliever; <sup>†</sup>advise about risk of neuropsychiatric adverse effects

ABBREVIATIONS: BUD-FORM: budesonide-formoterol; ICS: inhaled corticosteroid; LABA: long-acting beta2-agonist; LTRA: Leukotriene Receptor Antagonist; MART: maintenance and reliever therapy with ICS-formoterol; OCS: oral corticosteroids; SABA: short-acting beta2-agonist; SLIT: sublingual immunotherapy

REFERENCE: Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2024. Available from: [www.ginasthma.org](http://www.ginasthma.org)

**APPENDIX 4: SUGGESTED TOTAL DAILY DOSAGES for INHALED CORTICOSTEROIDS (ICS) IN ADULTS AND ADOLESCENTS (12 years and older):**

Inhaled Corticosteroid	Low Dose ICS (mcg)	Medium Dose ICS (mcg)	High Dose ICS (mcg)
Beclometasone dipropionate (pMDI, standard particle, HFA)	200-500	>500-1000	>1000
Beclometasone dipropionate (DPI or pMDI, extrafine particle, HFA)	100-200	>200-400	>400
Budesonide (DIP, or pMDI, standard particle, HFA)	200-400	>400-800	>800
Ciclesonide (pMDI, extrafine particle, HFA)	80-160	>160-320	>320
Fluticasone furoate (DPI)	100	100	200
Fluticasone propionate (DPI)	100-250	>250-500	>500
Fluticasone propionate (pMDI, standard particle, HFA)	100-250	>250-500	>500
Mometasone furoate (DPI)	Depends on DPI device – see product information		
Mometasone furoate (pMDI, standard particle, HFA)	200-400	200-400	>400

Reference: Box 4-2. Low, medium and high daily metered doses of inhaled corticosteroids (alone or with LABA)  
Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2024. Available from:  
[www.ginasthma.org](http://www.ginasthma.org)

**SUGGESTED TOTAL DAILY DOSAGES for INHALED CORTICOSTEROIDS (ICS) IN CHILDREN 6-11 YEARS:**

Inhaled Corticosteroid	Low Dose ICS (mcg)	Medium Dose ICS (mcg)	High Dose ICS (mcg)
Beclometasone dipropionate (pMDI, standard particle, HFA)	100-200	>200-400	>400
Beclometasone dipropionate (pMDI, standard particle, HFA)	50-100	>100-200	>200
Budesonide (DPI, or pMDI, standard particle, HFA)	100-200	>200-400	>400
Budesonide (nebulas)	250-500	>500-1000	>1000
Ciclesonide (pMDI, extrafine particle, HFA)	80	>80-160	>160
Fluticasone furoate (DPI)	50	50	NA
Fluticasone propionate (DPI)	50-100	>100-200	>200
Fluticasone propionate (pMDI, standard particle, HFA)	50-100	>100-200	>200
Mometasone furoate (pMDI, standard particle, HFA)	100	100	200

Reference: Box 4-2 . Low, medium and high daily metered doses of inhaled corticosteroids (alone or with LABA)  
Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2024. Available from:  
[www.ginasthma.org](http://www.ginasthma.org)

### APPENDIX 5:

**Dermatology Life Quality Index (DLQI):** A self-administered 10-item questionnaire that rates the impact of skin disease on symptoms and feelings, daily activities, leisure, work and school, personal relationships, and treatment. The average completion time of 2 minutes. The DLQI may be used for routine clinical use by clinicians in order to assist the clinical consultation, member evaluation and monitoring and to help with clinical decision-making process.

**Urticaria Activity Score (UAS):** A member reported CIU measure which captures intensity of pruritus and number of hives. Daily intensity of pruritus (range: 0 = none to 3 = severe) and number of hives ratings (range: 0 = none to 3 = more than 12 hives) are summed over a week to create the UAS7 (range: 0–42) score.

**FEV1 (forced expiratory volume in 1 second):** A measure of airway obstruction determined using spirometry. Individual FEV1 values are compared to predicted values based on age, height, sex and race. 'Estimated Comparative Daily Dosages for ICSs in Children' from the National Asthma Educational Prevention Program (NAEPP)-- EPR 3 Guidelines on Asthma by NAEPP. Figure 4–4b. Available at: [https://www.nhlbi.nih.gov/sites/default/files/media/docs/asthgdln\\_1.pdf](https://www.nhlbi.nih.gov/sites/default/files/media/docs/asthgdln_1.pdf)

### APPENDIX 6:

First generation H1 antihistamine: hydroxyzine, cyproheptadine

Second generation H1 antihistamine: cetirizine, levocetirizine, fexofenadine, loratadine, desloratadine

Leukotriene receptor antagonist (LTRA): montelukast (Singulair), zafirlukast (Accolate), zileuton (Zyflo)

H2-Antihistamines: cimetidine (Tagamet), famotidine (Pepcid), nizatidine (Axid), ranitidine (Zantac)

## BACKGROUND AND OTHER CONSIDERATIONS

### BACKGROUND:

#### NASAL POLYPS

The approval was supported by data from the phase 3 POLYP 1 (N=138) and POLYP 2 (N=127) trials evaluating the efficacy and safety of Xolair in adults with nasal polyps who had an inadequate response to nasal corticosteroids. Patients were randomized to receive either Xolair or placebo by subcutaneous injection every 2 to 4 weeks. The co-primary end points for both trials were change from baseline in Nasal Polyp Score (NPS) at week 24 and change from baseline in average daily Nasal Congestion Score (NCS) to week 24.

Results from both trials showed that patients treated with Xolair had a statistically significant greater improvement from baseline at week 24 in NPS and NCS compared with placebo, with improvements observed as early as week 4. Moreover, Xolair demonstrated statistically significant improvements on sense of smell score, post-nasal drip, and runny nose in both trials. The most common adverse reactions reported included headache, injection site reaction, arthralgia, upper abdominal pain and dizziness

#### ASTHMA

The National Heart, Lung and Blood Institute's Expert Panel Report 3 (EPR3) Guidelines for the Diagnosis and Management of Asthma recommend Xolair may be considered as adjunct therapy for patients 12 years and older with allergies and Step 5 or 6 (severe) asthma whose symptoms have not been controlled by ICS and LABA.

The Global Initiative for Asthma (GINA, 2022) recommends that patients 6 years and older may be treated with omalizumab as follows (Evidence A: Randomized controlled trials and meta-analyses. Rich body of evidence): Suggested add-on treatment for patients  $\geq 6$  years with moderate or severe allergic asthma that is:

- uncontrolled on Step 4-5 treatment (Evidence A)
- Patients with severe asthma, uncontrolled on Step 4 treatment, may benefit from phenotyping into categories such as severe allergic, aspirin-exacerbated, or eosinophilic asthma. Patients  $\geq 6$  years with severe allergic asthma with elevated IgE levels may benefit from omalizumab (anti-IgE) therapy (Evidence A).

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- Those with child-onset asthma and clinical history suggesting allergen-driven symptoms may predict a good asthma response to omalizumab therapy.
- Suggested initial trial of add-on anti-IgE for severe allergic asthma is at least 4 months. At that point, response to initial trial of add-on therapy should be reviewed. There are no well-defined criteria for good response, but exacerbations, symptom control, lung function, side effects, treatment intensity, and patient satisfaction should be considered. If the response is unclear, consider extending the trial to 6-12 months. If there is no response, stop the biologic therapy and consider switching to a different targeted therapy, if available

### Global Initiative for Asthma (GINA, 2024)

Add-on biologic therapy: options recommended by GINA for patients with uncontrolled severe asthma despite optimized maximal therapy include:

- Add-on anti-immunoglobulin E treatment (omalizumab [Xolair]) for patients age  $\geq 6$  years with **severe allergic asthma** (Evidence A)
- Add-on anti-interleukin- 5/5R treatment (SC mepolizumab [Nucala] for patients age  $\geq 6$  years; IV reslizumab [Cinqair] for ages  $\geq 18$  years or SC benralizumab [Fasenra] for ages  $\geq 12$  years), with **severe eosinophilic asthma** (Evidence A)
- Add-on anti-interleukin-4R $\alpha$  treatment (SC dupilumab [Dupixent]) for patients aged  $\geq 6$  years with **severe eosinophilic/type 2 asthma** or for **patients requiring treatment with maintenance OCS** (Evidence A)
- Add-On anti-thymic stromal lymphopoietin (anti TSLP) treatment (subcutaneous tezepelumab [Tezspire]) for patients aged  $\geq 12$  years with **severe asthma** (Evidence A)
- Suggested initial trial of add-on anti-IL5 for severe eosinophilic asthma is at least 4 months. At that point, response to initial trial of add-on therapy should be reviewed. There are no well- defined criteria for good response, but exacerbations, symptom control, lung function, side effects, treatment intensity, and patient satisfaction should be considered. If the response is unclear, consider extending the trial to 6-12 months. If there is no response, stop the biologic therapy and consider switching to a different targeted therapy, if available.

## CHRONIC URTICARIA

In 2014, the Joint Task Force on Practice Parameters (JTFPP), representing the American Academy of Allergy, Asthma & Immunology (AAAAI); the American College of Allergy, Asthma & Immunology (ACAAI); and the Joint Council of Allergy, Asthma & Immunology updated the practice parameter for the diagnosis and management of acute and chronic urticaria (CU). The practice parameter established a step-care approach to the treatment of chronic urticaria and angioedema. The task force recommended the following step-care treatment approach:

- Monotherapy with second-generation antihistamines: H1-antagonists are effective in the majority of patients with CU but might not achieve complete control in all patients.
- Dose advancement of H1-antihistamine therapy, combining first- and second-generation agents and adding an H2-antihistamine and/or an antileukotriene agent: Higher doses of second-generation antihistamines can provide greater efficacy when control is not achieved with conventional doses of these agents.
- Therapeutic trial of potent antihistamine (e.g., hydroxyzine or doxepin): First-generation antihistamines should be prescribed cautiously in the elderly or patients with occupations (e.g., machine operators, airline pilots, or alpine skiers) for which alertness is essential.
- Add an immunosuppressant or biologic agent: Omalizumab and cyclosporine have the greatest published experience documenting efficacy in patients with CU compared with all other alternative agents. The EAACI/GA2LEN/EDF/AAAAI/WAO Guideline for the Management of Urticaria include Xolair in combination with H1-antihistamines as a third line treatment option in patients who have failed to respond to higher doses of H1-Antihistamines.

The Joint Task Force on Practice Parameters representing various American allergy organizations include Xolair in combination with H1-antihistamines as a fourth line treatment option following a stepwise approach starting with a second-generation antihistamine. This is followed by one or more of the following: a dose increases of the second-generation antihistamine, or the addition of another second- generation antihistamine, H2-antagonist, LTRA, or first-generation antihistamine. Treatment with hydroxyzine or doxepin

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can be considered in patients whose symptoms remain poorly controlled.

### FOOD ALLERGIES

The safety and efficacy of Xolair was evaluated in a multi-center, randomized, double-blind, placebo-controlled Food Allergy (FA) trial [NCT03881696] in 168 adult patients and pediatric patients 1 year of age to less than 56 years who were allergic to peanut and at least two other foods, including milk, egg, wheat, cashew, hazelnut, or walnut (i.e., studied foods). The FA trial enrolled patients who experienced dose-limiting symptoms (e.g., moderate to severe skin, respiratory or gastrointestinal symptoms) to a single dose of  $\leq 100$  mg of peanut protein and  $\leq 300$  mg protein for each of the other two foods (milk, egg, wheat, cashew, hazelnut, or walnut) during the screening double-blind placebo-controlled food challenge (DBPCFC). *Patients with a history of severe anaphylaxis (defined as neurological compromise or requiring intubation) were excluded from the study.* Patients were randomized 2:1 to receive a subcutaneous dosage of Xolair or placebo based on serum total IgE level (IU/mL), measured before the start of treatment, and by body weight for 16 to 20 weeks. After 16 to 20 weeks of treatment, each patient completed a DBPCFC consisting of placebo and each of their 3 studied foods. Following the DBPCFC, the first 60 patients that included 59 pediatric patients and one adult patient who completed the double-blind, placebo-controlled phase of the study could continue to receive Xolair in a 24 to 28 week open-label extension.

Efficacy of Xolair is based on 165 pediatric patients who were included in the efficacy analyses provided below. The mean age of the pediatric patients was 8 years (age range: 1 to 17 years).

The primary efficacy endpoint was the percentage of patients who were able to consume a single dose of  $\geq 600$  mg of peanut protein without dose-limiting symptoms (e.g., moderate to severe skin, respiratory or gastrointestinal symptoms) during DBPCFC. Xolair treatment led to a statistically higher response rate (68%) than placebo (5%). The secondary efficacy endpoints were the percentage of patients who were able to consume a single dose of  $\geq 1000$  mg of cashew, milk, or egg protein without dose-limiting symptoms during DBPCFC. The study met the secondary endpoints and demonstrated that Xolair treatment led to statistically higher response rates than placebo for all three foods.

Seventeen percent of Xolair treated patients were not able to consume  $>100$  mg of peanut protein without moderate to severe dose-limiting symptoms. Eighteen, 22, and 41 percent of Xolair-treated patients were not able to consume  $>300$  mg of milk, egg, or cashew protein, respectively, without moderate to severe dose-limiting symptoms.

Additional secondary analyses included the percentage of patients who were able to consume at least two or all three foods during DBPCFC. For two foods, 71% of Xolair treated patients were able to consume a single dose of  $\geq 600$  mg versus 5% in the placebo group and 67% were able to consume a single dose of  $\geq 1000$  mg versus 4% in the placebo group. For a single dose of  $\geq 600$  mg of three foods, the response rates were 48% in the Xolair group versus 4% in the placebo group and for a single dose of  $\geq 1000$  mg of three foods, the response rate in the Xolair group was 39% while none of the placebo patients were able to consume the challenge dose without symptoms.

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 (PK) similarity. While efficacy cannot be established from uncontrolled, open-label studies, for 38 pediatric patients who continued Xolair for 24-28 weeks in an open-label extension, the percentage of patients who were able to consume  $\geq 600$  mg of peanut protein and  $\geq 1000$  mg of egg, milk, and/or cashew protein without moderate to severe dose-limiting symptoms was maintained.

### **CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:**

All other uses of Xolair (omalizumab) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to Xolair (omalizumab) include: Severe hypersensitivity reaction to omalizumab or any component of the formulation.

### **OTHER SPECIAL CONSIDERATIONS:**

Xolair (omalizumab) has a Black Boxed warning for Anaphylaxis, presenting as bronchospasm, hypotension, syncope, urticaria, and/or angioedema of the throat or tongue, has been reported to occur after administration of omalizumab. Anaphylaxis has been reported after the first dose of Xolair but also beyond one year after beginning treatment. Individuals should be closely observed after Xolair

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administration as well as informed of signs and symptoms of anaphylaxis and to seek care immediately should symptoms occur.

### CODING/BILLING INFORMATION

**CODING DISCLAIMER.** Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.

HCPCS CODE	DESCRIPTION
J2357	Injection, omalizumab, 5 mg

#### AVAILABLE DOSAGE FORMS:

Xolair SOLR 150MG single-dose vial  
Xolair SOAJ 75MG/0.5ML single-dose prefilled autoinjector  
Xolair SOAJ 150MG/ML single-dose prefilled autoinjector  
Xolair SOAJ 300MG/2ML single-dose prefilled autoinjector  
Xolair SOSY 75MG/0.5ML single-dose prefilled prefilled syringe  
Xolair SOSY 150MG/ML single-dose prefilled prefilled syringe  
Xolair SOSY 300MG/2ML single-dose prefilled prefilled syringe

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SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Coding/Billing Information Template Update Required Medical Information Continuation of Therapy Appendix Available Dosage Forms References	Q4 2024
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Age Restrictions Quantity FDA-Approved Uses Background References	Q2 2024



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REVISION- Notable revisions: Required Medical Information Continuation of Therapy Prescriber Requirements Drug Class FDA-Approved Uses Appendix Background Contraindications/Exclusions/Discontinuation References	Q4 2023
REVISION- Notable revisions: Required Medical Information References	Q1 2023
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Prescriber Requirements Age Restrictions Quantity FDA-Approved Uses Appendix Background Contraindications/Exclusions/Discontinuation References	Q4 2022
Q2 2022 Established tracking in new format	Historical changes on file