Original Effective Date:
Current Effective Date: 03/18/2023
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Next Review Due By: 01/2024
Policy Number: C5678-A

Xolair (Omalizumab)

PRODUCTS AFFECTED

Xolair (omalizumab)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.
This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Chronic spontaneous urticaria, Moderate to severe persistent asthma, Nasal polyps

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by-case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review.

A. CHRONIC SPONTANEOUS URTICARIA
1. Diagnosis of Chronic Spontaneous Urticaria (CSU) documented by the presence of urticaria (hives) that has been continuously or intermittently present for more than 6 weeks
AND
2. Prescriber attests that other underlying causes of member’s condition have been ruled out, 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 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 [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
   NOTE: First generation H1 antihistamine (doxepin, hydroxyzine, cyproheptadine), second generation H1 antihistamine (cetirizine, levocetirizine, fexofenadine, loratadine, desloratadine) MOLINA REVIEWER NOTE: If denying for prior utilization at high doses, please enter override for antihistamine quantity limits (Reference: AAAAI/ACAAI guideline on diagnosis and management acute and chronic urticaria (J Allergy Clin Immunol 2014 May;133(5):1270)
   AND
   (b) One H1-antihistamine IN COMBINATION with leukotriene receptor antagonist [(LTRA): montelukast (Singulair), zafirlukast (Accolate), zileuton (Zyflo)] 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 [e.g., cimetidine (Tagamet), famotidine (Pepcid), nizatidine (Axid), ranitidine (Zantac)] 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 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. MODERATE-TO-SEVERE PERSISTENT ALLERGIC ASTHMA
1. Documented diagnosis of moderate to severe persistent asthma
   AND
2. Documented diagnosis of allergic asthma
   AND
3. 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. Member has experienced exacerbation(s) or hospitalization(s), within the last 12 months documented by any of the following [DOCUMENTATION REQUIRED]:
   i. TWO (2) 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. Two-fold increase or greater in the dose of systemic corticosteroid treatment for asthma exacerbations OR
   iii. Asthma worsens upon tapering of oral corticosteroid therapy OR
   iv. Mechanical ventilation in the past 12 months OR
   v. 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

vi. Forced expiratory volume in 1 second (FEV1) < 80% predicted OR
vii. FEV1/forced vital capacity (FVC) < 0.80

AND

5. Symptoms inadequately controlled (as documented in criteria above) by the following adherent regimen of at least 3 months (within the past 90 days): (a) or (b)
   a. COMBINATION THERAPY of high-dose inhaled corticosteroid (ICS) AND an asthma controller medication with or without oral corticosteroid:
      i. Maximally tolerated dose of inhaled ICS (appropriately adjusted for age), OR Documented serious side effects, FDA labeled contraindication, or hypersensitivity to ICS [Appendix 2: Suggested total daily dosages for inhaled corticosteroids (ICS)]
      AND
      ii. ONE of the following ASTHMA CONTROLLER MEDICATION (LABA, LTRA, LAMA, AND theophylline), OR documented serious side effects, FDA labeled contraindication, or hypersensitivity to all these medications (LABA, LTRA, LAMA, AND theophylline)
         - Long-acting beta-2 agonist (LABA) [e.g., salmeterol products (Serevent) formoterol (Foradil)], OR
         - Leukotriene receptor antagonist (LTRA) [e.g., montelukast (Singulair); zafirlukast (Accolate); zileuton (Zyflo)], OR
         - Long-acting muscarinic antagonist (LAMA) [e.g., tiotropium bromide inhalation spray (Spiriva, Respimat)], OR
         - Theophylline (Theo-24, Uniphyl, TheoChron ER, generics)

   OR

   b. Combination ICS/LABA at maximum recommended doses or maximally tolerated dose [i.e., fluticasone/salmeterol (Advair), mometasone/formoterol (Dulera), budesonide/formoterol (Symbicort); fluticasone/vilanterol (Breo Ellipta)]
   MOLINA REVIEWER: 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. Xolair is prescribed concomitantly with an ICS plus either a LABA or LTRA OR Member has a documented intolerance, FDA labeled contraindication, or hypersensitivity to the standard therapies
   AND
9. Prescriber attests or clinical reviewer has found that Xolair 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)
   AND
10. Documentation of member's serum total IgE level (IU/ml) prior to the start of treatment and member's current body weight (within the last 30 days)

C. NASAL POLYPS:
   1. Documented diagnosis of chronic rhinosinusitis with nasal polyposis
      AND

2. 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 intranasal steroids OR preferred formulary oral corticosteroids
   AND
3. Prescriber attests that member has a history of sino-nasal surgery or is not eligible for surgery
   AND
4. Member is concurrently receiving treatment with one of the following agents: Intranasal steroids, Oral corticosteroids, Nasal saline irrigations, Antibiotics, or antileukotriene agents
   AND
5. Prescriber attests that Xolair (omalizumab) will not be used as monotherapy
   AND
6. Documentation of member's serum total IgE level (IU/ml) prior to the start of treatment and member's current body weight (within the last 30 days)
   AND
7. 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)
   AND
8. Prescriber attests or clinical reviewer has found that Xolair 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 (resilizumab), 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 IDIOPATHIC URTICARIA
   1. Clinical improvement as documented by improvement from baseline using objective clinical evaluation tools within the past 30 days [e.g., 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]

C. MODERATE-TO-SEVERE PERSISTENT ALLERGIC ASTHMA
   1. Positive clinical improvement (from pre-Xolair treatment baseline) as documented by ONE or more of the following:
      a. Improvement in lung function (increase in percent predicted FEV1 or PEF) from pre-treatment baseline

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 wakening wheezing, sustained improvement in 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 wakening, fatigue, sleep disturbance, or asthmatic symptoms upon awakening)

MOLINA REVIEWER NOTE: For members with unclear response after initial use, see Background (GINA 2022).
AND

2. Xolair is used in combination with other medications for long-term control of asthma [e.g., inhaled corticosteroids, long-acting beta-2 agonists (LABA), leukotriene receptor antagonists (LTRA), Long-acting muscarinic antagonist (LAMA), theophylline]

D. NASAL POLYPS:
1. Documentation of significant reduction in nasal congestion, loss of smell or sino-nasal symptoms reported at initial authorization

DURATION OF APPROVAL:
Initial authorization: 6 months, Continuation of therapy: 12 months

PRESCRIBER REQUIREMENTS:
Prescribed by, or in consultation with, an allergy/asthma specialist (allergist, immunologist, pulmonologist), dermatologist, or otorhinolaryngologist.
[If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:
Chronic idiopathic urticaria: 12 years of age and older
Asthma: 6 years of age and older
Nasal polyposis:18 years 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 OR 2 x 150mg vials)
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 Idiopathic 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) and body weight, measured before start of treatment.
For nasal polyps: MAX 600 mg every 2 weeks, with dosing determined by serum IgE level (IU/mL) and body weight, measured before start of treatment.

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)

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Subcutaneous

DRUG CLASS:
Monoclonal Antibody, Anti-Asthmatic

FDA-APPROVED USES:
XOLAIR® (omalizumab) for injection is indicated for:
Chronic spontaneous urticaria: Treatment of chronic spontaneous urticaria in adults and adolescents 12 years of age and older who remain symptomatic despite H1 antihistamine treatment *Limitation of Use: Not indicated for other allergic conditions or other forms of urticaria.*

Asthma: Treatment of moderate to severe persistent asthma in adults and pediatric patients 6 years of age and older who have a positive skin test or in vitro reactivity to a perennial aeroallergen and symptoms are inadequately controlled with inhaled corticosteroids
Limitation of Use: Not indicated for acute bronchospasm or status asthmaticus

Nasal polyps: Treatment of nasal polyps in adult patients 18 years of age and older with inadequate response to nasal corticosteroids, as add-on maintenance treatment

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

- 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.

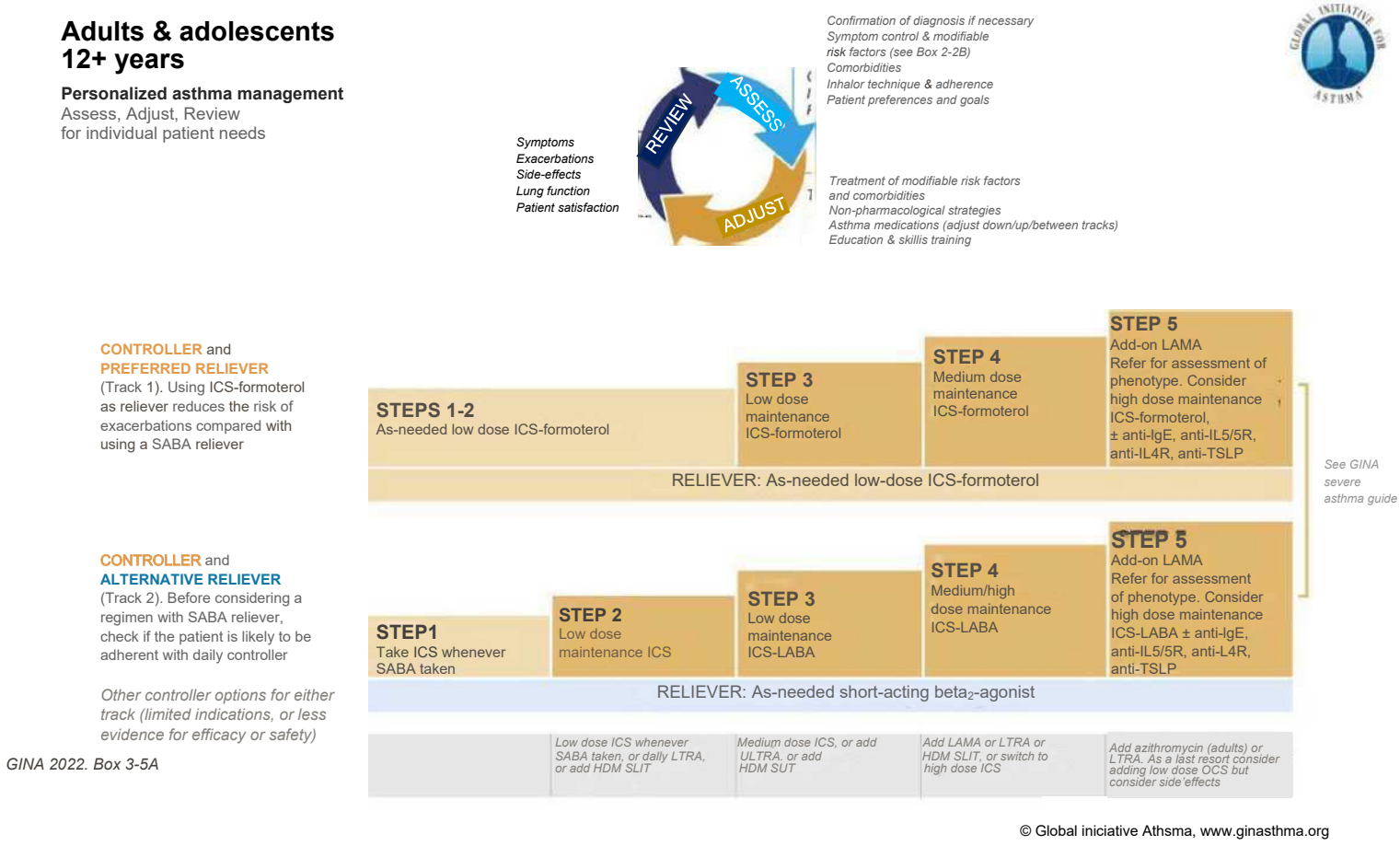
Inhaled Corticosteroids (list not all inclusive):
Beclometasone dipropionate (QVAR)
Budesonide DPI (Pulmicort Flexhaler)
Budesonide nebules (Pulmicort Respules)
Ciclesonide (Alvesco)
Flunisolide (Aerospan)
Mometasone furoate (Asmanex Twisthaler)
Mometasone furoate (Asmanex HFA)*
Fluticasone furoate (Arnuity Ellipta)
Fluticasone propionate (Flovent Diskus)
Fluticasone propionate (Flovent HFA)
**HFA: hydrofluoroalkane propellant metered dose inhaler*
**DPI: dry powder inhaler*

Combination Long-Acting Bronchodilator and Corticosteroid (list not all inclusive):
Budesonide/formoterol (Symbicort)
Fluticasone/salmeterol (Advair Diskus)
Fluticasone/salmeterol (Advair HFA)
Fluticasone/vilanterol(Breo Ellipta)
Mometasone/formoterol (Dulera)

Leukotriene receptor antagonist (LTRA) (list not all inclusive):
Montelukast (Singulair), Zafirlukast (Accolate), Zileuton (Zyflo)

- 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 3weeks of testing when asthma is in good control.

APPENDIX 1: Managing Asthma in Adults and Adolescents 12+ Years



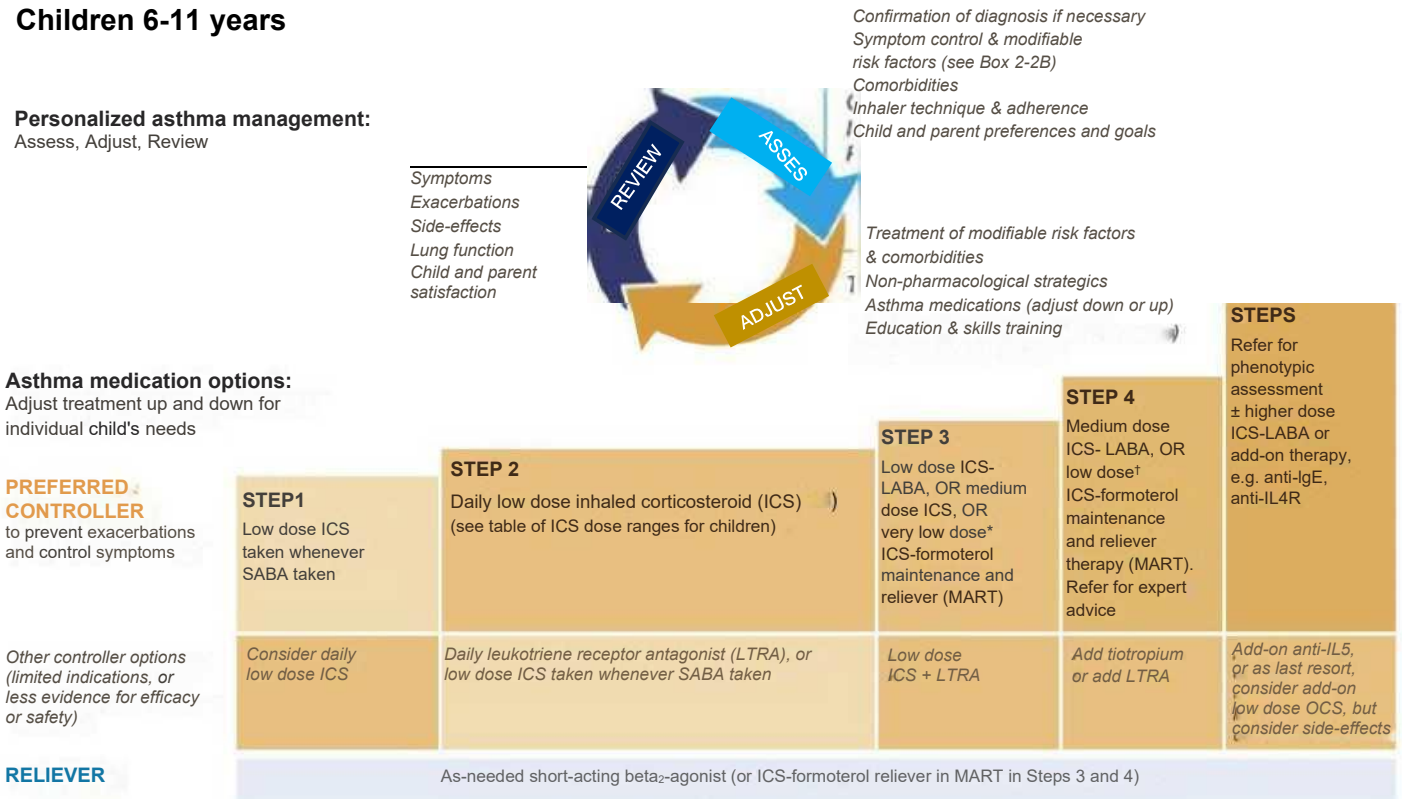
ABBREVIATIONS: HDM: house dust mite; ICS: inhaled corticosteroid; LABA: long-acting beta2-agonist; LAMA: long-acting muscarinic antagonist; LTRA: Leukotriene Receptor Antagonist; OCS: oral corticosteroids; SABA: short-acting beta2-agonist; SLIT: sublingual immunotherapy

REFERENCE: Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2022. Available from: www.ginasthma.org

Managing Asthma in Children 6-11 Years

Managing Asthma in Children 6-11 Years

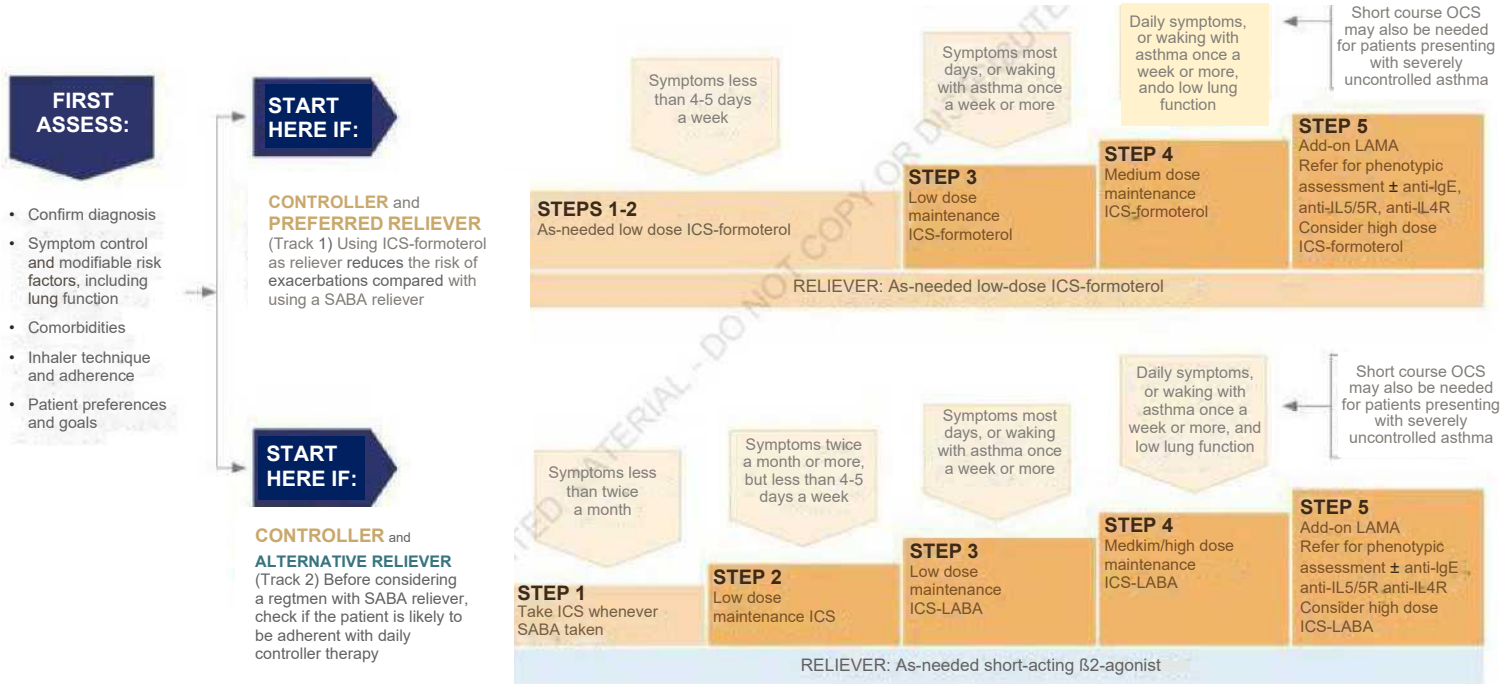
Children 6-11 years



*Very low dose: BUD-FORM 100/6 mcg
†(Low dose: BUD-FORM 200/6 mcg (metered doses).

Box 3-5B © Global Initiative for Asthma 2022, www.ginasthma.org

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, 2022. Available from: www.ginasthma.org



ICS: inhaled corticosteroid; LABA, long-acting beta$_2$-agonist; LAMA, long-acting muscarinic antagonist; MART, maintenance and reliever therapy with ICS-formoterol: OCS: oral corticosteroids; SABA: short-acting beta$_2$-agonist

APPENDIX 2: SUGGESTED TOTAL DAILY DOSAGES for INHALED CORTICOSTEROIDS (ICS) IN ADULTS AND ADOLESCENTS (12 years and older):

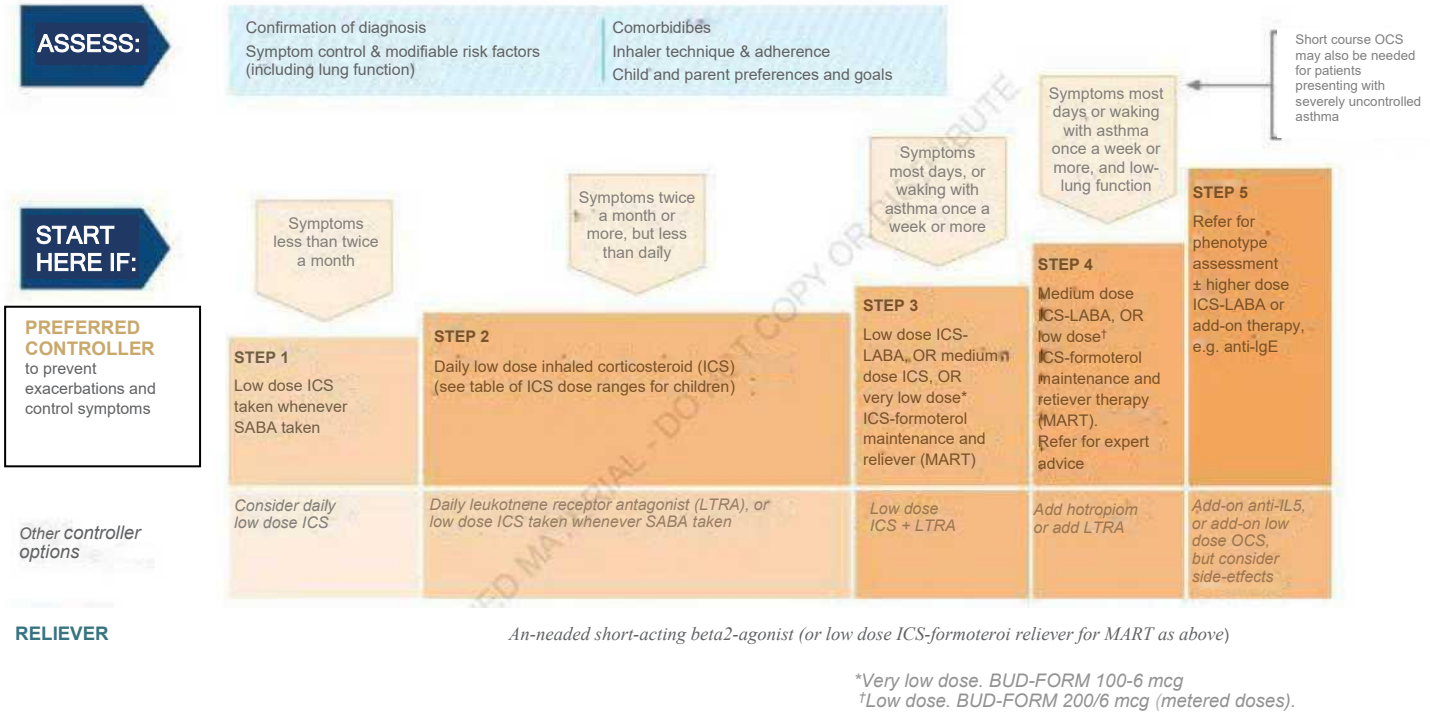
Inhaled Corticosteroid	Low Dose ICS (mcg)	Medium Dose ICS (mcg)	High Dose ICS (mcg)
Beclometasone dipropionate (pMDI, standard particle, HFA)	200-500	>500-1000	>1000
Beclometasone dipropionate (DPI or pMDI, extrafine particle, HFA)	100-200	>200-400	>400
Budesonide (DIP, or pMDI, standard particle, HFA)	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 (pMDI, standard particle, HFA)	200-400	200-400	>400

Reference: Box 3-6. 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, 2022. Available from: 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)	100-200	>200-400	>400
Budesonide (nebules)	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 3-6. 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, 2022. Available from: www.ginasthma.org



BUD-FORM; budesonlde-formoterol; ICS. inhaled corticosteroid; LABA: long-acting beta$_2$-agonist. LTRA. leukotriene receptor antagonist; MART, maintenance and reliever therapy with ICS-formoterol; OCS. oral corticosteroids. SABA: short-acting beta$_2$-agonist

Drug	Low Daily Dose Adult	Medium Daily Dose Adult	High Daily Dose Adult
Beclomethasone HFA 40 or 80 mcg/puff	80-240 mcg	>240-480 mcg	>480 mcg
Budesonide DPI 90, 180, or 200 mcg/inhalation	180-600 mcg	>600-1,200 mcg	>1,200 mcg
Flunisolide 250 mcg/puff	500-1,000 mcg	>1,000-2,000 mcg	>2,000 mcg
Flunisolide HFA 80 mcg/puff	320 mcg	>320-640 mcg	>640 mcg
Fluticasone **HFA/MDI:** 44, 110, or 220 mcg/puff **DPI:** 50, 100, or 250 mcg/mhaiation	88-264 mcg 100-300 mcg	>264-440mcg >300-500 mcg	>440 mcg >500 mcg
Mometasone DPI 200 mcg/inhalation	200 mcg	400 mcg	>400 mcg
Triamcinolone acetonide 75 mcg/puff	300-750 mcg	>750-1,500 mcg	>1,500 mcg

Key: DPI, dry powder inhaler; HFA hydrofluoroalkane; MDI, metered-dose inhaler

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 theUAS7 (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

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 ≥ 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 ≥6 years with severe allergic asthma with elevated IgE levels may benefit from omalizumab (anti-IgE) therapy (Evidence A).

• 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

• 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 can be considered in patients whose symptoms remain poorly controlled.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of Xolair 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.

DISCONTINUATION: Poor response to treatment as evidenced by physical findings and/or clinical symptoms; Intolerable adverse effects or drug toxicity; Persistent and uncorrectable problems with adherence to treatment EXCLUSION: Xolair is not used in combination with either 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 therapy [e.g. Tezspire (tezepelumab)].

OTHER SPECIAL CONSIDERATIONS:

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

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
J2357	Injection, omalizumab, 5 mg

AVAILABLE DOSAGE FORMS:
Xolair 150mg Powder for Injection (vial)
Xolair 150mg/mL Prefilled Syringe Solution for Injection
Xolair 75mg/0.5mL Prefilled Syringe Solution for Injection

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SUMMARY OF REVIEW/REVISIONS	DATE
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