Effective Date:
Last P&T Approval/Version: 10/27/2021
NextReview Due By: 11/2022
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 itscoverage 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 otherpractice 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 forthe 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 untilthe 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 IDIOPATHICURTICARIA
   1. Diagnosis of Chronic Idiopathic Urticaria (CIU) 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 has been ruled out, including bradykinin-related angioedema and interleukin-1-associated urticarial syndromes (auto- inflammatory disorders, urticarial vasculitis); AND if applicable, possible conditions or triggers for urticaria are being maximally managed without improvement
      AND

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3. 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 LifeQuality Index (DLQI), Angioedema Quality of Life (AE-QoL), or Chronic Urticaria Quality of Life Questionnaire(CU-Q2oL)]
   AND
4. Documentation that member continues to experience hives associated with itching despite adequate trials, minimum 4 weeks, of ALL of the following treatments. Prescriber to submit documentation of trial/failure with dates to drug therapy:
   (a) Two (2) different H1-antihistamines at the maximally tolerated doses (up to 4 times normal dose daily dose], unless medically contraindicated asmonotherapy
   NOTE: First generation H1 antihistamine (doxepin, hydroxyzine, cyproheptadine), second generation H1 antihistamine (cetirizine, levocetirizine, fexofenadine, loratadine, desloratadine), H2 antihistamine (ranitidine, famotidine, cimetidine)
   - MOLINA REVIEWER: *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 (1) H1-antihistamine IN COMBINATION with leukotriene receptor antagonist [(LTRA): montelukast (Singulair), zafirlukast (Accolate), zileuton (Zyflo)] at the maximally tolerated doses (up to 4 times normal dose daily dose), unless medically contraindicated AND
   (c) A H1-antihistamine at the maximally tolerated doses (up to 4 times normal dose 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
5. Xolair dosing requested is in accordance with the FDA-approved labeling for member's treatment of chronic idiopathic urticaria.

B. MODERATE-TO-SEVERE PERSISTENT ALLERGICASTHMA

1. Documentation of Diagnosis of moderate to severe persistent asthma as defined by the National Asthma Education and Prevention Program (NAEPP) (Step 3-6) or Global Initiative for Asthma (GINA;2019) (Step 3-6) – See Appendix
   AND
2. Allergic asthma confirmed by positive skin testing (i.e., prick/puncture test, intracutaneous test) or invitro reactivity (i.e., RAST, MAST, FAST, ELISA) to at least one perennial aeroallergen
   AND
3. Pre-treatment serum total IgE levels (measured prior to start of treatment): greater than or equal to 30IU/mL and less than or equal to 1500IU/mL
   AND
4. Asthma symptoms have not been adequately controlled by inhaled corticosteroids after at least3 months of therapy by member has experiencing exacerbation(s) or hospitalization(s), within the last 12 months documented by any of the following:
   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 therapyOR
   iv. Mechanical ventilation in the past 12months
      OR
   v. Poor symptom control indicated by Asthma Control Questionnaire (ACQ) score consistentlygreater than 1.5 or Asthma Control Test (ACT) score consistently less than 20

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OR

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

AND

5. Inadequate symptom control (as documented in criterion above) demonstrated by a compliant, trial of at least 3 months of ONE of the following:
   a) Combination controller therapy of medium- to high- dose inhaled corticosteroids plus long- acting beta-2 agonists (LABA) or leukotriene receptor antagonists (LTRA)-- (GINA 2018),
   OR
   b) LABA plus either a LTRA, Long-acting muscarinic antagonist (LAMA), or theophylline,
   OR
   c) Member has a documented intolerance, FDA labeled contraindication, or hypersensitivity to the standard therapies (in #5aand #5b)

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. Not prescribed for concurrent use with either of the following: Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)], OR Anti-interleukin 5 therapy [e.g., Nucala (mepolizumab), Cinqair (resilizumab), Fasenra (benralizumab)]
   AND
10. Xolair dosing requested is within the defined dosing of the FDA-approved labeling based on pre-treatment serum IgE level and member's body weight

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 intolerance to one of the following medications unless contraindicated: preferred formulary intranasal steroids OR preferred formulary oral corticosteroids
   AND
3. 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 (a, b, c, d or e): (a)Intranasal steroids, (b) Oral corticosteroids, (c) Nasal saline irrigations (d) Antibiotics or (e) antileukotriene agents
   AND
5. Documentation of members serum total IgE level (IU/ml) prior to the start of treatment and member's body weight

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 aninfection, causing temporary discontinuation (documentation required)

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AND

2. Member has not experienced ANY of the following: Intolerable adverse effects or absence of 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, worseningpulmonary symptoms, cardiac complications, and/ or neuropathy, especially upon reduction of oral corticosteroids]; Poor response to treatment as evidenced by physical findings and/or clinical symptoms
   AND
3. Xolair dosing requested is in accordance with the FDA-approved labeling for member's treatment

B. CHRONIC IDIOPATHICURTICARIA
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), AngioedemaQuality of Life (AE- QoL), or Chronic Urticaria Quality of Life Questionnaire(CU- Q2oL)].Documentation of current UAS7, AAS, DLQI, AE-QoL, or Cu-Q2oL must be submitted.

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. Reduction use of ICS, leukotriene or beta agonist therapy
   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)

   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], OR Member has a documented intolerance, FDA labeled contraindication, or hypersensitivity to the standard therapies
   AND
3. 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 (resilizumab), Fasenra (benralizumab)]

D. NASAL POLYPS:
1. Documentation of significant reduction in nasal congestion, loss of smell or sino-nasal symptoms reported at initial authorization
   AND
2. 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 (resilizumab), Fasenra (benralizumab)]

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

PRESCRIBER REQUIREMENTS:
Chronic idiopathic urticaria and Asthma:
Prescribed by, or in consultation with, an allergy/asthma specialist (allergist, immunologist, or pulmonologist) or dermatologist (for CIU).
Nasal polyposis: Prescribed by or in consultation with an otolaryngologists. [If prescribed in consultation, consultation notes must be submitted within initial request and reauthorization requests]

AGE RESTRICTIONS:
Chronic idiopathic urticaria: 12 years of age or older; Asthma: 6 years of age or 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 2x 150mg vials
Dose (375mg) = 1 x 75mg syringe + (2 x 150mg syringe OR 2x 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
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: 75 to 600 mg SC every 2 or 4 weeks.
Maximum quantity and frequency allowable is the recommended subcutaneous XOLAIR Doses Every 2 or 4 Weeks for Adult Patients with Nasal Polyps per product FDA label per member's Pretreatment Serum IgE (IU/mL)and bodyweight.*

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

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DRUG CLASS:
Monoclonal Antibody, Anti-Asthmatic

FDA-APPROVED USES:
XOLAIR® (omalizumab) for injection is indicated for:
Chronic idiopathic urticaria: Treatment of chronic idiopathic urticaria in adults and adolescents 12 years and older who remain symptomatic despite H1 antihistamine treatment Not for treating other forms of urticaria.

Asthma: Treatment of moderate to severe persistent asthma in adults and patients 6 years and older who have a positive skin test or in vitro reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids

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 overthe 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 (PulmicortFlexhaler)
Budesonide nebules (Pulmicort Respules)
Ciclesonide (Alvesco)
Flunisolide (Aerospan) Mometasonefuroate (Asmanex Twisthaler) Mometasone furoate (Asmanex HFA) 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 andrace.
- PEF (peak expiratory flow): PEF is often described as a percent of personal best measurement.

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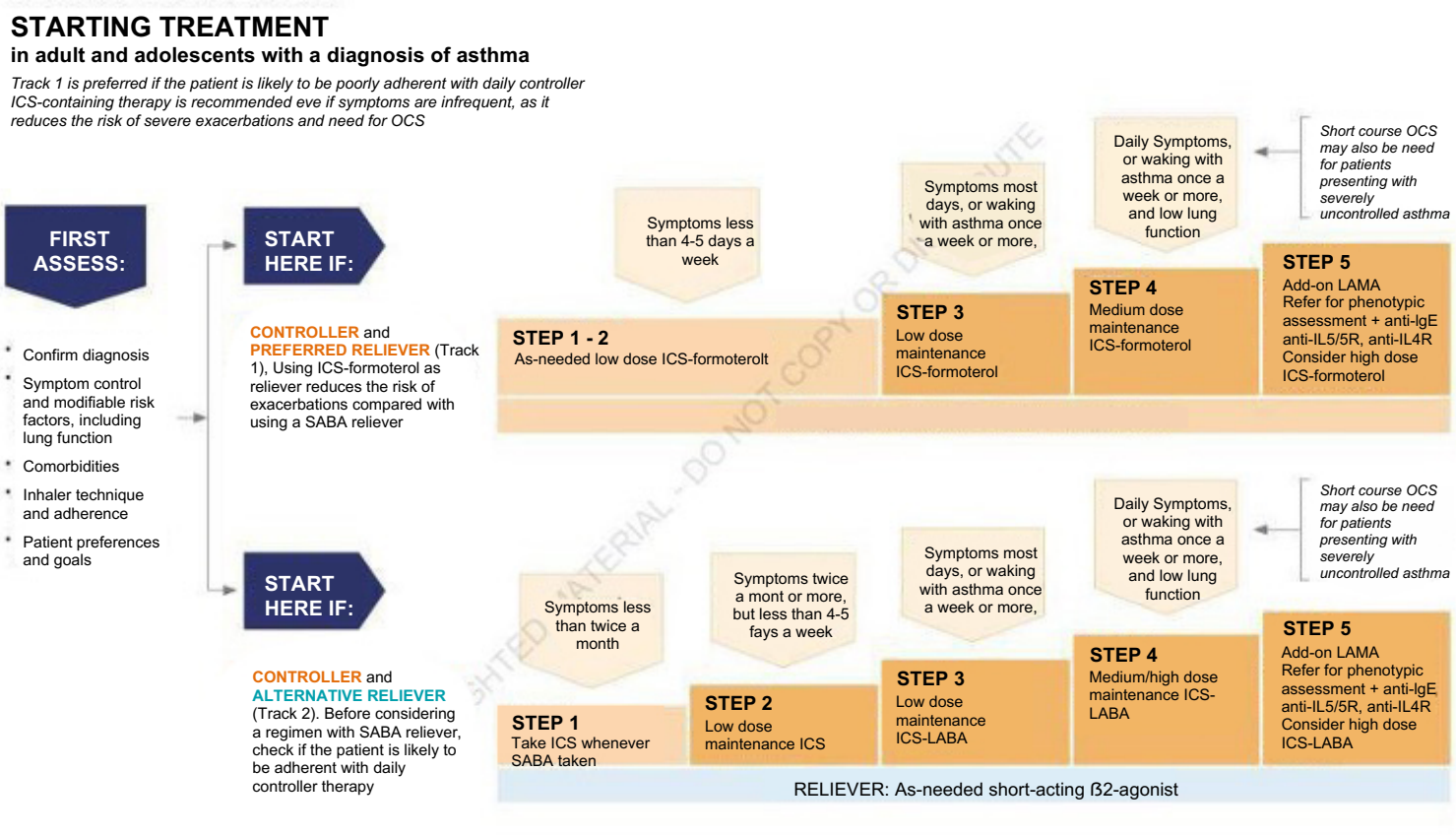
Personal best PEF is the highest PEF value attained after 2 to 3weeks of testing when asthma is in good control.

APPENDIX 1: Managing Asthma in Youths > 12 years of age and adults



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

NOTE: Alphabetical order is used when more than one treatment option is listed within either preferred or alternative therapy. ABBREVIATIONS: ICS, inhaled corticosteroid; LABA, inhaled long-acting beta2-agonist; Leukotriene Receptor Antagonists (LTRAs), SABA, inhaled short-acting beta2-agonist
REFERENCE: Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2021. Available from www.ginasthma.org

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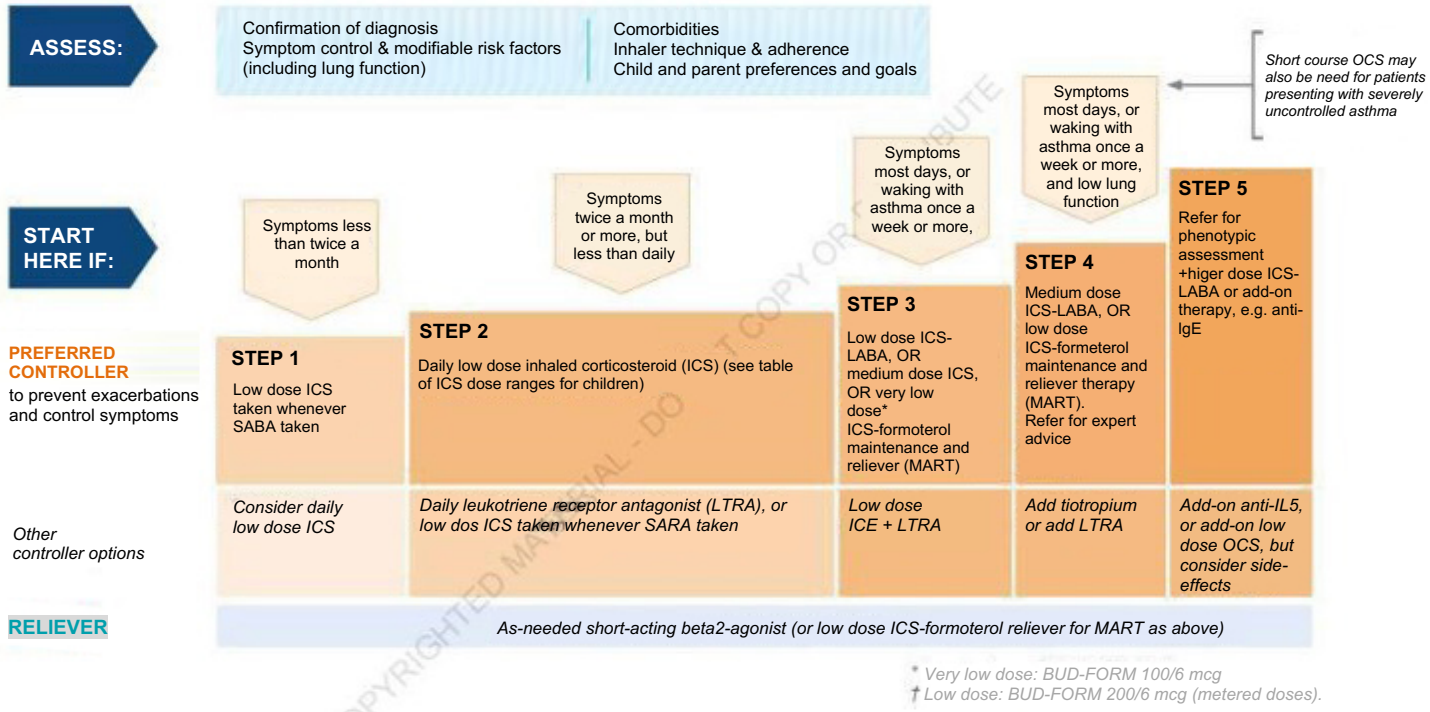
STARTING TREATMENT

Children 6-11 years with a diagnosis of asthma



BUD-FORM: budesonide-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

ESTIMATED COMPARATIVE DAILY DOSAGES for INHALEDCORTICOSTEROIDS (ICS) in YOUTH ≥12 YEARS of AGE and ADULTS:

Drug	Low Daily Dose Adult	Medium Daily Dose Adult	High Daily Dose Adult
Beciomethasone HFA 40 o 80 mcg/puff	80-240 mcg	>240-80 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/inhalation	88-264 mcg 100-300 mcg	>264-440 mcg >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

Reference: Section 4, Stepwise Approach for Managing Asthma in Youths ≥12 Years of Age and Adults Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma. National Asthma Education and Prevention Program, Third Expert Panel on the Diagnosis and Management of Asthma. Bethesda (MD): National Heart, Lung, and Blood Institute(US); 2007 Aug.

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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, memberevaluation 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 injectionevery 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 senseof 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 yearsand older with allergies and Step 5 or 6 (severe) asthma whose symptoms have not been controlled by ICSand LABA.

The Global Initiative for Asthma (GINA, 2021) 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).

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

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the followingstep-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)]

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

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AVAILABLE DOSAGE FORMS:

Xolair 150mg Powder for Injection (vial); Xolair 150mg/mL Prefilled Syringe Solution for Injection; Xolair75mg/0.5mL Prefilled Syringe Solution for Injection

REFERENCES

1. Xolair (omalizumab) [prescribing information]. San Francisco, CA: Genentech Inc; July 2021
2. Global Initiative for Asthma. Global strategy for asthma management and prevention. Updated 2021.Available at:http://www.ginasthma.org.
3. National Asthma Education and Prevention Program (NAEPP). Expert Panel Report 3(EPR-3): Guidelines for the Diagnosis and Management of Asthma. Clinical Practice Guidelines, NationalInstitutesof Health, National Heart, Lung, and Blood Institute, NIHPublication No. 08-4051, prepublication 2007. http://www.nhlbi.nih.gov/guidelines/asthma/asthgdln.pdf. Accessed March 2019.
4. 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. Bernstein J,et al. Practice parameter: the diagnosisand management of acute and chronic urticaria: 2014 update. J Allerg Clin Immunol. 2014;133(5):1270-1277.
5. Bernstein JA, Lang DM, Khan DA, et al. The diagnosis and management of acute and chronicurticaria:2014 update. J Allergy Clin Immunol. 2014; 133(5); 1270-1277.
6. Fine LM, Bernstein JA. Guideline of Chronic Urticaria Beyond. Allergy Asthma ImmunolRes. 2016 September; 8(5): 396-403.
7. Ghazanfar MN, Thomsen SF. Successful and safe treatment of chronic spontaneous urticaria with omalizumab in a woman during two consecutive pregnancies. Case Rep Med. 2015
8. González-Medina M, Curto-Barredo L, Labrador-Horrillo M, Giménez-Arnau A. Omalizumab use during pregnancy for chronic spontaneous urticaria (CSU): report of two cases. J Eur Acad Dermatol Venereol.2017;31(5):e245-e246
9. Maurer, Marcus, M.D., et al. Omalizumab for the Treatment of Chronic Idiopathic or Spontaneous Urticaria. The New England Journal of Medicine. 2013; 368:924-935.
10. Schaefer, Paul MD, PhD. Acute and Chronic Urticaria: Evaluation andTreatment.AmericanAcademy ofFamily Physicians. 2017; 95 (11): 717-724.
11. Zuberbier T, Aberer W, Asero R, et al. EAACI/GA (2) LEN/EDF/WAO guideline for the Definition,Classification, Diagnosis and Management of Urticaria. The 2017 Revision and Update. Allergy. 2018
Jan 15. doi:10.1111/all.13397.
12. Zuberbier T, Aberer W, Asero R, et al. The EAACI/GA(2) LEN/EDF/WAO Guideline for the definition, classification, diagnosis, and management of urticaria: the 2013 revision and update.Allergy 2014;69:868-87.
13. Rosenfeld RM, Piccirillo JF, Chandrasekhar SS, et al. Clinical practice guideline (update):adultsinusitis. Otolaryngol Head Neck Surg 2015; 152:S1.
14. Rudmik L, Soler ZM. Medical Therapies for Adult Chronic Sinusitis: A Systematic Review.JAMA2015; 314:926.

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