Mass General Brigham
Health Plan

Asthma and Allergy Injectables
Cinqair (reslizumab)
Dupixent (dupilumab)
Fasenra (benralizumab)
Nucala (mepolizumab)
Xolair (omalizumab)
Tezspire (tezepelumab-ekko)
Effective 07/31/2023

Plan	☒ MassHealth ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☒ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☒ Medical Benefit (NLX)		
Specialty Limitations	These medications have been designated specialty and must be filled at a contracted specialty pharmacy when obtained through the pharmacy benefit.		
Contact Information	**Specialty Medications**		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	Cinqair is available on the Medical Benefit only		

Overview

Cinqair and Fasenra are interleukin-5 antagonist monoclonal antibodies indicated for:

- Add-on maintenance treatment of severe asthma for members with an eosinophilic phenotype.

Nucala is an interleukin-5 antagonist monoclonal antibody indicated for*:*

- Treatment of severe asthma with an eosinophilic phenotype
- Eosinophilic granulomatosis with polyangiitis
- Hypereosinophilic syndrome (HES)
- Chronis rhinosinusitis with nasal polyps (CRSwNP)

Dupixent is an interleukin-4 receptor alpha agonist indicated for:

- Atopic Dermatitis
- Chronis rhinosinusitis with nasal polyps (CRSwNP)
- Moderate to severe asthma with an eosinophilic phenotype
- Eosinophilic esophagitis (EoE)
- Prurigo nodularis (PN)

Xolair is an anti-IgE antibody indicated for:

- Treatment of moderate to severe persistent allergic asthma
- Chronic Idiopathic Urticaria (CIU)
- Treatment of nasal polyps in adults

Tezspire is a thymic stromal lymphopoietin (TSLP) blocker monoclonal antibody IgG2λ indicated for:

- Add-on maintenance treatment of adult and pediatric patients 12 years of age and older with severe asthma

Drugs that require PA
Cinqair (reslizumab) [MB]
Dupixent (dupilumab) [PD]
Fasenra (benralizumab) [DUAL]
Nucala (mepolizumab) [DUAL]
Tezspire (tezepelumab-ekko) [DUAL]
Xolair (omalizumab) [DUAL]

PD=preferred drug. (Requirement of a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class.)
MB This drug is available through the health care professional who administers the drug or in an outpatient Up or inpatient hospital setting. The plan does not pay for this drug to be dispensed through the retail pharmacy
DUAL This drug is available through both pharmacy and medical benefits

Coverage Guidelines
Authorization may be reviewed on a case by case basis for members new to the plan who are currently receiving treatment and stable with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance program
OR
Authorization may be granted for members who meet all the following criteria and documentation has been provided:

Chronic Idiopathic Urticaria (CIU)
Xolair (omalizumab)
ALL of the following:

1. Diagnosis of chronic idiopathic urticaria
2. Prescriber is a specialist (i.e., allergist/immunologist or dermatologist) or consult notes from a specialist are provided
3. Member is ≥ 12 years of age
4. Paid claims or physician documented inadequate response (defined as ≥14 days of therapy) or adverse reaction to at least **TWO** different histamine$_1$ antihistamines, or contraindication to **ALL** histamine$_1$ antihistamines (See appendix for examples)
5. Paid claims or physician documented inadequate response (defined as ≥14 days of therapy), adverse reaction or contraindication to a histamine$_1$ antihistamine in combination with a histamine$_2$ antihistamine (See appendix for examples)
6. Appropriate dosing: 150 mg or 300 mg every 28 days. (See Appendix for dosing requests > 300 mg every 28 days)
7. If request is for the 150 mg syringe, medical necessity for the 150 mg syringe instead of the 150 mg vial (e.g., member will be self-administering)

Eosinophilic granulomatosis with polyangiitis (EGPA)
Nucala (mepolizumab)
ALL of the following:

1. Diagnosis of eosinophilic granulomatosis with polyangiitis
2. Member is ≥ 18 years of age

3. Prescriber is a specialist (i.e., allergist, cardiologist, hematologist, immunologist, pulmonologist, rheumatologist, etc.) or consult notes from a specialist are provided
4. Paid claims or physician documented inadequate response (defined as ≥ 30 days of therapy) or adverse reaction to **ONE** systemic glucocorticoid, or contraindication to **ALL** systemic glucocorticoids
5. **ONE** of the following:
    a. Paid claims or physician documented inadequate response (defined as ≥ 30 days of therapy), adverse reaction to **ONE** of the following*:*
        i. azathioprine
        ii. methotrexate
    b. Documented contraindication to **BOTH** of the following:
        i. azathioprine
        ii. methotrexate
6. Appropriate dosing (300 mg subcutaneously every 28 days)

Hypereosinophilic syndrome (HES)
Nucala (mepolizumab)
ALL of the following:
1. Diagnosis of hypereosinophilic syndrome
2. Documentation of diagnosis without an identifiable non-hematologic secondary cause
3. Prescriber is a specialist (i.e., allergist, cardiologist, GI, hematologist, immunologist, pulmonologist, etc) or consult notes from a specialist are provided
4. Member is ≥12 years of age
5. Paid claims or physician documented inadequate response (defined as ≥ 30 days of therapy) or adverse reaction to **ONE** systemic glucocorticoid, or contraindication to **ALL** systemic glucocorticoids
6. **ONE** of the following:
    a. Paid claims or physician documented inadequate response (defined as ≥ 30 days of therapy) or adverse reaction to **ONE** of the following:
        i. hydroxyurea
        ii. methotrexate
        iii. interferon alfa
    b. Documented contraindication to **ALL** of the following:
        i. hydroxyurea
        ii. methotrexate
        iii. interferon alfa
7. Appropriate dosing (300 mg subcutaneously every 28 days)

Moderate to Severe Allergy Related Asthma
Xolair (omalizumab)
ALL of the following:
1. Diagnosis of moderate to severe allergy-related asthma
2. Member is ≥ 6 years of age
3. Paid claim or physician documentation that the member is symptomatic despite receiving **ONE** of the following:
    a. Combination inhaler (Advair®, Breo®, Dulera®, fluticasone/salmeterol [Airduo®], or Symbicort®)
    b. Combination of an inhaled corticosteroid (Alvesco®, ArmonAir®, Arnuity®, Asmanex®, Flovent®, Pulmicort® or Qvar®) **AND** a long-acting β-agonist inhaler (Serevent®)
    c. Chronic oral corticosteroids (defined as ≥ 90 days of therapy within the last 120 days)
4. Baseline serum IgE between 30 IU/mL to 700 IU/mL ***see Appendix for higher IgE levels***

5. Physician documentation of evidence of specific allergic sensitivity (i.e. positive skin test or blood test [radioallergosorbent test or RAST] for IgE)
6. Prescriber is an asthma specialist (i.e., allergist, immunologist, pulmonologist) or consult notes from a specialist are provided
7. Appropriate dosing (Dosing range is 75 to 375 mg subcutaneously every two to four weeks [not exceeding 6 units/28 days for the 150 mg vial, 4 units/28 days for the 150 mg syringe, and 2 units/28 days for the 75 mg syringe]) †
8. If request is for the 150 mg syringe, medical necessity for the 150 mg syringe instead of the 150 mg vial (e.g., member will be self-administering)

Moderate to severe atopic dermatitis
Dupixent (dupilumab)
ALL of the following:
1. Diagnosis of moderate to severe atopic dermatitis
2. Member is ≥ 6 months of age
3. Prescriber is a specialist (i.e., allergist/immunologist or dermatologist) or consult notes from a specialist are provided
4. **ONE** of the following:
    a. Paid claim or physician documented inadequate response or adverse reaction to **ONE** superpotent or potent topical corticosteroid †
    b. Contraindication to **ALL** superpotent or potent topical corticosteroids*‡
5. **ONE** of the following:
    a. Paid claim or physician documented inadequate response or adverse reaction to topical tacrolimus§ or Eucrisa® (crisaborole) ‖
    b. Contraindication to both topical tacrolimus§ and Eucrisa® (crisaborole)
6. Appropriate dosing**

*Trials with topical corticosteroids may be bypassed if the request clearly states that the treatment area is a sensitive area (facial/groin) or the affected area is noted to be too widespread
‡ Trial of superpotent corticosteroid can be bypassed in children < 12 years of age
†If member has tried systemic immunomodulatory therapy and trial with a superpotent or potent topical corticosteroid has not been documented, the trial may be bypassed
‖ Trial of Eucrisa can be bypassed if disease is noted to be severe or if the affected area is noted to be too widespread (BSA ≥ 10%)
§ Trial of tacrolimus can be bypassed in children < 2 years of age or if the affected area is noted to be too widespread (BSA ≥ 10%)
**For requests for once weekly dosing, please see appendix below '*Moderate to Severe Atopic Dermatitis: Dupilumab requests for once weekly treatment' for additional guidance*

Moderate-severe eosinophilic asthma or oral corticosteroid-dependent asthma
Dupixent® (dupilumab)
ALL of the following:
1. Diagnosis of moderate-severe eosinophilic asthma or oral corticosteroid-dependent asthma
2. Member is ≥ 6 years of age
3. Paid claims or physician documentation member is symptomatic despite receiving **ONE** of the following:
    a. Combination inhaler (Advair®, Breo®, Dulera®, fluticasone/salmeterol [Airduo®], or Symbicort®)
    b. Combination of an inhaled corticosteroid (Alvesco®, ArmonAir®, Arnuity®, Asmanex®, Flovent®, Pulmicort® or Qvar®) **AND** a long-acting β-agonist inhaler (Serevent®)
    c. Chronic oral corticosteroids (defined as ≥ 90 days of therapy within the last 120 days)

4. **ONE** of the following:
    a. Physician documented evidence of an eosinophilic phenotype (i.e. peripheral blood eosinophil count ≥ 150 cells/µL, elevated sputum eosinophils or FeNO)
    b. Member is receiving chronic oral corticosteroids (defined as ≥ 90 days of therapy within the last 120 days)
    c. Member has documented concomitant diagnosis of atopic dermatitis or CRSwNP and either moderate-to-severe eosinophilic asthma or OCS-dependent asthma
5. Prescriber is an asthma specialist (i.e., allergist, immunologist, pulmonologist) or consult notes from a specialist are provided
6. Appropriate dosing

Eosinophilic Esophagitis (EoE)
Dupixent (dupilumab)
ALL of the following:
1. Diagnosis of eosinophilic esophagitis (EoE)
2. Prescriber is a specialist (i.e., allergist, hematologist, immunologist, gastroenterologist, etc.) or consult notes from a specialist are provided
3. Member is ≥ 12 years of age
4. Paid claim or physician documented inadequate response (defined as ≥ 60 days of therapy) or adverse reaction to **ONE** proton pump inhibitor, or contraindication to **ALL** proton pump inhibitors
5. Paid claim or physician documented inadequate response (defined as ≥ 30 days of therapy) or adverse reaction to budesonide or fluticasone propionate, or contraindication to **BOTH** budesonide and fluticasone propionate
6. Appropriate dosing (300 mg subcutaneously every week)

Prurigo Nodularis (PN)
Dupixent (dupilumab)
ALL of the following:
1. Diagnosis of prurigo nodularis
2. Prescriber is a specialist (i.e., allergist/immunologist or dermatologist) or consult notes from a specialist are provided
3. Member is ≥ 18 years of age
4. **ONE** of the following*:
    a. Paid claims within last 2 years or physician attestation of inadequate response or adverse reaction to **ONE** potent or superpotent topical corticosteroid, or contraindication to **ALL** potent or superpotent topical corticosteroids
    b. Paid claims or physician attestation of inadequate response or adverse reaction to **ONE** or contraindication to **ALL** intralesional corticosteroids
    c. Inadequate response, adverse reaction or contraindication to phototherapy
5. Appropriate dosing (loading dose of 600 mg subcutaneously followed by 300 mg subcutaneously every other week)

*Trials with topical or intralesional corticosteroids may be bypassed if the request clearly states that the treatment area is a sensitive area (facial/groin) or the affected area is too widespread.(>10 lesions present)

Nasal Polyps
Dupixent (dupilumab)
ALL of the following:
1. Diagnosis of nasal polyps

2. Member is ≥ 18 years of age
3. Prescriber is a specialist (i.e., allergist, immunologist, pulmonologist) or consult notes from a specialist are provided
4. **ONE** of the following:
    a. Paid claims or physician documented inadequate response or adverse reaction to **ONE** oral corticosteroid
    b. Paid claims or physician documented inadequate response or adverse reaction to **ONE** intranasal corticosteroid
    c. Inadequate response or adverse reaction to prior nasal surgery
    d. Contraindication to both oral corticosteroids and intranasal corticosteroids
5. Appropriate dosing (300 mg subcutaneously every 14 days)
6. Documentation that agent will be used as adjunctive therapy

Nasal Polyps
Nucala (mepolizumab)
Xolair (omalizumab)
ALL of the following:
1. Diagnosis of nasal polyps
2. Member is ≥ 18 years of age
3. Prescriber is a specialist (i.e., allergist, immunologist, otolaryngologist, pulmonologist) or consult notes from a specialist are provided
4. Paid claims or physician documented inadequate response or adverse reaction to **ONE** oral corticosteroid, or contraindication to **ALL** oral corticosteroids
5. Paid claims or physician documented inadequate response or adverse reaction to **ONE** intranasal corticosteroid, or contraindication to **ALL** intranasal corticosteroids
6. Appropriate dosing:
    a. Nucala: 100 mg every 4 weeks
    b. Xolair: based on weight and serum total IgE level: 75 to 600 mg every 14 to 28 days
7. If request is for Xolair 150 mg syringe, medical necessity for the 150 mg syringe instead of the 150 mg vial (e.g., member will be self-administering)
8. Documentation that agent will be used as adjunctive therapy

Severe Eosinophilic Asthma
Cinqair (reslizumab),
Fasenra (benralizumab)
Nucala (mepolizumab)
ALL of the following:
1. Diagnosis of severe eosinophilic asthma
2. Member is ≥ 6 years of age (for Nucala®), ≥ 12 years of age (for Fasenra®) or ≥ 18 years of age (for Cinqair®)
3. Paid claim or physician documentation the member is symptomatic despite receiving **ONE** of the following:
    a. Combination inhaler (Advair®, Breo®, Dulera®, fluticasone/salmeterol [Airduo®], or Symbicort®)
    b. Combination of an inhaled corticosteroid (Alvesco®, ArmonAir®, Arnuity®, Asmanex®, Flovent®, Pulmicort® or Qvar®) **AND** a long-acting β-agonist inhaler (Serevent®)
    c. Chronic oral corticosteroids (defined as ≥ 90 days of therapy within the last 120 days)

4. Physician attestation of evidence of an eosinophilic phenotype (i.e. peripheral blood eosinophil count ≥ 150 cells/µL [for Nucala® and for Fasenra®], or ≥ 400 cells/µL [for Cinqair®], elevated sputum eosinophils or FeNO)
5. Prescriber is an asthma specialist (i.e., allergist, immunologist, pulmonologist) or consult notes from a specialist are provided
6. Dosing is appropriate:
    a. Cinqair®: 3 mg/kg intravenously every 4 weeks
    b. Fasenra®: 30 mg every 4 weeks for 3 doses, then 30 mg every 8 weeks
    c. Nucala®: 100 mg subcutaneously every four weeks in those ≥ 12 years of age and 40 mg subcutaneously every four weeks in those 6 to 11 years of age

Severe Asthma

Tezspire (tezepelumab-ekko)

1. Diagnosis of severe asthma
2. Member is ≥ 12 years of age
3. Prescriber is an asthma specialist (i.e., allergist, immunologist, pulmonologist) or consult notes from a specialist are provided
4. Paid claims or physician documentation the member is symptomatic despite receiving **ONE** of the following:
    a. Combination inhaler (Advair®, Breo®, Dulera®, fluticasone/salmeterol [Airduo®], or Symbicort®)
    b. Combination of an inhaled corticosteroid (Alvesco®, ArmonAir®, Arnuity®, Asmanex®, Flovent®, Pulmicort® or Qvar®) **AND** a long-acting β-agonist inhaler (Serevent®)
    c. Chronic oral corticosteroids (defined as ≥ 90 days of therapy within the last 120 days)
5. Appropriate dosing

Continuation of Therapy

Reauthorization requires physician attestation of continuation of therapy and positive response to therapy.

Limitations

1. Initial approvals will be granted for the following:
    a. Chronic idiopathic urticaria: 4 months
    b. All other indications: 6 months
    c. Dupixent (all indications): 12 months
2. Reauthorizations will be granted for the following:
    a. Chronic idiopathic urticaria: 4 months
    b. All other diagnosis: 12 months
3. **Requests for Brand Name when generic is preferred:** In addition to any prior authorization requirements that may be listed above, if an A-rated generic equivalent is available, such prior authorization requests require medical records documenting an allergic response, adverse reaction, or inadequate response to the generic equivalent drug (history of allergic reaction to the inactive ingredients used in the manufacturing process of a certain drug is acceptable).
4. **Requests for generic when Brand Name is preferred:** There are some drugs for which the Plan has determined it will be cost effective to prefer the use of the Brand Name formulation. In this case, the generic equivalent formulation is considered non-preferred and requires prior authorization. These requests require medical records documenting an allergic response, adverse reaction, or inadequate response to the Brand Name formulation. For the most up to date list of drugs where the Brand Name formulation is

preferred, see the MassHealth Brand Name Preferred Over Generic Drug List (BOGL) at www.mass.gov/druglist.

Appendix

Appendix A:

Examples of Traditional Therapies for CIU

H_1-Antihistamines (first generation):
Brompheniramine, carbinoxamine, chlorpheniramine, clemastine, cyproheptadine, diphenhydramine, hydroxyzine, promethazine, and doxepin

H_1-Antihistamines (second generation):
acrivastine/pseudoephedrine, cetirizine, desloratadine, fexofenadine, levocetirizine, loratadine

H_2-Antihistamines:
cimetidine, famotidine, nizatidine, ranitidine

Leukotriene Modifiers:
montelukast, zafirlukast, zileuton

Appendix B:

CIU: Omalizumab requests for > 300 mg every 4 Weeks

Requests for 450 mg every four weeks or 150 mg every two weeks can be approved for 3 months. If member has not achieved adequate response to this dosing, an allowance to 600 mg every four weeks or 300 mg every two weeks can be considered for a 3-month approval if provider submits request.

Recertification with either dosing will require documentation of positive response.

Appendix C:

Table 1. Moderate to Severe Allergy-Related Asthma for Patients ≥ 12 Years of Age: Xolair® (omalizumab) administered every 2 to 4 weeks

Pre-treatment Serum IgE (IU/mL)	Body Weight (kg)			
	30-60	>60-70	>70-90	>90-150
≥ 30-100	150 mg	150 mg	150 mg	300 mg
> 100-200	300 mg	300 mg	300 mg	225 mg
> 200-300	300 mg	225 mg	225 mg	300 mg
> 300-400	225 mg	225 mg	300 mg	DO NOT DOSE
> 400-500	300 mg	300 mg	375 mg	
> 500-600	300 mg	375 mg		
> 600-700	375 mg			
Every 2 weeks dosing				
Every 4 weeks dosing				

Table 2. Moderate to Severe Allergy-Related Asthma for Patients 6 to < 12 Years of Age: Xolair® (omalizumab) administered every 2 to 4 weeks*

Pre-treatment Serum IgE (IU/mL)	Body Weight (kg)						
	20-25	>25-30	>30-40	>40-50	>50-60	>60-70	> 70-80
≥ 30-100	75 mg	75 mg	75 mg	150 mg	150 mg	150 mg	150 mg
> 100-200	150 mg	150 mg	150 mg	300 mg	300 mg	300 mg	300 mg
> 200-300	150 mg	150 mg	225 mg	300 mg	300 mg	225 mg	225 mg
> 300-400	225 mg	225 mg	300 mg	225 mg	225 mg	225 mg	300 mg
> 400-500	225 mg	300 mg	225 mg	225 mg	300 mg	300 mg	375 mg
> 500-600	300 mg	300 mg	225 mg	300 mg	300 mg	375 mg	
> 600-700	300 mg	225 mg	225 mg	300 mg	375 mg		
>700-800	225 mg	225 mg	300 mg	375 mg			
>800-900	225 mg	225 mg	300 mg	375 mg			
>900-1000	225 mg	300 mg	375 mg				
>1000-1100	225 mg	300 mg	375 mg				
>1100-1200	300 mg	300 mg					
>1200-1300	300 mg	375 mg					
Every 2 weeks dosing							
Every 4 weeks dosing							
Do Not Dose							

*Additional dosing parameters are available for patients weighing >80 kg

Table 3. Nasal Polyps for Adults: Xolair® (omalizumab) administered every 2 to 4 weeks[1]

Pre-treatment Serum IgE (IU/mL)	Body Weight (kg)						
	>30-40	>40-50	>50-60	>60-70	>70-80	>80-90	> 90-125*
30-100	75 mg	150 mg	150 mg	150 mg	150 mg	150 mg	300 mg
> 100-200	150 mg	300 mg	300 mg	300 mg	300 mg	300 mg	450 mg
> 200-300	225 mg	300 mg	300 mg	450 mg	450 mg	450 mg	600 mg
> 300-400	300 mg	450 mg	450 mg	450 mg	600 mg	600 mg	450 mg
> 400-500	450 mg	450 mg	600 mg	600 mg	375 mg	375 mg	525 mg
> 500-600	450 mg	600 mg	600 mg	375 mg	450 mg	450 mg	600 mg
> 600-700	450 mg	600 mg	375 mg	450mg	450 mg	525 mg	
>700-800	300 mg	375 mg	450 mg	450 mg	525 mg	600 mg	
>800-900	300 mg	375 mg	450 mg	525 mg	600 mg		
>900-1000	375 mg	450 mg	525 mg	600 mg			
>1000-1100	375 mg	450 mg	600mg				
>1100-1200	450 mg	525 mg	600 mg				
>1200-1300	450 mg	525 mg					
>1300-1500	525 mg	600 mg					
Every 2 weeks dosing							
Every 4 weeks dosing							
Do Not Dose							

*Refer to package insert for weight > 125 kg

Moderate to Severe Atopic Dermatitis: Dupilumab requests for once weekly treatment

Consideration can be given for a **3-month approval** of weekly dosing if member has been stable on the FDA-approved regimen of dupilumab 200 mg or 300 mg every other week for at least four months.

OR

Consideration can be given for a **12-month approval** of weekly dosing if member meets for **ANY** of the following:

- Worsening disease severity that is impacting activities of daily living
- Documentation that member initially had response/partial response on the every other week dosing but now is noting increased symptoms such as pruritus prior to next scheduled dose
- Member is currently stabilized on weekly dosing and has noted continued response to therapy
- Member has failed alternative FDA-approved therapies for moderate to severe AD such as Adbry®(tralokinumab) or oral JAK inhibitors Cibinqo®(abrocitinib) or Rinvoq®(upadacitinib) or prescriber notes rationale why these therapies are not appropriate

Recertification for weekly dosing must have documentation of continued positive response to therapy. (Approval duration: 12 months)

References

1. Xolair® [package insert]. South San Francisco (CA): Genetech Inc.; 2022 May.
2. Asthma statistics [webpage on the Internet]. South San Francisco (CA): Genentech Inc [cited 2021 Oct 18]. Available from: http://www.gene.com/gene/products/education/immunology/asthma-facts.html.
3. Rambasek TE, Lang DM, Kavuru MS. Omalizumab: where does it fit into current asthma management? Cleve Clin J Med. 2004 Mar;71(3):251-61.
4. National Asthma Education and Prevention Program Coordinating Committee Expert Panel Working Group: 2020 Focused Updates to the Asthma Management Guidelines. National Heart Lung and Blood Institute. 2020 Dec [cited 2021 Oct 18]. Available from: https://www.nhlbi.nih.gov/health-topics/all-publications-and-resources/2020-focused-updates-asthma-management-guidelines**.**
5. Global Strategy for Asthma Management and Prevention. [guideline on the internet]. Bethesda (MD): Global Initiative for Asthma (GINA); 2021 [cited 2021 Oct 16]. Available from: https://ginasthma.org/wp-content/uploads/2021/05/GINA-Main-Report-2021-V2-WMS.pdf.
6. Holgate S, Bousquet J, Wenzel S, et al. Efficacy of omalizumab, an antiimmunoglobulin E antibody, in patients with allergic asthma at high risk of serious asthma-related morbidity and mortality. Curr Med Res Opin. 2001b;17:233-40.
7. Walker S, Monteil M, Phelan K, Lasserson TJ, Walters EH. Anti-IgE for chronic asthma in adults and children. Cochrane Database Syst Rev. 2006 Apr 19;(2):CD003559.
8. Rodrigo GJ, Neffen H, Castro-Rodriguez JA. Efficacy and safety of subcutaneous omalizumab versus placebo as add on therapy to corticosteroids for children and adults with asthma: a systematic review. Chest. 2011 Jan;139(1):28-35.
9. Nucala® [package insert]. Research Triangle Park (NC): GlaxoSmithKline; 2021 Oct.
10. Nucala® (mepolizumab) product Dossier. 2015 Nov. GlaxoSmithKline. Data on file.
11. FDA Approves Nucala to treat severe asthma [press release on the Internet]. FDA.gov. Silver Spring (MD). 2015 Nov 4 [cited 2015 Dec 17]. Available from: http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm471031.htm.
12. Cinqair® [package insert]. Frazer (PA): Teva; 2020 Jun.
13. Fasenra® [package insert]. Wilmington (DE): AstraZeneca Pharmaceuticals LP; 2021 Feb.
14. Dupixent® [package insert]. Tarrytown (NY): Regeneron Pharmaceuticals, Inc.; 2021 Oct.

15. Tezspire® [prescribing information]. Thousand Oaks (CA): Amgen, Inc.; 2021 Dec.
16. Chung KF, Wenzel SE, Brozek JL, Bush A, Castro M, Sterk PJ, et al. International ERS/ATS guidelines on definition, evaluation and treatment of severe asthma. Eur Respir J. Feb 2014;43(2):343-73.
17. Wenzel S. Severe asthma phenotypes. In:Basow DS Ed). UpToDate [database on the Internet]. Waltham (MA): UpToDate; 2021 [cited 2021 Oct 18]. Available from: http://www.uptodate.com/contents/severe-asthma-phenotypes?source=machineLearning&search=eosinophilic+asthma&selectedTitle=1%7E150&sectionRank=2&anchor=H3#H111786377.
18. Garcia G, Taille C, Laveneziana P, Bourdin A, Chanez P, Humbert M. Anti-interlekin-5 therapy in severe asthma. Eur Respir Rev. 2013;22(129):251-57.
19. Hide M, Francis DM, Grattan CEH, et al Autoantibodies against the high affinity IgE receptor as a cause for histamine release in chronic urticaria. New Engl J Med 1993; 328:1599-1604.
20. Nimii N, Francis DM, Kermani F, et al Dermal mast cell activation by autoantibodies against the high affinity IgE receptor in chronic urticaria. J Invest Dermatol 1996; 106:1001-1010.
21. Fiebiger E, Maurer D, Holub H, et al Serum IgG autoantibodies directed against the α chain of Fc epsilon RI: a selective marker and pathogenetic factor for a distinct subset of chronic urticaria patients. J Clin Invest 1995; 96:2606-2612.
22. Tong LJ, Balakrishnan G, Kochan JP, et al Assessment of autoimmunity in patients with chronic urticaria. J Allergy Clin Immunol 1997; 99:461-465.
23. Bernstein JA, Lang DM, Khan DA, Craig T, Dreyfus D, Hsieh F, et al. The diagnosis and management of acute and chronic urticaria: 2014 update. J Allergy Clin Immunol. 2014;133(5):1270-7.
24. Zuberbier T, Aberer W, Asero R, Bindslev-Jensen C, Brzoza Z, Canonica GW, et al. EAACI/GA2LEN/EDF/WAO guideline for the definition, classification, diagnosis and management of urticaria. Allergy. 2018 Jul;73(7):1393-1414.
25. Grattan CE, Humphreys F, British Association of Dermatologists Therapy Guidelines and Audit Subcommittee. Guidelines for evaluation and management of urticaria in adults and children. Br J Dermatol. 2007 Dec;157(6):1116-23.
26. Groh M, Pagnoux C, Baldini C, Bel E, Bottero P, Cottin V et al. Eosinophilic granulomatosis with polyangiitis (Churg-Strauss) (EGPA) Consensus Task Force recommendations for evaluation and management. Eur J Intern Med 2015; 26:545.
27. Hellmich B, Agueda A, Monti S, Buutgereit F, de Boysson H, Brouwer E, et al. 2018 Update of the EULAR recommendations for the management of large vessel vasculitis. Ann Rheum Dis. 2020. 79:19-30. Doi: 10.1136/aarheumdis-2019-215672.
28. King TE. Treatment and prognosis of eosinophilic granulomatosis with polyangiitis (Churg-Strauss).
1. In: Basow DS (Ed). UpToDate [database on the Internet]. Waltham (MA): UpToDate; 2021 [cited 2021 Oct 18]. Available from: http://www.utdol.com/utd/index.do.
29. Roufosse F, Klion AD, Weller PF**.** Hypereosinophilic syndromes: Clinical manifestations, pathophysiology, and diagnosis**.** In: Basow DS (Ed). UpToDate [database on the internet]. Waltham (MA): UpToDate; 2021 [cited 2021 Oct 18]. Available from: http://www.utdol.com/utd/index.do.
30. Roufosse F, Klion AD, Weller PF. Hypereosinophilic syndromes: Treatment**.** In: Basow DS (Ed). UpToDate [database on the internet]. Waltham (MA): UpToDate; 2021 [cited 2021 Oct 18]. Available from: http://www.utdol.com/utd/index.do.
31. Orlandi RR, Kingdom TT, Hwang PH, Smith TL, Bleier B, DeConde A, et al. International consensus statement on allergy and rhinology: rhinosinusitis 2021. International Forum of Allergy & Rhinology. 2021; 11:213-739.
32. Fokkens WJ, Lund VJ, Hopkins C, Hellings PW, Kern R, Reitsma S, et al. European Position Paper on Rhinosinusitis and Nasal Polyps 2020. 2020 Feb;58(29): 1-481. Available from: https://www.rhinologyjournal.com/Rhinology_issues/manuscript_2353.pdf.

33. Dykewicz, MS, Wallace, DV, Amrol, DJ, Baroody, FM, Bernstein, JA, et al. Rhinitis 2020: A Practice parameter update. J Allerg Clinical Immun. 2020 Oct. 146(4):721-767. Available from: https://www.aaaai.org/Aaaai/media/MediaLibrary/PDF%20Documents/Practice%20and%20Parameters/Rhinitis-2020-A-practice-parameter-update.pdf.
34. Lanier B, Bridges T, Kulus M, Taylor AF, Berhane I, Vidaurre CF. Omalizumab for the treatment of exacerbations in children with inadequately controlled allergic (IgE-mediated) asthma. J Allergy Clin Immunol. 2009;124(6):1210-6.
35. Walker S, Monteil M, Phelan K, Lasserson TJ, Walters EH. Anti-IgE for chronic asthma in adults and children. Cochrane Database Syst Rev. 2006;19;(2):CD003559.
36. Milgrom H, Berger W, Nayak A, Gupta N, Pollard S, McAlary M, et al. Treatment of childhood asthma with anti-immunoglobulin E antibody (omalizumab). Pediatrics. 2001;108(2):E36.
37. Berger W, Gupta N, McAlary M, Fowler-Taylor A. Evaluation of long-term safety of the anti-IgE antibody, omalizumab, in children with allergic asthma. Ann Allergy Asthma Immunol. Aug 2003;91(2):182-8.
38. Kulus M, Hébert J, Garcia E, Fowler Taylor A, Fernandez Vidaurre C, et al. Omalizumab in children with inadequately controlled severe allergic (IgE-mediated) asthma. Curr Med Res Opin. 2010 Apr 8. [Epub].
39. Vignola AM, Humbert M, Bousquet J, Boulet LP, Hedgecock S, Blogg M, et al. Efficacy and tolerability of anti-immunoglobulin E therapy with omalizumab in patients with concomitant allergic asthma and persistent allergic rhinitis: SOLAR. Allergy 2004;59:709-17.
40. Xolair® (omalizumab) for subcutaneous injection - Baseline IgE levels or weight outside range. 2012 [cited 2012 May 24]. Genentech. Data on file.
41. Stokes J, Casale TB. Anti-IgE therapy. In: Basow DS (Ed). UpToDate [database on the internet]. Waltham (MA): UpToDate; 2021 [cited 2021 Oct 18] Available from: http://www.utdol.com/utd/index.do.
42. Türk M, Kocatürk E, Cüre K, Yılmazİ. Two-week intervals during omalizumab treatment may provide better symptom control in selected patients with chronic urticaria. J Allergy Clin Immunol Pract. 2018;6(4):1389.
43. Kocaturk E, Deza G, Kizitac K, Gimenz-Arnau AM. Omalizumab updosing for better disease control in chronic spontaneous urticaria patients. Int Arch Allergy Immunol 2018;177:360–364.
44. Saini S, Rosen KE, Hsieh HJ, Wong DA, Conner E, Kaplan A, et al. A randomized, placebo-controlled, dose-ranging study of single-dose omalizumab in patients with H1-antihistamine-refractory chronic idiopathic urticaria. J Allergy Clin Immunol. 2011 Sep;128(3):567-73.e1.
45. Maurer M, Metz M, Brehler R, Hillen U, Jakob T, Mahler V, et al. Omalizumab treatment in patients with chronic urticaria: A systematic review of published evidence. J Allergy Clin Immunol. 2018 Feb;141(2):638-649.
46. Netchiporouk E, Nguyen CH, Thuraingham T, Jafarian F, Maurer M, et al. Management of pediatric chronic spontaneous and physical urticaria patients with omalizumab: case series. PAI. 2015 May 25. https://doi.org/10.1111/pai.12407.
47. Pharmacokinetics and pharmacodynamics of mepolizumab administered subcutaneously in children. In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2015- [cited 2016 Jan 20]. Available from: https://clinicaltrials.gov/ct2/show/NCT02377427?term=mepolizumab+in+children&rank=2.
48. Castro M, Zangrilli J, Weschsler ME, Bateman ED, Brusselle GG, Bardin P, et al. Reslizumab for inadequately controlled asthma with elevated blood eosinophil counts: results from two multicentre, parallel, double-blind, randomized, placebo-controlled, phase 3 trials. Lancet Respir Med 2015;3:355-66.
49. Bjermer L, Lemiere C, Maspero J, Weiss S, Zangrilli J and Germinaro M. Reslizumab for inadequately controlled asthma with elevated blood eosinophil levels: a randomized phase 3 study. CHEST (2016), doi: 10.1016/j.chest.2016.06.032.
50. Mepolizumab for treating severe eosinophilic asthma. National Institute for Health and Care Excellence. NICE technology appraisal guidance TA671. 2021 Feb 3 [cited 2021 Oct 18]. Available from: https://www.nice.org.uk/guidance/TA671.

51. Chatham WW. Glucocorticoid effects on the immune system. In:Basow DS (Ed). UpToDate [database on the Internet]. Waltham (MA): UpToDate; 2021 [cited 2021 Oct 18]. Available from: http://www.utdol.com/utd/index.do.
52. Blauvelt A, de Bruin-Weller M, Gooderham M, Cather JC, Weisman J, Pariser D, Simpson EL, Papp KA, et al. Long-term management of moderate-to-severe atopic dermatitis with dupilumab and concomitant topical corticosteroids (LIBERTY AD CHRONOS): a 1-year, randomized, double-blinded, placebo-controlled, phase 3 trial. *Lancet*. 2017 Jun 10;389(10086):2287-2303.
53. Eosinophilic esophagitis. Mayo Clinic. 2022 [cited 2022 Jun 13]. Available from: https://www.mayoclinic.org/diseases-conditions/eosinophilic-esophagitis/symptoms-causes/syc-20372197.
54. Bonis PA, Gupta SK. Treatment of eosinophilic esophagitis (EoE). In:Basow DS Ed). UpToDate [database on the Internet]. Waltham (MA): UpToDate; 2022 [cited 2022 Jun 13]. Available from: https://www.uptodate.com/contents/treatment-of-eosinophilic-esophagitis-eoe?search=treatment%20of%20EoE&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1.
55. Watsky K. Prurigo nodularis. In: Basow DS (Ed). UpToDate [database on the internet]. Waltham (MA): UpToDate; 2022 Sep [cited 2022 Oct 26]. Available from: http://www.utdol.com/utd/index.do
56. FDA approves first treatment for prurigo nodularis [press release on the internet]. U.S. Food & Drug Administration. 2022 Sept 29 [cited 2022 Oct 26]. Available from: https://www.fda.gov/drugs/news-eventshuman-drugs/fda-approves-first-treatment-prurigo-nodularis.

Review History

09/24/2018 – Updated

11/20/2019 – Updated to require only failure of separate ICS inhaler w/ LABA or combination product and removed requirement of DX based on diagnostic criteria

03/18/2020 – Reviewed and Updated P&T Mtg; age updated ≥ 6 years old for moderate to severe eosinophilic asthma (effective 6/1/20)

11/05/2020- Updated; Effective 1/1/21 Updated to be in compliance with the Masshealth partial unified formulary requirements

03/16/2022 – Updated and Reviewed for March P&T; Guideline updated based on FDA-expanded indication for use of Nucala (mepolizumab) in CRSwNP. Decision made to follow same criteria as Dupixent and Xolair for this indication. However, it was also decided to remove requirement of a trial with a leukotriene antagonist (LTRA) given the updated black box warnings regarding potential for serious neuropsychiatric events that have been reported with the use of montelukast. In addition, current guidelines mention that there is a low quality of available evidence comparing montelukast with nasal corticosteroids and do not routinely recommend use unless there is an allergic component to the disease. Similar decision was also made for Xolair CIU criteria to remove the requirement of LTRA trial. Based on expanded indication for use of dupilumab as add-on maintenance treatment of patients aged 6 to 11 years with moderate-to-severe asthma characterized by an eosinophilic phenotype or with oral-corticosteroid dependent asthma, criteria was updated to include new age range and new dupilumab formulation 100 mg/0.67 mL syringe was added to the internal guideline. Doxepin was added to appendix section as suitable option for H1 antihistamine trial for CIU and appendix section was updated for moderate to severe allergy-related asthma for omalizumab requests for members < 6 years of age based on consensus guideline recommendations for alternative agents. Two new appendices (Dupilumab requests for once weekly treatment and Dupilumab requests attempting to bypass systemic immunomodulatory agent) were included. The appendix “Omalizumab requests for members with high (>700 IU/mL) IgE levels or weight (<30 kg or >150 kg)” was removed.

05/18/2022 – Reviewed and Updated for May P&T. Updated references. Matched MH UPPL. Guideline updated following NDR for Tezspire® (tezepelumab-ekko). Dupixent is preferred drug. Requirement for systemic immunomodulatory agent removed from Dupixent in AD criteria; criteria for Dupixent in nasal polyps changed

to just one requirement to oral corticosteroid, intranasal corticosteroid, prior nasal surgery, or contraindication to both OCS and INS. Dupixent initial approvals changed from 6 months to 1 year duration. Reference table updated to include Preferred Drug footnote. Added the appendix "CIU: Omalizumab requests for > 300 mg every 4 weeks." The appendix "Moderate to Severe Atopic Dermatitis: Dupilumab requests attempting to bypass systemic immunomodulatory agent" was removed. Removed Foradil as a less costly alternative due to obsolete status. Effective 7/1/22.
11/16/2022 – Reviewed and updated for Nov P&T. Matched MH UPPL. Guideline update for expanded indications for Dupixent in children ≥ 6 months with moderate to severe atopic dermatitis as well as individuals ≥ 12 years of age with eosinophilic esophagitis. Effective 11/01/2022
3/15/23 – Reviewed and updated for Mar P&T. Admin update: Cinqair available through medical benefit. Effective 4/1/23.
05/10/23 – Reviewed and updated for P&T. Expanded indication for Dupixent in prurigo nodularis was added. Revision to Dupixent atopic dermatitis note section to allow for bypass of Eucrisa trial if disease is noted to be severe or if the affected area is noted to be too widespread. Included note that topical tacrolimus could be also bypassed if affected area noted to be too widespread. Added once-weekly dosing to Appendix. Effective 6/5/23.
07/12/23 – Reviewed and updated for P&T. Formatting changes made throughout policy. Brand preferred and mandatory generic language was added under Limitations. No clinical changes. Effective 7/31/23