Asthma and Allergy Injectables
Cinqair (reslizumab)
Dupixent (dupilumab)
Fasenra (benralizumab)
Nucala (mepolizumab)
Xolair (omalizumab)
Effective January 1, 2021

Plan	☐ MassHealth ☒ MassHealth (PUF) ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☒ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☒ Medical Benefit (NLX)		
Specialty Limitations	This medication has 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)

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

- Atopic Dermatitis
- Chronis rhinosinusitis with nasal polyps
- Moderate to severe asthma with an eosinophilic phenotype

Xolair is an anti-IgE antibody indicated for:

- Treatment of moderate to severe persistent allergic asthma
- Chronic Idiopathic Urticaria (CIU)

Coverage Guidelines

Authorization may be reviewed on a case by case basis for members new to AllWays Health Partners 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 with severe asthma who meet all the following criteria and documentation has been provided:

Chronic Idiopathic Urticaria

Xolair (omalizumab)

Prescriber provides documentation of **ALL** of the following:

1. Appropriate diagnosis
2. Member is ≥ 12 years of age
3. Paid claims or physician documented inadequate response (defined as ≥14 days of therapy), adverse reaction or contraindication to at least **TWO** different histamine$_1$ antihistamines (See appendix for examples)
4. 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 leukotriene antagonist* (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. For initial requests, starting dose of ≤150 mg every four weeks or clinical rationale for using a starting dose >150 mg every four weeks (see Appendix for dosing requests > 150 mg for the initial request)
7. **ONE** of the following:
    a. Prescriber is an allergist/immunologist or dermatologist
    b. Prescriber provides consultation notes from an allergist/immunologist or dermatologist regarding the diagnosis and treatment recommendations
8. If request is for the 150 mg syringe, medical necessity for the 150 mg syringe instead of the 150 mg vial

Chronic Rhinisinusitis with Nasal Polyposis (CRSwNP)

Dupixent (dupilumab)

Prescriber provides documentation of **ALL** of the following:

1. Appropriate diagnosis
2. Member is ≥ 18 years of age
3. Prescriber is a specialist (i.e., allergist, immunologist, pulmonologist)
4. Paid claims or physician documented inadequate response, adverse reaction or contraindication to **ONE** oral corticosteroid
5. Paid claims or physician documented inadequate response, adverse reaction or contraindication to **ONE** intranasal corticosteroid
6. Paid claims or physician documented inadequate response, adverse reaction or contraindication to **ONE** leukotriene antagonist
7. Dosing is appropriate (300 mg subcutaneosuly every 2 weeks)
8. Documentation that dupilumab will be used as adjunctive therapy

Eosinophilic granulomatosis with polyangiitis (EGPA)

Nucala (mepolizumab)
Prescriber provides documentation of **ALL** of the following:
1. Appropriate diagnosis
2. Member is ≥ 18 years of age
3. Paid claims or physician documented inadequate response (defined as ≥ 30 days of therapy), adverse reaction or contraindication to **ONE** systemic glucocorticoid
4. Paid claims or physician documented inadequate response (defined as ≥ 30 days of therapy), adverse reaction or contraindication to **ONE** of the following:
    a. azathioprine
    b. methotrexate
5. Prescriber is a specialist (i.e., allergist, immunologist, pulmonologist, rheumatologist)
6. Dosing is appropriate (300 mg subcutaneously every 28 days)

Moderate to Severe Allergy Related Asthma
Xolair (omalizumab)
Prescriber provides documentation of **ALL** of the following:
1. Appropriate diagnosis
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 (Foradil® or 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)
7. Dosing is appropriate (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

Moderate to severe atopic dermatitis
Dupixent (dupilumab)
Prescriber provides documentation of **ALL** of the following:
1. Appropriate diagnosis
2. Member is ≥6 years of age
3. Prescriber is an allergist/immunologist or dermatologist, or provides consultation notes from an allergist/immunologist or dermatologist
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 topical tacrolimus and Eucrisa® (crisaborole)

6. **ONE** of the following:
   a. Paid claim or physician documented inadequate response or adverse reaction to **ONE** systemic immunomodulatory agent† (e.g. azathioprine, cyclosporine, methotrexate, mycophenolate mofetil, mycophenolic acid)
   b. Contraindication to **ALL** systemic immunomodulatory agents
7. Appropriate dosing

Moderate-severe eosinophilic asthma or oral corticosteroid-dependent asthma
Dupixent® (dupilumab)
Prescriber provides documentation of **ALL** of the following:

1. Appropriate diagnosis
2. Member is ≥ 12 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 (Foradil® or Serevent®)*
   c. Chronic oral corticosteroids (defined as ≥ 90 days of therapy within the last 120 days)
4. **ONE** of the following:
   a. Evidence of an eosinophilic phenotype (i.e. peripheral blood eosinophil count ≥ 150 cells/µL, elevated sputum eosinophils or FeNO) (MD documentation on prior authorization form is sufficient to meet this criterion)
   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)
6. Dosing is appropriate

Severe Eosinophilic Asthma
Cinqair (reslizumab),
Fasenra (benralizumab)
Nucala (mepolizumab)
Prescriber provides documentation of **ALL** of the following:

1. Appropriate diagnosis
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 (Foradil® or Serevent®)
c. Chronic oral corticosteroids (defined as ≥ 90 days of therapy within the last 120 days)

4. Physician documentation 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)
6. Dosing is appropriate (3 mg/kg intravenously every four weeks [for Cinqair®], 30 mg every 4 weeks for 3 doses, then 30 mg every 8 weeks [for Fasenra®], or 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 [for Nucala®])

Continuation of Therapy
Reauthorization requires physician documentation 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 diagnosis: 6 months
2. Reauthorizations will be granted for the following:
   a. Chronic idiopathic urticaria: 4 months
   b. All other diagnosis: 12 months

Appendix A
Examples of Traditional Therapies for CIU
H_1-Antihistamines (first generation):
Brompheniramine, carbinoxamine, chlorpheniramine, clemastine, cyproheptadine, diphenhydramine, hydroxyzine, promethazine

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
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

Pre-treatment Serum IgE (IU/mL)	Body Weight (kg)			
	30-60	>60-70	>70-90	>90-150
> 200-300	300 mg	225 mg	225 mg	300 mg
> 300-400	225 mg	225 mg	300 mg	
> 400-500	300 mg	300 mg	375 mg	
> 500-600	300 mg	375 mg	DO NOT DOSE	
> 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

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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

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