Asthma and Allergy Injectables
Cinqair (reslizumab)
Dupixent (dupilumab)
Fasenra (benralizumab)
Nucala (mepolizumab)
Xolair (omalizumab)
Effective 05/01/22

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)
- Treatment of nasal polyps in adults

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. 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), adverse reaction or contraindication to at least **TWO** different 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. 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

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) or consult notes from a specialist are provided
6. Appropriate dosing (300 mg subcutaneously every 28 days)

Hypereosinophilic syndrome (HES)
Nucala (mepolizumab)
Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of hypereosinophilic syndrome (HES)
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), adverse reaction or contraindication to ONE systemic glucocorticoid
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)
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) 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

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 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 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**

§For requests to bypass these criteria, please see appendix below 'Moderate to Severe Atopic Dermatitis: Dupilumab requests attempting to bypass systemic immunomodulatory agent' for additional guidance
***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)
Prescriber provides documentation of **ALL** of the following:
1. Appropriate diagnosis
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 (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) or consult notes from a specialist are provided
6. Appropriate dosing

Nasal Polyps
Dupixent (dupilumab)
Xolair (omalizumab)
Nucala (mepolizumab)
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) or consult notes from a specialist are provided
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. Appropriate dosing:
    a. Dupixent: 300 mg subcutaneously every 14 days
    b. Nucala: 100 mg every 4 weeks
    c. 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, physician documentation of 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)
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 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 four 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

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 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, 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
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

Appendix C: Moderate to Severe Atopic Dermatitis: Dupilumab requests attempting to bypass systemic immunomodulatory agent

Pregnancy Considerations

- Several DMARDs are either contraindicated or should only be used if benefits outweigh the risks in women who are pregnant or planning to become pregnant as well as men and/or women of childbearing potential.
- Trials with azathioprine, cyclosporine, methotrexate, mycophenolate mofetil, or mycophenolic acid may be bypassed if the physician documents that they are contraindicated in a male or female member of child-bearing potential or in a female member who is pregnant or planning to become pregnant.
    - **Approve with standard duration of authorization if all other criteria are met**

Children aged 6 to 12 years old and adolescents

- Given potential for long-term adverse events with use of oral immunosuppressant agents in this population, trials of azathioprine, cyclosporine, methotrexate, mycophenolate mofetil, or mycophenolic acid may be bypassed if the provider documents concern/risk with long-term adverse events with these agents.
    - **Approve with standard duration of authorization if all other criteria are met**

Members with chronic skin infections

- There is an increased risk of infection with all of the systemic immunomodulatory agent (e.g. azathioprine, cyclosporine, methotrexate, mycophenolate mofetil, mycophenolic acid), it would be appropriate to bypass a trial with one of these agents in a member with documented history of skin infections related to atopic dermatitis (e.g., infection caused by skin breakage due to chronic itching) requiring treatment with antibiotics or hospitalizations
    - **Approve for three-month trial if all other criteria are met**

References

1. Nucala (mepolizumab) [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; September 2020.
2. Smetzer J, Cohen M, Shastay A, Jenkins R, Litman, RS, eds. Check for proper Nucala dose preparation. *ISMP Medication Safety Alert! Acute Care Edition*. 2018;23(18):1-2
3. National Heart, Lung, and Blood Institute (NHLBI/NIH). Guidelines for the Diagnosis and Management of Asthma (EPR-3). URL: nhlbi.nih.gov/health-ro/guidelines/current/asthma guidelines. Available from internet. Accessed 2016 April 2018
4. Gunsoy NB, Cockle SM, Yancey SW, et al. Evaluation of Potential Continuation Rules for Mepolizumab Treatment of Severe Eosinophilic Asthma. J Allergy Clin Immunol Pract 2018; 6:874
5. Wechsler ME, Akuthota P, Jayne D, et al; EGPA Mepolizumab Study Team. Mepolizumab or Placebo for Eosinophilic Granulomatosis with Polyangiitis. *N Engl J Med*. 2017;376(20):1921-1932.[PubMed 28514601]
6. Ortega HG, Mark SD, Pavord ID, et al. Mepolizumab treatment in patients with severe eosinophilic asthma. N Eng J Med. 2014; 371: 1198-1207
7. Talmadge EK. Treatment and prognosis of eosinophilic granulomatosis with polyangiitis (ChurgStrauss). In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. (Accessed on December 26, 2017).
8. Roufosse F, Kahn J-E, Rothenberg ME, Wardlaw AJ, Klion AD, Kirby SY, Gilson MJ, Bentley JH, Bradford ES, Yancey SW, Steinfeld J, Gleich GJ, Efficacy and safety of

mepolizumab in hypereosinophilic syndrome: a Phase III, randomized, placebo-controlled trial, *Journal of Allergy and Clinical Immunology* (2020), doi: https://doi.org/10.1016/j.jaci.2020.08.037

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. Effective 05/01/2022

Disclaimer

AllWays Health Partners complies with applicable federal civil rights laws and does not discriminate or exclude people on the basis of race, color, national origin age, disability, or sex.