

Asthma and Allergy Injectables
Cinqair (reslizumab)
Dupixent (dupilumab)
Fasenra (benralizumab)
Nucala (mepolizumab)
Xolair (omalizumab)
Effective 01/01/2024

Plan	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit		
Specialty Limitations	These medications have been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	Medical and Specialty Medications		
	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
Exceptions	Non-Specialty Medications		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029
	Cinqair and Xolair solutions are only available through the Medical Benefit		
	Dupixent and Xolair Pen are only available through the Pharmacy Benefit		

Overview

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

- As 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)
- Rhinosinusitis with nasal polyps

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

- Atopic Dermatitis
- Chronic rhinosinusitis with nasal polyps
- Moderate to severe asthma with an eosinophilic phenotype
- Eosinophilic esophagitis
- Prurigo nodularis

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 granted for members new to the plan who are currently receiving treatment with the requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs

OR

Authorization may be granted for members when all the following criteria have been met:

Cinqair

Severe Asthma

1. The member has a diagnosis of severe asthma with an eosinophilic phenotype
2. The member is ≥ 18 years of age
3. The member is not an active smoker
4. The prescriber is an asthma specialist (i.e., allergist, immunologist, pulmonologist)
5. Documentation of an eosinophilic phenotype (i.e., peripheral blood eosinophil count ≥ 300 cells/ μ L, elevated sputum eosinophils)
6. The member is symptomatic despite receiving ONE of the following:
 - Combination inhaler containing an inhaled corticosteroid and a long-acting β -agonist
 - Combination of an inhaled corticosteroid and a long-acting β -agonist inhaler as separate agents
 - Chronic oral steroids
7. The prescriber must confirm that Cinqair will be administered only in a healthcare setting
8. The member has had an inadequate response, or intolerance to at least THREE (3) of the following preferred products: Dupixent, Fasenra, Nucala, and/or Xolair.
9. Dose does not exceed 3mg/kg intravenously every four weeks
10. Cinqair will be used as add-on maintenance treatment

Dupixent

Moderate-to-severe atopic dermatitis

1. The member has a diagnosis of moderate to severe atopic dermatitis
2. The member is at least 6 months old
3. Affected body surface is greater than or equal to 10% body surface area OR crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
4. Member has had an inadequate treatment response to a high potency topical corticosteroid (see Appendix) or a topical calcineurin inhibitor in the past 180 days, or the use of topical corticosteroids and topical calcineurin inhibitors is not advisable for the member (e.g., due to contraindications or prior intolerances).

Prurigo Nodularis

1. The member has a diagnosis of prurigo nodularis
2. The member is 18 years of age or older
3. The member must have a minimum of 20 nodular lesions
4. The member meets ONE of the following:
 - a. Inadequate response to ONE of the following:
 - i. Medium to super high potency topical steroid (see Appendix A)
 - ii. Topical calcineurin inhibitor
 - iii. Phototherapy (e.g., UVB, PUVA)
 - iv. Pharmacologic treatment with methotrexate or cyclosporine
 - b. Intolerance or a clinical reason to avoid ANY of the following:
 - i. Medium to super high potency topical corticosteroid (see Appendix A) and topical calcineurin inhibitor



- ii. Pharmacologic treatment with methotrexate and cyclosporine (see Appendix B)

Eosinophilic Esophagitis

1. The member has a diagnosis of eosinophilic esophagitis as evidenced by BOTH of the following:
 - a. Chronic symptoms of esophageal dysfunction (e.g., dysphagia, food impaction, food refusal, abdominal pain, heartburn, regurgitation, chest pain, odynophagia)
 - b. Findings from esophageal biopsies (e.g., eosinophil-predominant inflammation)
2. The member is at least 12 years of age weighing at least 40kg
3. Provider documents poor control requiring additional treatment despite a trial of a proton pump inhibitor (unless intolerant or contraindication)

Asthma

1. The member has a diagnosis of moderate to severe asthma
2. The member is at least 6 years old
3. Member meets ONE of the following criteria:
 - a. Member has inadequate asthma control (e.g. hospitalization or emergency medical care visit within the past year) despite current treatment with ALL of the following medications at optimized doses*:
 - i. inhaled corticosteroid
 - ii. Additional controller (long acting beta2-agonist, leukotriene modifier, or sustained-release theophylline)
 - iii. Oral glucocorticoids (at least 5 mg per day of prednisone/prednisolone or equivalent)
 - b. The Member has a baseline blood eosinophil count of at least 150 cells per microliter and inadequate asthma control (e.g. hospitalization or emergency medical care visit within the past year) despite current treatment with BOTH of the following medications at optimized doses:
 - i. Inhaled corticosteroid
 - ii. Additional controller (long acting beta2-agonist, leukotriene modifier, or sustained-release theophylline)
4. The member will not use Dupixent as monotherapy

*Members should be receiving treatment with inhaled corticosteroid and additional controller for at least the previous 3 months, and oral glucocorticoids for most days during the previous 6 months (e.g. 50% of days, 3 steroid bursts in the previous 6 months).

Chronic rhinosinusitis with nasal polyposis (CRSwNP)

1. The member is at least 18 years old
2. Member has a diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP)
3. Member has had a trial and failure, contraindication, or intolerance to 2 months of treatment with an intranasal corticosteroid
4. Medication will be used in combination with another agent for CRSwNP (e.g., intranasal corticosteroid)
5. Prescribed by or in consultation with one of the following: Allergist/Immunologist, Otolaryngologist, Pulmonologist,

Fasenra

Severe Asthma

1. The member has a diagnosis of severe asthma
2. Member is 12 years of age or older.
3. Member meets ONE of the following criteria:
 - a. Member has a baseline blood eosinophil count of at least 150 cells per microliter; or



- b. Member is dependent on systemic corticosteroids
- 4. Member has inadequate asthma control (e.g., hospitalization or emergency medical care visit within the past year) despite current treatment with both of the following medications at optimized doses:
 - a. Inhaled corticosteroid
 - b. Additional controller (long-acting beta₂-agonist, leukotriene modifier, or sustained-release theophylline)
- 5. Member will not use Fasenra as monotherapy.

Nucala

Severe Asthma

1. The member has a diagnosis of severe asthma
2. Member is 6 years of age or older
3. Member meets ONE of the following criteria:
 - a. Member has a baseline blood eosinophil count of at least 150 cells per microliter; or
 - b. Member is dependent on systemic corticosteroids
4. Member has inadequate asthma control (e.g., hospitalization or emergency medical care visit within the past year) despite current treatment with both of the following medications at optimized doses:
 - a. Inhaled corticosteroid
 - b. Additional controller (long-acting beta₂-agonist, leukotriene modifier, or sustained-release theophylline)
5. Member will not use Nucala as monotherapy.

Chronic rhinosinusitis with nasal polyposis (CRSwNP)

1. The member is 18 years of age or older
2. Member has a diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP)
3. Medication will be used in combination with another agent for CRSwNP (e.g., intranasal corticosteroid)
4. Prescribed by or in consultation with one of the following: Allergist/Immunologist, Otolaryngologist, Pulmonologist,

Eosinophilic granulomatosis with polyangiitis

1. The member has a diagnosis of eosinophilic granulomatosis with polyangiitis
2. Member is 18 years of age or older.
3. Member has a history or the presence of an eosinophil count of more than 1000 cells per microliter or a blood eosinophil level of greater than 10%.
4. Member has at least TWO of the following disease characteristics of EGPA:
 - a. Biopsy showing histopathological evidence of eosinophilic vasculitis, perivascular eosinophilic infiltration, or eosinophil-rich granulomatous inflammation
 - b. Neuropathy, mono or poly (motor deficit or nerve conduction abnormality)
 - c. Pulmonary infiltrates, non-fixed; sino-nasal abnormality
 - d. Cardiomyopathy (established by echocardiography or magnetic resonance imaging)
 - e. Glomerulonephritis (hematuria, red cell casts, proteinuria)
 - f. Alveolar hemorrhage (by bronchoalveolar lavage)
 - g. Palpable purpura
 - h. Anti-neutrophil cytoplasmic anti-body (ANCA) positive (Myeloperoxidase or proteinase 3)
5. Member has had at least one relapse (requiring increase in oral corticosteroids dose, initiation/increased dose of immunosuppressive therapy or hospitalization) within 2 years prior to starting treatment with Nucala or has a refractory disease.



Hypereosinophilic syndrome (HES)

1. The member has a diagnosis of hypereosinophilic syndrome (HES)
2. The member is ≥ 12 years of age
3. The member has a diagnosis of HES without another identifiable non-blood related cause
4. The member has had at least 2 HES flares within the past 12 months
5. The member has had an inadequate response (defined as ≥ 30 days of therapy), adverse reaction or contraindication to one systemic steroid
6. The member has had an absolute eosinophil count > 1500 cells per microliter for greater than six months
7. The prescriber is a specialist (i.e., allergist, cardiologist, hematologist, or immunologist)

Xolair

Moderate to Severe Asthma

1. The member has a diagnosis of moderate to severe asthma
2. Member is 6 years of age or older.
3. Member has a positive skin test or in vitro reactivity to at least one perennial aeroallergen.
4. Member has a pre-treatment IgE level greater than or equal to 30 IU/mL.
5. Member has inadequate asthma control (e.g., hospitalization or emergency medical care visit within the past year) despite current treatment with both of the following medications at optimized doses:
 - a. Inhaled corticosteroid
 - b. Additional controller (long acting beta₂-agonist, leukotriene modifier, or sustained-release theophylline)
6. Member will not use Xolair as monotherapy.

Chronic idiopathic urticaria

1. The member has a diagnosis of chronic idiopathic urticaria
2. Member is 12 years of age or older.
3. Member remains symptomatic despite treatment with a second-generation H₁ antihistamine (e.g., cetirizine, fexofenadine, levocetirizine, loratadine) for at least 2 weeks.
4. Member has been evaluated for other causes of urticaria, including bradykinin-related angioedema and interleukin-1-associated urticarial syndromes (auto-inflammatory disorders, urticarial vasculitis).
5. Member has experienced a spontaneous onset of wheals, angioedema, or both, for at least 6 weeks.

Nasal Polyps:

1. The member is using Xolair as add-on maintenance for the diagnosis of nasal polyps
2. Member is 18 years of age or older
3. The physician specialty is allergist, immunologist, or otolaryngologist
4. Member has had ≥ 3 -month trial of intranasal corticosteroid
5. Member meets ONE of the following:
 - a. Member is concurrently being treated with an intranasal corticosteroid
 - b. Member has a contraindication or intolerance to intranasal corticosteroid

Continuation of Therapy

Cinqair:

1. Severe Asthma: Authorization of 12 months may be granted for continuation of treatment of asthma in members 18 years of age or older when all of the following criteria are met:
 - a. Asthma control has improved on Cinqair treatment as demonstrated by at least one of the following:



- i. A reduction in the frequency and/or severity of symptoms and exacerbation
- ii. A reduction in the daily maintenance oral corticosteroid dose
- b. Member will not use Cinqair as monotherapy

Dupixent:

1. Atopic Dermatitis: Reauthorizations may be granted for up to 12 months for members 6 months of age or older who achieve or maintain positive clinical response with Dupixent therapy for moderate-to-severe atopic dermatitis as evidenced by low disease activity (i.e., clear or almost clear skin), or improvement in signs and symptoms of atopic dermatitis (e.g., redness, itching, oozing/crusting).
2. Asthma: Authorization of 12 months may be granted for continuation of treatment of asthma in members 6 years of age or older when all of the following criteria are met:
 - a. Asthma control has improved on Dupixent treatment as demonstrated by at least one of the following:
 - iii. A reduction in the frequency and/or severity of symptoms and exacerbation
 - iv. A reduction in the daily maintenance oral corticosteroid dose
 - b. Member will not use Dupixent as monotherapy
3. Prurigo Nodularis: Authorization of 12 months may be granted for members 18 years of age or older who are using Dupixent for prurigo nodularis when the member has achieved or maintained positive clinical response with Dupixent therapy as evidenced by one of the following:
 1. Low disease activity (i.e., clear or almost clear skin).
 2. Reduction in pruritis intensity and improvement in extent and severity of nodular lesions.
4. Chronic rhinosinusitis with nasal polyposis (CRSwNP): Authorization of 12 months may be granted for continuation of treatment of chronic rhinosinusitis with nasal polyposis in members 18 years of age or older who achieve or maintain positive clinical response to Dupixent therapy as evidenced by improvement in signs and symptoms of CRSwNP (e.g., improvement in nasal congestion, nasal polyp size, loss of smell, anterior or posterior rhinorrhea, sinonasal inflammation, hyposmia and/or facial pressure or pain or reduction in corticosteroid use).
5. Eosinophilic esophagitis: Authorization of 12 months may be granted for continuation of treatment of eosinophilic esophagitis in members 12 years of age or older weight 40kg when provider attests to improvement in symptoms of esophageal dysfunction (e.g., dysphagia, pain upon swallowing, food impact, etc.)

Fasenra

1. Asthma: Authorization of 12 months may be granted for treatment of asthma when all of the following criteria are met:
 - a. Member is 12 years of age or older.
 - b. Asthma control has improved on Fasenra treatment as demonstrated by at least ONE of the following:
 - i. A reduction in the frequency and/or severity of symptoms and exacerbations
 - ii. A reduction in the daily maintenance oral corticosteroid dose
 - c. Member will not use Fasenra as monotherapy.

Nucala

1. Asthma: Authorization of 12 months may be granted for continuation of treatment of asthma when ALL of the following criteria are met:
 - a. Member is 6 years of age or older.
 - b. Asthma control has improved on Nucala treatment as demonstrated by at least ONE of the following:
 - i. A reduction in the frequency and/or severity of symptoms and exacerbations



- ii. A reduction in the daily maintenance oral corticosteroid dose
 - c. Member will not use Nucala as monotherapy.
2. Eosinophilic granulomatosis with polyangiitis: Authorization of 12 months may be granted for continuation of treatment of eosinophilic granulomatosis with polyangiitis when all of the following criteria are met:
 - a. Member is 18 years of age or older.
 - b. Member has beneficial response to treatment with Nucala as demonstrated by any of the following:
 - i. A reduction in the frequency of relapses, or
 - ii. A reduction in the daily oral corticosteroid dose, or
 - iii. No active vasculitis
 3. HES: Reauthorizations may be granted for up to 12 months when clinical documentation is submitted showing member has had a decrease in absolute eosinophils and improvement in condition
 4. Chronic rhinosinusitis with nasal polyposis (CRSwNP): Authorization of 12 months may be granted for continuation of treatment of chronic rhinosinusitis with nasal polyposis in members 18 years of age or older who achieve or maintain positive clinical response to Nucala therapy as evidenced by improvement in signs and symptoms of CRSwNP (e.g., improvement in nasal congestion, nasal polyp size, loss of smell, anterior or posterior rhinorrhea, sinonasal inflammation, hyposmia and/or facial pressure or pain or reduction in corticosteroid use).

Xolair

1. Asthma: Authorization of 12 months may be granted for continuation of treatment of asthma when ALL of the following criteria are met:
 - a. Member is 6 years of age or older.
 - b. Asthma control has improved on Xolair treatment as demonstrated by at least one of the following:
 - i. A reduction in the frequency and/or severity of symptoms and exacerbations
 - ii. A reduction in the daily maintenance oral corticosteroid dose¹⁰
 - c. Member will not use Xolair as monotherapy.
2. CIU: Authorization of 12 months may be granted for continuation of treatment of chronic idiopathic urticaria when all of the following criteria are met:
 - a. Member is 12 years of age or older.
 - b. Member has experienced a response (e.g., improved symptoms, decrease in weekly urticaria activity score [UAS7]) since initiation of therapy
3. Nasal Polyps: Authorization of 12 months may be granted for continuation of treatment for nasal polyps when all the following criteria are met:
 - a. Member is 18 years of age or older
 - b. The physician specialty is allergist, immunologist, or otolaryngologist
 - c. Provider documents member has experienced therapeutic response (e.g. sinus ventilation, control of mucosal inflammation/edema, reduction in exacerbations)

Limitations:

1. Initial approvals will be approved medication and diagnosis specific as follows:

Cinqair:

- Severe Asthma: 4 months

Dupixent:



- Moderate to Severe Atopic Dermatitis and Prurigo nodularis: 4 months
- Asthma or Chronic Rhinosinusitis with Nasal Polyps (CRSwNP) and eosinophilic esophagitis: 6 months

Fasenra:

- Asthma: 6 months

Nucala:

- Asthma: 6 months
- Eosinophilic granulomatosis with polyangiitis: 12 months
- Hypereosinophilic syndrome: 4 months
- Chronic rhinosinusitis with nasal polyposis (CRSwNP): 6 months

Xolair:

- Asthma, Chronic Idiopathic Urticaria, Nasal Polyps: 6 months

2. The following quantity limits apply:

Dupixent prefilled syringe	2 pens per 28 days
Fasenra Pen	1 pen per 56 days
Nucala auto-injector 100mg/ml	3 injectors per 28 days
Nucala prefilled syringe 100mg/ml	3 syringes per 28 days
Xolair Pens 150mg	4 pens per 28 days
Xolair vials 150mg	6 vials per 28 days

Appendix

Appendix A: Relative potency of select topical corticosteroid products

Potency	Drug	Dosage form	Strength
I. Super-high potency (group 1)	Augmented betamethasone dipropionate	Ointment, Lotion, Gel	0.05%
	Clobetasol propionate	Cream, Gel, Ointment, Solution, Cream (emollient), Lotion, Shampoo, Foam, Spray	0.05%
	Fluocinonide	Cream	0.1%
	Flurandrenolide	Tape	4 mcg/cm ²
	Halobetasol propionate	Cream, Lotion, Ointment, Foam	0.05%
II. High potency (group 2)	Amcinonide	Ointment	0.1%
	Augmented betamethasone dipropionate	Cream	0.05%
	Betamethasone dipropionate	Ointment	0.05%
	Clobetasol propionate	Cream	0.025%
	Desoximetasone	Cream, Ointment, Spray	0.25%
		Gel	0.05%
	Diflorasone diacetate	Ointment, Cream (emollient)	0.05%
	Fluocinonide	Cream, Ointment, Gel, Solution	0.05%
	Halcinonide	Cream, Ointment	0.1%
Halobetasol propionate	Lotion	0.01%	
III. High potency (group 3)	Amcinonide	Cream, Lotion	0.1%
	Betamethasone dipropionate	Cream, hydrophilic emollient	0.05%
	Betamethasone valerate	Ointment	0.1%



Potency	Drug	Dosage form	Strength
		Foam	0.12%
	Desoximetasone	Cream, Ointment	0.05%
	Diflorasone diacetate	Cream	
	Fluocinonide	Cream, aqueous emollient	0.05%
	Fluticasone propionate	Ointment	0.005%
	Mometasone furoate	Ointment	0.1%
	Triamcinolone acetonide	Cream, Ointment	0.5%
IV. Medium potency (group 4)	Betamethasone dipropionate	Spray	0.05%
	Clocortolone pivalate	Cream	0.1%
	Fluocinolone acetonide	Ointment	0.025%
	Flurandrenolide	Ointment	0.05%
	Hydrocortisone valerate	Ointment	0.2%
	Mometasone furoate	Cream, Lotion, Solution	0.1%
	Triamcinolone acetonide	Cream	0.1%
		Ointment	0.05% and 0.1%
		Aerosol Spray	0.2 mg per 2-second spray
V. Lower-mid potency (group 5)	Betamethasone dipropionate	Lotion	0.05%
	Betamethasone valerate	Cream	0.1%
	Desonide	Ointment, Gel	0.05%
	Fluocinolone acetonide	Cream	0.025%
	Flurandrenolide	Cream, Lotion	0.05%
	Fluticasone propionate	Cream, Lotion	0.05%
	Hydrocortisone butyrate	Cream, Lotion, Ointment, Solution	0.1%
	Hydrocortisone probutate	Cream	0.1%
	Hydrocortisone valerate	Cream	0.2%
	Prednicarbate	Cream (emollient), Ointment	0.1%
	Triamcinolone acetonide	Lotion	0.1%
VI. Low potency (group 6)		Ointment	0.025%
	Alclometasone dipropionate	Cream, Ointment	0.05%
	Betamethasone valerate	Lotion	0.1%
	Desonide	Cream, Lotion, Foam	0.05%
	Fluocinolone acetonide	Cream, Solution, Shampoo, Oil	0.01%
	Triamcinolone acetonide	Cream, lotion	0.025%
VII. Least potent (group 7)	Hydrocortisone (base, less than 2%)	Cream, Ointment, Solution	2.5%
		Lotion	2%
		Cream, Ointment, Gel, Lotion, Spray, Solution	1%
		Cream, Ointment	0.5%
	Hydrocortisone acetate	Cream	2.5%
		Lotion	2%
	Cream	1%	



References

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Review History

09/24/18 – Updated

11/20/19 – 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 \geq 6 years old for moderate to severe eosinophilic asthma (effective 6/1/20)

11/18/2020- Updated: changed criteria name to *Asthma & Allergy Injectables*, made one document for Cinqair, Dupixent, Fasentra, Nucala and Xolair criteria, added preferred trials for Cinqair, added new indication of HES for Nucala: Matching the CVS SGM criteria for Xolair, Nucala, Fasentra, and Dupixent. Effective 1/1/21.

09/22/2021 – Reviewed and Updated September P&T; added indication for nasal polyps for Xolair. Effective 01/01/2022

03/16/2022 – Reviewed and Updated for March P&T; updated age requirement from 12 years to 6 years for Dupixent for asthma per manufacture recommendations; added new indication and criteria for Nucala for nasal polyps; references updated; added appendix with high and very high corticosteroid list. Effective 05/01/2022

11/16/2022 – Reviewed and Updated for Nov P&T; updated age requirement for Dupixent from 12 years of age to 6 months for moderate to severe atopic dermatitis. Effective 02/01/2023.

01/11/2023 – Reviewed and updated for Jan P&T; Fasentra solution and Nucala solution available on pharmacy benefit. Added new indication of eosinophilic esophagitis and prurigo nodularis for Dupixent. Effective 4/1/23

6/23/2023 – Reviewed and Updated for July P&T; added initial approval duration of 4 months for Dupixent prurigo nodularis under limitations. Effective 09/01/2023

11/15/2023 – Reviewed and Updated for Nov P&T; updated age requirement for reauthorization for Dupixent to 6 months of age. Effective 1/1/2024

12/13/2023 – Reviewed and Updated for Dec P&T; For all Drugs: removed “The member will not use requested medication concomitantly with other biologics indicated for asthma”. Dupixent for purigo nodularis: Removed pruritis lasting 6 weeks and history of signs of repeated itch scratch cycle. Dupixent and Nucala for CRSwNP: Removed disease involvement, including bilateral nasal endoscopy or rhinoscopy, removed nasal obstruction with rhinorrhea OR reduction or loss of smell. Xolair for Nasal polyps removed the requirement of a leukotriene inhibitor, only requires intranasal corticosteroid. Effective 1/1/24

