Mass General Brigham
Health Plan

Asthma and Allergy Injectables
Cinqair (reslizumab)
Dupixent (dupilumab)
Fasenra (benralizumab)
Nucala (mepolizumab)
Xolair (omalizumab)
Effective 09/01/2023

Plan	☐ MassHealth ☒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 and Xolair solutions are Medical Benefit only Dupixent and Xolair Pen are Pharmacy Benefit Only and obtained through specialty pharmacy		

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
- Chronis 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/µL, 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 an 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 has had pruritis lasting at least 6 weeks
4. The member has history or signs of repeated itch-scratch cycle (e.g., scratching, picking, itching)
5. The member must have a minimum of 20 nodular lesions
6. 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 weighting 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. High-dose 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
5. The member will not use Dupixent concomitantly with other biologics indicated for asthma (e.g., Cinqair, Fasenra, Nucala, or Xolair).

*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 bilateral nasal polyposis and chronic symptoms of sinusitis despite intranasal corticosteroid treatment for at least 2 months unless contraindicated or not tolerated; and
3. The member has CRSwNP despite ONE of the following:
   a. Prior sino-nasal surgery

b. Prior treatment with systemic corticosteroids within the last two years was ineffective, unless contraindicated or not tolerated
4. Member has a bilateral nasal endoscopy or anterior rhinoscopy showing polyps reaching below the lower border of the middle turbinate or beyond in each nostril
5. Member has nasal obstruction plus ONE of the following additional symptoms:
    a. Rhinorrhea (anterior/posterior
    b. Reduction or loss of smell
6. Member will be using a daily intranasal corticosteroid while being treated with Dupixent, unless contraindicated or not tolerated.

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 $beta_2$-agonist, leukotriene modifier, or sustained-release theophylline)
5. Member will not use Fasenra as monotherapy.
6. Member will not use Fasenra concomitantly with other biologics indicated for asthma (e.g., Cinqair, Dupixent, Nucala, Xolair).

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 $beta_2$-agonist, leukotriene modifier, or sustained-release theophylline)
5. Member will not use Nucala as monotherapy.
6. Member will not use Nucala concomitantly with other biologics indicated for asthma (e.g., Cinqair, Dupixent, Fasenra, Xolair).

Chronic rhinosinusitis with nasal polyposis (CRSwNP)

1. The member is 18 years of age or older
2. The member has bilateral nasal polyposis and chronic symptoms of sinusitis despite intranasal corticosteroid treatment for at least 2 months unless contraindicated or not tolerated
3. The member has CRSwNP despite ONE of the following:
    a. Prior sino-nasal surgery

b. Prior treatment with systemic corticosteroids within the last two years was ineffective, unless contraindicated or not tolerated

4. Member has a bilateral nasal endoscopy or anterior rhinoscopy showing polyps reaching below the lower border of the middle turbinate or beyond in each nostril
5. Member has nasal obstruction plus ONE of the following additional symptoms:
    a. Rhinorrhea (anterior/posterior
    b. Reduction or loss of smell
6. Member will be using a daily intranasal corticosteroid while being treated with Nucala, unless contraindicated or not tolerated.

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 proteinease 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 beta$_2$-agonist, leukotriene modifier, or sustained-release theophylline)

6. Member will not use Xolair as monotherapy.
7. Member will not use Xolair concomitantly with other biologics indicated for asthma (e.g., Cinqair, Dupixent, Fasenra, Nucala).

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 H_1 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 with a leukotriene modifier
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
    c. Member will not use Cinqair concomitantly with other biologics indicated for asthma (e.g., Dupixent, Fasenra, Nucala, or Xolair)

Dupixent:

2. Atopic Dermatitis: Reauthorizations may be granted for up to 12 months for members 6 years 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).
3. 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:
    d. 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
    e. Member will not use Dupixent as monotherapy

f. Member will not use Dupixent concomitantly with other biologics indicated for asthma (e.g., Cinqair, Fasenra, Nucala, or Xolair)

4. 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.
5. 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).
6. 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.
    d. Member will not use Fasenra concomitantly with other biologics indicated for asthma (e.g., Cinqair, Dupixent, Nucala, Xolair).

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.
    d. Member will not use Nucala concomitantly with other biologics indicated for asthma (e.g., Cinqair, Dupixent, Fasenra, Xolair).
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 dose[10]
    c. Member will not use Xolair as monotherapy.
    d. Member will not use Xolair concomitantly with other biologics indicated for asthma (e.g., Cinqair, Dupixent, Fasenra, Nucala).
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%
		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%

Potency	Drug	Dosage form	Strength
	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%
		Ointment	0.025%
VI. Low potency (group 6)	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

1. Nucala (mepolizumab) [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; September 2020
2. Dupixent (dupilumab) [prescribing information]. Tarrytown, NY: Regeneron Pharmaceuticals; December 2021
3. Cinqair (reslizumab) [prescribing information]. West Chester, PA: Teva Respiratory, LLC; June 2020
4. Fasenra (benralizumab) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; October 2019

5. Xolair (omalizumab) [prescribing information]. San Francisco, CA: Genentech Inc; May 2019
6. 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
7. 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
8. Pham TH, Damera G, Newbold P, Ranade K. Reductions in eosinophil biomarkers by benralizumab in patients with asthma. Respir Med 2016; 111:21
9. Silverberg JI, Yosipovitch G, Simpson EL, et al. Dupilumab treatment results in early and sustained improvements in itch in adolescents and adults with moderate to severe atopic dermatitis: Analysis of the randomized phase 3 studies SOLO 1 and SOLO 2, AD ADOL, and CHRONOS. J Am Acad Dermatol 2020; 82:1328
10. Paller AS, Siegfried EC, Thaçi D, et al. Efficacy and safety of dupilumab with concomitant topical corticosteroids in children 6 to 11 years old with severe atopic dermatitis: A randomized, double-blinded, placebo-controlled phase 3 trial. J Am Acad Dermatol 2020
11. Chong LY, Piromchai P, Sharp S, et al. Biologics for chronic rhinosinusitis. Cochrane Database Syst Rev 2020; 2:CD013513
12. Bachert C, Han JK, Desrosiers M, et al. Efficacy and safety of dupilumab in patients with severe chronic rhinosinusitis with nasal polyps (LIBERTY NP SINUS-24 and LIBERTY NP SINUS-52): results from two multicentre, randomised, double-blind, placebo-controlled, parallel-group phase 3 trials. Lancet 2019; 394:1638
13. Tsurumaki H, Matsuyama T, Ezawa K, et al. Rapid Effect of Benralizumab for Hypereosinophilia in a Case of Severe Asthma with Eosinophilic Chronic Rhinosinusitis. Medicina (Kaunas) 2019; 55
14. Zuberbier T, Aberer W, Asero R, et al. The EAACI/GA²LEN/EDF/WAO guideline for the definition, classification, diagnosis and management of urticaria. Allergy 2018; 73:1393
15. van den Elzen MT, van Os-Medendorp H, van den Brink I, et al. Effectiveness and safety of antihistamines up to fourfold or higher in treatment of chronic spontaneous urticaria. Clin Transl Allergy 2017; 7:4
16. Wan KS. Efficacy of leukotriene receptor antagonist with an anti-H1 receptor antagonist for treatment of chronic idiopathic urticaria. J Dermatolog Treat 2009; 20:194
17. Straesser MD, Oliver E, Palacios T, et al. Serum IgE as an immunological marker to predict response to omalizumab treatment in symptomatic chronic urticaria. J Allergy Clin Immunol Pract 2018; 6:1386
18. Talmadge EK. Treatment and prognosis of eosinophilic granulomatosis with polyangiitis (ChurgStrauss). In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. (Accessed on December 26, 2017).
19. 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

09/24/18 – 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 ≥ 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, Fasenra, Nucala and Xolair criteria, added preferred trials for Cinqair, added new indication of HES for Nucala: Matching the CVS SGM criteria for Xolair, Nucala, Fasenra, 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; Fasenra 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