Asthma and COPD Agents: Monoclonal Antibodies

WA.PHAR.158 **Effective Date: 10/1/2026**

Related medical policies:

Policy Number	Policy Name
WA.PHAR.49.AB	Cytokine and CAM Antagonists: IL-4/IL-13/IL-31 Inhibitors

Note: *New-to-market drugs included in this class based on the Apple Health Preferred Drug List are non-preferred and subject to this prior authorization (PA) criteria. Non-preferred agents in this class require an inadequate response or documented intolerance due to severe adverse reaction or contraindication to at least TWO preferred agents. If there is only one preferred agent in the class documentation of inadequate response to ONE preferred agent is needed. If a drug within this policy receives a new indication approved by the Food and Drug Administration (FDA), medical necessity for the new indication will be determined on a case-by-case basis following FDA labeling.*

To see the list of the current Apple Health Preferred Drug List (AHPDL), please visit:
https://www.coordinatedcarehealth.com/providers/pharmacy.html

Medical necessity

Drug	Medical Necessity
benralizumab (Fasenra) depemokimab-ulaa (Exdensur) mepolizumab (Nucala) omalizumab-igec (Omlyclo) omalizumab (Xolair) reslizumab (Cinqair) tezepelumab-ekko (Tezspire)	**Asthma and COPD Agents: Monoclonal Antibodies** may be considered medically necessary in patients who meet the criteria described in the clinical policy below. If all criteria are not met, the clinical reviewer may determine there is a medically necessary need and approve on a case-by-case basis. The clinical reviewer may choose to use the reauthorization criteria when a patient has been previously established on therapy and is new to Apple Health.

Clinical policy:

Clinical Criteria	
Moderate to Severe Asthma omalizumab-igec (Omlyclo) omalizumab (Xolair) tezepelumab-ekko (Tezspire)	Omalizumab (Xolair) and Omalizumab-igec (Omlyclo) may be approved when all the following documented criteria are met: 1. Patient is 6 years of age or older; **AND** 2. Prescribed by, or in consultation with a provider who specializes in the treatment of asthma; **AND** 3. Not used in combination with another monoclonal antibody indicated for the treatment of asthma; **AND** 4. Patient has a serum total IgE level, measured before the start of treatment, of either: a. ≥ 30 IU/mL and ≤ 700 IU/mL in patients age ≥ 12 years; **OR** b. ≥ 30 IU/mL and ≤ 1300 IU/mL in patients aged 6 to <12 years; **AND**

	5. Patient has a confirmed allergy showing reactivity to a perennial aeroallergen; **AND** 6. Patient has **MODERATE** asthma as defined by <u>one</u> of the following: a. Documentation of functional impairment due to poor asthma control or exacerbations (e.g. limitation of activities of daily living, nighttime awakenings > 1x/week but not nightly); **OR** b. Short acting Beta Agonist (SABA) use for symptom control occurs daily; **OR** c. Lung function (percent predicted FEV1) >60%, but <80%; **OR** 7. Patient has **SEVERE** asthma as defined by <u>one</u> of the following: a. Documentation of functional impairment due to poor asthma control or exacerbations (e.g. limitation of activities of daily living, nighttime awakenings often 7x/week); **OR** b. SABA use for symptom control occurs several times per day; **OR** c. Lung function (percent predicted FEV1) <60%; **AND** 8. Patient is currently being treated with: a. A medium- to high-dose, or maximally tolerated inhaled corticosteroid (ICS); **AND** b. One asthma controller medication: i. long-acting beta-2 agonist (LABA); ii. long-acting muscarinic antagonist (LAMA); iii leukotriene receptor antagonist; **OR** c. A maximally tolerated ICS/LABA combination product; **AND** 9. Asthma controller medications will be continued unless contraindicated. Tezepelumab-ekko (Tezspire) may be approved when all the following documented criteria are met: 10. Patient is 12 years of age or older; **AND** 11. Criteria 2, 3, 7, 8, and 9 above. If ALL criteria are met, the request will be authorized for **12 months.**
	Criteria (Reauthorization) Omalizumab (Xolair), Omalizumab-igec (Omlyclo) and tezepelumab-ekko (Tezspire) may be approved when all the following documented criteria are met: 1. Criteria 2 and 3 above continue to be met; **AND** 2. Documentation is submitted demonstrating disease stability or a positive clinical response (e.g., reduced asthma exacerbations, FEV1, reduced hospitalizations); **AND**

	3. Asthma controller medications (e.g., ICS/LABA) will be continued to be used unless contraindicated. If ALL criteria are met, the request will be authorized for **12 months.**
Chronic rhinosinusitis with nasal polyps (CRSwNP) mepolizumab (Nucala) omalizumab-igec (Omlyclo) omalizumab (Xolair) tezepelumab-ekko (Tezspire)	Omalizumab (Xolair) may be approved when all the following documented criteria are met: 1. Patient is 18 years of age or older; **AND** 2. Prescribed by, or in consultation with a provider who specializes in the treatment of CRSwNP; **AND** 3. Diagnosis of CRSwNP; **AND** 4. Not used in combination with another monoclonal antibody indicated for the treatment of CRSwNP; **AND** 5. Diagnosis of bilateral sinonasal polyposis as evidenced by an endoscopy or computed tomography (CT); **AND** 6. Patient ongoing nasal congestion, blockage, or obstruction with moderate to severe symptom severity; **AND** 7. Patient has at least one of the following symptoms: a. Nasal discharge; **OR** b. Facial pain or pressure; **OR** c. Reduction or loss of smell; **AND** 8. History of failure, contraindication, or intolerance to either of the following: a. Intranasal corticosteroids for at leasttwo months); **OR** b. Oral systemic corticosteroid therapy for 10 to 14 days within the last 24 months; **AND** 9. Intranasal corticosteroid will be continued unless contraindicated. Tezepelumab-ekko (Tezspire) may be approved when all the following documented criteria are met: 10. Criteria 2-9 above are met; **AND** 11. The patient is 12 years of age or older. Mepolizumab (Nucala) may be approved when all the following documented criteria are met: 12. Criteria 1-9 above is met; **AND** 13. Treatment with dupilumab (Dupixent), omalizumab (Xolair), and tezepelumab-ekko (Tezspire) has been ineffective, contraindicated, or not tolerated [minimum trial of 1 year]. If ALL criteria are met, the request will be authorized for **12 months.**
	Criteria (Reauthorization)
	Omalizumab (Xolair), omalizumab-igec (Omlyclo), mepolizumab (Nucala), and tezepelumab-ekko (Tezspire) may be approved when all the following documented criteria are met: 1. Criteria 3 and 4 above continue to be met; **AND**

	2. Intranasal corticosteroid will be continued unless contraindicated; **AND** 3. Documentation is submitted demonstrating disease stability or a positive clinical response (e.g., improvement in nasal congestion/obstruction severity, reduction in nasal polyps). If ALL criteria are met, the request will be authorized for **12 months.**
Chronic spontaneous urticaria (CSU) omalizumab-igec (Omlyclo) omalizumab (Xolair)	Omalizumab (Xolair) and omalizumab-igec (Omlyclo) may be approved when all the following documented criteria are met: 1. Patient is 12 years of age or older, **AND** 2. Prescribed by, or in consultation with a provider who specializes in the treatment of CSU; **AND** 3. Diagnosis of CSU; **AND** 4. Not used in combination with another monoclonal antibody indicated for CSU; **AND** 5. Patient has experienced urticaria for ≥ 8 consecutive weeks; **AND** 6. Urticaria Activity Score (UAS7) ≥ 16; **AND** 7. Patient has tried and failed **TWO** second generation H-1 antihistamines up to maximally tolerated dose or after titration up to 2-4 times FDA approved dose for a minimum of two weeks each, unless all are contraindicated. If ALL criteria are met, the request will be authorized for **12 months.**
	Criteria (Reauthorization) Omalizumab (Xolair) may be approved when all the following documented criteria are met: 1. Criteria 3 and 4 above continue to be met; **AND** 2. Documentation is submitted demonstrating disease stability or a positive clinical response (e.g., improvement in UAS7 score). If ALL criteria are met, the request will be authorized for **12 months.**
COPD with eosinophilic phenotype mepolizumab (Nucala)	Mepolizumab (Nucala) may be approved when all the following documented criteria are met: 1. Patient is 18 years of age or older, **AND** 2. Prescribed by, or in consultation with a provider who specializes in the treatment of COPD with eosinophilic phenotype; **AND** 3. Diagnosis of COPD with eosinophilic phenotype; **AND** 4. Not used in combination with another monoclonal antibody indicated for the treatment of COPD with eosinophilic phenotype; **AND** 5. Absolute blood eosinophil count ≥ 300 cells/µL within the last 12 months; **AND** 6. Lung function (percent predicted FEV1) between 20-80% measured within the last 12 months; **AND**

	7. Two moderate or one severe exacerbation in the last 12 months; **AND** 8. Patient is currently being treated with either of the following: a. Maximal inhaled therapy (ICS + LABA + LAMA); **OR** b. Double maintenance therapy (LABA + LAMA) if ICS is contraindicated; **AND** 9. Treatment with dupilumab has been ineffective after a minimum trial of 12 weeks, unless, contraindicated, or not tolerated. If ALL criteria are met, the request will be authorized for **12 months.** **Criteria (Reauthorization)** mepolizumab (Nucala) may be approved when all the following documented criteria are met: 1. Criteria 3 and 4 above continue to be met; **AND** 2. Documentation is submitted demonstrating disease stability or a positive clinical response (e.g. improvement in FEV1, dyspnea score, reduced COPD exacerbations). If ALL criteria are met, the request will be authorized for **12 months.**
Eosinophilic granulomatosis with polyangiitis (EGPA) benralizumab (Fasenra) mepolizumab (Nucala)	Benralizumab (Fasenra) may be approved when all the following documented criteria are met: 1. Patient is 18 years of age or older; **AND** 2. Prescribed by, or in consultation with a provider who specializes in the treatment of EGPA; **AND** 3. Diagnosis of EGPA; **AND** 4. Not used in combination with another monoclonal antibody indicated for the treatment of eosinophilic granulomatosis with polyangiitis (e.g., mepolizumab); **AND** 5. History of asthma and eosinophilia (150cells/µL or > 10% of leukocytes); **AND** 6. History of relapsing or refractory disease treated with background prednisolone/prednisone with or without immunosuppressive therapy; **AND** 7. Presence of at least **TWO** of the following characteristics typical of EGPA: a. Biopsy showing white blood cells present outside blood vessels (extravascular eosinophils); **OR** b. Pulmonary infiltrates; **OR** c. Paranasal sinus abnormality; **OR** d. Cardiomyopathy; **OR** e. Mononeuropathy (including multiplex) or polyneuropathy; **OR** f. Glomerulonephritis; **OR** g. Alveolar hemorrhage; **OR**

	h. Palpable purpura; **OR** i. Anti-neutrophil cytoplasmic antibody (ANCA) positive. Mepolizumab (Nucala) may be approved when all the following documented criteria are met: 8. Criteria 1-7 above is met; **AND** 9. Treatment with benralizumab has been ineffective after a minimum trial of 1 year unless, contraindicated, or not tolerated. If ALL criteria are met, the request will be authorized for **12 months.** **Criteria (Reauthorization)** benralizumab (Fasenra) or mepolizumab (Nucala) may be approved when all the following documented criteria are met: 1. Criteria 3 and 4 above continue to be met; **AND** 2. Documentation is submitted demonstrating disease stability or a positive clinical response (e.g., reduction in relapses, severity or frequency of EGPA-related symptoms). If ALL criteria are met, the request will be authorized for **12 months.**
Hypereosinophilic syndrome (HES) benralizumab (Fasenra) mepolizumab (Nucala)	Benralizumab (Fasenra) may be approved when all the following documented criteria are met: 1. Patient is 12 years of age or older, **AND** 2. Prescribed by, or in consultation with a provider who specializes in the treatment of HES; **AND** 3. Diagnosis of HES; **AND** 4. Not used in combination with another monoclonal antibody; **AND** 5. Patient has experienced HES for ≥ 6 months; **AND** 6. Patient has a history of ≥ 2 flares in the past 12 months; **AND** 7. Patient has FIP1L1-PDGFRα-negative disease; **AND** 8. Provider attests the patient does not have an identifiable non-hematologic secondary cause of HES (e.g., drug hypersensitivity, parasitic helminth infection, HIV, non-hematologic malignancy); **AND** 9. Blood eosinophil count ≥ 1,000 cells/µL within the last 12 months. Mepolizumab (Nucala) may be approved when all the following documented criteria are met: 10. Criteria 1-9 above are met; **AND**

	11. Treatment with benralizumab has been ineffective after a minimum trial for 1 year unless contraindicated, or not tolerated. If ALL criteria are met, the request will be authorized for **12 months.** **Criteria (Reauthorization)** Benralizumab (Fasenra) and mepolizumab (Nucala) may be approved when all the following documented criteria are met: 1. Criteria 3 and 4 above continue to be met; **AND** 2. Documentation is submitted demonstrating disease stability or a positive clinical response (e.g., decrease in HES flares). If ALL criteria are met, the request will be authorized for **12 months.**
IgE-mediated food allergy omalizumab-igec (Omlyclo) omalizumab (Xolair)	Omalizumab (Xolair) and omalizumab-igec (Omlyclo) may be approved when all the following documented criteria are met: 1. Patient is 1 year of age or older, **AND** 2. Prescribed by, or in consultation with a provider who specializes in the treatment of IgE-mediated food allergies; **AND** 3. Diagnosis of IgE-mediated food allergy; **AND** 4. Not used in combination with another monoclonal antibody; **AND** 5. IgE-mediated food allergy has been confirmed by any of the following (a-c): a. Food specific skin prick test; **OR** b. IgE antibody testing; **OR** c. Oral food challenge; **AND** 6. Provider attests patient has been prescribed or has access to epinephrine for emergencies. If ALL criteria are met, the request will be authorized for **12 months.** **Criteria (Reauthorization)** omalizumab (Xolair) and omalizumab-igec (Omlyclo) may be approved when all the following documented criteria are met: 1. Criteria 3 and 4 above continue to be met; **AND** 2. Documentation is submitted demonstrating disease stability or a positive clinical response (e.g., reduction in allergic reactions). If ALL criteria are met, the request will be authorized for **12 months.**
Severe asthma with eosinophilic phenotype benralizumab (Fasenra) depemokimab-ulaa (Exdensur)	Benralizumab (Fasenra) may be approved when all the following documented criteria are met: 1. Patient is 6 years of age or older; **AND**

mepolizumab (Nucala) reslizumab (Cinqair)	2. Prescribed by, or in consultation with a provider who specializes in the treatment of severe asthma with eosinophilic phenotype; **AND** 3. Patient has **SEVERE** asthma as defined by one of the following: a. Documentation of functional impairment due to poor asthma control or exacerbations (e.g. limitation of activities of daily living, nighttime awakenings often 7x/week); **OR** b. SABA (e.g. albuterol, levalbuterol) use for symptom control occurs several times per day; **OR** c. Lung function (percent predicted FEV1) <60%; **AND** 4. Not used in combination with another monoclonal antibody indicated for the treatment of severe asthma with eosinophilic phenotype; **AND** 5. Documentation of blood eosinophil count (in the absence of other potential causes of eosinophilia) of **ONE** of the following: a. Greater than or equal to (≥) 150 cells/µL in prior 6 weeks; **OR** b. Greater than or equal to (≥) 300 cells/µL in prior 12 months; **AND** 6. Patient is currently being treated with: a. A high-dose, or maximally tolerated inhaled corticosteroid (ICS); **AND** b. One asthma controller medication: i. long-acting beta-2 agonist (LABA); ii. long-acting muscarinic antagonist; **OR** iii leukotriene receptor antagonist; **AND** 7. Asthma controller medications will be continued unless contraindicated. Reslizumab (Cinqair) may be approved when all the following documented criteria are met: 8. Patient is 18 years of age or older; **AND** 9. Criteria 2-7 above is met. Mepolizumab (Nucala) may be approved when all the following documented criteria are met: 10. Patient is 6 years of age or older; **AND** 11. Criteria 2-7 above is met; **AND** 12. Treatment with benralizumab, dupilumab, and reslizumab have been ineffective after a minimum trial of 12 weeks each unless, contraindicated, or not tolerated. Depemokimab-ulaa (Exdensur) may be approved when all the following documented criteria are met: 13. Patient is 12 years of age or older; **AND** 14. Criteria 2-7 above is met; **AND**

	15. Treatment with benralizumab, dupilumab, mepolizumab, and reslizumab have been ineffective after a minimum trial of 12 weeks each unless, contraindicated, or not tolerated. If ALL criteria are met, the request will be authorized for **12 months.**
	Criteria (Reauthorization)
	benralizumab (Fasenra), depemokimab-ulaa (Exdensur), mepolizumab (Nucala) and reslizumab (Cinqair) may be approved when all the following documented criteria are met: 1. Criteria 2, 4, 6, and 7 above continue to be met; **AND** 2. Documentation is submitted demonstrating disease stability or a positive clinical response (e.g. reduced asthma exacerbations, FEV1, reduced systemic corticosteroid requirements, reduced hospitalizations). If ALL criteria are met, the request will be authorized for **12 months.**

Dosage and quantity limits

Drug	Indication	Approved Dose	Dosage Form and Quantity Limit
Cinqair	Severe asthma with eosinophilic phenotype	3 mg/kg IV over 20-50 minutes every 4 weeks	• 100 mg/10 mL vial: weight based dosing
Exdensur	Severe asthma with eosinophilic phenotype	100mg subQ every 6 months	• 100mg/mL pre-filled syringe/PEN per 6 months
Fasenra	EGPA and HES	30 mg subQ once every 4 weeks	• 30 mg/mL pre-filled syringe/autoinjector: 1 mL per 28 days
Fasenra	Severe asthma with eosinophilic phenotype	<u>6-11 years old; < 35 kg:</u> 10 mg subQ every 4 weeks for the first 3 doses and then once every 8 weeks <u>6-11 years ≥ 35 kg OR 12 years or older</u> 30 mg subQ once every 4 weeks for the first 3 doses and then once every 8 weeks	• 10 mg/0.5 mL prefilled syringe: Initial= 0.5 mL per 28 days for doses 1-3 Maintenance= 0.5 mL per 56 days (doses 4-beyond) • 30 mg/mL pre-filled syringe/autoinjector: Initial= 1 mL per 28 days (doses 1-3) Maintenance= 1 mL per 56 days (doses 4-beyond)
Nucala	CRSwNP COPD with eosinophilic phenotype	100 mg every 4 weeks subQ	• 100 mg single dose vial: 1 vial per 28 days • 100 mg/mL prefilled syringe/autoinjector: 1 mL per 28 days

Nucala	EGPA HES	300 mg every 4 weeks subQ	• 100 mg single dose vial: 3 vials per 28 days • 100 mg/mL prefilled syringe/autoinjector: 3 mL per 28 days
Nucala	Severe asthma with eosinophilic phenotype	6-11 years old 40 mg every 4 weeks 12 years or older 100 mg every 4 weeks	• 40 mg/0.4 mL prefilled syringe: 0.4 mL per 28 days • 100 mg single dose vial: 1 vial per 28 days • 100 mg/mL prefilled syringe/autoinjector: 1 mL per 28 days
Xolair	Moderate and Severe Asthma	75 to 375 mg administered subcutaneously by a health care provider every 2 or 4 weeks. Determine dose (mg) and dose frequency by serum total IgE level (IU/mL), measured before the start of treatment, and body weight (kg). See appendix below.	• 75 mg/0.5mL prefilled syringe • 150 mg/mL prefilled syringe • 150 mg vial • 300 mg/2mL prefilled syringe
Xolair	CRSwNP IgE-mediated food allergy	75 to 600 mg SC administered subcutaneously by a health care provider every 2 or 4 weeks. Determine dose (mg) and dose frequency by serum total IgE level (IU/mL), measured before the start of treatment, and body weight (kg). See appendix below.	• 75 mg/0.5mL prefilled syringe • 150 mg/mL prefilled syringe • 150 mg vial • 300 mg/2mL prefilled syringe
Xolair	CSU	150 or 300 mg administered subcutaneously by a health care provider every 4 weeks. Dose and dose frequency are not dependent on serum IgE or body weight.	• 150 mg/mL prefilled syringe: 1 mL per 28 days • 150 mg vial: 1 vial per 28 days • 300 mg/2mL prefilled syringe: 2 mL per 28 days
Tezspire	Severe Asthma CRSwNP	210 mg administered once every 4 weeks	• 210 mg/1.91 mL vial/syringe/pen: • 1 vial per 28 days OR 1.91 mL per 28 days

Coding:

HCPCS Code	Description
J0517	Injection, benralizumab, 1 mg
J2361	Injection, depemokimab-ulaa, 1 mg

J2182	Injection, mepolizumab, 1 mg
J2356	Injection, tezepelumab-ekko, 1 mg
J2357	Injection, omalizumab, 5 mg
J2786	Injection, reslizumab, 1 mg

Appendix

Asthma Dose Recommendations

Omalizumab Doses Administered Every 2 or 4 Weeks (mg) for Pediatric Patients Ages of 6 to <12 Years

Pre-treatment IgE (IU/mL)	Dosing Freq.	Body Weight (kg)									
		20-25	>25-30	>30-40	>40-50	>50-60	>60-70	>70-80	>80-90	>90-125	>125-150
30-100	Every 4 Weeks	75	75	75	150	150	150	150	150	300	300
>100-200		150	150	150	300	300	300	300	300	225	300
>200-300		150	150	225	300	300	300	225	225	300	375
>300-400		225	225	300	225	225	225	300	300		
>400-500		225	300	225	225	225	225	375	375		
>500-600		300	300	225	300	300	300				
>600-700		300	225	225	300	300					
>700-900	Every 2 Weeks	225	225	300	375						
>900-1100		225	300	375							
>1100-1200		300	300								
>1200-1300		300	375								

Do Not Dose

Omalizumab Doses Administered Every 2 or 4 Weeks (mg) for Patients 12 Years of Age and Older

Pre- treatment IgE (IU/mL)	Dosing Freq.	Body Weight (kg)			
		30 to 60	> 60 to 70	> 70 to 90	> 90 to 150
30-100	Every 4 Weeks	150	150	150	300
>100-200		300	300	300	225
>200-300		300	225	225	300
>300-400	Every 2 weeks	225	225	300	
>400-500		300	300	375	
>500-600		300	375		
>600-700		375			

Do Not Dose

Chronic Rhinosinusitis with Nasal Polyposis Dosing Recommendations (CRSwNP)

Omalizumab Doses Every 2 or 4 Weeks* for Adult Patients with CRSwNP

Pre-treatment IgE (IU/mL)	Dosing Freq.	Body Weight (kg)							
		>30-40	>40-50	>50-60	>60-70	>70-80	>80-90	>90-125	>125-150
30-100	Every 4 Weeks	75	150	150	150	150	150	300	300
>100-200		150	300	300	300	300	300	450	600
>200-300		225	300	300	450	450	450	600	375
>300-400		300	450	450	450	600	600	450	525

>400-500		450	450	600	600	375	375	525	600
>500-600		450	600	600	375	450	450	600	
>600-700		450	600	375	450	450	525		
>700-800	Every 2 Weeks	300	375	450	450	525	600		
>800-900		300	375	450	525	600			
>900-1000		375	450	525	600				
>1000-1100		375	450	600					
>1100-1200		450	525	600					
>1200-1300		450	525						
>1300-1500		525	600						

Do Not Dose

IgE-Mediated Food Allergy Dosing Recommendations

Omalizumab Doses Every 2 or 4 Weeks* Patients 1 years of Age and Older with IgE-Mediated Food Allergy

Pre-treatment IgE (IU/mL)	Dosing Freq.	Body Weight (kg)												
		>10-12	>12-15	>15-20	>20-25	>25-30	>30-40	>40-50	>50-60	>60-70	>70-80	>80-90	>90-125	>125-150
30-100	Every 4 Weeks	75	75	75	75	75	75	150	150	150	150	150	300	300
>100-200		75	75	75	150	150	150	300	300	300	300	300	450	600
>200-300		75	75	150	150	150	225	300	300	450	450	450	600	375
>300-400		150	150	150	225	225	300	450	450	450	600	600	450	525
>400-500		150	150	225	225	300	450	450	600	600	375	375	525	600
>500-600		150	150	225	300	300	450	600	600	375	450	450	600	
>600-700		150	150	225	300	225	450	600	375	450	450	525		
>700-800	Every 2 Weeks	150	150	150	225	225	300	375	450	450	525	600		
>800-900		150	150	150	225	225	300	375	450	525	600			
>900-1000		150	150	225	225	300	375	450	525	600				
>1000-1100		150	150	225	225	300	375	450	600					
>1100-1200		150	150	225	300	300	450	525	600					
>1200-1300		150	225	225	300	375	450	525						
>1300-1500		150	225	300	300	375	525	600						
>1500-1850			225	300	375	450	600							

Do Not Dose

References

Policy: Asthma and COPD Agents: Monoclonal Antibodies

1. Cinqair. Package insert. Teva SP, Inc; June 2026.
2. Exdensur. Package insert. Glaxosm, Inc; June 2026.
3. Fasenra. Package insert. Astraze, Inc; June 2026.
4. Nucala. Package insert. Glaxosm, Inc; June 2026.
5. Tezspire. Package insert. Amgen, Inc; June 2026.
6. Xolair. Package insert. Genentech, Inc; June 2026.
7. National Asthma Education and Prevention Program (NAEPP). Guidelines for the diagnosis and management of asthma. Expert Panel Report 3. Bethesda, MD: National Institutes of Health (NIH), National Heart, Lung, and Blood Institute (NHLBI); August 2007.
8. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention. 2026 Update. Available from: http://www.ginasthma.org. Accessed June 2026.
9. Gevaert P, Omachi TA, Corren J et al. Efficacy and safety of omalizumab in nasal polyposis: 2 randomized phase 3 trials. *J Allergy Clin Immunol* 2020;146(3):595-605. Available at: https://pubmed.ncbi.nlm.nih.gov/32524991/. Accessed January 27, 2021.
10. Peters AT, Spector S, Hsu J, et al. Diagnosis and management of rhinosinusitis: a practice parameter Update. *Ann Allergy Asthma Immunol* 2014 (113):347-385. Available at: http://www.aaaai.org/Aaaai/media/MediaLibrary/PDF%20Documents/Practice%20and%20Parameters/2014-October_Rhinosinusitis_Update.pdf. Accessed January 27, 2021.
11. 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(7):1393-1414.
12. UptoDate. Anti-IGgE Therapy, Updated November 18, 2021. Accessed August 17, 2023.
13. Busse W, Corren J, Lanier BQ, et al. Omalizumab, anti-lgE recombinant humanized monoclonal antibody, for the treatment of severe allergic asthma. *J Allergy Clin Immunol.* 2001;108(2):184-190. doi:10.1067/mai.2001.117880

History

Approved Date	Effective Date	Version	Action and Summary of Changes
06/05/2026	10/1/2026	WA.PHAR.158-1	• Combined policies WA.PHAR.29 and WA.PHAR.30 into one policy • Added new drug indications when applicable • Replaced prescribed by, or in consultation with various specialists to “prescribed by, or consultation with a provider who specializes in the treatment of [insert indication]. • Removed drug names from criteria. • Added additional criteria for nonpreferred drugs to step through all less costly alternatives. • Removed the background section. • Added package inserts for all drugs in the references. • Updated guidelines in references. • Consolidated the dose and quantity table. • Moved the appendix section above references section.
Previous Policy changes relevant from Antiasthmatic Monoclonal Antibody- Anti- IgE Antibodies and IL-5 Antagonists)			

Date	Effective Date	Version	Action and Summary of Changes
02/28/2024	08/01/2024	WA.PHAR.29-3	• Approved by DUR Board • Policy renumbered to new nomenclature • CRSwNP indication added
01/27/2020	05/01/2020	WA.PHAR.30-2	• General formatting updates and updated footnote date to January 27, 2020
01/13/2020	05/01/2020	WA.PHAR.30-1	• Changed effective date to May 1, 2020
12/10/2019		WA.PHAR.30-1	• Updated definition of severe asthma. Removed cardiology and hematology specialty from EGPA criteria
10/16/2019	05/01/2020	WA.PHAR.29-2	• Approved by DUR Board General formatting updates were made from 09/24/2019-01/27/2020
10/11/2019		WA.PHAR.30-1	• Updated preferred/non-preferred status
10/03/2019		WA.PHAR.30-1	• General formatting updates; added the note at the top.
07/07/2019		WA.PHAR.30-1	• Clinical criteria update for diagnosis of severe asthma with an eosinophilic phenotype AND diagnosis of EGPA
02/21/2018	07/01/2018	WA.PHAR.29-1	• New policy created