Targeted Immune Modulators for Severe Asthma and Atopic Dermatitis

Goal(s):

- Promote use that is consistent with national clinical practice guidelines, medical evidence, and OHP-funded conditions. Allow case-by-case review for members covered under the EPSDT program.
- Promote use of cost-effective products.

Length of Authorization:

- Up to 12 months

Requires PA:

- All targeted immune modulators with indications for severe asthma, atopic dermatitis, or other indications (see **Table 1** below) for both pharmacy and physician-administered claims.
- This PA does not apply to topical agents for inflammatory skin conditions which are subject to separate clinical PA criteria.

Covered Alternatives:

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

Table 1. FDA-Approved Indications and Ages

Generic Name/ BRAND NAME	Eosinophilic Asthma	Moderate to Severe Allergic Asthma	Difficult To Treat, Severe Asthma	Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP)	Eosinophilic Esophagitis	Atopic Dermatitis (AD)	IgE-Mediated Food Allergy	Other
Abrocitinib CIBINQO						≥12 yrs		
Benralizumab FASENRA	≥6 yrs							EPGA ≥18 yrs
Dupilumab DUPIXENT	≥6 yrs (or with oral corticosteroid dependent asthma)			≥12 yrs	≥1 yr & weighing ≥15 kg	≥6 months	≥18 yrs	PN ≥18 yrs COPD ≥18 yrs CSU ≥ 12 yrs
Lebrikizumab EBGLYSS						≥12 yrs		
Mepolizumab NUCALA	≥6 yrs			≥18 yrs				HES ≥ 12 yrs EPGA ≥18 yrs
Nemolizumab NEMLUVIO								PN ≥ 18 yrs
Omalizumab XOLAIR		≥6 yrs		≥18 yrs			≥ 1 yo	CSU ≥ 12 yrs
Reslizumab CINQAIR	≥18 yrs							
Tezepelumab TEZSPIRE			≥ 12 yrs					
Tralokinumab ADBRY						≥12 yrs		

Abbreviations: COPD = chronic obstructive pulmonary disease; CSU = chronic spontaneous urticaria; EGPA = eosinophilic granulomatosis with polyangiitis; HES = hypereosinophilic syndrome; PN = prurigo nodularis

Table 2. Recommended First-Line Conventional Treatments

Indication	Conventional treatment
Atopic Dermatitis	4-week trial of either one the following treatments: • Moderate to high potency topical corticosteroid (e.g., clobetasol, desoximetasone, desonide, mometasone, betamethasone, halobetasol, fluticasone, or fluocinonide) in combination with a topical calcineurin inhibitor (e.g., tacrolimus) OR • Oral immunomodulator therapy (e.g., cyclosporine, methotrexate, or oral corticosteroids)?
Eosinophilic granulomatosis with polyangiitis (EGPA)	4-week trial of oral corticosteroid therapy (equivalent to oral prednisone or prednisolone 7.5 to 50 mg per day)
Nasal polyps	Intranasal corticosteroids (2 or more courses administered for at least 12 weeks each)
Asthma	Maximally dosed inhaled corticosteroid (**Table 3**) AND 2 additional controller drugs (i.e., long-acting inhaled beta-agonist, montelukast, zafirlukast, tiotropium)
Eosinophilic esophagitis	• Proton pump therapy for at least 8 weeks OR • Corticosteroid therapy with local administration of fluticasone multi-use inhaler for at least 8 weeks (use nasal inhaler and swallow contents of the spray).
Chronic Obstructive Pulmonary Disease (COPD)	• Triple inhaler therapy (inhaled corticosteroid (ICS) with long-acting beta agonist (LABA) and long-acting muscarinic antagonist (LAMA) inhalers) for at least 3 months
Other	Documentation for conventional treatment(s) are not required

Table 3. Maximum Adult Doses for Inhaled Corticosteroids

High Dose Corticosteroids:	Maximum Dose
Qvar (beclomethasone)	320 mcg BID
Pulmicort Flexhaler (budesonide)	720 mcg BID
Alvesco (ciclesonide)	320 mcg BID
Arnuity Ellipta (fluticasone furoate)	200 mcg daily
Armonair (fluticasone propionate)	232 mcg BID
Flovent HFA (fluticasone propionate)	880 mcg BID
Flovent Diskus (fluticasone propionate)	1000 mcg BID
Asmanex Twisthaler (mometasone)	440 mcg BID
Asmanex HFA (mometasone)	400 mcg BID
High Dose Corticosteroid / Long-acting Beta-agonists	**Maximum Dose**
Symbicort (budesonide/formoterol)	320/9 mcg BID
Advair Diskus (fluticasone/salmeterol)	500/50 mcg BID
Advair HFA (fluticasone/salmeterol)	460/42 mcg BID
Wixela Inhub (fluticasone/salmeterol)	500/50 mcg BID
AirDuo Digihaler (fluticasone/salmeterol)	232/14 mcg BID
Airduo RespiClick (fluticasone/salmeterol)	232/14 mcg BID
Breo Ellipta (fluticasone/vilanterol)	200/25 mcg daily
Dulera (mometasone/formoterol)	400/10 mcg BID

Table 4. Required baseline documentation of disease severity

Indication	Disease severity definitions

Atopic dermatitis or prurigo nodularis	Functional impairment as indicated by Dermatology Life Quality Index (DLQI) ≥ 11 or Children's Dermatology Life Quality Index (CDLQI) ≥ 13 (or severe score on another validated tool) AND one or more of the following: • At least 10% body surface area involved, or • Hand, foot, face, or mucous membrane involvement
Asthma	• At least 4 asthma exacerbations requiring systemic corticosteroids in the previous 12 months OR • taking continuous oral corticosteroids at least the equivalent of prednisolone 5 mg per day for the previous 6 months OR • at least 1 hospitalization or ≥ 2 emergency department (ED) visits in the past 12 months while on conventional treatment outlined in **Table 2 and 3**
IgE-mediated food allergy	• Number of epinephrine administrations and hospital/emergency department visits (if any) in past 12 months which were caused by presumed exposure to food that triggered an allergic response
Hypereosinophilic syndrome (HES)	• Duration of disease of at least 6 months without an identifiable non-hematologic secondary cause
Chronic Obstructive Pulmonary Disease (COPD)	• Blood eosinophil count ≥ 300 cells/μL AND • at least 1 hospitalization or ≥ 2 emergency department (ED) visits in the past 12 months while on conventional treatment outlined in **Table 2 and 3**

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Is the request for an FDA-approved age and indication (**Table 1**)?	**Yes:** Go to #3	**No:** Pass to RPh. Deny; medical appropriateness.
3. Is the diagnosis an OHP-funded diagnosis? Note: chronic idiopathic urticaria and mild-to-moderate atopic dermatitis are not OHP-funded conditions	**Yes**: Go to #5	**No:** If not eligible for EPSDT review: Pass to RPh. Deny; not funded by the OHP. If eligible for EPSDT review: Go to #4
4. Is there documentation that the condition is of sufficient severity that it impacts the patient's health (e.g., quality of life, function, growth, development, ability to participate in school, perform activities of daily living, etc)?	**Yes:** Go to #5	**No:** Pass to RPh. Deny; medical necessity.
5. Is this a request for continuation of therapy previously approved by the FFS program?	**Yes:** Go to **Renewal Criteria**	**No:** Go to #6

Approval Criteria		
6. Does the patient have a concurrent prescription for EpiPen® or equivalent so they are prepared to manage delayed anaphylaxis if it occurs after monoclonal antibody therapy?	**Yes:** Go to #7	**No:** Pass to RPh. Deny; medical appropriateness.
7. Is the medication being prescribed by, or in consultation with, an appropriate specialist? Examples include allergist for any condition, dermatologist for atopic dermatitis, otolaryngologist for nasal polyps, or pulmonologist for asthma	**Yes:** Go to #8	**No:** Pass to RPh. Deny; medical appropriateness.
8. Is there documentation of failure to have benefit with, or contraindication to, recommended conventional first-line treatments options (**Table 2 and 3**)?	**Yes:** Go to #9	**No:** Pass to RPh. Deny; medical appropriateness.
9. Is there documentation of disease severity prior to initiation of a targeted immune modulator (**Table 4**)?	**Yes:** Go to #10	**No:** Pass to RPh. Deny; medical appropriateness.
10. Is the request for treatment of difficult to treat, severe asthma? Note: Difficult to treat, severe asthma is defined as asthma with poor symptom control on high-dose inhaled corticosteroid-long-acting beta agonist (ICS-LABA) or maintenance oral corticosteroids (OCS).	**Yes:** Go to #11	**No:** Go to #13
11. Has the patient been adherent to current asthma therapy in the past 12 months?	**Yes:** Go to #12	**No:** Pass to RPh. Deny; medical appropriateness.
12. Is the patient currently receiving another monoclonal antibody (e.g., dupilumab, omalizumab, mepolizumab, benralizumab, reslizumab, tezepelumab etc.) without documentation indicating the patient is switching between treatments?	**Yes:** Pass to RPh. Deny; medical appropriateness.	**No:** Go to #13
13. Is the request for eosinophilic asthma, allergic asthma, or food allergies?	**Yes:** Go to #14	**No:** Go to #15

Approval Criteria		
14. Is there diagnostic documentation for the requested indication? • Eosinophilic asthma: blood eosinophil count ≥150 cells/μL OR fractional exhaled nitric oxide (FeNO) ≥25 ppb in the past 12 months • Allergic IgE-mediated asthma: positive skin test OR in vitro reactivity to perennial allergen • Food allergy: IgE-mediated food allergy with skin testing to confirm allergy OR in vitro reactivity to perennial allergen	**Yes:** Approve for up to 12 months. Document test and result:_____	**No:** Pass to RPh. Deny; medical appropriateness.
15. Is the request for a JAK inhibitor (e.g., abrocitinib)?	**Yes:** Go to #16	**No:** Go to #17
16. Has the patient failed to have benefit with or have intolerance or contraindication to alternative targeted immunodulatory therapy?	**Yes:** Go to #17	**No:** Pass to RPh. Deny; medical appropriateness.
17. Duration of approval based on indication:	Asthma, COPD, hypereosinophilic syndrome, eosinophilic granulomatosis with polyangiitis, and chronic spontaneous urticaria: 12 months All other conditions: requested duration or 6 months, whichever is less	

Renewal Criteria		
1. Is the request to renew therapy for inflammatory skin disease?	**Yes:** Go to #2	**No:** Go to #3
1. Have the patient's symptoms improved with targeted immune modulator therapy? • at least a 50% reduction in the Eczema Area and Severity Index score (EASI 50) from when treatment started OR • at least a 4-point reduction in the Dermatology Life Quality Index (DLQI) or Children's Dermatology Life Quality Index (CDLQI from when treatment started OR • at least a 2-point improvement on the Investigators Global Assessment (IGA) score?	**Yes:** Approve for 12 months	**No:** Pass to RPh. Deny; medical appropriateness.

Renewal Criteria		
2. Is the request to renew therapy for asthma or COPD?	**Yes:** Go to #4	**No:** Go to #6
3. Is the patient currently taking an inhaled corticosteroid and 2 additional controller drugs (i.e., long-acting inhaled beta-agonist, montelukast, zafirlukast, tiotropium) for asthma or triple inhaler therapy (ICS/LABA/LAMA) for COPD?	**Yes:** Go to #5	**No:** Pass to RPh. Deny; medical appropriateness.
4. Has the number of emergency department (ED) visits or hospitalizations in the last 12 months been reduced from baseline, or has the patient reduced their systemic corticosteroid dose by ≥50% compared to baseline or has the number of COPD exacerbations decreased?	**Yes:** Approve for up to 12 months.	**No:** Pass to RPh. Deny; medical appropriateness.
5. Is the request to renew therapy for another FDA approved indication?	**Yes:** Go to #7	**No:** Pass to RPh. Deny; medical appropriateness.
6. Have the patient's symptoms improved with therapy?	**Yes:** Approve for 12 months	**No:** Pass to RPh. Deny; medical appropriateness.

1. *Oregon Health Evidence Review Commission. Coverage Guidance and Reports.* *http://www.oregon.gov/oha/hpa/csi-herc/pages/index.aspx Accessed May 2, 2023.*
2. National Institute for Health and Care Excellence (NICE) Guidance. Mepolizumab for Treating Severe Eosinophilic Asthma. https://www.nice.org.uk/guidance/ta671 February 2021.
3. National Institute for Health and Care Excellence (NICE) Guidance. Dupilumab for Treating Severe Asthma with Type 2 Inflammation. https://www.nice.org.uk/guidance/ta751 December 2021
4. Global Initiative for Asthma. Global strategy for asthma management and prevention (2021 update). 2021. https://ginasthma.org/wp-content/uploads/2021/05/GINA-Main-Report-2021-V2-WMS.pdf

P&T Review: *12/24 (DM), 8/24; 6/23; 10/22; 6/22; 8/2; 10/20,7/19; 7/18; 7/16*
Implementation: *1/1/25; 9/1/24; 7/1/23; 1/1/23; 7/1/22; 1/1/22*