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Prior Authorization Criteria Update: Omalizumab (XOLAIR)

Purpose of Update: Omalizumab (XOLAIR) recently received expanded Food and Drug Administration (FDA) approval for reduction of allergic reactions or anaphylaxis that may occur in patients with food allergies exposed to foods that generate an immunoglobulin E (IgE)-mediated response. The purpose of this update is to review the evidence for the safety and efficacy of omalizumab for use in managing food allergies in susceptible individuals.

Plain Language Summary:

- Food allergy affects many people in the United States. Symptoms range from tingling of the tongue and lips and can progress to severe symptoms such as tongue swelling, difficulty breathing, or even death. The current treatment for food allergy is to avoid eating foods that may cause an allergic reaction and to keep medications such as epinephrine available in case of a reaction. Accidental exposure to foods that can trigger an allergic reaction is a major concern.
- PALFORZIA, an oral powder, is available to reduce severity of symptoms caused by accidental peanut exposure in people with a confirmed peanut allergy.
- The FDA recently approved another medicine to reduce allergic food reactions, called omalizumab (XOLAIR). This medicine is injected under the skin by a health care provider or caregiver. If the health care provider completes education about this medicine, then patients can be taught to inject themselves with the medicine at home. This medicine has been available for several other uses, including moderate to severe allergic asthma.
- In a clinical trial of omalizumab, it was better than placebo at decreasing the number of people who had allergic symptoms after eating peanuts, cashews, milk, and eggs. Most people were able to take omalizumab without any side effects. If people had a side effect, they developed a rash or itching where the medicine was injected, or a fever. A rare, but serious side effect of this medicine is called anaphylaxis, which can result in difficulty breathing and swelling of the lips and tongue. Food allergy can also cause anaphylaxis.
- The Oregon Health Authority asks health care providers to explain why a person needs omalizumab before Medicaid will pay for it. This process is called prior authorization.

Recommendation:

- Revise PA criteria for targeted immune modulators (TIMs) for Severe Asthma and Atopic Dermatitis to include use of omalizumab for treatment of food allergies in patients at high risk of frequent and/or severe allergic reactions due to accidental exposure to foods. Add clerical edits to PA criteria for expanded indications.

Background:

Food allergy affects about 15 million people in the United States.[1] The current treatment for food allergy is to avoid eating the foods that may cause an allergic reaction and have medications such as epinephrine on hand in case of a reaction. However, accidental exposures can be extremely difficult to avoid. The risks of accidental exposures and life-threatening reactions can place a large burden on patients and their families.[1]

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Peanut allergen powder (PALFORZIA) is FDA-approved to desensitize patients with a peanut allergy. Prior authorization criteria for peanut allergy powder are presented in **Appendix 1**. The Oregon Health Plan (OHP) prioritized list includes funding for peanut allergy treatment in Guideline Note 203.[2] Pharmaceutical treatment with medications to reduce reaction severity are included on line 123 when specified criteria are met.[2] Peanut allergy must be diagnosed clinically based on history of serious reaction or anaphylaxis, with skin or serologic testing, and with a double-blind, placebo-controlled oral food challenge test.[2] Any treatment must be by, or in consultation with, an allergist or immunologist.[2]

Two guidelines discuss management of food allergies and support OHP recommendations.[3,4] In 2014, a joint task force representing the American Academy of Allergy, Asthma, and Immunology and the Joint Council of Allergy, Asthma and Immunology issued recommendations for management of people with food allergies.[3] The council recommended that clinicians should determine whether the reported history of food allergy, which often proves inaccurate, and laboratory data are sufficient to diagnose food allergy or whether an oral food challenge is necessary (strong recommendation; high-quality evidence).[3] Clinicians should consider oral food challenges to aid in the diagnosis of IgE-mediated food allergy (strong recommendation; high-quality evidence).[3] Double-blind, placebo controlled challenges are the gold standard for oral food challenges.[3] In 2022, high-quality guidance from the Global Allergy and Asthma European Network (GA^2LEN) was published. The GA^2LEN task force supports documentation of IgE-mediated systemic allergic reactions and/or positive oral food challenge and evidence of allergic sensitization via skin prick testing before initiating allergen immunotherapy for food allergy.[4] The task force recommends offering peanut oral immunotherapy under specialist supervision with standardized evidence-based protocols using peanut products (or licensed pharmaceutical products, where appropriate), to selected children (aged 4 years and older) with clinically diagnosed, severe, IgE-mediated, peanut allergy to increase the amount of peanut tolerated while on therapy (high certainty of evidence).[4] Due to insufficient evidence in 2022, no recommendations were made by the task force for the use of omalizumab for treating food allergy, alone or in combination with immunotherapy.[4]

Omalizumab inhibits binding of IgE to high affinity IgE receptors on the surface of mast cells and basophils resulting in downregulation on these cells.[5] In February 2024, the FDA expanded the indication for omalizumab to include reduction of Type 1 allergic reactions, including anaphylaxis, that may occur with accidental exposure to one more foods in adults and pediatric patients aged 1 year and older with IgE-mediated food allergy.[5] Omalizumab is also FDA-approved for treatment of moderate to severe persistent asthma, chronic rhinosinusitis with nasal polyps (CRSwNP), and chronic spontaneous urticaria.[5] Omalizumab is not indicated for management of acute bronchospasm or status asthmaticus, emergency treatment of anaphylaxis, or other forms of urticaria.[5] Management of asthma and CRSwNP are funded by the Oregon Health Evidence Review Commission (HERC), while management of urticaria is not funded.[2]

The safety and efficacy of omalizumab in managing allergic response to food was evaluated in a multi-center, randomized, double-blind, placebo-controlled phase 3 trial (OUtMATCH; NCT03881696).[6] The trial was conducted in 168 adult and pediatric patients aged 1 to 56 years who were allergic to peanut and at least two other protocol-specified foods: milk, egg, wheat, cashew, hazelnut, or walnut.[6] Other food allergies (e.g., soy and seafood were not included in the protocol). Prior to enrollment, patients were screened with skin testing. If the results of skin-prick and laboratory testing confirmed the specific food allergies, double-blind, placebo-controlled oral food challenges followed. The trial enrolled patients who experienced dose-limiting symptoms (e.g., moderate to severe skin, respiratory or gastrointestinal symptoms) to a single dose of ≤ 100 mg of peanut protein and ≤ 300 mg protein for each of two other protocol-specific foods during the double-blind, placebo-controlled oral food challenge.[6] Patients that did not meet the food inclusion criteria for 3 foods were excluded from enrollment. Of the 435 patients screened, 213 patients (49%) were excluded for not meeting food allergy inclusion criteria.[6] Seventy-four patients (35%) did not meet the oral food challenge criteria and 139 (65%) did not meet the skin prick test criteria.[6] In addition, patients with a history of severe anaphylaxis (defined as neurological compromise or requiring intubation), poorly controlled atopic dermatitis, and poorly controlled or severe asthma, were excluded from the study.[6] Patients who received treatment with monoclonal antibody therapy, such as omalizumab, dupilumab, benralizumab, mepolizumab, reslizumab or other immunomodulatory therapy within 6 months of screening were also excluded from trial enrollment.

Patients were randomized 2:1 to receive a subcutaneous dosage of omalizumab or placebo for 16 to 20 weeks (Stage 1).[6] Dosing was based on weight and IgE serum levels according to study protocol.[6] After 16 to 20 weeks of treatment, each patient completed a double blind, placebo-controlled oral food challenge consisting of placebo and each of their 3 food allergens identified in pre-enrollment screening.[6] The primary outcome was the number of enrolled patients who successfully consumed a single dose of peanut protein ≥ 600 mg without dose-limiting symptoms during the food challenge conducted at the end of Stage 1 of treatment.[6] Secondary end points included consumption in escalating doses up to 4000 mg of a single food, of at least two foods, and of all three foods without dose-limiting symptoms; and the number of foods consumed at various doses (one dose of ≥600 mg or ≥1000 mg, at least one dose of 2000 mg, or two doses of 2000 mg) without dose-limiting symptoms.[6] The prespecified threshold dose of peanut protein was a single dose of at least 600 mg; for cashew, egg, milk, walnut, hazelnut, and wheat protein, the prespecified threshold was a single dose of at least 1000 mg.[6] Additional end points included quality of life, safety, skin-prick testing, and basophil-activation testing at the end of Stage 1.[6] Following the oral food challenge the first 60 patients who completed the double-blind, placebo-controlled phase of the study could continue to receive omalizumab in a 24 to 28 week open-label extension period (Stage 2).[6]

Three adults and 165 pediatric patients were included in the efficacy analyses.[6] The mean age of the pediatric patients was 8 years (age range: 1 to 17 years); 37% were less than 6 years of age, 38% were 6 to less than 12 years of age, and 25% were 12 to less than 18 years of age.[5] Patients were 56% male, 63% White, 13% Asian, 7% Black, and 16% were Other.[6] Enrolled patients were highly atopic, with a median total IgE level of 700 international units (IU) per milliliter.[6] Asthma, atopic dermatitis, allergic rhinitis, or all 3, were reported in a majority of the participants.[6]

After 16 to 20 weeks of treatment, a significantly greater percentage of omalizumab-treated patients compared to placebo-treated patients were able to consume a single dose of peanut protein ≥ 600 mg without dose-limiting symptoms (67% versus 7%; difference: 60%; 95% CI 47 to 70; p <0.001) during the double-blind, placebo-controlled oral food challenge trial.[6] Similar results were observed with administration of milk, wheat, hazelnut, walnut and egg proteins with a significant difference in food tolerability ranging from 50 to 67% of patients who received omalizumab versus placebo.[6] The reported difference between omalizumab and placebo in people with cashew allergy was lower at 38 , but still significant (95% CI 19 to 52; p <0.001).[6] Some clear treatment failures and variability in response rates were observed, as omalizumab failed to increase the tolerated food allergen dose in 17% of patients with peanut allergies and in 18%, 22%, and 41% of those with milk, egg, or cashew allergies, respectively.[6] The recommended omalizumab dosage for IgE-mediated food allergy is 75 mg to 600 mg by subcutaneous injection every 2 or 4 weeks based on pre-treatment serum total IgE level and body weight.[5] At this time, the appropriate duration of treatment is not known.

The incidence and severity of adverse events and the subset of treatment-related adverse events were similar between omalizumab and placebo, with the exception of injection-site reactions, which were more common in the omalizumab group.[6] One serious adverse event occurred in a 1-year-old participant in whom liver enzyme levels became elevated during the first stage of the trial; the participant was withdrawn from the trial and the child's parents were informed of the child's assigned group (omalizumab); the serious adverse event was determined to be possibly related to omalizumab, but a complete evaluation concluded that omalizumab was unlikely to be the cause.[6] No other serious adverse effects due to omalizumab administration were reported. Safety data provided in **Table 1** are from the primary analysis population of pediatric patients aged 1 years to 17 years from this trial.[5] Safety data obtained from adults (n=3) in this trial was limited.[5] **Table 1** lists the adverse reactions occurring in ≥3% of omalizumab-treated pediatric patients and more frequently than in patients treated with placebo in the trial.[5] There were no discontinuations due to adverse reactions.[5] Omalizumab has a black boxed warning regarding the risk of anaphylaxis that has occurred with the first dose of medication and beyond one year of starting treatment.[5] For these reasons, healthcare providers should closely observe patients after administering omalizumab.[5] Selection of patients for omalizumab self-administration should be based on criteria to mitigate risk from anaphylaxis.[5]

Table 1. Adverse Reactions Occurring in ≥ 3% of Omalizumab-Treated Pediatric Patients Aged 1 Year and Older[5]

Adverse Reaction	Omalizumab N=110	Placebo N=55
Injection Site Reaction	17 (15.5%)	6 (10.9%)
Pyrexia	7 (6.4%)	2 (3.6%)

References:

1. Omalizumab as Monotherapy and as Adjunct Therapy to Multi-Allergen Oral Immunotherapy in Food Allergic Participants (OUtMATCH). ClinicalTrials.gov ID NCT03881696. https://clinicaltrials.gov/study/NCT03881696?term=NCT03881696&rank=1#publications Accessed April 30, 2024.
2. Oregon Health Authory: Health Evidence Review Commission. Prioritized List of Health Services. January 2024. https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Prioritized-List.aspx Accessed April 29, 2024.
3. Sampson HA, Aceves S, Bock SA, et al. Food allergy: a practice parameter update-2014. *The Journal of allergy and clinical immunology.* 2014;134(5):1016-1025.e1043.
4. Muraro A, de Silva D, Halken S, et al. Managing food allergy: GA^{2}LEN guideline 2022. *The World Allergy Organization journal.* 2022;15(9):100687.
5. Omalizumab (XOLAIR) for subcutaneous injection. Prescribing Information. South San Francisco, CA; Genentech, Inc. February 2024.
6. Wood RA, Togias A, Sicherer SH, et al. Omalizumab for the Treatment of Multiple Food Allergies. *N Engl J Med.* 2024;390(10):889-899.

Appendix 1. Proposed Prior Authorization Criteria

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 2** 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)	Avoidance of Food Allergies	Other
Abrocitinib CIBINQO						≥12 yrs		
Benralizumab FASENRA	≥6 yrs							
Dupilumab DUPIXENT	≥6 yrs (or with oral corticosteroid dependent asthma)			≥18 yrs	≥1 yr & weighing ≥15 kg	≥6 months		PN ≥18 yrs
Mepolizumab NUCALA	≥6 yrs			≥18 yrs				HES ≥ 12 yrs EPGA ≥18 yrs
Omalizumab		≥6 yrs		≥18 yrs			≥ 1 yo	CSU ≥ 12 yrs

XOLAIR								
Reslizumab CINQAIR	≥18 yrs							
Tezepelumab TEZSPIRE			≥ 12 yrs					
Tralokinumab ADBRY						≥12 yrs		
Abbreviations: CSU = Chronic spontaneous urticaria; EPGA = Eosinophilic Granulomatosis with Polyangiitis; HES = Hyper-eosinophilic 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).
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 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 other 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

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.

Approval Criteria		
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:** Current age ≥ 21 years: Pass to RPh. Deny; not funded by the OHP. Current Age < 21 years: 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
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.

Approval Criteria		
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
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 AND double-blind placebo-controlled oral food challenge	**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

Approval Criteria		
16. Has the patient failed to have benefit with or have intolerance or contraindication to alternative targeted immumodulatory therapy?	**Yes:** Go to #17	**No:** Pass to RPh. Deny; medical appropriateness.
17. Duration of approval based on indication:	Asthma, 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
2. 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.
3. Is the request to renew therapy for asthma?	**Yes:** Go to #4	**No:** Go to #6

Renewal Criteria		
4. Is the patient currently taking an inhaled corticosteroid and 2 additional controller drugs (i.e., long-acting inhaled beta-agonist, montelukast, zafirlukast, tiotropium)?	**Yes:** Go to #5	**No:** Pass to RPh. Deny; medical appropriateness.
5. 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?	**Yes:** Approve for up to 12 months.	**No:** Pass to RPh. Deny; medical appropriateness.
6. Is the request to renew therapy for another FDA approved indication?	**Yes:** Go to #7	**No:** Pass to RPh. Deny; medical appropriateness.
7. 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

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P&T Review: *8/24 (DM); 6/23 (DM); 10/22 (DM) 6/22 (DM); 8/21 (DM); 10/20 (KS),7/19; 7/18; 7/16*
Implementation: *TBD; 7/1/23; 1/1/23; 7/1/22; 1/1/22*

Targeted Immune Modulators for Severe Asthma and Atopic Dermatitis

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Dulera (mometasone/formoterol)	400/10 mcg BID

Table 2. 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)	Other
Abrocitinib CIBINQO						≥12 yrs	
Benralizumab FASENRA	≥12 yrs						
Dupilumab DUPIXENT	≥6 yrs (or with oral corticosteroid dependent asthma)			≥18 yrs	≥12 yrs & weighing ≥40 kg	≥6 months	PN ≥18 yrs
Mepolizumab NUCALA	≥6 yrs			≥18 yrs			HES ≥ 12 yrs EPGA ≥18 yrs
Omalizumab XOLAIR		≥6 yrs		≥18 yrs			CSU ≥ 12 yrs
Reslizumab CINQAIR	≥18 yrs						
Tezepelumab TEZSPIRE			≥ 12 yrs				
Tralokinumab ADBRY						≥12 yrs	
*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).							
Abbreviations: CSU = Chronic spontaneous urticaria; EPGA = Eosinophilic Granulomatosis with Polyangiitis; HES = Hyper-eosinophilic Syndrome; PN = prurigo nodularis							

Table 3. Abrocitinib Dosing Adjustments for Atopic Dermatitis

Assessment	Recommended Dose
CYP2C19 Poor Metabolizer	50 mg once daily and may increase to 100 mg once daily after 12 weeks if inadequate response to 50 mg once daily
GFR 30 to 59 mL/min	Start with 50 mg once daily and may increase to 100 mg once daily after 12 weeks if inadequate response to 50 mg once daily
GFR < 30 mL/min	Use is not recommended
Severe hepatic impairment (Child-Pugh Class C)	Use is not recommended

Table 4. FDA-Approved Dosing for Monoclonal Antibodies Used to Treat Severe Asthma Phenotypes

Generic Name	Brand Name	Asthma Indication	Initial Dose and Administration Route	Maintenance Dose and Administration Route

Benralizumab	FASENRA	Severe asthma with an eosinophilic phenotype	30 mg SC every 4 weeks for the first 3 doses	30 mg SC every 8 weeks
Dupilumab	DUPIXENT	Add on maintenance treatment for moderate to severe asthma with an eosinophilic phenotype or with oral corticosteroid dependent asthma	Ages 6 to 11 yo**:** An initial loading dose is not necessary Ages ≥ 12 yo : 400 mg to 600 mg SC x 1 dose	Ages 6 – 11 yo (weight 15 to 30 kg) 100 mg SC every 2 weeks OR 300 mg SC every 4 weeks Ages ≥ 12 yo: 200 to 300 mg SC every 2 weeks
Mepolizumab	NUCALA	Severe asthma with an eosinophilic phenotype	N/A	Ages ≥ 6 – 11 yo: 40 mg SC every 4 weeks Ages ≥ 12 yo: 100 mg SC every 4 weeks
Omalizumab	XOLAIR	Moderate to severe persistent asthma and positive allergy testing	N/A	75 to 375 mg SC every 2 to 4 weeks based on weight and serum IgE levels
Reslizumab	CINQAIR	Severe asthma with an eosinophilic phenotype	N/A	3 mg/kg IV infusion every 4 weeks
Tezepelumab	TEZSPIRE	Severe asthma	N/A	210 mg SC every 4 weeks
Abbreviations: IgE = immunoglobulin E; IV = intravenous; kg = kilogram; mg = milligram; N/A = Not Applicable; SC = subcutaneous; yo = years old				

Table 5. Dupilumab Dosing by Indication

Indication	**Dose (Subcutaneous)**
Atopic Dermatitis in adults	600 mg followed by 300 mg every 2 weeks
Atopic Dermatitis in pediatric patients (aged 6 to 17 years)	600 mg followed by 300 mg every 4 weeks (15 to 29 kg) 400 mg followed by 200 mg every 2 weeks (30 to 59 kg) 600 mg followed by 300 mg every 2 weeks (≥ 60 kg)
Asthma in adults and adolescents (aged 12 years and older)	400 mg followed by 200 mg every 2 weeks or 600 mg followed by 300 mg every 2 weeks
Asthma in pediatric patients (aged 6 to 11 years)	100 mg every 2 weeks or 300 mg every 4 weeks (15 to 29 kg) 200 mg every 2 weeks (≥ 30 kg)
Chronic rhinosinusitis with nasal polyps in adults	300 mg every other week
Eosinophilic esophagitis in adults and adolescents (aged 12 years and older)	300 mg once a week
Prurigo nodularis in adults	600 mg followed by 300 mg given every 2 weeks

Approval Criteria	
1. What diagnosis is being treated?	Record ICD10 code.

Approval Criteria		
2. Is the request for an FDA-approved indication and indications (**Table 2**)?	**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 #4	**No:** Current age ≥ 21 years: Pass to RPh. Deny; not funded by the OHP. Current Age < 21 years: Go to #4
4. Is the request for dupilumab?	**Yes:** Go to # 5	**No:** Go to #6
5. If the request is for dupilumab, is the dose appropriate for the indication (**Table 5**)?	**Yes:** Go to #6	**No:** Pass to RPh. Deny; medical appropriateness.
6. Is the request for continuation of therapy?	**Yes:** Go to **Renewal Criteria**	**No:** Go to #7
7. 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 #8	**No:** Pass to RPh. Deny; medical appropriateness.
8. Is the diagnosis Severe Atopic Dermatitis (AD)? Severe disease is defined as:[1] • Having functional impairment as indicated by Dermatology Life Quality Index (DLQI) ≥ 11 or Children's Dermatology Life Quality Index (CDLQI) ≥ 13 (or severe score on other validated tool) AND one or more of the following: ○ At least 10% body surface area involved, or ○ Hand, foot, face, or mucous membrane involvement	**Yes:** Go to #9	**No:** Go to #17
9. Is the medication being prescribed by or in consultation with a dermatologist, allergist, or a provider who specializes in care of atopic dermatitis?	**Yes:** Go to #10	**No:** Pass to RPh. Deny; medical appropriateness

Approval Criteria		
10. Is the request for abrocitinib?	**Yes:** Go to #11	**No:** Go to #16
11. Are baseline labs (platelets, lymphocytes, lipids) documented? *Note: Abrocitinib therapy should not be initiated if platelet count is < 150,000/mm^3, absolute lymphocyte count is < 500/mm^3, absolute neutrophil count is < 1,000/mm^3, or hemoglobin is < 8 g/dL	**Yes:** Go to #12 Document Lab and Date Obtained: Platelets:_____ Lymphocytes:_____ Lipids:_____ Hemoglobin:_____	**No:** Pass to RPh. Deny; medical appropriateness
12. Is the patient currently taking other targeted immune modulators or oral immunosuppressants?	**Yes:** Pass to RPh. Deny; medical appropriateness.	**No:** Go to #13
13. If the patient has renal or hepatic impairment has the dose been adjusted as described in Table 3?	**Yes:** Go to #14	**No:** Pass to RPh. Deny; medical appropriateness
14. Is the patient taking a strong CYP2C19 inhibitor, CYP2C9 inhibitor, CYP2C9 inducer, CYP2C19 inducer, or antiplatelet inhibitor?	**Yes:** Go to #15	**No:** Go to #16
15. If the patient is taking a strong CYP2C19 inhibitor (e.g., fluvoxamine, fluoxetine), or CYP2C9 inhibitor (e.g., fluconazole, amiodarone), or CYP2C9 inducer (e.g., rifampin, phenobarbital), or CYP2C19 inducer (carbamazepine), or antiplatelet agent has the abrocitinib dose been adjusted in Table 3 or has the interacting drug been discontinued if necessary? *Note: agents with antiplatelet properties (NSAIDs, SSRIs, etc.) should not be used during the first 3 months of abrocitinib therapy. Do not use aspirin at doses ≥ 81 mg/day with abrocitinib during the first 3 months of therapy.	**Yes:** Go to #16	**No:** Pass to RPh. Deny; medical appropriateness

Approval Criteria		
16. Does the patient have a documented contraindication or failed 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)?	**Yes**: Document drug and dates trialed and intolerances (if applicable): 1._____(dates) 2._____(dates) Approve for length of treatment; maximum 6 months.	**No**: Pass to RPh. Deny; medical appropriateness
17. Is the request for eosinophilic granulomatosis with polyangiitis (EGPA, formerly known as Churg-Strauss Syndrome) for at least 6 months that is refractory to at least 4 weeks of oral corticosteroid therapy (equivalent to oral prednisone or prednisolone 7.5 to 50 mg per day)?	**Yes:** Approve for 12 months. Mepolizumab dose: 300 mg (3 x 100mg syringes) every 4 weeks	**No:** Go to #18
18. Is the request for the treatment of a patient with hypereosinophilic syndrome (HES) with a duration of 6 months or greater without an identifiable non-hematologic secondary cause?	**Yes:** Approve for 12 months. Mepolizumab dose: 300 mg (3 x 100mg syringes) every 4 weeks	**No:** Go to #19
19. Is the request for treatment of nasal polyps?	**Yes:** Go to #20	**No:** Go to #22
20. Is the prescriber an otolaryngologist, or allergist who specializes in treatment of chronic rhinosinusitis with nasal polyps?	**Yes:** Go to #21	**No:** Pass to RPh. Deny; medical appropriateness
21. Has the patient failed medical therapy with intranasal corticosteroids (2 or more courses administered for 12 to 26 weeks)?	**Yes:** Approve for 6 months	**No:** Pass to RPh. Deny; medical appropriateness
22. Is the request for treatment of severe asthma?	**Yes:** Go to #23	**No:** Go to #30
23. Is the prescriber a pulmonologist or an allergist who specializes in management of severe asthma?	**Yes:** Go to #24	**No:** Pass to RPh. Deny; medical appropriateness

Approval Criteria		
24. Has the patient experienced one of the following: ○ 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 receiving a maximally-dosed inhaled corticosteroid (Table 1) AND 2 additional controller drugs (i.e., long-acting inhaled beta-agonist, montelukast, zafirlukast, tiotropium)?	**Yes:** Go to #25 Document number asthma exacerbations over the previous 12 months or oral corticosteroid dose over the previous 6 months or number of hospitalizations or ED visits in the past 12 months _____. This is the baseline value to compare to in renewal criteria.	**No:** Pass to RPh. Deny; medical appropriateness.
25. Has the patient been adherent to current asthma therapy in the past 12 months?	**Yes:** Go to #26	**No:** Pass to RPh. Deny; medical appropriateness.
26. Is the patient currently receiving another monoclonal antibody (e.g., dupilumab, omalizumab, mepolizumab, benralizumab, reslizumab, tezepelumab etc.)?	**Yes:** Pass to RPh. Deny; medical appropriateness.	**No:** Go to #27
27. Is the request for tezepelumab?	**Yes:** Approve for up to 12 months.	No: Go to #28
28. Is the request for omalizumab and can the prescriber provide documentation of allergic IgE-mediated asthma diagnosis, confirmed by a positive skin test or in vitro reactivity to perennial allergen?	**Yes:** Approve once every 2-4 weeks for up to 12 months. Document test and result:_____	**No:** Go to #29

Approval Criteria		
29. Is the request for asthma with an eosinophilic phenotype and can the prescriber provide documentation of one of the following biomarkers: • severe eosinophilic asthma, confirmed by blood eosinophil count ≥150 cells/µL OR • fractional exhaled nitric oxide (FeNO) ≥25 ppb in the past 12 months?	**Yes:** Approve up to 12 months, based on dosing outlined in **Table 4**. Document eosinophil count (or FeNO date):_____	**No:** Pass to RPh. Deny; medical appropriateness.
30. Is the request for treatment of eosinophilic esophagitis?	**Yes:** Go to #31	**No:** Go to #32
31. Does the patient have a documented contraindication or failed trial of the following treatments: • 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).	**Yes**: Document drug and dates trialed and intolerances (if applicable): _____(dates) Approve for length of treatment; maximum 6 months.	**No**: Pass to RPh. Deny; medical appropriateness
32. 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 #33	**No:** Pass to RPh. Deny; medical necessity.
33. Is there documentation from the provider that alternative treatments for the condition are inappropriate, unavailable, or ineffective?	**Yes:** Approve for 12 months.	**No:** Pass to RPh. Deny; medical appropriateness.

Renewal Criteria		
1. Is the request to renew therapy for atopic dermatitis?	**Yes:** Go to #2	**No:** Go to #3
2. 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) 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.
3. Is the request to renew therapy for asthma?	**Yes:** Go to #4	**No:** Go to #6
4. Is the patient currently taking an inhaled corticosteroid and 2 additional controller drugs (i.e., long-acting inhaled beta-agonist, montelukast, zafirlukast, tiotropium)?	**Yes:** Go to #5	**No:** Pass to RPh. Deny; medical appropriateness.
5. 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?	**Yes:** Approve for up to 12 months.	**No:** Pass to RPh. Deny; medical appropriateness.
6. Is the request to renew therapy for another FDA approved indication?	**Yes:** Go to #7	**No:** Pass to RPh. Deny; medical appropriateness.
7. Have the patient's symptoms improved with therapy?	**Yes:** Approve for 12 months	**No:** Pass to RPh. Deny; medical appropriateness.

5. *Oregon Health Evidence Review Commission. Coverage Guidance and Reports.* *http://www.oregon.gov/oha/hpa/csi-herc/pages/index.aspx Accessed May 2, 2023..*
6. National Institute for Health and Care Excellence (NICE) Guidance. Mepolizumab for Treating Severe Eosinophilic Asthma. https://www.nice.org.uk/guidance/ta671 February 2021.
7. 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
8. 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: *6/23 (DM); 10/22 (DM) 6/22 (DM); 8/21 (DM); 10/20 (KS),7/19; 7/18; 7/16*
Implementation: *7/1/23; 1/1/23; 7/1/22; 1/1/22; 9/1/21; 8/19/19, 8/15/18, 8/16*

Author: Moretz

August 2024

Peanut (arachis hypogaea) Allergen Powder-dnfp (Palforzia)

Goal(s):

- To ensure appropriate use of desensitization products in patients with peanut allergies

Length of Authorization:

- 12 months

Requires PA:

- Peanut (arachis hypogaea) allergen powder-dnfp (Palforzia) (both pharmacy and physician administered claims)

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/

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Is the request by, or in consultation with, an allergist or immunologist?	**Yes:** Go to #3	**No:** Pass to RPh. Deny; medical appropriateness
3. Is the request for continuation of current therapy previously approved by the FFS program?	**Yes:** Go to **Renewal Criteria**	**No:** Go to #4
4. Is the request for an FDA-approved indication and age?	**Yes:** Go to #5	**No:** Pass to RPh. Deny; medical appropriateness
5. Does the patient have a history of serious peanut allergy or anaphylaxis?	**Yes:** Go to #6	**No:** Pass to RPh. Deny; medical necessity
6. Is there baseline documentation of number of epinephrine administrations and hospital/emergency department visits (if any) in past 12 months which were caused by presumed peanut exposure.	**Yes:** Go to #7 Epi administrations: _____ Hospital/ED visits: _____	**No:** Pass to RPh. Deny; medical appropriateness

Approval Criteria		
7. Does the patient have a history of severe peanut reaction that included circulatory shock or need for mechanical ventilation?	**Yes:** Pass to RPh. Deny; medical appropriateness	**No:** Go to #8
8. Does the patient have a peanut-specific positive IgE of ≥ 0.35 kU_a/L OR a skin prick test wheal of ≥ 3 mm?	**Yes**: Go to #9	**No:** Pass to RPh. Deny; medical appropriateness
9. Does the patient have a peanut allergy confirmed with a double-blind, placebo-controlled food challenge?	**Yes:** Go to #10	**No:** Pass to RPh. Deny; medical appropriateness
10. Does the patient have uncontrolled asthma, history of eosinophilic esophagitis, or other eosinophilic gastrointestinal disease?	**Yes:** Pass to RPh. Deny; medical appropriateness	**No:** Go to #11
11. Are the healthcare setting and the prescriber certified in the Palforzia REMS program AND will the patient be enrolled in the REMS program upon PA approval?	**Yes:** Approve for 12 months	**No:** Pass to RPh. Deny; medical appropriateness

Renewal Criteria		
1. Is the request for the full 300 mg daily maintenance dose of peanut allergen powder?	**Yes**: Go to #3	**No:** Go to #2
2. Is the patient new to OHA FFS and has the patient not yet completed the initial dose titration prior to FFS enrollment?	**Yes:** Approve for 12 months; Document baseline epinephrine use and hospital/emergency department visits	**No:** Pass to RPh. Deny; medical appropriateness

Renewal Criteria		
3. Has the patient had a reduced number of allergic attacks since beginning peanut allergen powder as evidenced by either: • Absence of, or reduction in the number of needed epinephrine administrations due to presumed peanut exposure? OR • Absence of, or reduction in the number of hospital/emergency department visits due to presumed peanut exposure?	**Yes**: Approve for 12 months	**No:** Pass to RPh. Deny; medical appropriateness

P&T/DUR Review: 8/24 (DM); 8/23 (DM); 2/21 (SF)
Implementation: TBD; 3/1/21