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Prior Authorization Criteria Update: Targeted Immune Modulators for Severe Asthma and Atopic Dermatitis AND Targeted Immune Modulators for Autoimmune Conditions

Plain Language Summary:

- The Oregon Health Evidence Review Commission serves Oregon citizens by ensuring that certain medical procedures, devices and tests paid for with Medicaid health care dollars are safe and proven to work.[1] This Commission decides which health care services to put on the Oregon Health Plan's Prioritized List of Health Services.
- As of February 1, 2023 the Health Evidence Review Commission revised guidance regarding coverage for severe inflammatory skin disease medical treatments to require a 4-week trial and failure (or documented contraindication) of 2 topical medications or one oral medication that are proven to alleviate symptoms of atopic dermatitis (also known as eczema) before advancing to disease modifying drug such as dupilumab or upadacitinib.
- The Drug Use Research & Management program is recommending the atopic dermatitis prior authorization criteria be revised to align with the guidance approved by the Health Evidence Review Commission.

Purpose of Update: Revise prior authorization (PA) criteria for targeted immune modulators (TIMs) used to treat atopic dermatitis (i.e., dupilumab and upadacitinib) to align with updated 2023 Health Evidence Review Commission (HERC) guidance.

The HERC revised Guideline Note 21 which provides funding guidance for severe inflammatory skin diseases effective February 1, 2023. For severe atopic dermatitis/eczema, funded treatments include: topical moderate- to high- potency corticosteroids, topical calcineurin inhibitors (i.e. tacrolimus), and oral immunomodulatory therapy (e.g. cyclosporine, methotrexate, or oral corticosteroids).[1] Targeted immune modulators (i.e. dupilumab and upadacitinib) are included on this line when:

A) Prescribed in consultation with a dermatologist or allergist or immunologist, AND

B) The patient has failed (defined as inadequate efficacy, intolerable side effects, or side effects that pose a health risk) either:

    1) a 4-week trial of a combination of a topical moderate to high potency topical steroid and a topical non-steroidal agent (e.g., tacrolimus)

    OR

    2) an oral immunomodulator.[1]

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Recommendation:

- Revise PA criteria for "Targeted Immune Modulators for Severe Asthma and Atopic Dermatitis" and "Targeted Immune Modulators for Autoimmune Conditions" to require a 4-week trial and failure (or contraindication) of either moderate to high potency topical steroids in combination with a topical calcineurin inhibitor (e.g., tacrolimus) or an oral immunomodulator (e.g., cyclosporine, methotrexate, or oral corticosteroids) before approval of dupilumab or upadacitinib treatment for atopic dermatitis as presented in **Appendix 1**.

References:

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.

Appendix 1. Proposed Prior Authorization Edits

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. 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 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						≥18 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.	
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

Approval Criteria		
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
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

Approval Criteria		
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

Approval Criteria		
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
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 #6	**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

Targeted Immune Modulators for Autoimmune Conditions

Goal(s):

- Promote use that is consistent with national clinical practice guidelines and medical evidence.
- Restrict use of targeted immune modulators to OHP-funded diagnoses in adults. 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 for autoimmune conditions (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/

Table 1. Approved and Funded Indications for Targeted Immune Modulators

Drug Name	Ankylosing Spondylitis	Crohn's Disease	Juvenile Idiopathic Arthritis	Plaque Psoriasis	Psoriatic Arthritis	Rheumatoid Arthritis	Ulcerative Colitis	Atopic Dermatitis	Other
Abatacept (ORENCIA)			≥2 yo		≥18 yo	≥18 yo			aGVHD ≥ 2 yo
Adalimumab (HUMIRA) and biosimilars	≥18 y	≥6 yo	≥2 yo	≥18 yo	≥18 yo	≥18 yo	≥5 yo (Humira) ≥18 yo (biosimilars)		Uveitis (non-infectious) ≥2 yo (Humira) HS ≥ 12 yo
Anakinra (KINERET)						≥18 yo			COVID ≥ 18 yo (hospitalized) NOMID DIRA

Drug Name	Ankylosing Spondylitis	Crohn's Disease	Juvenile Idiopathic Arthritis	Plaque Psoriasis	Psoriatic Arthritis	Rheumatoid Arthritis	Ulcerative Colitis	Atopic Dermatitis	Other
Apremilast (OTEZLA)				≥18 yo	≥18 yo				Oral Ulcers associated with BD ≥ 18 yo
Baricitinib (OLUMIANT)						≥18 yo			COVID ≥ 18 yo (hospitalized)
Brodalumab (SILIQ)				≥18 yo					
Canakinumab (ILARIS)			≥2 yo						FCAS ≥4 yo MWS ≥4 yo TRAPS ≥ 4 yo HIDS ≥ 4 yo MKD ≥ 4 yo FMF ≥ 4 yo Stills Disease ≥ 2 yo
Certolizumab (CIMZIA)	≥18 yo	≥18 yo		≥18 yo	≥18 yo	≥18 yo			Nr-axSpA ≥18 yo
Etanercept (ENBREL) and biosimilars	≥18 yo		≥2 yo	≥4 yo (Enbrel & biosimilars)	≥18 yo	≥18 yo			
Golimumab (SIMPONI and SIMPONI ARIA)	≥18 yo		≥2 yo active polyarticular course		≥2 yo	≥18 yo	≥18 yo (Simponi)		
Guselkumab (TREMFYA)				≥18 yo	≥18 yo				
Infliximab (REMICADE) and biosimilars	≥18 yo	≥6 yo		≥18 yo	≥18 yo	≥18 yo	≥6 yo		
Ixekizumab (TALTZ)	≥ 18 yo			≥6 yo	≥18 yo				Nr-axSpA ≥18 yo
Risankizumab-rzaa (SKYRIZI)		≥18 yo		≥18 yo	≥ 18 yo				
Rituximab (RITUXAN) and biosimilars						≥18 yo			CLL ≥18 yo DLBCL≥6 mo BL≥6 mo BLL≥6 mo B-AL≥6 mo NHL ≥18 yo GPA ≥2yo MPA ≥ 2 yo Pemphigus Vulgaris ≥18 yo (Rituxan only)
Sarilumab (KEVZARA)						≥18 yo			PMR ≥18 yo
Secukinumab (COSENTYX)	≥18 yo			≥6 yo	≥2 yo				ERA ≥ 4 yo Nr-axSpA ≥18 yo
Tildrakizumab-asmn (ILUMYA)				≥18 yo					
Tocilizumab (ACTEMRA)			≥2 yo			≥18 yo			COVID ≥ 18 yo (hospitalized) CRS ≥2 yo GCA ≥18 yo

Drug Name	Ankylosing Spondylitis	Crohn's Disease	Juvenile Idiopathic Arthritis	Plaque Psoriasis	Psoriatic Arthritis	Rheumatoid Arthritis	Ulcerative Colitis	Atopic Dermatitis	Other
									SSc-ILD ≥ 18 yo
Tofacitinib (XELJANZ)	≥18 yo		≥2 yo active poly-articular course		≥18 yo	≥18 yo	≥18 yo		
Upadacitinib (RINVOQ)	≥18 yo				≥18 yo	≥18 yo	≥18 yo	≥12 yo	Nr-axSpA ≥18 yo
Ustekinumab (STELARA)		≥ 18 yo		≥6 yo	≥6 yo		≥18 yo		
Vedolizumab (ENTYVIO)		≥18 yo					≥18 yo		

Abbreviations: aGVHD = acute Graft Versus Host Disease; BD = Behcet's Disease; BL = Burkitt Lymphoma; BLL = Burkitt-like Lymphoma; B-AL = mature B-cell acute leukemia; CLL = Chronic Lymphocytic Leukemia; COVID = Covid-19 infection; CRS = Cytokine Release Syndrome; DIRA = Deficiency of Interleukin-1 Receptor Antagonist; DLBCL = Diffuse Large B-Cell Lymphoma; ERA = Enthesitis-Related Arthritis; FCAS = Familial Cold Autoinflammatory Syndrome; FMF = Familial Mediterranean Fever; GCA = Giant Cell Arteritis; GPA = Granulomatosis with Polyangiitis (Wegener's Granulomatosis); HIDS: Hyperimmunoglobulin D Syndrome; HS: Hidradenitis Suppurativa; MKD = Mevalonate Kinase Deficiency; mo = months old; MPA = Microscopic Polyangiitis; MWS = Muckle-Wells Syndrome; NHL = Non-Hodgkin's Lymphoma; NOMID = Neonatal Onset Multi-Systemic Inflammatory Disease; Nr-axSpA = Non-Radiographic Axial Spondyloarthritis; PMR = Polymyalgia Rheumatica; SSc-ILD = Systemic Sclerosis-Associated Interstitial Lung Disease; TRAPS = Tumor Necrosis Factor Receptor Associated Periodic Syndrome; yo = years old.

Approval Criteria	
1. What diagnosis is being treated?	Record ICD-10 code.

Approval Criteria		
2. Is the diagnosis funded by OHP? Notes: A. Mild-to-moderate psoriasis, plaque psoriasis, and atopic dermatitis are unfunded, severe forms are funded. B. Mild Hidradenitis Suppurativa (HS) is unfunded, moderate-to-severe HS (e.g., Hurley Stage II or III) is funded. C. Alopecia areata is unfunded. Psoriasis and atopic dermatitis are severe in nature when resulting in functional impairment as indicated by Dermatology Life Quality Index (DLQI) ≥ 11 or Children's DLQI ≥ 13 (or severe score on other validated tool) AND one or more of the following: • At least 10% body surface area involvement; OR • Hand, foot, face, or mucous membrane involvement?	**Yes:** Go to # 4	**No:** For current age ≥ 21 years: Pass to RPh. Deny; not funded by the OHP. For current age < 21 years: Go to #3.
3. 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 #4	**No:** Deny, medical necessity.

Approval Criteria		
4. Has the patient been annually screened for latent or active tuberculosis and if positive, started tuberculosis treatment? * *(Note: this requirement does not apply to requests for apremilast.)	**Yes:** Go to # 5	**No:** Pass to RPh. Deny; medical appropriateness. If patient meets all other criteria, may approve once for up to 3 months to allow time for screening for ongoing therapy to avoid interruptions in care.
5. Is this a request for continuation of therapy?	**Yes**: Go to **Renewal Criteria**	**No:** Go to # 6
6. Is the request for a non-preferred product and will the prescriber consider a change to a preferred product? Message: • Preferred products are reviewed for comparative effectiveness and safety by the Oregon Pharmacy and Therapeutics Committee.	**Yes:** Inform prescriber of preferred alternatives. Go to #6	**No:** Go to # 7
7. Is the request for an FDA-approved medication with a corresponding diagnosis listed in the "Other" column of Table 1?	**Yes:** Approve for length of treatment or up to 1 year, whichever is longer.	**No:** Go to # 8
8. Is the diagnosis ankylosing spondylitis and the request for a drug FDA-approved for this condition as defined in Table 1?	**Yes:** Go to # 9	**No:** Go to # 10
9. Is this a request for a preferred agent OR if the request is for a non-preferred agent, has the patient failed to respond or had inadequate response to a Humira® branded product or an Enbrel® branded product after a trial of at least 3 months?	**Yes:** Approve for up to 6 months. Document therapy with dates.	**No:** Pass to RPh. Deny; medical appropriateness.

Approval Criteria		
10. Is the diagnosis plaque psoriasis and the request for a drug FDA-approved for this condition as defined in Table 1?	**Yes:** Go to # 11	**No**: Go to #12
11. Has the patient failed to respond or had inadequate response to each of the following first-line treatments: • Topical high potency corticosteroid (e.g., betamethasone dipropionate 0.05%, clobetasol propionate 0.05%, fluocinonide 0.05%, halcinonide 0.1%, halobetasol propionate 0.05%; triamcinolone 0.5%); AND • At least one other topical agent: calcipotriene, tazarotene, anthralin; AND • Phototherapy; AND • At least one other systemic therapy: acitretin, cyclosporine, or methotrexate; AND • One biologic agent: either a Humira® product or an Enbrel® product for at least 3 months?	**Yes**: Approve for up to 6 months. Document each therapy with dates.	**No:** Pass to RPh. Deny; medical appropriateness.
12. Is the request for a drug FDA-approved for atopic dermatitis as defined in Table 1?	**Yes:** Go to # 13	**No**: Go to #14
13. Does the patient have a documented contraindication or failed a 4-week trial of either of 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

Approval Criteria		
14. Is the diagnosis rheumatoid arthritis, juvenile idiopathic arthritis, or psoriatic arthritis and the request for a drug FDA-approved for these conditions as defined in Table 1?	**Yes:** Go to # 15	**No:** Go to # 18
15. Has the patient failed to respond or had inadequate response to at least one of the following medications: • Methotrexate, leflunomide, sulfasalazine or hydroxychloroquine for ≥ 6 months; OR • Have a documented intolerance or contraindication to disease-modifying antirheumatic drugs (DMARDs)? AND • Had treatment failure with at least one biologic agent: a Humira® branded product or an Enbrel® branded product for at least 3 months? AND • Is the patient on concurrent DMARD therapy with plans to continue concomitant use?	**Yes:** Go to # 16 Document each therapy with dates. If applicable, document intolerance or contraindication(s).	**No:** Pass to RPh. Deny; medical appropriateness. Biologic therapy is recommended in combination with DMARDs (e.g. methotrexate) for those who have had inadequate response with DMARDs.
16. Is the request for tofacitinib, baricitinib, or upadacitinib?	**Yes:** Go to # 17	**No:** Approve for up to 6 months
17. Is the patient currently on other biologic therapy or on a potent immunosuppressant like azathioprine, tacrolimus OR cyclosporine? Note: Tofacitinib, baricitinib, and upadacitinib may be used concurrently with methotrexate or other nonbiologic DMARD drugs. Tofacitinib, baricitinib, or upadacitinib are not recommended to be used in combination with other JAK inhibitors, biologic DMARDs, azathioprine, or cyclosporine.	**Yes:** Pass to RPh. Deny; medical appropriateness.	**No:** Approve baricitinib or upadacitinib for up to 6 months. Approve tofacitinib for up to 6 months at a maximum dose of 10 or 11 mg daily for Rheumatoid Arthritis OR 10 mg twice daily for 8 weeks then 5 or 10 mg twice daily for Ulcerative Colitis

Approval Criteria		
18. Is the request for adalimumab in an adult with moderate-to-severe Hidradenitis Suppurativa (HS)?	**Yes:** Go to # 19	**No:** Go to # 20
19. Has the patient failed to respond, had inadequate response, or do they have an intolerance or contraindication to a 90-day trial of conventional HS therapy (e.g. oral antibiotics)? Note: Treatment of moderate-to-severe HS with adalimumab is funded on the Prioritized List of Health Services per Guideline Note 198.	**Yes:** Approve for up to 12 weeks of therapy	**No:** Pass to RPh. Deny; medical appropriateness.
20. Is the diagnosis Crohn's disease or ulcerative colitis and the request for a drug FDA-approved for these conditions as defined in Table 1?	**Yes:** Go to # 21	**No:** Go to # 25
21. Has the patient failed to respond or had inadequate response to at least one of the following conventional immunosuppressive therapies for ≥6 months: • Mercaptopurine, azathioprine, or budesonide; <u>or</u> • Have a documented intolerance or contraindication to conventional therapy?	**Yes:** Go to #22	**No:** Pass to RPh. Deny; medical appropriateness.
22. Is the request for risankizumab?	**Yes:** Go to #23	**No:** Go to # 24
23. Have baseline liver enzymes and bilirubin been obtained?	**Yes:** Go to #24 Document Labs & Date: LFTs:________________ Bilirubin:________________	**No:** Pass to RPh. Deny; medical appropriateness

Approval Criteria		
24. Is the request for a preferred product or has the patient tried and failed a 3-month trial of a Humira® product?	**Yes:** Approve for up to 12 months. Document each therapy with dates. If applicable, document intolerance or contraindication(s).	**No:** Pass to RPh. Deny; medical appropriateness.
25. Is the diagnosis for an FDA approved diagnosis and age as outlined in Table 1, and is the requested drug rituximab for *induction or maintenance* of remission?	**Yes:** Approve for length of treatment.	**No:** Pass to RPh. Deny; medical appropriateness.

Renewal Criteria		
1. Is the request for treatment of psoriatic arthritis, plaque psoriasis, ulcerative colitis, Crohn's disease, or rheumatoid arthritis?	**Yes:** Go to # 6	**No:** Go to # 2
2. Is the request to renew therapy for atopic dermatitis?	**Yes:** Go to #3	**No:** Go to #4
3. Have the patient's symptoms improved with upadacitinib 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.

Renewal Criteria		
4. Is the request for continuation of adalimumab to treat moderate-to-severe Hidradenitis Suppurativa in an adult?	**Yes:** Go to # 5	**No:** Go to # 6
5. Has the patient had clear evidence of response to adalimumab therapy as evidenced by: • a reduction of 25% or more in the total abscess and inflammatory nodule count, AND • no increase in abscesses and draining fistulas.	**Yes:** Approve for an additional 12 weeks of therapy	**No:** Pass to RPh. Deny; medical appropriateness.
6. Has the patient been adherent to both biologic and DMARD therapy (if DMARD therapy has been prescribed in conjunction with the biologic therapy)?	**Yes:** Go to #7	**No:** Pass to RPh. Deny; medical appropriateness.
7. Has the patient's condition improved as assessed by the prescribing provider and provider attests to patient's improvement.	**Yes:** Approve for 6 months. Document baseline assessment and provider attestation received.	**No:** Pass to RPh; Deny; medical appropriateness.

P&T/DUR Review: *6/23 (DM); 10/22 (DM); 6/22(DM); 10/21; 10/20; 2/20; 5/19; 1/19; 1/18; 7/17; 11/16; 9/16; 3/16; 7/15; 9/14; 8/12*

Implementation: *7/1/23; 1/1/23; 7/1/22; 1/1/22; 1/1/2021; 7/1/2019; 3/1/19; 3/1/18; 9/1/17; 1/1/17; 9/27/14; 12/12*