# 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) ≥18 yo (biosimilars) HS ≥ 12 yo |
| **Anakinra (KINERET)** | | | | | | ≥18 yo | | | COVID ≥ 18 yo (hospitalized) NOMID DIRA |
| **Apremilast (OTEZLA)** | | | | ≥18 yo | ≥18 yo | | | | Oral Ulcers associated with BD ≥ 18 yo |
| **Baricitinib (OLUMIANT)** | | | | | | ≥18 yo | | | COVID ≥ 18 yo (hospitalized) |
| **Bimekizumab (BIMZELX)** | | | | ≥18 yo | | | | | |
| **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 Gout flares ≥18 yo |
| **Certolizumab (CIMZIA)** | ≥18 yo | ≥18 yo | | ≥18 yo | ≥18 yo | ≥18 yo | | | Nr-axSpA ≥18 yo |
| **Deucravacitinib (SOTYKTU)** | | | | ≥18 yo | | | | | |
| **Etanercept (ENBREL) and biosimilars** | ≥18 yo | | ≥2 yo | ≥4 yo (Enbrel & biosimilars) | ≥18 yo | ≥18 yo | | | |
| **Etrasimod (VELSIPITY)** | | | | | | | ≥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 | | | | |

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|---|---|---|---|---|---|---|---|---|---|
| **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 |
| **Mirikizumab (OMVOH)** | | | | | | | ≥18 yo | | |
| **Risankizumab-rzaa (SKYRIZI)** | | ≥18 yo | | ≥18 yo | ≥ 18 yo | | | | |
| **Rituximab (RITUXAN) and biosimilars** | | | | | | ≥18 yo | | | CLL ≥18 yo<br>DLBCL≥6 mo<br>BL≥6 mo<br>BLL≥6 mo<br>B-AL≥6 mo<br>NHL ≥18 yo<br>GPA ≥2yo<br>MPA ≥ 2 yo<br>Pemphigus Vulgaris ≥18 yo (Rituxan only) |
| **Sarilumab (KEVZARA)** | | | | | | ≥18 yo | | | PMR ≥18 yo |
| **Secukinumab (COSENTYX)** | ≥18 yo | | | ≥6 yo | ≥2 yo | | | | ERA ≥ 4 yo<br>Nr-axSpA ≥18 yo<br>HS ≥18 yo |
| **Tildrakizumab-asmn (ILUMYA)** | | | | ≥18 yo | | | | | |
| **Tocilizumab (ACTEMRA)** | | | ≥2 yo | | | ≥18 yo | | | COVID ≥ 18 yo (hospitalized)<br>CRS ≥2 yo<br>GCA ≥18 yo<br>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 | ≥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 | | |
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| 2. Is the diagnosis funded by OHP?<br><br>Notes:<br>A. Mild-to-moderate psoriasis, plaque psoriasis, and atopic dermatitis are unfunded, severe forms are funded.<br>B. Mild Hidradenitis Suppurativa (HS) is unfunded, moderate-to-severe HS (e.g., Hurley Stage II or III) is funded.<br>C. Alopecia areata is unfunded.<br><br>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:<br>• At least 10% body surface area involvement; OR<br>• 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.<br><br>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. |
| 4. Has the patient been annually screened for latent or active tuberculosis and if positive, started tuberculosis treatment? *<br>*(Note: this requirement does not apply to requests for apremilast.) | **Yes:** Go to # 5 | **No:** Pass to RPh. Deny; medical appropriateness.<br><br>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 |

| Approval Criteria | | |
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| 6. Is the request for a non-preferred product and will the prescriber consider a change to a preferred product?<br><br>Message:<br>• 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.<br>Document therapy with dates. | **No:** Pass to RPh. Deny; medical appropriateness. |
| 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:<br>• 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<br>• At least one other topical agent: calcipotriene, tazarotene, anthralin; AND<br>• Phototherapy; AND<br>• At least one other systemic therapy: acitretin, cyclosporine, or methotrexate; AND<br>• One biologic agent: either a Humira® product or an Enbrel® product for at least 3 months? | **Yes**: Approve for up to 6 months.<br><br>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 |

| Approval Criteria | | |
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| 13. Does the patient have a documented contraindication or failed a 4-week trial of either of the following treatments:<br>• 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<br>• Oral immunomodulator therapy (e.g., cyclosporine, methotrexate,or oral corticosteroids)? | **Yes**: Document drug and dates trialed and intolerances (if applicable):<br>1._____(dates)<br>2._____(dates)<br><br>Approve for length of treatment; maximum 6 months. | **No**: Pass to RPh. Deny; medical appropriateness |
| 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:<br>• Methotrexate, leflunomide, sulfasalazine or hydroxychloroquine for ≥ 6 months; OR<br>• Have a documented intolerance or contraindication to disease-modifying antirheumatic drugs (DMARDs)? AND<br>• Had treatment failure with at least one biologic agent: a Humira® branded product or an Enbrel® branded product for at least 3 months? AND<br>• Is the patient on concurrent DMARD therapy with plans to continue concomitant use? | **Yes:** Go to # 16<br><br>Document each therapy with dates.<br><br>If applicable, document intolerance or contraindication(s). | **No:** Pass to RPh. Deny; medical appropriateness.<br><br>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 |

| Approval Criteria | | |
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| 17. Is the patient currently on other biologic therapy or on a potent immunosuppressant like azathioprine, tacrolimus OR cyclosporine?<br><br>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<br>OR<br>10 mg twice daily for 8 weeks then 5 or 10 mg twice daily for Ulcerative Colitis |
| 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)?<br><br>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:<br>• Mercaptopurine, azathioprine, or budesonide; or<br>• 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<br><br>Document Labs & Date:<br>LFTs: _____<br><br>Bilirubin: _____ | **No:** Pass to RPh. Deny; medical appropriateness |

| Approval Criteria | | |
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| 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.<br><br>Document each therapy with dates.<br><br>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 | | |
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| 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?<br>• at least a 50% reduction in the Eczema Area and Severity Index score (EASI 50) from when treatment started, OR<br>• at least a 4-point reduction in the Dermatology Life Quality Index (DLQI) from when treatment started, OR<br>• 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. |
| 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:<br>• a reduction of 25% or more in the total abscess and inflammatory nodule count, AND<br>• no increase in abscesses and draining fistulas. | **Yes:** Approve for an additional 12 weeks of therapy | **No:** Pass to RPh. Deny; medical appropriateness. |

| Renewal Criteria | | |
|---|---|---|
| 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.<br>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*