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Update on Targeted Immune Modulators Used to Manage Selected Autoimmune Conditions

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Targeted immune modulators (TIMs) are used to treat autoimmune disorders including atopic dermatitis (AD), rheumatoid arthritis (RA), ankylosing spondylitis (AS), plaque psoriasis (PsO), psoriatic arthritis (PsA), Crohn's disease (CD), and ulcerative colitis (UC). A summary of TIMs approved for management of selected auto-immune conditions is presented in **Table 5**. Targeted immune modulators include biologic disease-modifying anti-rheumatic drugs (DMARDs) and targeted synthetic DMARDs. Biologic DMARDs are large, complex, proteins that must be administered parentally. Targeted synthetic DMARDs are small chemical molecules that can be taken orally. In the past 2 years substantial information about specific agents within this class of drugs has been published due to expanded indications, including new pediatric approvals. This newsletter will provide an update on recent Food and Drug Administration (FDA)-approved TIMs and updated indications for TIMs that occurred in 2024 and 2025. In addition, revisions to the Oregon Health Plan (OHP) Fee-for-Service (FFS) prior authorization (PA) criteria for the TIMs used to manage auto-immune conditions are summarized.

Guideline-Directed Therapy with TIMs

Standard of care for treatment of RA, AS, PsO, or PsA is to initiate therapy with a tumor necrosis factor inhibitor (TNF-I) or appropriate interleukin inhibitor if a conventional DMARD (i.e., methotrexate) has failed or if the patient has contraindications to conventional therapy.[17-19] Nonsteroidal anti-inflammatory drugs and exercise are recommended as first-line therapies to alleviate pain and stiffness in patients with AS.[20,21] Janus kinase (JAK) inhibitors can be considered to manage autoimmune conditions that are FDA-approved, but pertinent risk factors (cardiovascular events and malignancies) should be evaluated prior to starting therapy.[17] Other targeted synthetic DMARDs approved to manage PsO include the phosphodiesterase-4 inhibitor, apremilast and the recently approved tyrosine kinsase-2 inhibitor, deucravacitinib.

The 2019 American College of Gastroenterology (ACG)[22] and the National Institute for Health and Care Excellence (NICE)[23] guidelines recommend the use of TIMs for treating moderately to severely active UC in adults whose disease has responded inadequately to conventional therapy including aminosalicylates (i.e., sulfasalazine, mesalamine), corticosteroids, azathioprine or mercaptopurine. For management of CD, NICE guidance recommends TNFi for induction, but only after failure of conventional therapy with corticosteroids, aminosalicylates, azathioprine or mercaptopurine, and should only be used for maintenance if there is clear evidence of active disease.[24] The American College of Gastroenterology (ACG) strongly recommends induction with a TNFi to maintain remission in patients who have moderate-to-severe CD despite treatment with conventional therapy.[25]

New Targeted Immune Modulators

Ustekinumab Biosimilars

Eight new intravenous and subcutaneous (SC) biosimilar products for the reference product of STELARA (ustekinumab) received FDA approval in 2024 and 2025.[1] These products include: OTULFI (ustekinumab-aauz), IMULDOSA (ustekinumab-srlf), SELARSDI (ustekinumab-aekn), YESTINTEK (ustekinumab-kfce), STEQEYMA (ustekinumab-stba), WEZLANA (ustekinumab-auub), PYZCHIVA (ustekinumab-ttwe) and STARJEMZA (ustekinumab-hmny).[1] According to the FDA, all of the STELARA biosimilar products have FDA interchangeable status except for IMULDOSA.[1] The means they can be substituted for STELARA at the pharmacy level without requiring a prescription change from the healthcare provider. All the ustekinumab biosimilar products are indicated for treatment of adults with moderate to severe PsO, CD, UC, or active PsA and pediatric patients 6 years and older with moderate to severe PsO or active PsA.[2]

New Interleukin-31 Inhibitor: Nemolizumab

NEMLUVIO (nemolizumab) is an interleukin (IL)-31 receptor antagonist FDA-approved for: 1) adults with prurigo nodularis (PN)[3] and 2) patients 12 years of age and older with moderate-to-severe AD in combination with a topical corticosteroid (TCS) and/or a topical calcineurin inhibitor (TCI) when AD is not adequately controlled with topical therapies alone.[4]

Moderate-quality evidence from 2 randomized, double-blind, multi-center, placebo-controlled, phase 3 trials (OLYMPIA 1 and OLYMPIA 2) showed nemolizumab is effective for treating PN over 16 weeks.[5,6] Patients were randomized 2:1 to receive nemolizumab or placebo. After completion of either randomized controlled trial (RCT), patients were eligible to enter an ongoing long-term extension trial (OLYMPIA LTE). The co-primary endpoints were decreased itching and improvement in PN skin lesions. Pruritus was evaluated using the patient-reported itch response (a reduction of ≥ 4 points on the Peak Pruritus Numerical Rating Scale [PP-NRS; scores range from 0 to 10, with higher scores indicating more severe itch]) and skin lesions were evaluated using an Investigator's Global Assessment

(IGA) response (a score of 0 [clear] or 1 [almost clear] on the IGA [scores range from 0 to 4] and an IGA reduction from baseline to week 16 of ≥2 points).[5,6] Study results are presented in **Table 1**. For both assessments nemolizumab was significantly more effective in decreasing itching and improving skin lesions compared with placebo.

Table 1. Results from OLYMPIA 1 and 2 Trials[5,6]

	Percent of Patients with Itch Response at Week 16	Percent of Patients with IGA Response at Week 16
OLYMPIA 1[5] N=276	Nemolizumab vs Placebo: 58.4% vs. 16.7% Difference 41.7% 95% CI 29.4 to 50.8 P<0.001; NNT = 2	Nemolizumab vs Placebo: 26.3% vs 7.3% Difference 19% 95% CI 6.7 to 22.6 P=0.003; NNT = 3
OLYMPIA 2[6] N=274	Nemolizumab vs Placebo: 56.3% vs. 20.9% Difference 35.4% 95% CI 26.3 to 48.5 p<0.001; NNT = 5	Nemolizumab vs Placebo: 37.7% vs. 11.0% Difference 26.7% 95% CI 18.8 to 38.2 P<0.001; NNT =4
Abbreviations: CI = Confidence Interval; IGA = Investigators Global Response; NNT = Number Needed To Treat		

The most frequently reported adverse events with nemolizumab in the PN trials were headache (nemolizumab 6% vs. placebo 3%) and worsening AD (nemolizumab 4% vs placebo 0.5%).[3] In the United States, PN may disproportionally affect more Black than White patients (3:1 ratio) and may be less common in other race/ethnic groups.[6] However, people identifying as Black were underrepresented in both RCTs (9.8% in Olympia 1 and 4.4% in Olympia 2).[5,6] As PN is a chronic disease, studies of longer duration are needed to support long-term use.[5] An open-label extension study of 184-week duration is ongoing.

Moderate-quality evidence from 2 identical, multicenter, phase 3 RCTs (ARCADIA 1 and ARCADIA 2) showed nemolizumab is effective in treating moderate-to-severe AD over 16 weeks.[7] Patients at least 12 years of age with moderate-to-severe AD were randomized 2:1 to receive nemolizumab 30 mg SC every 4 weeks (after a loading dose of 60 mg at week 0) plus a TCS or TCI, or matching placebo plus a TCS or TCI over 16 weeks.[7] Skin clearance was measured by IGA success as defined above and Eczema Area and Severity Index (EASI)-75 response at 16 weeks.[7] Study results are presented in **Table 2**. For both assessments nemolizumab was significantly more effective in achieving a response compared with placebo, though the number needed to treat was higher than that for PN.

Table 2. Results from ARCADIA 1 and 2 Trials[7]

	People with IGA Success at Week 16	People with EASI-75 Response at Week 16
ARCADIA 1 N=941	Nemolizumab vs Placebo 35.6% vs. 24.6% Difference 11% 97.5% CI 4.7 to 18.3 P=0.0003; NNT = 9	Nemolizumab vs Placebo 43.5% vs. 29% Difference 14.5% 97.5% CI 7.8 to 22.0 P<0.0001; NNT = 9
ARCADIA 2 N=787	Nemolizumab vs Placebo 37.7% vs. 26% Difference 11.7% 97.5% CI 4.6 to 19.8 P=0.0006; NNT = 7	Nemolizumab vs Placebo 42.1% vs. 30.2% Difference 11.9% 97.5% CI 4.6 to 20.3 P=0.0006; NNT = 9
Abbreviations: CI = Confidence Interval; EASI = Eczema Area and Severity Index; IGA = Investigators Global Response; NNT = Number Needed to Treat		

In clinical trials for AD efficacy, the most commonly reported events reported were headache, arthralgia, urticaria, and myalgia.[4]

Limitations of the AD trials include the absence of long-term safety data.[7] A long-term extension study is ongoing. People enrolled in trials were predominantly White and other races and ethnicities were under-represented.[7] Patients with uncontrolled asthma were excluded from enrollment for safety reasons, presumably due to the risk of hypersensitivity reactions with administration of a monoclonal antibody. In addition, people who received 16-week treatment with dupilumab and experienced worsening of AD or failed to achieve improvement were excluded from trial enrollment. Investigators did not justify the reasons for excluding this patient population. Comparative trials with other TIMs approved for AD with nemolizumab have not been conducted.

New Interleukin-13 Inhibitor: Lebrikizumab

EBGLYSS (lebrikizumab) is a monoclonal antibody that targets IL-13. Lebrikizumab is approved for the treatment of moderate to severe AD in patients ≥ 12 years old who weigh ≥ 40 kg and are not adequately controlled with topical prescription therapies.[8] It can be used with or without other topical therapies (TCS or TCI).[8] Dosing is 500 mg SC at week 0 and Week 2, followed by 250 mg SC every 2 weeks until Week 16 or later, when adequate clinical response is achieved.[8] The maintenance dose is 250 mg SC every 4 weeks.[8]

Data from 3 high-quality, randomized, double-blind clinical trials (ADvocate 1 ADvocate 2, and ADhere) indicate that 16-week induction of lebrikizumab (administered every 2 weeks) is significantly more effective than placebo for improving skin clearance.[9,10] In these 3 RCTs, patients 12 years and older with moderate-to-severe AD uncontrolled with topical therapies were randomized 2:1 to lebrikizumab or placebo.[9,10] In the ADvocate trials co-administration of TCS/TCI was not permitted, while in the ADhere trial patients were permitted to use TCS or TCI.[9,10] Study results are presented in **Table 3**. In all 3 trials lebrikizumab was significantly more effective in achieving a response compared with placebo.

Table 3. Results from ADvocate and ADhere Trials[9,10]

	Percent of Patients with IGA Success at Week 16	Percent of Patients with EASI-75 Response at Week 16
ADvocate 1[9] N=424	Lebrikizumab vs Placebo 43.1% vs. 12.7% Difference 29.7% 95% CI 21.6 to 37.8 P<0.001; NNT = 4	Lebrikizumab vs Placebo 58.8% vs. 16.2% Difference 42% 95% CI 33.3 to 50.6 P<0.001; NNT = 3
ADvocate 2[9] N=427	Lebrikizumab vs Placebo 33.2% vs 10.8% Difference 21.9% 95% CI 14.2 to 29.6 P<0.001; NNT = 5	Lebrikizumab vs Placebo 52.1% vs. 18.1% Difference 33.3% 95% CI 14.23 to 29.6 P<0.001; NNT = 3
ADhere[10] N=228	Lebrikizumab vs Placebo 41.2% vs. 22.1% Difference 18.3% 95% CI 5.1 to 31.5 P<0.05; NNT = 6	Lebrikizumab vs Placebo 69.5% vs. 42.2% Difference 26.4% 95% CI 12.1 to 40.8 P<0.01; NNT = 4
Abbreviations: CI = Confidence Interval; EASI = Eczema Area and Severity Index; IGA = Investigators Global Response; Number Needed to Treat		

One 52-week trial, which re-randomized responders from the 2 ADvocate induction trials, indicated that continuing lebrikizumab (every 4 weeks) was associated with significantly better skin clearance, itching, and quality of life outcomes (Strength of Evidence: moderate) relative to placebo withdrawal.[11] In this trial lebrikizumab was generally well tolerated; the most commonly reported adverse effects were conjunctivitis (5.9%) and herpes (5.9%).[8] No head-to-head trials comparing lebrikizumab to other TIMs or other immunosuppressives have been conducted.

Expanded FDA-Approved Indications

The FDA continues to review and approve expanded indications and age ranges for the TIMs. Table 4 summarizes recently approved indications for TIMS to manage auto-immune conditions.

Table 4. Expanded FDA-Approved Indications

Drug	New Indication	Prexisting Indication(s)
Apremilast[12]	▪ PsA in patients ≥ 6 yo and weighing at least 20 kg	▪ PsA in adults ▪ PsO in patients ≥ 6 yo ▪ Oral ulcers associated with Bechet's Disease in adults
Guselkumab[13]	▪ UC in adults ▪ CD in adults ▪ PsO in patients ≥ 6 yo ▪ PsA in patients ≥ 6 yo	▪ PsO in adults ▪ PsA in adults
Certolizumab Pegol[14]	▪ pJIA in patients ≥ 2 yo	▪ CD in adults ▪ PsA in adults ▪ PsO in adults ▪ AS in adults ▪ Nr-axSpA in adults
Bimekizumab[15]	▪ PsA in adults ▪ AS in adults ▪ nr-axSpA in adults ▪ HS in adults	▪ PsO in adults
Mirkizumab[16]	▪ CD in adults	▪ UC in adults
Abbreviations: AS = Ankylosing Spondylitis; CD = Crohn's Disease; HS = Hidradenitis Suppurativa; nr-axSpA = Non-Radiographic Axial; pJIA = Polyarticular Juvenile Idiopathic Arthritis; SpondyloArthritis; PsA = Psoriatic Arthritis; PsO = Plaque Psoriasis; UC = Ulcerative Colitis		

Changes to OHP Prior Authorization Criteria

At the October 2025 Pharmacy and Therapeutics (P & T) Committee meeting, the committee approved adding nemolizumab and lebrikizumab to the Preferred Drug List (PDL) as non-preferred therapies. The PA criteria for the "TIMs for Severe Asthma and Atopic Dermatitis" were updated to include these 2 medications. In addition, based upon recent guidance, pediatric patients were removed from a trial and failure of an oral immunosuppressant (e.g. methotrexate, azathioprine) prior to initiating dupilumab for management of AD in children and adolescents. The requirement for a concurrent prescription for an EpiPen was modified to only apply to omalizumab requests. All the TIMs approved for management of moderate-to-severe AD (abrocitinib, dupilumab, tralokinumab, upadacitinib) are non-preferred and require PA prior to starting therapy.

At that same meeting, the P & T committee reviewed new evidence for the PDL class of "TIMs for Auto-Immune Conditions". Prior authorization criteria were updated to include expanded indications for the recent FDA approvals outlined in this newsletter. All TIMs are subject to PA before OHP FFS will pay for the claims. After executive session, where overall comparative costs and drug rebates were assessed, the following recommendations for updating the PDL were approved by the Committee and will become effective January 1, 2026:

Three agents were designated as preferred using the following definitions:

- Tier 1 agents are preferred, first line medications.
- Tier 2 agents are preferred, second line medications.
- Tier 3 agents are nonpreferred, third line medications.

The following recommendations were implemented:

- Make infliximab preferred, Tier 1
- Make ustekinumab biosimilar (PYZCHIVA) syringes and vials preferred, Tier 2 and
- Make guselkumab (TREMFYA) preferred, Tier 2.

Complete evidence reviews, the OHP FFS Drug Class list and PA criteria can be accessed at this website: https://orpdl.org/drugs/

Oregon Health Plan
Prior Authorization Criteria for TIMs for Autoimmune Conditions

- Humira and Enbrel are preferred, Tier 1.
- Infliximab-axxq (AVSOLA), generic infliximab, Simlandi (branded only), AMJEVITA (100 mg/mL aka "high-concentration" only), and non-branded adalimumab-fkjp (50 mg/mL aka "low-concentration" only) are preferred, Tier 1.
- Ixekizumab (TALTZ), apremilast (OTEZLA), tofacitinib citrate (XELJANZ), ustekinumab biosimilar (PYZCHIVA), and guselkumab (TREMFYA) are designated as preferred, Tier 2.
- All other products are designated as non-preferred, Tier 3.

Conclusion

In the past 2 years, two new TIMs, nemolizumab and lebrikizumab, received FDA-approval to manage moderate-to-severe AD in adults and adolescents. Eight new biosimilar products for the reference product of STELARA (ustekinumab) are now available in the United States market. New therapies and expanded indications have provided more options for managing many auto-immune conditions, as presented in **Table 5.** Oregon Health Plan PA criteria are based on guideline-directed therapy, with an emphasis on using the most cost-effective therapies for appropriate indications.

Table 5. FDA-Approved TIMs for Selected Auto-Immune Conditions

Drug – Route of Administration	Molecular Target	Common Approved Indication(s)
Biologic DMARDs		
Adalimumab (HUMIRA) - SC	TNFα	AS, RA, PsA, PsO, CD, UC
Certolizumab Pegol (CIMZIA) - SC		AS, RA PsA, PsO, CD
Golimumab - (SIMPONI and SIMPONI ARIA) - IV or SC		AS, RA, PsA, UC
Infliximab (REMICADE) – IV, SC		AS, RA, PsA, PsO, CD, UC
Etanercept (ENBREL) - SC	TNFα, TNFβ	AS, RA, PsA, PsO
Anakinra (KINERET) - SC	IL-1 receptor	RA
Dupliumab (DUPIXENT) – SC	IL-4 receptor α subunit	AD
Sarilumab (KEVZARA) - SC	IL-6 receptor	RA
Tocilizumab (ACTEMRA) – IV or SC		RA
Lebrikizumab (EBGLYSS) -SC	IL-13	AD
Tralokinumab (ADBRY) – SC		AD
Ustekinumab (STELARA) – IV or SC	IL-12 and IL-23	PsA, PsO, CD, UC
Bimekizumab (BIMZELX) - SC	IL-17A, IL-17F, IL-17AF	AS, PsO, PsA
Brodalumab (SILIQ) - SC	IL-17 receptor	PsO
Ixekizumab (TALTZ) - SC	IL-17A	AS, PsA, PsO
Secukinumab (COSYNTEX) - SC		AS, PsA, PsO
Guselkumab (TREMFYA) – SC and IV	IL-23	PsA, PsO, CD, UC
Mirikizumab (OMVOH) – IV (initial dose) followed by SC		UC, CD
Risankizumab (SKYRIZI) - SC		PsA, PsO, CD, UC
Tildrakizumab (ILUMYA) - SC		PsO
Nemolizumab (NEMLUVIO) – SC	IL-31 receptor	AD, PN
Vedolizumab (ENTYVIO) – IV	Integrin receptor	CD, UC
Natalizumab (TYSABRI) – IV		CD
Abatacept (ORENCIA) - IV or SC	T-lymphocyte	RA, PsA
Rituximab (RITUXAN) - IV	B-lymphocyte	RA
Spesolimab (SPEVIGO) – IV for acute flares, SC for maintenance to prevent flares	IL-36 receptor	GPP
Targeted Synthetic DMARDs		
Abrocitinib (CIBINQO) - PO	JAK 1	AD
Baricitinib (OLUMIANT) - PO	JAK 1,2	RA
Tofacitinib (XELJANZ)- PO	JAK 1,2,3	RA, PsA, UC
Upadacitinib (RINVOQ) - PO	JAK 1	AS, RA, PsA, CD, UC, AD
Apremilast (OTEZLA) - PO	PDE4	PsA, PsO
Ozanimod (ZEPOSIA) – PO	S1P receptor	UC
Etrasimod (VELSIPITY)– PO		UC
Deucravacitinib (SOTYKTU) – PO	TYK2	PsO

Abbreviations: Atopic Dermatitis; AS=ankylosing spondylitis; CD=Crohn's Disease; DMARD=Disease-Modifying Antirheumatic Drug; FDA=Food and Drug Administration; IL=interleukin; GPP= Generalized Pustular Psoriasis;

IV=intravenous; JAK=Janus Kinase; PDE=phosphodiesterase; PN=Prurigo Nodularis; PO=oral; PsA=psoriatic arthritis; PsO=plaque psoriasis; S1P=sphingosine 1-phosphate; RA=rheumatoid arthritis; SC=subcutaneous; TNF=tumor necrosis factor; TYK2=tyrosine kinase 2; UC=Ulcerative Colitis

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