Dermatology Biologics Chart

By Emily C. Milam, MD

DRUG	CLASS & MECHANISM	FDA APPROVED INDICATIONS	OFF-LABEL USES IN DERMATOLOGY	DOSING	ROUTE	MONITORING	PREG. CATEGORY	SIDE EFFECTS/ ADVERSE EVENTS	NOTES
Adalimumab (Humira)	TNF-α Inhibitor Fully human recombinant antibody; binds specifically to TNF-α, blocking interaction with p55 and p75 cell surfaces.	Dermatologic: → Psoriasis → HS Other: → PsA → RA → JIA → Crohn's disease → UC → AS → Uveitis	→ PG → Behcet's disease → Aphtous stomatitis → Other neutrophilic dermatoses → Vasculitis → Pustular dermatosis → PRP → IgA pemphigus → Sarcoidosis → Disseminated GA → SAPHO syndrome → Relapsing polychondritis	**Plaque psoriasis** → Initial dose of 80mg, followed by 40mg every other week (starting 1 week after initial dose) **HS** → 160 mg (given in 1 day or split over 2 consecutive days), followed by 80 mg on day 15, and then 40 mg every week starting on day 29	SubQ	*Before starting:* Test for TB and hepatitis B. Consider testing for hepatitis C and HIV. *Interval Monitoring:* Annual TB Test. Routine TBSE.	B	**Common:** Injection site reaction, URI, UTI, headache, nausea, rash, HLD, abdominal or back pain, flu-like symptoms, HTN, hypersensitivity reactions. **Rare But Serious:** CHF; melanoma & NMSC; uveitis; central demyelinating disorders; cytopenias; new-onset psoriasis (especially palmoplantar pustulosis); cutaneous small vessel vasculitis; eczematous eruptions; lichenoid dermatitis. ***Black Box Warnings:*** 1. Serious and fatal infections 2. Lymphoma and other malignancies Screen for: CHF, IBD, demyelinating diseases	Syringe contains latex. Avoid live vaccines. Lupus-like syndromes and autoimmune hepatitis can arise in patients on TNF-α inhibitors Efficacy may wane over time due to development of neutralizing anti-chimeric antibodies. Avoid concurrent administration with IL-1 receptor antagonists (ie Anakinra).
Alefacept (Amevive)	Anti-T-cell agent. Recombinant humanized fusion protein that binds to CD2 and inhibits T-cell activation, and selectively reduces memory T cells.	Dermatologic: → Psoriasis Other: None	→ Lichen planus → SCLE → Chronic GVHD → ?Alopecia areata → ?PG → ?Cutaneous T cell lymphoma	**Psoriasis** → IV: 7.5mg once weekly x 12 weeks IM: 15mg once weekly x 12 weeks	IM, IV	*Before starting:* Test $CD4^+$ T-cell count (should be >500 cells/mcl). *Interval Monitoring:* $CD4^+$ T-cell count every other week.	B	**Common:** Injection site reaction, infections, hypersensitivity reactions (urticarial, angioedema). Causes lymphopenia and a dose-dependent decrease in $CD4^+$ and $CD8^+$ T-cell counts. **Rare But Serious:** Hepatotoxicity; Potentially increased risk of malignancy. **Contraindications:** 1. CD4 count < 250 cells/mcl 2. HIV infection 3. Active infection or malignancy	No longer available in the US; discontinued by pharmaceutical company.
Apremilast (Otezla)	PDE-4 Inhibitor Selectively inhibits PDE-4, increasing intracellular cAMP, which decreases inflammatory TNF-α and IL-23, and increases anti-inflammatory IL-10.	*Dermatologic:* → Psoriasis *Other* → PsA	Not well established. → ?Alopecia areata	**Psoriasis** → *Initial:* 10mg, then titrate up by additional 10mg per day until day 6 *Maintenance:* 30 mg BID If CrCl <30, start 10mg daily x 3 days, then 20mg daily x 2 days, then 30mg daily.	PO	*Before starting:* None indicated. *Interval Monitoring:* None indicated.	C	**Common:** Diarrhea, nausea, vomiting, weight loss, HA, back pain, fatigue, insomnia, URI. Use with caution in patients with depression, suicidal ideation, or if CrCl <30.	GI side effects often improve after first few weeks of treatment.
Anakinra (Kineret)	IL-1 Receptor Inhibitor Recombinant form of human IL-1 receptor antagonist.	*Dermatologic:* None *Other* → RA → Neonatal onset multisystem inflammatory disease (NOMID)	→ Urticarial lesions associated with Schnitzler's Syndrome → Periodic fever syndromes	**Adult RA Dose** → 100 mg/daily. For CrCl <30, consider q48h dosing. Pediatric Dose: 2mg/kg	SubQ	*Before starting:* Baseline Cr, CBC, TB. *Interval Monitoring:* CBC and Cr monthly x 3 months, then q3 months.	B	**Common:** Injection site reaction, URI, HA, nausea, vomiting, diarrhea, fever, rash, arthralgia, abdominal pain, flu-like symptoms. Rare but Serious: Malignancy, neutropenia, & thrombocytopenia Avoid in patients with severe renal impairment, active infections, asthma, or hypersensitivity to E. coli proteins.	Syringe contains latex. Avoid live vaccines. Do not give concurrently with other TNF- α modifiers. Efficacy may wane due to development of neutralizing anti-chimeric antibodies.

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Brodalumab (Siliq)	IL-17 Receptor Antagonist Human monoclonal IgG2 antibody that blocks IL-17 receptor A.	*Dermatologic:* → Psoriasis	Not well established.	**Psoriasis** → 210mg at Weeks 0, 1, and 2, followed by 210mg q2 weeks	SubQ	*Before starting:* Test for TB. *Interval Monitoring:* Annual TB test.	Not known	**Common:** Arthralgia, HA, fatigue, diarrhea, oropharyngeal pain, nausea, myalgia, injection site reactions, neutropenia, and tinea infections. **Rare But Serious:** Neutropenia. **Contraindications:** Crohn's disease. ***Black Box Warnings:*** 1. Suicidal ideation and behavior	Avoid live vaccines. Because of risk of suicidal behavior, it is only available through a restricted program called Siliq Risk Evaluation & Mitigation Strategy (REMS).
Certolizumab Pegol (Cimzia)	TNF-α Inhibitor Recombinant humanized pegylated antibody Fab' fragment that binds to TNF-α. Selectively neutralizes TNF-α but does not neutralize lymphotoxin α (TNF-B).	*Dermatologic*: None Other → RA → Crohn's disease → PsA → AS	Not well established.	**PsA** → Start 400mg at weeks 0, 2, and 4, followed by 200mg every 2 weeks (or, some do 400g monthly)	SubQ	*Before starting:* Test for TB and hepatitis B. Consider testing HIV and hepatitis C. *Interval Monitoring:* Annual TB test.	Not known	**Common:** URIs, UTIs; abdominal pain; HA; nausea; rash; injection site reactions; allergic reactions. **Rare But Serious:** CHF; melanoma & NMSC; uveitis; central demyelinating disorders; cytopenias; new-onset psoriasis (especially palmoplantar pustulosis); cutaneous small vessel vasculitis; eczematous eruptions; lichenoid dermatitis. ***Black Box Warnings:*** 1. Serious & fatal infections 2. Malignancy (lymphoma and other malignancies) **Screen for:** CHF, demyelinating diseases	Avoid live vaccines. Lupus-like syndromes and autoimmune hepatitis can arise in patients on TNF-α Inhibitors. Efficacy may wane due to development of neutralizing anti-chimeric antibodies. May interfere with aPTT tests.
Dupilumab (Dupixent)	IL-4 receptor Inhibitor Binds to and inhibits the alpha subunit of the IL-4 receptor, which interferes with IL-4 and IL-13 cytokines.	*Dermatologic:* → Atopic dermatitis	Not well established.	**Atopic dermatitis** → Initial dose of 600mg divided into 2 sites, then 300mg q2 weeks.	SubQ	No baseline or routine tests recommended. Consider CBC with diff q6 months.	Not known	**Common:** Injection site reactions, conjunctivitis, HSV outbreak, dry eyes. **Rare But Serious:** Keratitis, serum sickness-like reaction, hypersensitivity reaction. Use with caution in patients with asthma or possible helminth infection.	Efficacy may wane due to development of neutralizing antibodies.
Efalizumab (Raptiva)	Inhibits activation and migration of T cells. Recombinant, humanized, monoclonal IgG1 antibody. Binds to CD11a of α-subunit of T cell marker leukocyte function-associated antigen (LFA)-1, preventing it from binding to intercellular adhesion molecule 1.	*Dermatologic*: → Psoriasis	→ Granuloma annulare → Cutaneous lupus → Cutaneous dermatomyositis → Atopic dermatitis → Alopecia areata	**Psoriasis** → Initial dose of 0.7 mg/kg as a conditioning dose, followed in 1 week with 1 mg/kg weekly (Max: 200 mg/dose)	SubQ	*Before starting:* CBC and LFTs. *Interval Monitoring:* CBC (monitor platelets).	C	**Common:** HA, fever, nausea, vomiting, myalgias. **Rare But Serious:** PML, hemolytic anemia, thrombocytopenia, infections, NMSC.	**Withdrawn from USA market due to PML risk** in patients receiving long-term therapy. Avoid live vaccines.

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Etanercept (Enbrel)	TNF-α Inhibitor Dimeric fusion protein w/ extracellular ligand-bonding portion of human TNF receptor linked to the Fc portion of IgG1. Inhibits binding of TNF-α and TNF-B to cell surface TNF receptors, rendering TNF biologically inactive.	*Dermatologic:* → Adult plaque psoriasis *Other:* → PsA → RA → JIA → AS	→ Pediatric psoriasis → PG → Behcet's disease → Aphtous stomatitis → Other neutrophilic dermatoses → Subcorneal pustular dermatoses → HS → GVHD → Severe SCLE → Autoimmune bullous disease → Lichen planus → Dermatomyositis → Sarcoidosis → SAPHO syndrome → Scleroderma → Generalized GA → MRH	**Psoriasis →** FDA Dosing: Initial dose of 50mg twice weekly x 3 months, followed by 50mg once weekly. Recommended dose for pediatric psoriasis is 0.8mg/kg weekly (maximum of 50mg).	SubQ	*Before starting:* Test for TB. Consider testing for hepatitis B/C and HIV. *Interval Monitoring:* Annual TB Test. Routine TBSE.	B	**Common:** injection site reactions, URI, diarrhea, rash, pruritus, fever, urticarial. **Rare But Serious:** CHF; melanoma & NMSC; uveitis; central demyelinating disorders; cytopenias; new-onset psoriasis (especially palmoplantar pustulosis); cutaneous small vessel vasculitis; eczematous eruptions; lichenoid dermatitis. ***Black Box Warnings:*** 1. Serious and fatal infections 2. Lymphoma and other malignancies Screen for: CHF, IBD, demyelinating diseases	Syringe contains latex. Avoid live vaccines. Lupus-like syndromes and autoimmune hepatitis can arise in patients on TNF-α Inhibitors. However, some case reports show improvement in SCLE with etanercept. Okay to use in conjunction with MTX and UV therapy. Avoid concurrent administration with IL-1 receptor antagonists (ie Anakinra).
Golimumab (Simponi)	TNF-α Inhibitor Fully humanized recombinant IgG1k monoclonal antibody that binds to both the soluble and transmembrane bioactive forms of human TNF-α.	*Dermatologic:* None *Other:* → PsA → RA → AS → UC	Not well established.	**PsA, RA, AS →** 50mg monthly	SubQ	*Before starting:* Test for TB and hepatitis B. Consider testing for hepatitis C and HIV. *Interval Monitoring:* Annual TB Test. Routine TBSE.	Not known	**Common:** URI, injection site reaction, HSV outbreak, ALT/ALT elevation, HTN, rash, fever, dizziness, paresthesias. **Rare But Serious:** CHF; melanoma & NMSC; uveitis; central demyelinating disorders; cytopenias; new-onset psoriasis (especially palmoplantar pustulosis); cutaneous small vessel vasculitis; eczematous eruptions; lichenoid dermatitis. ***Black Box Warnings:*** 1. Serious and fatal infections 2. Lymphoma and other malignancies **Screen for:** CHF, demyelinating diseases	Syringe contains latex. Avoid live vaccines. Lupus-like syndromes and autoimmune hepatitis can arise in patients on TNF-α Inhibitors. Okay to administer alongside MTX.
Guselkumab (Tremfya)	IL-23 Inhibitor Recombinant humanized monoclonal Ab; Selectively blocks IL-23 (but not IL-12)	*Dermatologic*: → Psoriasis	Not well established.	**Psoriasis →** 100mg at Week 0, Week 4, then q8 weeks thereafter	SubQ	*Before starting:* Test for TB. *Interval Monitoring:* Annual TB test.	Not known	**Common:** URI, HA, injection site reactions, arthralgia, diarrhea, gastroenteritis, tinea, HSV, elevated liver enzymes.	Avoid live vaccines.

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Infliximab (Remicade)	TNF-α Inhibitor Chimeric (human-mouse) IgG1k monoclonal antibody specific for human TNF-α. Neutralizes the biological activity of TNF-α by binding w/ high affinity to the soluble and transmembrane forms of TNF-α, inhibiting it from binding w/ its receptors.	*Dermatologic:* → Psoriasis *Other:* → PsA → Adult & pediatric Crohn's → UC → RA → AS	→ PG → Bechet's disease → Granulomatous cheilitis → Vasculitides → PRP → Reactive arthritis → Subcorneal pustular dermatoses → HS → GVHD → Sjogren's → SLE → Dermatomyositis → Scleroderma → Sarcoidosis → Granuloma annulare → MRH → Pemphigus vulgaris → SAPHO syndrome → TEN	**Psoriasis**→ 5mg/kg given as an IV induction regimen at 0, 2, and 6 weeks, followed by maintenance regimen of 5 mg/kg every 8 wks thereafter. Doses ranging from 3-10 mg/kg have been used. Infusion should be administered over 2 or more hours.	IV	*Before starting:* Test for TB. Consider testing for hepatitis B/C and HIV. *Interval Monitoring:* Annual TB Test. Routine TBSE.	B	**Common:** Infusion-related reactions, including fever, chills, pruritus, hypo- or hypertension, chest pain, urticaria, shortness of breath, and (rarely) anaphylaxis; URI, nausea, headache, abdominal pain, rash, dyspepsia, arthralgia, pruritus, fever, HTN. **Rare But Serious:** CHF; melanoma & NMSC; hepatotoxicity; uveitis; central demyelinating disorders; allergic reactions; serum-sickness; cytopenias; new-onset psoriasis (especially palmoplantar pustulosis); cutaneous small vessel vasculitis; eczematous eruptions; lichenoid dermatitis. **Contraindications:** - Allergy to murine proteins ***Black Box Warnings:*** 1. Serious & fatal infections 2. Malignancy (lymphoma and other malignancies) Screen for: CHF, demyelinating diseases	Lupus-like syndromes and autoimmune hepatitis can arise in patients on TNF-α inhibitors. Avoid live vaccines. Efficacy may decrease over time due to development of neutralizing anti-chimeric antibodies. Concurrent use of low-dose weekly MTX may help prevent antibody formation. Avoid concurrent administration with IL-1 receptor antagonists (ie Anakinra).
Ixekizumab (Taltz)	IL-17 Inhibitor Humanized IL-17A antagonist, inhibiting release of associated inflammatory cytokines and chemokines.	*Dermatologic:* → Psoriasis	Not well established.	**Psoriasis**→ Initial dose of 160mg once, then 80mg q2 weeks x 12 weeks, then 80mg q4 weeks.	SubQ	*Before starting:* Test for TB. *Interval Monitoring:* Annual TB test.	Not known	**Common:** Injection site reactions, URI, nausea, tinea infections. **Rare But Serious:** New or exacerbated cases of IBD; hypersensitivity reaction, neutropenia; thrombocytopenia. Screen for: IBD.	Avoid live vaccines. Efficacy may wane due to development of neutralizing antibodies.
Omalizumab (Xolair)	IgE Inhibitor Humanized recombinant monoclonal antibody (IgG1). Blocks IgE's high affinity Fc receptor, decreasing IgE and blocking its attachment to mast cells, basophils, and dendritic cells.	*Dermatologic:* → Chronic idiopathic urticaria *Other:* → Asthma	→ Atopic dermatitis	→ **Chronic urticaria** 150-375mg q2-4 weeks (Max of 150mg per injection site) Doses calculated based on body weight and baseline serum total IgE levels.	SubQ	*Before starting:* Serum total IgE levels	B	**Common:** Injection site reactions, arthritis, rash, fever, pruritus, URIs. **Rare But Serious:** Anaphylaxis and malignancy. ***Black Box Warnings:*** 1. Anaphylaxis after first dose, and even after >1 year of treatment	Live virus vaccines should be given cautiously during omalizumab treatment until more data are available.

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Rituximab (Rituxan)	CD20 Inhibitor Chimeric monoclonal antibody that binds to CD20 antigen found on surface of mature B cells and causes apoptosis of these cells or existing plasma cells.	*Dermatologic:* None *Other:* → RA → non-Hodgkin B-cell lymphoma → CLL →Granulomatosis with Polyangiitis ((Wegener's) and Microscopic Polyangiitis (MPA)	→ Cutaneous B-cell lymphoma → Autoimmune bullous dermatoses (pemphigus vulgaris, bullous pemphigoid, paraneoplastic pemphigus, EBA) → SLE → Cutaneous lupus → Dermatomyositis → Chronic GVHD → Vasculitis → Other B-cell-mediated autoimmune and inflammatory diseases	Doses vary widely by indication.	IV	*Before starting:* Test for hepatitis B and TB. Consider testing hepatitis C, CBC. *Interval Monitoring:* Consider annual TB and semi-frequent CBCs.	C	Severe infusion reactions can occur (typically with the first infusion). Serious infections (bacterial, fungal, and viral) can occur up to 1 year after completing therapy, or reactivation of viral infections (especially hepatitis B). Reported cases of bowel obstruction and perforation, cardiac arrhythmias and angina, SJS/TEN, and onset of paraneoplastic pemphigus. **Contraindications:** Hypersensitivity to murine proteins; serious infections. Take precaution in patients with history of angioedema or hypotension. ***Black Box Warnings:*** 1. Serious or fatal infusion reactions 2. Severe mucocutaneous reactions (i.e. SJS/TEN, paraneoplastic pemphigus). 3. HBV Reactivation 4. PML	Useful in B-cell mediated skin diseases. Cases of PML have been reported. Tumor lysis syndrome can occur in lymphoma patients. Efficacy may decrease over time due to development of neutralizing anti-chimeric antibodies. Patients should be counseled to avoid live vaccinations while on medication. IV methylprednisone 100mg typically given prior to infusion.
Secukinumab (Cosentyx)	IL-17 Inhibitor Human IgG1 monoclonal antibody that binds to IL-17A, inhibiting release of associated inflammatory cytokines and chemokines.	*Dermatologic:* → Psoriasis *Other:* → PsA → AS	**Psoriasis** → 300 mg subcutaneously at weeks 0, 1, 2, 3, and 4 followed by 300 mg every 4 weeks. 150 mg may be acceptable for some patients.	**Psoriasis** → Initial dose 150mg weekly x 5 weeks, followed by 150mg q4 weeks. Can consider increasing dose to 300mg q4 week if active disease persists.	SubQ	*Before starting:* Test for TB. *Interval Monitoring:* Annual TB test	B	**Common:** URIs, diarrhea. **Rare But Serious:** Anaphylactic or hypersensitivity reactions, neutropenia, severe infections. Use with caution if history of IBD.	Syringe contains latex. Avoid live vaccines. Efficacy may decrease over time due to development of neutralizing anti-chimeric antibodies.
Tofacitinib (Xeljanz)	JAK3 Inhibitor Inhibits JAKs, intracellular enzymes that transmit signals arising from cytokine or growth factor receptor interactions, decreasing downstream interferons, interleukins, & erythropoietin.	Dermatologic: None Other: → RA	→ ?Alopecia areata	**RA** → 5mg BID Consider dose decreased to 5mg daily in severe hepatic or renal impairment.	PO	*Before starting:* Test for TB, CBC, CMP, and lipids. *Interval Monitoring:* CBC at 4 and 8 weeks, then q3 months. Lipids 4-6 weeks after starting. Periodic CMP.	C	**Common:** URI, UTI, HA, diarrhea, ALT/AST increase, Cr increase, cholesterol increase, transient lymphocytosis. **Rare But Serious:** Increased risk of infections, NMSC, pancytopenia, GI perforation. Tofacitinib is not recommended for patients with severe hepatic or renal impairment. ***Black Box Warnings:*** 1. Serious & fatal infections (including new TB or reactivation) 2. Lymphoma and other malignancies	Avoid live vaccines. Okay to use with MTX. Do not use in combination with other biologics or immunosuppressants.

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Ustekinumab (Stelara)	IL-12/IL-23 Inhibitor Human IgG1k monoclonal antibody that binds w/ high affinity and specificity to p40 protein subunit by both the IL-12 and IL-23 cytokines.	*Dermatologic:* → Adult plaque psoriasis *Other:* → PsA → Crohn's disease	Not well established.	**Psoriasis →** For pts <100kg, 45mg initially and 4 wks later, followed by 45mg every 12 wks. For pts >100kg, recommend dose is 90mg initially and 4 wks later, followed by 90mg every 12 wks.	SubQ	*Before starting:* Test for TB. *Interval Monitoring:* Annual TB test	B	**Common:** URIs, HA, injection site reaction, back pain, fatigue. **Rare But Serious:** Possible increased risk of adverse cardiovascular events, severe infections, NMSC, and malignancy. Pustular and erythrodermic psoriasis cases have been noted post-marketing.	Syringe contains latex. Avoid live vaccines. Patients deficient in IL-12/ IL-23 have increased risk of severe infections with mycobacteria and *Salmonella*.

Abbreviations:

TNF = Tumor necrosis factor
HS = Hidradenitis suppurativa
AS = Ankylosing spondylitis
PsA = Psoriatic arthritis
TEN = Toxic epidermal necrolysis
IBD = Inflammatory bowel disease
JIA = Juvenile idiopathic arthritis
RA = Rheumatoid arthritis
GVHD = Graft versus host disease
PG = Pyoderma gangrenosum
SCLE = Subacute cutaneous lupus erythematous
PDE = Phosphodiesterase
MRH = Multicentric reticulohistiocytosis
PRP = Pityriasis rubra pilaris

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