Crutchfield Dermatology

Charles E. Crutchfield III, M.D.
Board Certified Dermatologist
Mayo Clinic Medical School Graduate

Biologic Medication Information

Medication	Dosing	Device Type	Lab work	Indication	Contraindication	Immunization	Mechanism of action	Black box warning
Enbrel 50mg (etanercept)	**Initial:** Inject 50mg SQ twice weekly x 3 months on the same day. **Maint:** Starting month 4, then inject 50mg SQ once weekly on the same day.	Sureclick (Pen), Pre-filled syringe or Vial	TB (Mantoux) prior and every year while on Enbrel	Psoriasis and Psoriatic Arthritis	Use of Enbrel with Anakinra or Abatacept is not recommended these are both immunosuppressant drugs. Congestive Heart failure, Lupus and Multiple Sclerosis	Use of Enbrel with Anakinra or Abatacept is not recommended these are both immunosuppressant drugs.	Etanercept is adimeric soluble form of the p75 TNF receptor that can bind TNF molecules. Etanercept inhibits binding of TNF-α and TNF-β (lymphotoxin alpha [LT-alpha]) to cell surface TNFRs, rendering TNF biologically inactive.	Serious infections and Malignancy (see full prescribing for complete boxed warning)
Enbrel 25mg (etanercept) **Pediatric Dosing (4-7 years old)**	*Recommended weekly dose 0.8mg/kg up to a maximum dose of 50mg every week. -0.8mg/kg (0.36mg/lb) for pediatric patients who weight <138lb (63kg) -50mg for pediatric patients who weight >135 lbs (63kg) Convert pounds to Kilograms for accurate dosing Ex: lbs x 0.4536= kg Less than 68lb (25mg) 68lb to <138lbs: (25mg) >138lbs: (25mg, 50mg)	Multiple-Use Vial, Prefilled Syringe And SureClick Autoinjector	TB (Mantoux) prior and every year while on Enbrel	Chronic Moderate to severe Plaque Psoriasis	The use of Enbrel in patient's receiving concurrent cyclophosphamide therapy is not recommended. The risk of serious infection may increase with concomitant us if abatacept. Concurrent therapy with Enbrel and anakinra is not recommended. Hypoglycemia has been reported followings initiation of Enbrel therapy in patients receiving medications fir diabetes, necessitating a reduction in anti-diabetes in some pt.	Use of Enbrel with Anakinra or Abatacept is not recommended these are both immunosuppressant drugs	Etanercept is adimeric soluble form of the p75 TNF receptor that can bind TNF molecules. Etanercept inhibits binding of TNF-α and TNF-β (lymphotoxin alpha [LT-α]) to cell surface TNFRs, rendering TNF biologically inactive.	Serious infections and Malignancy (see full prescribing for complete boxed warning)

Medication	Dosing	Device Type	Lab work	Indication	Contraindication	Immunization	Mechanism of action	Black box warning
Humira 40mg/0.8ml (adalimumab)	**Initial:** Inject 80mg (2pens) SQ on Day 1, then inject 40mg (1pen) SQ on Day 8, **Maint:** Then Inject 40mg SQ every other week on the same day.	Auto-injector (pen), or Prefilled syringe	TB (mantoux) prior to starting and every year while on Humira	Psoriasis and Psoriatic Arthritis	Congestive Heart failure, Lupus and Multiple Sclerosis	No live vaccines, Make sure pt is up-to-date on all immunizations prior to starting Humira	Adalimumab binds specifically to TNF-α and blocks its interaction with the p55 and p75 cell surface TNF receptors	Serious infections and Malignancy (see full prescribing for complete boxed warning)
Humira 40mg/0.8ml (adalimumab)	**Initial:** Inject 160mg (4 pens) SQ on day 1, then inject 80mg (2pens) SQ on Day 15, **Maint:** Day 29 Inject 40mg SQ once weekly on the same day and thereafter.	Auto-injector (pen), or Prefilled syringe	TB (mantoux) prior to starting and every year while on Humira	Hidradenitis Suppurativa	Congestive Heart failure, Lupus and Multiple Sclerosis	No live vaccines, Make sure pt is up-to-date on all immunizations prior to starting Humira	Adalimumab binds specifically to TNF-α and blocks its interaction with the p55 and p75 cell surface TNF receptors	Serious infections and Malignancy (see full prescribing for complete boxed warning)
Stelara 45mg (ustekinumab)	(Less than 200 lbs) **Initial:** Inject 45mg SQ on Day 0, and then inject 45mg SQ on Day 28. **Maint:** then inject 45 mg once every 12 weeks.	Prefilled Syringe	TB (mantoux) prior to starting and every year while on Stelara and BCG vaccines should not be given during treatment with Stelara or for one year following d/c.	Psoriasis and Psoriatic Arthritis	Clinically significant hypersensitivity to Stelara or to any of the excipients.	No live vaccines make sure pt is up-to-date on immunizations prior to starting Stelara.	Ustekinumab is a human IgG1κ monoclonal antibody that binds with specificity to the p40 protein subunit used by both the IL-12 and IL-23 cytokines. IL-12 and IL-23 are naturally occurring cytokines that are involved in inflammatory and immune responses, such as natural killer cell activation and CD4+ T-cell differentiation and activation. In in vitro models, ustekinumab was shown to disrupt IL-12 and IL-23 mediated signaling and cytokine cascades by disrupting the interaction of these cytokines with a shared cell-surface receptor chain, IL-12Rβ1.	None

Medication	Dosing	Device Type	Lab work	Indication	Contraindication	Immunization	Mechanism of action	Black box warning
Stelara 90mg (ustekinumab)	(Over 200lbs) **Initial:** Inject 90mg SQ on Day 0, And then inject 90mg SQ on Day 28. **Maint:** then inject 90mg once every 12 weeks.	Prefilled Syringe	TB (mantoux) prior to starting and every year while on Stelara and BCG vaccines should not be given during treatment with Stelara or for one year following d/c.	Psoriasis and Psoriatic Arthritis	Clinically significant hypersensitivity to Stelara or to any of the excipients.	No live vaccines make sure pt is up-to-date on immunizations prior to starting Stelara.	See above information	None
Cosentyx (secukinumab)	**Initial:** Inject 300mg (2pens) SQ weekly on week 0, 1, 2, 3, 4. **Maint:** Inject 300mg (2pens) once every 4 weeks.	Sensoready Pen (Auto-injector) or Prefilled Syringe	TB (Mantoux) prior starting and ever year while on Cosentyx	Psoriasis and Psoriatic Arthritis	Patient is allergic to Cosentyx.	No live vaccines Make sure pt is up-to-date on all immunizations prior to starting Cosentyx.	Secukinumab is a human IgG1 monoclonal antibody that selectively binds to the interleukin- 17A(IL17A)cytokine and Inhibits its interaction with the IL-17 receptor.	None
Taltz 80mg (ixekizumab)	**Initial:** Inject 160mg (2pens) SQ on Day 0, 1st 12weeks: then Inject 80mg (1pen) SQ every 2 weeks x 12 weeks on the same day, **Maint:** After 12 weeks: Then Inject 80 mg SQ every 4 weeks on the same day.	Auto-injector and Prefilled Syringes	TB (Mantoux) prior to starting and every year while on Taltz	Psoriasis and Psoriatic Arthritis	Serious hypersensitivity reaction to Taltz or to any excipients.	No Live Vaccines make sure pt is up-to-date on all vaccines before starting Taltz	Ixekizumab is humanized IgG4 monoclonal antibody that selectively binds with the interleukin 17A (IL-17A) cytokine and inhibits its interaction with the IL-17 receptor. IL-17A is a naturally occurring cytokine that is involved in normal inflammatory and immune responses. Ixekizumab inhibits the release of proinflammatory cytokines and chemokines	None

Medication	Dosing	Device Type	Lab work	Indication	Contraindication	Immunization	Mechanism of action	Black box warning
Otezla (apremilast) Otezla (apremilast) is not a biologic agent, but we are including it in the chart because it is FDA approved treat psoriasis in situations where a biologic may be considered, and for reader convenience	**Starter Pak:** Take as directed (Given in office). **Maintenance:** Take 30mg twice daily. (12 hours apart)	Tablets	No lab work needed	Psoriasis and Psoriatic Arthritis	Hypersensitivity to Apremilast or to any excipients in the formulation	The effect of apremilast on vaccine-mediated immune responses has not been clinically assessed.	Apremilast is an oral small-molecule inhibitor of phosphodiesterase 4 (PDE4) specific for cyclic adenosine monophosphate (cAMP) PDE4 inhibition results in increased intracellular cAMP levels.	None
Dupixent (dupilumab)	**Initial Dose:** Inject 600mg (2 pens) Subcutaneously on Day 1. **Maintenance Dose:** Inject 300mg (1pen) Subcutaneously every 2 weeks starting Day 15 and thereafter.	Prefilled Syringe	None	Dupixent is an interleukin-4 receptor alpha antagonist for the treatment of **ADULT** over the age of 18 patients with moderate-to-severe **ATOPIC DERMATITS** whose disease id not adequately controlled with topical prescription therapies or when therapies are not advisable. Dupixent can be used with or without corticosteroids.	Dupixent is contraindicated in patients who have known hypersensitivity to dupixent or any if it excipient (see 5.1 on the Medication guided for further information)	NO LIVE Vaccines while on DUPIXENT	Dupilumab is a human monoclonal IgG4 antibody that inhibits interleukin-4 (IL-4) and interleukin-13 (IL-13) signaling by specifically binding to the IL-4Ra subunit shared by the IL-4 and IL-13 receptor complexes. Dupilumab inhibits IL-4 signaling via the Type I receptor and both IL-4 and IL-13 signaling through the Type II receptor. Blocking IL-4a with dupilumab inhibits IL-4 and IL-13 cytokinr-induced responses, including the release of proinflammatory, cytokines, chemokines and IgE.	None

Medication	Dosing	Device Type	Lab work	Indication	Contraindication	Immunization	Mechanism of action	Black box warning
Remicade (INFLIXMAB)	**Initial Dose:** 5 mg/kg given as an intravenous induction regimen at 0, 2 and 6 weeks. **Maintenance:** regimen of 5 mg/kg every 8 weeks thereafter for the treatment of chronic severe (i.e., extensive and/or disabling) plaque psoriasis.	IV infusion	TB (Mantoux) prior starting and yearly	Plaque Psoriasis and Psoriatic Arthritis	REMICADE at doses >5 mg/kg should not be administered to patients with moderate to severe heart failure. In a randomized study evaluating REMICADE in patients with moderate to severe heart failure (New York Heart Association REMICADE ® (infliximab) REMICADE ® (infliximab) 4 [NYHA] Functional Class III/IV), REMICADE treatment at 10 mg/kg was associated with an increased incidence of death and hospitalization due to worsening heart failure [see Warnings and Precautions (5.5) and Adverse Reactions (6.1)]. REMICADE should not be re-administered to patients who have experienced a severe hypersensitivity reaction to REMICADE. Additionally, REMICADE should not be administered to patients with known hypersensitivity to inactive components of the product or to any murine proteins.	No live vaccines	Infliximab neutralizes the biological activity of TNF-α by binding with high affinity to the soluble and transmembrane forms of TNF-α and inhibits binding of TNF-α with its receptors. Infliximab does not neutralize TNF-β (lymphotoxin-alpha), a related cytokine that utilizes the same receptors as TNF-α. Biological activities attributed to TNF-α include: induction of pro-inflammatory cytokines such as interleukins (IL) 1 and 6, enhancement of leukocyte migration by increasing endothelial layer permeability and expression of adhesion molecules by endothelial cells and leukocytes, activation of neutrophil and eosinophil functional activity, induction of acute phase reactants and other liver proteins, as well as tissue degrading enzymes produced by synoviocytes and/or chondrocytes. Cells expressing transmembrane TNF-α bound by infliximab can be lysed in vitro or in vivo. Infliximab inhibits the functional activity of TNF-α in a wide variety of in vitro bioassays utilizing human fibroblasts, endothelial cells, neutrophils, B and T-lymphocytes and epithelial cells. The relationship of these biological response markers to the mechanism(s) by which REMICADE exerts its clinical effects is unknown. Anti-TNF-α antibodies reduce disease activity in the cotton-top tamarin colitis model, and decrease synovitis and joint erosions in a murine model of collagen-induced arthritis. Infliximab prevents disease in transgenic mice that develop polyarthritis as a result of constitutive expression of human TNF-α, and when administered after disease onset, allows eroded joints to heal.	Serious Infections and Malignancies (see package insert for complete details)

Medication	Dosing	Device Type	Lab work	Indication	Contraindication	Immunization	Mechanism of action	Black box warning
Xolair (Omalizumab)	**Asthma:** Xolair 75 to 375mg SC every 2 or 4 weeks. -Determine dose (mg) and dosing frequency by serum total IgE level (IU/mL), measured before the start of treatment, and body weight (kg) **Urticaria:** Xolair 150 or 300mg SC every 4 weeks. Dosing in CIU is not dependent on serum IgE level or body weight.	Vial	In asthma patients, a blood test for a substance called IgE must be performed prior to starting XOLAIR to determine the appropriate dose and dosing frequency. No labs needed for patient with chronic idiopathic Urticaria	Moderate to severe persistent asthma in patients 6 years of age and older or Chronic Idiopathic Urticaria.	Patients who are allergic to omalizumab or any of the ingredients.	Have any other allergies (such as food allergy or seasonal allergies) Have sudden breathing problems (bronchospasm) Have ever had a severe allergic reaction called anaphylaxis Have or have had a parasitic infection Cancer are pregnant or plan to become pregnant. Breastfeeding or plan to breastfeed.	Asthma Omalizumab inhibits the binding of IgE to the high-affinity IgE receptor (FcεRI) on the surface of mast cells and basophils. Reduction in surface-bound IgE on FcεRI -bearing cells limits the degree of release of mediators of the allergic response. Treatment with Xolair also reduces the number of FcεRI receptors on basophils in atopic patients. Chronic Idiopathic Urticaria Omalizumab binds to IgE and lowers free IgE levels. Subsequently, IgE receptors (FcεRI) on cells down -regulate. The mechanism by which these effects of omalizumab	NAPHYLAXIS See full prescribing information for complete boxed warning. Anaphylaxis, presenting as bronchospasm, hypotension, syncope, urticaria, and/or angioedema of the throat or tongue, has been reported to occur after administration of Xolair. Anaphylaxis has occurred after the first dose of Xolair but also has occurred beyond 1year after beginning treatment. Closely observe patients for an appropriate period of time after Xolair administration and be prepared to manage anaphylaxis that can be life-threatening. Inform patients of the signs and symptoms of anaphylaxis and have them seek immediate medical care should symptoms occur. (5.1)

Medication	Dosing	Device Type	Lab work	Indication	Contraindication	Immunization	Mechanism of action	Black box warning
TREMFYA (guselkumab)	**Inject 100 mg/ml Subcutaneously at week 0 and week 4. Then inject 100mg every 8 weeks thereafter.** **Urticaria: Xolair 150 or 300mg SC every 4 weeks. Dosing in CIU is not dependent on serum IgE level or body weight.**	Prefilled Syringe	TB (mantoux) prior to starting therapy	Adult patient with moderate-severe plaque Psoriasis	NONE	Avoid live vaccines and all age appropriate immunizations according to current immunization guidelines.	Guselkumab is a human monoclonal IgG1λ antibody that selectively binds to the p19 subunit of interleukin 23 (IL-23) and inhibits its interaction with the IL-23 receptor. IL-23 is a naturally occurring cytokine that is involved in normal inflammatory and immune responses. Guselkumab inhibits the release of proinflammatory cytokines and chemokines.	NONE

Medication	Dosing	Device Type	Lab work	Indication	Contraindication	Immunization	Mechanism of action	Black box warning
SILIQ (brodalumab)	**Inject 210mg Sub Q at week 0, 1, 2.** **Then inject 210mg Sub Q every 2 weeks.**	Prefilled Syringe	TB (mantoux) prior to starting and yearly	Moderate to severe plaque Psoriasis in Adults	Crohn's disease	Avoid live vaccines	Brodalumab is a human monoclonal IgG2 antibody that selectively binds to human IL-17RA and inhibits its interactions with cytokines IL-17A, IL-17F, IL-17C, IL-17A/F heterodimer and IL-25. IL-17RA is a protein expressed on the cell surface and is a required component of receptor complexes utilized by multiple IL-17 family cytokines. Blocking IL-17RA inhibits IL-17 cytokine-induced responses including the release of pro-inflammatory cytokines and chemokines.	WARNING: SUICIDAL IDEATION AND BEHAVIOR See full prescribing information for complete boxed warning. • Suicidal ideation and behavior, including completed suicides, have occurred in patients treated with SILIQ. (5.1, 6.1) • Prior to prescribing, weigh potential risks and benefits in patients with a history of depression and/or suicidal ideation or behavior. (5.1) • Patients with new or worsening suicidal thoughts and behavior should be referred to a mental health professional, as appropriate. (5.1) • Advise patients and caregivers to seek medical attention for manifestations of suicidal ideation or behavior, new onset or worsening depression, anxiety, or other mood changes. (5.1) • SILIQ is available only through a restricted program called the SILIQ REMS Program. (5.2)

Before starting check TB status, HIV status, Hepatitis panel and fungal serologies, if indicated, (e.g. participates outdoor activities with high rate of blasto/other exposure).

Many people on Cosentyx experience weight loss, be sure to monitor for weight change at visits.

IL-17 antagonists have been reported to cause a flare in patients with inflammatory bowel disease, be sure to consider this when starting a ptient on an IL-17 antagonist (Talz and Cosentyx)