

Antibodies and Beyond: The Expanding Biologics Landscape

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Learning Objectives

1. Explain how biologic medications work in the body
2. Analyze patient disease states in digestive health, dermatology, and rheumatology to select appropriate biologic therapy classes and justify their use based on mechanism of action and approved indications
3. List important monitoring steps, including labs and infection prevention
4. Describe new developments in biologic medications and delivery methods

Biologics 101

Autoimmune Diseases

- Autoimmune Disease – a disorder where the body’s immune system attacks itself
 - Leads to chronic inflammation, tissue damage, and system dysfunction
 - Affects ~10% of the global population
 - Over 100 distinct autoimmune diseases have been identified
- In the US:
 - >15 million people are living with an autoimmune disease
 - This is 4.6% of the total population
 - 34% have more than 1 autoimmune disease
 - Women are 2x more likely to have an autoimmune disease than men

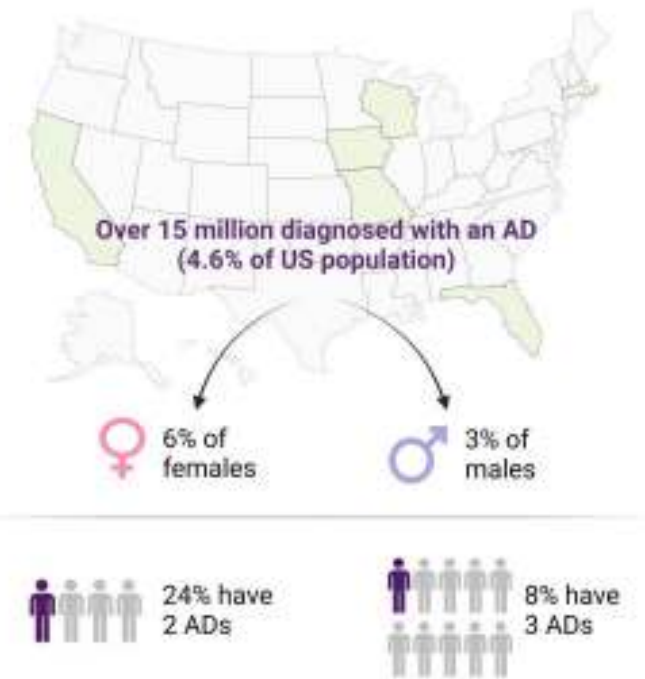


IMAGE SOURCE: ABEND AH, HE I, BAHROOS N, CHRISTIANAKIS S, ET AL.

Table 3. Top 20 most prevalent autoimmune diseases

Rank	Autoimmune Disease	Computed Estimated US Prevalence			Female Ratio	Rate/100,000
		Female	Male	Total ^A		
1	Rheumatoid arthritis	1,827,271	653,179	2,480,449	74%	744.2
2	Psoriasis	1,065,966	1,005,908	2,071,875	51%	621.6
3	Diabetes mellitus type 1	894,091	982,002	1,876,093	48%	562.9
4	Graves' disease	1,293,040	415,444	1,708,484	76%	512.6
5	Autoimmune thyroiditis	1,058,454	187,061	1,245,515	85%	373.7
6	Crohn's disease	622,853	574,725	1,197,578	52%	359.3
7	Multiple sclerosis	809,019	325,368	1,134,387	71%	340.4
8	Systemic lupus erythematosus	860,667	131,187	991,854	87%	297.6
9	Ulcerative colitis	464,741	483,672	948,413	49%	284.6
10	Sjögren's disease	545,176	79,187	624,363	87%	187.3
11	Celiac disease	393,901	173,765	567,666	69%	170.3
12	Polymyalgia rheumatica	304,398	202,417	506,815	60%	152.1
13	Autoimmune gastritis	171,229	100,441	271,670	63%	81.5
14	Vitiligo	130,263	120,299	250,562	52%	75.2
15	Autoimmune thrombocytopenic purpura	130,821	117,297	248,118	53%	74.4
16	Aplastic anemia	116,647	122,113	238,761	49%	71.6
17	Alopecia areata	130,762	97,928	228,690	57%	68.6
18	Juvenile rheumatoid arthritis	155,002	69,415	224,417	69%	67.3
19	Systemic sclerosis	180,092	40,344	220,435	82%	66.1
20	Autoimmune hepatitis	146,491	45,090	191,582	76%	57.5

1. ABEND AH, HE I, BAHROOS N, CHRISTIANAKIS S, ET AL.. ESTIMATION OF PREVALENCE OF AUTOIMMUNE DISEASES IN THE UNITED STATES USING ELECTRONIC HEALTH RECORD DATA. J CLIN INVEST. 2024 DEC 12;135(4):E178722. DOI: 10.1172/JCI178722. PMID: 39666393; PMCID: PMC11827834.

What are Biologic Medications?



“Biologic” is often used interchangeably with “monoclonal antibody” (-mab drugs)

- “Biologic” actually includes a whole host of medications including:
 - Monoclonal antibodies (rituximab, adalimumab, infliximab)
 - Vaccines
 - Blood and blood products
 - Insulin
 - Gene Therapy
 - Stem Cell Therapy
- Biologic medications are an example of “biotechnology”
- **We will be focusing on Monoclonal Antibody Therapies today**



What are Biosimilar Medications?

- Biosimilar - highly similar and no clinically meaningful differences from reference product
- Biologics cannot be copied exactly due to the due to size and complexity
- Biosimilar has to show it is highly similar to and has no clinically meaningful differences in terms of safety, purity, and potency than the original biologic product
- Complications: side effects and efficacy, “biological drift”, “similar but not the same”

 Biologic	 Biosimilar
A new treatment	Nearly identical to FDA-approved biologic
Made from a living source	Made from a living source
15 years to develop	8-10 years to develop
\$1.2 billion to develop	\$100-\$200 million to develop
Patentable	Non-patentable


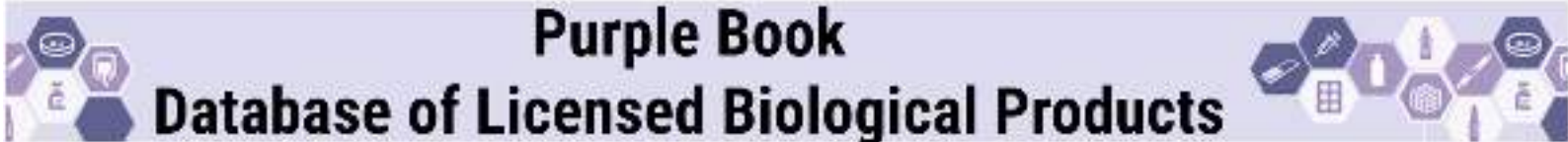


Image Source: [Generic and Biosimilar Medications | National MS Society](#)

1. OVERVIEW FOR HEALTH CARE PROFESSIONALS. U.S. FOOD AND DRUG ADMINISTRATION. AUGUST 1, 2024. ACCESSED MARCH 9, 2026. [HTTPS://WWW.FDA.GOV/DRUGS/BIOSIMILARS/OVERVIEW-HEALTH-CARE-PROFESSIONALS](https://www.fda.gov/drugs/biosimilars/overview-health-care-professionals).
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Purple Book




Purple Book Database of Licensed Biological Products

The Purple Book database contains information on all FDA-licensed (approved) biological products regulated by the Center for Drug Evaluation and Research (CDER), including licensed biosimilar and interchangeable products, and their reference products.

The Purple Book also contains information about all FDA-licensed allergenic, cellular and gene therapy, hematologic, and vaccine products regulated by the Center for Biologics Evaluation and Research (CBER).

Enter a product's proprietary (brand) name or the nonproprietary (proper) name to find biological products. As you type, a list of potential results will begin to appear below the search box based on what you are typing. Click on a product from the auto-populated results list below to view the results page. The results page for your selected product will include all biological products that share a core name (i.e., biosimilar, interchangeable, reference, and related biological products).

 Enter at least 3 letters

[Advanced Search](#) *Database last updated: February 27, 2026*

Disease Specific Biologics

RHEUMATOID ARTHRITIS, PSORIASIS, ECZEMA, ULCERATIVE COLITIS,
& CROHN'S DISEASE

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Rheumatology –Rheumatoid Arthritis

- Chronic autoimmune disease
 - Causes pain, swelling and stiffness in the lining of the joints
 - most commonly affects fingers, hands, wrists, knees, ankles, feet and toes
 - Occurs bilaterally
 - Typically diagnosed between ages of 30-60
- Risk factors:
 - Family history, Female, Obesity, Smoking
- Complications:
 - Heart disease, Deformity of joints, Osteoporosis, Cancer
- Treatment:
 - DMARDs (methotrexate)
 - NSAIDs
 - Corticosteroids
 - Biologics & JAK inhibitors



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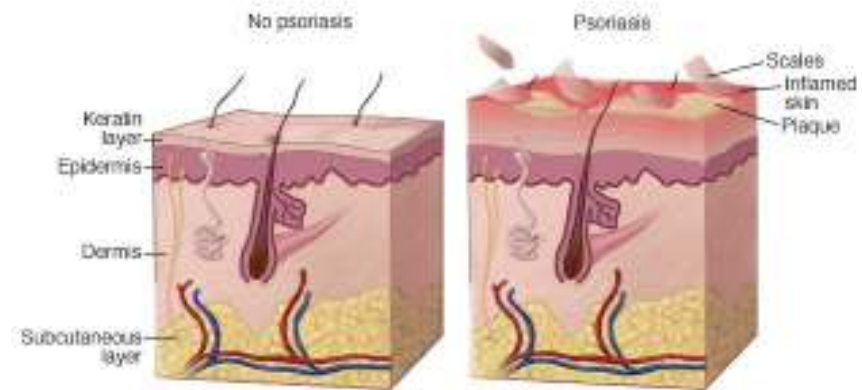
Image Source: [Rheumatoid arthritis - Symptoms and causes - Mayo Clinic](#)

Biologics Used for Rheumatoid Arthritis

Tumor Necrosis Factor- α (TNF) Inhibitors	B-cell Inhibitors	Interleukin Inhibitors	Selective Co-stimulation Modulators
<ul style="list-style-type: none">• Adalimumab• Certolizumab pegol• Etanercept• Golimumab• Infliximab	<ul style="list-style-type: none">• Rituximab	<ul style="list-style-type: none">• Sarilumab• Tocilizumab	<ul style="list-style-type: none">• Abatacept

Dermatology – Psoriasis

- Chronic autoimmune disease
 - Causes inflammation of the skin
 - Characterized by “plaques” – thick, scaly areas
 - Several types; can occur anywhere on skin
 - Affects ~3% of the population
- Complications due to ongoing inflammation:
 - Heart disease, Diabetes, Obesity, Arthritis
- Treatment:
 - DMARDs (methotrexate)
 - Topical Therapies
 - Light/UV therapies
 - Biologics & JAK inhibitors



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Image Source: [Psoriasis - Symptoms and causes - Mayo Clinic](#)

Biologics Used for Plaque Psoriasis

Tumor Necrosis Factor- α (TNF) Inhibitors	Interleukin Inhibitors
<ul style="list-style-type: none">• Adalimumab• Certolizumab pegol• Etanercept• Infliximab	<ul style="list-style-type: none">• Bimekizumab• Secukinumab• Brodalumab• Ixekizumab• Risankizumab• Ustekinumab• Tildrakizumab• Guselkumab

Dermatology – Atopic Dermatitis (Eczema)

- Chronic autoimmune disease
 - causes dry, itchy and discolored patches of skin
 - Atopic dermatitis is the most common type of eczema
 - Affects children and adults
- Risk factors:
 - Family history, Asthma, Hay Fever or other allergies
- Complications:
 - Infection
- Treatment:
 - Topical Therapies
 - Biologics & JAK inhibitors



Biologics Used for Eczema

Interleukin Inhibitors

- Dupilumab
- Tralokinumab
- Lebrikizumab
- Nemolizumab

Digestive Health – Ulcerative Colitis

- Chronic autoimmune disease
 - Causes inflammation & ulcers in the colon (large intestine)
 - Symptoms include abdominal pain, bloody diarrhea, mucus
 - Most common type of IBD
- Risk factors:
 - Family history, Age, Gut Microbiome
- Complications:
 - Ulcerations, Bleeding, Toxic Megacolon, Fulminant Colitis
 - Colitis is associated with increased risk of colon cancer
- Treatment:
 - Corticosteroids
 - Aminosalicylate(mesalamine, sulfasalazine)
 - Immunomodulators (mercaptopurine)
 - Biologics & JAK inhibitors

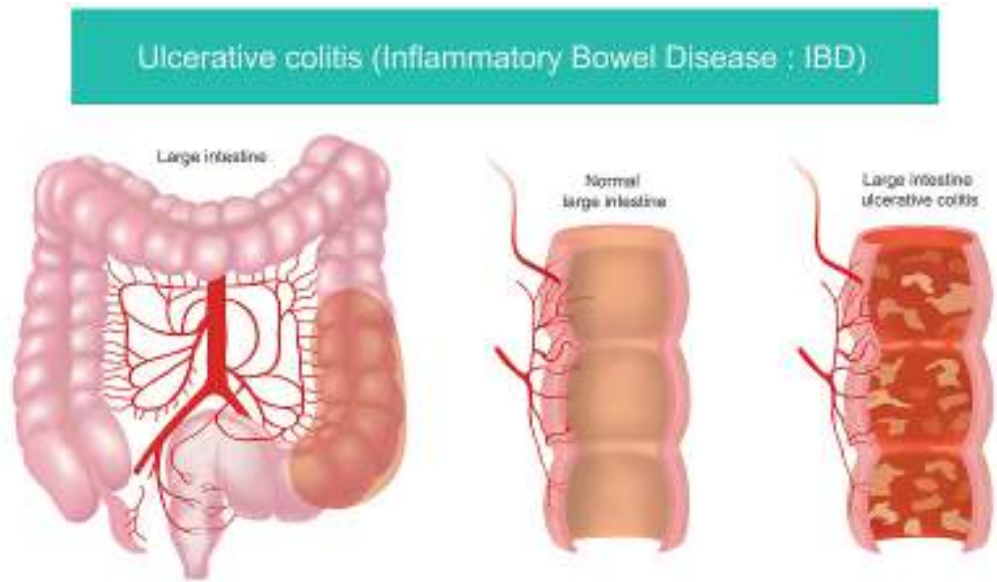


Image Source: [Ulcerative Colitis Basics | IBD | CDC](https://my.clevelandclinic.org/health/diseases/10351-ulcerative-colitis)

Biologics Used for Ulcerative Colitis

Tumor Necrosis Factor- α (TNF) Inhibitors	Integrin Inhibitors	Interleukin Inhibitors
<ul style="list-style-type: none">• Adalimumab• Golimumab• Infliximab	<ul style="list-style-type: none">• Vedolizumab	<ul style="list-style-type: none">• Ustekinumab• Risankizumab• Mirikizumab• Guselkumab

Digestive Health – Crohn's Disease

- Chronic autoimmune disease
 - Causes inflammation in the digestive tract
 - Leads to thickening of intestinal walls; damage “patches”
 - most commonly affects small & large intestines but can appear ANYWHERE in digestive tract
 - Symptoms include abdominal pain, chronic diarrhea, fatigue, fistulas, extraintestinal manifestations
- Risk factors:
 - Family history, Age, Appendectomy?, Smoking, Stress
- Complications:
 - Anemia, Strictures, Fistulas, Abscesses, Obstruction
- Treatment:
 - Corticosteroids
 - Immunomodulators/DMARDs (methotrexate)
 - Biologics & JAK inhibitors

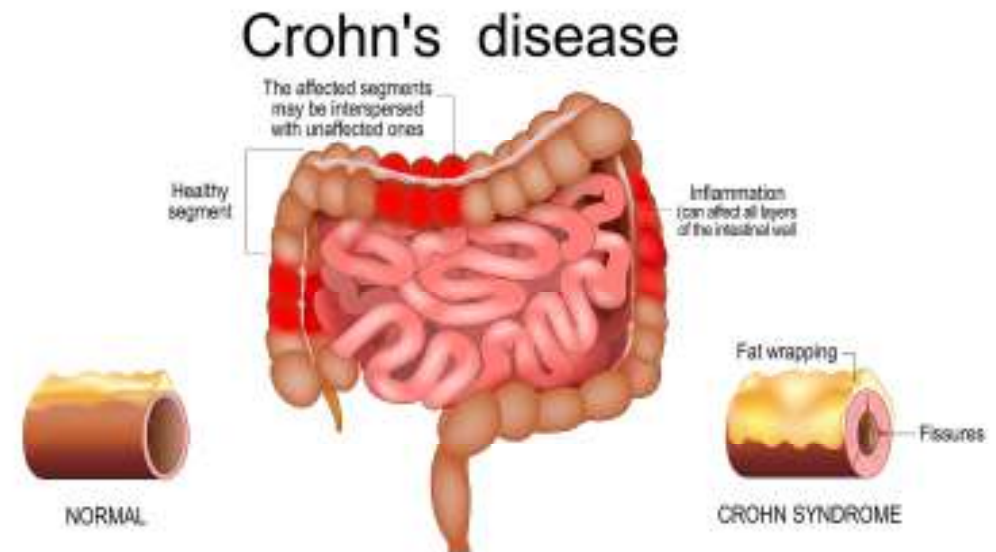


Image Source: [Crohn's Disease Basics | IBD | CDC](https://my.clevelandclinic.org/health/diseases/9357-crohns-disease)

Biologics used for Crohn's Disease

Tumor Necrosis Factor- α (TNF) Inhibitors	Integrin Inhibitors	Interleukin Inhibitors
<ul style="list-style-type: none">• Adalimumab• Certolizumab Pegol• Infliximab	<ul style="list-style-type: none">• Vedolizumab	<ul style="list-style-type: none">• Ustekinumab• Risankizumab• Mirikizumab• Guselkumab

Monoclonal Antibodies

“MAB” BIOLOGIC MEDICATIONS



Types of Monoclonal Antibodies

Engineered versions of antibodies naturally produced by the body

Four types for nomenclature:

1. Murine (-omab) - Mouse
2. Chimeric (-ximab) – Mouse or Human
3. Humanized (-zumab)
4. Human (-umab)

Tumor Necrosis Factor Inhibitors

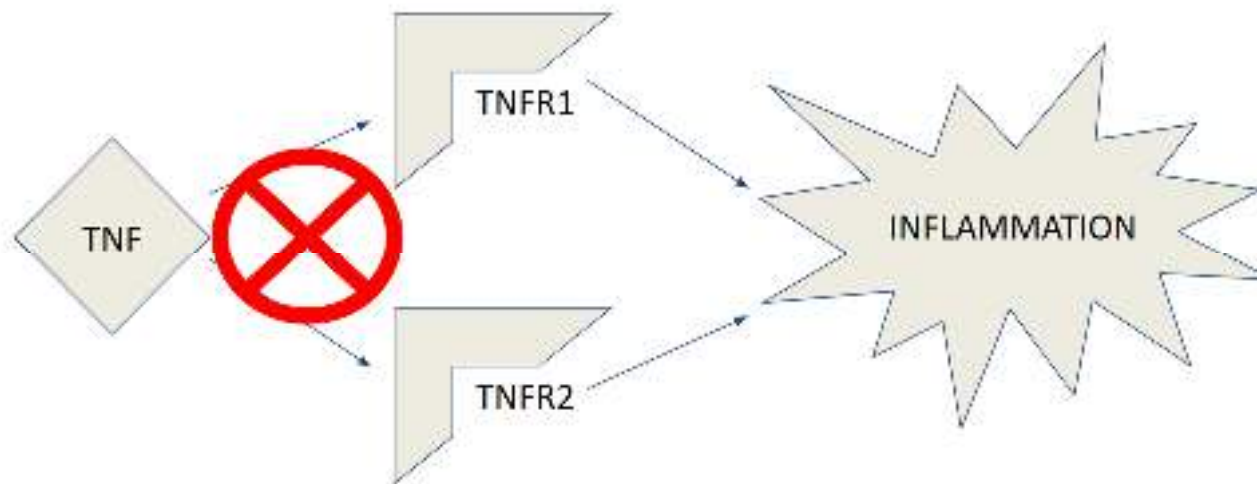
TNF INHIBITORS



TNF Inhibitors

Mechanism of Action

- Inhibits TNF-alpha, which is responsible for stimulating inflammatory cytokines (inflammation and cell death)
- TNF Inhibitors cause apoptosis of TNF-alpha producing cells



	Adalimumab (Humira and biosimilars)	Etanercept (Enbrel)	Infliximab (Remicade and biosimilars)	Certolizumab pegol (Cimzia)	Golimumab (Simponi)
Dosing Will Vary By Disease State					
How Supplied	<ul style="list-style-type: none"> • Citrate vs Citrate Free • Autoinjector • Prefilled Syringe • Packaging may contain latex 	<ul style="list-style-type: none"> • Autoinjector • Prefilled Syringe • Enbrel Mini (reusable autoinjector) 	<ul style="list-style-type: none"> • IV Infusion • Autoinjector • Prefilled Syringe 	<ul style="list-style-type: none"> • Prefilled Syringe 	<ul style="list-style-type: none"> • IV Infusion (Simponi Aria) • Autoinjector • Prefilled Syringe
Side Effects/ADRs	BLACK BOX WARNINGS: Serious infections, Malignancy PRECAUTIONS: Antibody formation, Pancytopenia, HF, Hepatotoxicity Headache Injection Site Reactions Nausea Abdominal Pain Infections Elevations in LFTs				
Monitoring	CBC (every 3-6 months) CMP (every 3-6 months) Hepatitis B/C (baseline) TB Quantiferon (baseline) Signs/symptoms of infection (periodically)				

Interleukin Inhibitors

IL-4, IL-6, IL-12/IL-23, IL-17



Mechanism of Action

Mechanism of Action

- Interleukin Inhibitors act by blocking cytokines or their receptors to stop downstream immune system activation.

Example: IL-23 Inhibitors



Interleukin-12/23 Inhibitors

IL-12/IL-23



	Ustekinumab (Stelara and biosimilars) IL12/23	Risankizumab (Skyrizi) IL23	Mirikizumab (OmvoH) IL23 UC & Crohn's	Guselkumab (Tremfya) IL23	Tildrakizumab (Ilumya) IL23 Psoriasis
Dosing Will Vary By Disease State					
How Supplied	<ul style="list-style-type: none"> • Prefilled Syringe • Autoinjector (Pyzchiva only) • IV Infusion (UC or Crohn's, loading dose only) 	<ul style="list-style-type: none"> • Autoinjector • Prefilled Syringe • Skyrizi On-Body Injector (UC or Crohn's only) • IV Infusion (UC or Crohn's, Induction only) 	<ul style="list-style-type: none"> • IV Infusion (Induction only) • Autoinjector • Prefilled Syringe 	<ul style="list-style-type: none"> • Prefilled Syringe • Autoinjector • IV Infusion (UC or Crohn's, Induction only) 	<ul style="list-style-type: none"> • Prefilled Syringe
Side Effects/ADRs	PRECAUTIONS: Malignancy, Infection, Antibodies, Posterior Reversible Encephalopathy Syndrome (PRES) Headache & Fatigue Arthralgia Upper Respiratory Infections Injection Site Reactions Hepatotoxicity				
Monitoring	CBC (every 3-6 months) CMP (every 3-6 months) Hepatitis B/C (baseline) TB Quantiferon (baseline)				

Interleukin-6 Inhibitors

IL-6

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	Tocilizumab (Actemra & Biosimilars)	Sarilumab (Kevzara)
	RA	RA
Dosing Will Vary By Disease State		
Dose Adjustments	Neutropenia Thrombocytopenia Hepatic Function	Neutropenia Thrombocytopenia Hepatic Function Do NOT initiate if ANC < 2000/mm³, platelets < 150,000mm³, or AST/ALT 1.5x ULN
How Supplied	<ul style="list-style-type: none"> • Prefilled Syringe • Autoinjector • IV Infusion 	<ul style="list-style-type: none"> • Autoinjector • Prefilled Syringe
Side Effects/ADRs	PRECAUTIONS: Infection, Neutropenia, Thrombocytopenia, Elevated Liver Enzymes, GI Perforation (history of diverticulitis) Injection Site Reactions Herpes Simplex Virus Reactivation Lipid Abnormalities	
Monitoring	CBC (every 4-8 weeks for the first 6 months followed by every 3 months) CMP (every 4-8 weeks for the first 6 months followed by every 3 months) Hepatitis B/C (baseline) TB Quantiferon (baseline) Lipids (baseline, 4-8 weeks after initiation and then every 6 months or as clinically indicated)	

Interleukin-17 Inhibitors

IL-17

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	Secukinumab (Cosentyx)	Ixekizumab (Taltz)	Brodalumab (Siliq)	Bimekizumab (Bimzelx)
Dosing Will Vary By Disease State				
How Supplied	<ul style="list-style-type: none"> • Prefilled Syringe • Autoinjector • IV Infusion (Used in other rheumatological conditions) 	<ul style="list-style-type: none"> • Autoinjector • Prefilled Syringe 	<ul style="list-style-type: none"> • Prefilled Syringe 	<ul style="list-style-type: none"> • Prefilled Syringe • Autoinjector
Side Effects/ADRs	<p>BLACK BOX WARNING: Suicidal Ideation (Brodalumab)</p> <p>REMS PROGRAM: Brodalumab</p> <p>PRECAUTIONS: Suicidal Ideation (Brodalumab & Bimekizumab), Infections, IBD</p> <p>Injection Site Reactions</p> <p>Infections</p> <p>GI Upset/Bloating</p> <p>Eczematic Eruptions</p>			
Monitoring	<p>CBC</p> <p>CMP</p> <p>Hepatitis B/C (baseline)</p> <p>TB Quantiferon (baseline)</p>			

Other Interleukin Inhibitors

IL-4, IL-13



Other Interleukin Inhibitors

- Dupilumab (Dupixent) → IL-4
- Tralokinumab (Adbry) → IL-13
- Lebrikizumab (Ebglyss) → IL-13
- Nemolizumab → IL-31

Integrin Receptor Antagonist

Vedolizumab

Mechanism of Action:

- Integrins are proteins help cells bind/ “stick” together and to the surrounding matrix
- Vedolizumab is gut-specific and works by blocking integrins from binding to the gut endothelium
- This stops immune cells from entering the gut

ONLY USED IN CROHN’S AND ULCERATIVE COLITIS

Dosing:

- 300mg IV on weeks 0, 2, and 6 then every 8 weeks thereafter
- Also available as a SQ injection → transition after the 2nd IV dose

BLACK BOX WARNINGS: Increased risk of PML

PRECAUTIONS: Infusion reactions, hepatic injury, Infection

Side effects/ADRs: Headache, Fatigue, Arthralgias

Monitoring: CBC, LFTs, TB quantiferon

Anti-CD20 Monoclonal Antibody

CD-20

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Rituximab

Mechanism of Action:

- Binds to B cells and mediates B-cell lysis to deplete B cells, which dampens T-cell activation and decreases inflammatory cytokine production

USED IN MANY DISEASE STATES

Dosing varies by indication → 1g IV every 2 weeks x 2 doses administered every 6 months

BLACK BOX WARNINGS: Infusion reactions, Tumor Lysis Syndrome, PML

PRECAUTIONS: Infections, Arrhythmias, Renal Toxicity, Bowel Obstruction/Perforation

Side effects/ADRs: Infusion reactions, fever, chills, CBC abnormalities

Monitoring: CBC, LFTs, TB quantiferon, Hepatitis B/C

Janus Kinase Inhibitors

JAK



JAK Inhibitors

Not biologics, but should be mentioned

- Small molecules that block Janus Kinases (JAK)
- JAK are enzymes transmit signals from cytokines to cells
- Inhibiting JAK = inhibiting communication through the pro-inflammatory cytokine pathway

Fast acting, oral medications

BLACK BOX WARNING: Mortality, thrombosis, major adverse CV events in patients 50+ years old with 1+ CV risk factor (Age 65+, Male, Previous CV event, HTN, DM, tobacco/nicotine use, concurrent use of glucocorticoid, antithrobic, statin, and aspirin)

Currently Available: tofacitinib (Xeljanz), upadacitinib (Rinvoq), ritlecitinib (Litfulo), baricitinib (Olumiant), abrocitinib (Cibinqo)

Infection Risk

Vaccines

LIVE VACCINES

AVOID LIVE VACCINES

- Generally contraindicated with biologics

If live vaccine must be administered:

- Administer 4 weeks PRIOR to starting biologics
- May need to hold biologics for 3-6 months, administer vaccine, restart after 4-8 weeks
- Always follow ID & manufacturer guidance

NON-LIVE VACCINES

Safe during biologic therapy, but may blunt immune response

Do not delay biologic therapy for non-live vaccines

Recommend non-live vaccines:

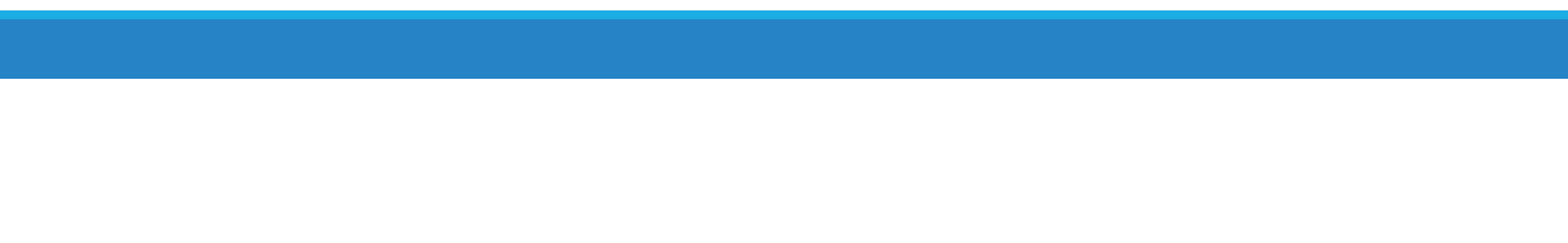
- COVID-19
- Influenza
- RSV > 60 years old
- Tdap
- Shingles
- HPV if indicated
- Pneumococcal
- Hepatitis B

Holding Biologics

Due to Active Infection:

- Per prescriber preference
- General rule – for severe infections, while on antibiotics, and fever free for 24-48 hours
- COVID – Hold until improvement of symptoms, completion of antivirals; usually 10-14 days
- Always keep disease severity & flare risk in mind when making recommendations to hold therapy

Due to Surgery

- Per surgeon preference
 - General rule – hold for 1 dosing interval preoperatively
 - May have patients continue regimen depending on biologic
 - Resume 1-2 weeks post-op per surgeon follow up
- 

Insurance Coverage



Insurance Coverage

Medical vs. Pharmacy Coverage

- Infusions – generally through medical benefits
- SQ injections – generally through pharmacy benefits
- Manufacturer Assistance is available for most of these medications

Infusion Options

- Infusion Center
- Home Infusion

Buy & Bill vs. Specialty Pharmacy

Biosimilar Preferences

- Insurance formularies

THESE MEDICATIONS WILL LIKELY REQUIRE A PRIOR AUTHORIZATION AND/OR AN APPEAL



What's Next?

WHAT'S IN THE PIPELINE?



Novel Treatment Strategies

Personalized Medicine:

- Biomarkers and Pharmacogenomics

Treat to Target Strategies

- Early, aggressive use of biologics

Combination Therapies:

- Dual biologics, biologic + small molecule combinations

Pipeline Medications

Oncology


Rare Diseases

- Gene Therapies (RGX-121 for Hunter Syndrome)

Immunologic and Inflammatory Conditions

- Oral IL-23 (Icotrokinra – psoriasis)
- **BIOSIMILARS**

Weight Management & Diabetes

- New Insulins (Awiqli – once weekly)
 - New GLP-1s (Orforglipron, Retatrutide)
 - Oral PCSK9 (Enlicitide)
- 

Questions?

CONTACT INFORMATION

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