

Advanced Therapy: Biologic DMARDs

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Objectives

01

BIOLOGICS & INDICATIONS

18 drugs

02

BIOLOGICS

Biologics including small molecule drugs

03

BIOSIMILARS

Doing the same job at a lower cost

04

NAVIGATING RESOURCES

How to pay for expensive drugs





What are Biologics?

Biologic drugs are genetically engineered, large protein molecules made using biological sources. They target specific parts of the immune system to lower inflammation and prevent joint damage. Often, due to their large molecular size, biologic drugs are formulated to be given as self-injectable or intravenous drugs.



List of Abbreviations

Indications

- RA = rheumatoid arthritis
- PsA = psoriatic arthritis
- AS = ankylosing spondylitis
- JIA = juvenile idiopathic arthritis
- SLE = systemic lupus erythematosus “lupus”

Classes

- DMARDs = disease modifying antirheumatic drugs
- csDMARDs = conventional synthetic DMARDs
- tsDMARDs = targeted synthetic DMARDs
- bDMARDs = biologic DMARDs
- bsDMARDs = biosimilar DMARDs

List of Abbreviations Cont'd

- ABA = abatacept (Orencia[®])
- ADA = adalimumab (Humira[®])
- ANK = anakinra (Kineret[®])
- BAR = baricitinib (Olumiant[®])
- BEL = belimumab (Benlysta[®])
- CAN = canakinumab (Ilaris[®])
- CMZ = certolizumab (Cimzia[®])
- ETN = etanercept (Enbrel[®])
- GOL = golimumab (Simponi[®], Simponi Aria[®])
- INF = infliximab (Remicade[®])
- IXE = ixekizumab (Taltz[®])
- RTX = rituximab (Rituxan[®])
- SAR = sarilumab (Kevzara[®])
- SEC = secukinumab (Cosentyx[®])
- TCZ = tocilizumab (Actemra[®])
- TOF* = tofacitinib (Xeljanz[®], XR[®])
- UPD* = upadacitinib (Rinvoq[®])
- UST = ustekinumab (Stelara[®])

*denotes tsDMARDs

Up to date as of March 25, 2022

FDA Approved Indications

Dx / Rx	A D A	E T N	I N F	G O L	C M Z	A B A	R T X	T C Z	S A R	B A R	A N K	S E C	U S T	I X E	C A N	B E L	T O F	U P D
RA	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓						✓	✓
PsA	✓	✓	✓	✓	✓	✓						✓	✓	✓			✓	✓
AS	✓	✓	✓	✓	✓							✓		✓			✓	
JIA				✓*		✓					✓				✓		✓	
SLE																✓		

**Simponi Aria only*

Up to date as of March 25, 2022

Question 1

Which of the following DMARDs is treated as a biologic even though it falls under a small molecule, targeted synthetic DMARDs?

1. Tofacitinib
2. Belimumab
3. Ustekinumab
4. Abatacept

Biologics by Drug Class- TNF α Inhibitors

Name	Dose	Route of Administration	Frequency
Adalimumab	40 mg	SQ	Every 2 weeks
Certolizumab pegol	200 mg	SQ	Every 2 weeks after titration
Etanercept	50 mg 25 mg	SQ	Once weekly Twice weekly
Golimumab	50-100 mg 2 mg/kg	SQ IV (Aria)	Monthly Every 2 months after titration
Infliximab	3-10 mg/kg	IV	Every 4-8 weeks

Biologics by Drug Class- IL inhibitors

Class	Name	Dose	Route of Administration	Frequency
IL-1i	anakinra	100 mg	SQ	daily
IL-1 β i	canakinumab	4 mg/kg (max 300 mg)	SQ	Monthly
IL-6i	tocilizumab	162 mg 8 mg/kg	SQ IV	Weekly Monthly
	sarilumab	150-200 mg	SQ	Every 2 weeks
IL-17 α i	ixekizumab	80 mg	SQ	Monthly (after titration)
	Secukinumab	150-300 mg	SQ	Monthly (after titration)
IL-12/23i	ustekinumab	45-90 mg	SQ	Every 3 months (after titration)

Biologics by Drug Class - Others

Class	Name	Dose	Route of Administration	Frequency
CD20 depleting antibody	rituximab	500-1000 mg	IV	On days 1 and 15, repeated every 4-6 months
CD80/86 Costimulation inhibitor	abatacept	125 mg 500, 750, or 1000mg based on weight	SQ IV	Once weekly Once monthly after titration
BLyS inhibitor	belimumab	200 mg	SQ	Weekly (after titration for lupus nephritis) Monthly (after titration)
		10 mg/kg	IV	
JAKi	tofacitinib (IR, XR)	5-10 mg 11 mg (XR)	PO	BID Daily
	upadacitinib (ER)	15 mg	PO	Daily
	baricitinib	2 mg	PO	Daily

Question 2

Which of the following vaccines may be given when it is due without regards to the patient's biologic therapy?

1. FluMist
2. Shingrix
3. MMRV
4. Yellow Fever

Screening for a Biologic



- | | | |
|----------|-----------------------|--|
| A | Sources of Infections | TB, cocci, hepatitis B&C, HIV, VZV, etc. |
| B | CXR | As a baseline, monitor for granulomas |
| C | Immunizations | Annual influenza, shingles, COVID-19, etc. |
| D | Immunoglobulin | For rituximab |
| E | Baseline labs | CBC, CMP, ESR, CRP + others based on drugs |

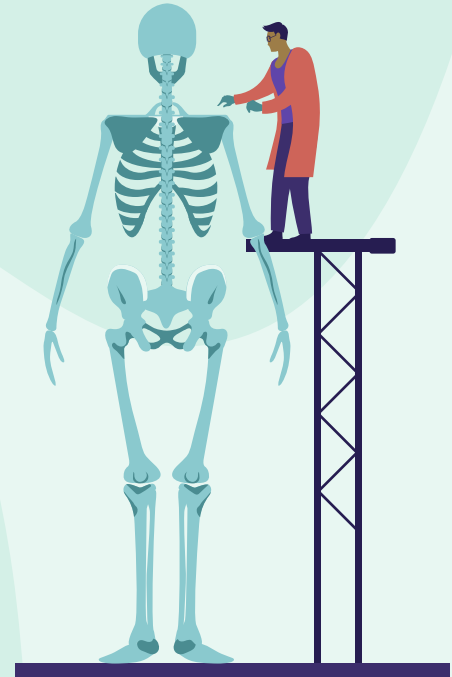
Cautions and Contraindications

●
Infections

●
Malignancy or MS

●
NYHA Stage
III/IV HF

●
Cautions
Lupus, lymphomas,
psoriasis, demyelinating
disease



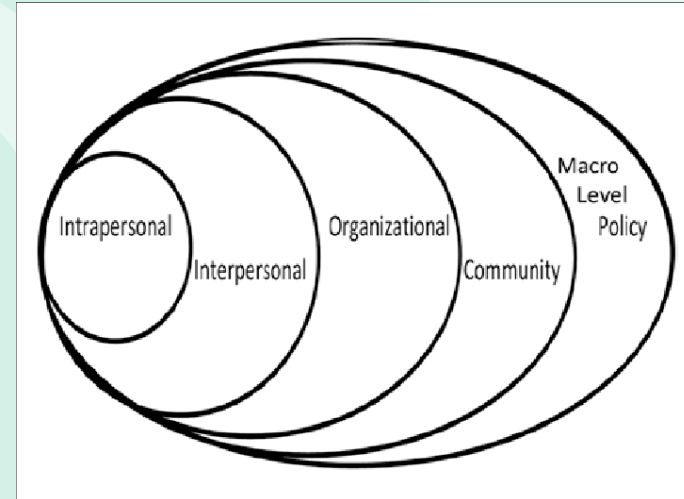
Common Questions from Patients & Providers

Do I have to continue taking methotrexate and sulfasalazine even after starting (*insert your favorite biologic here*)?

I have a patient on Humira who has an upcoming TKA. What do I do with his Humira? When does he stop and start?

I am on Renflexis infusion but my doctor switched me to tofacitinib. When do I start?

I have a rheumatology patient with (*insert your most commonly seen limitations e.g. transportation, lack of refrigerator, learning disability, visual impairment, etc.*) but he needs a bDMARD. What should I do?



FDA's Purple Book



Purple Book

Database of Licensed Biological Products



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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: March 22, 2022

Infliximab Biosimilars and Costs

Generic	Proprietary Name	Manufacturer	Approval Date	Cost (\$/vial)	Commercially Available?
Infliximab	Remicade	Centocor	8/24/1998	325.01	Y
Infliximab-dyyb	Inflectra	Celltrion / Pfizer	4/5/2016	321.01	Y
Infliximab-abda	Renflexis	Samsung Bioepis	4/21/2017	117.93	Y
Infliximab-qbtx	Ixifi	Pfizer	12/13/2017	N/A	N
Infliximab-axxq	Avsola	Amgen	12/06/2019	311.02	Y

Adalimumab Biosimilars and Costs

Generic	Proprietary Name	Manufacturer	Approval Date	Cost (\$/pen)	Commercially Available?
Adalimumab	Humira	AbbVie	12/31/2002	414.58	Y
Adalimumab-atto	Amjevita	Amgen	9/23/2016	N/A	N
Adalimumab-adbm	Cyltezo*	Boehringer Ingelheim	8/25/2017	N/A	N
Adalimumab-adaz	Hyrimoz	Sandoz	10/30/2018	N/A	N
Adalimumab-bwwd	Hadlima	Samsung Bioepis	7/23/2019	N/A	N
Adalimumab-afzb	Abrilada	Pfizer	11/15/2019	N/A	N
Adalimumab-fkjp	Hulio	Mylan Pharms	7/6/2020	N/A	N
Adalimumab-aqvh	Yusimry	Coherus Biosciences	12/17/2021	N/A	N

**Interchangeable*

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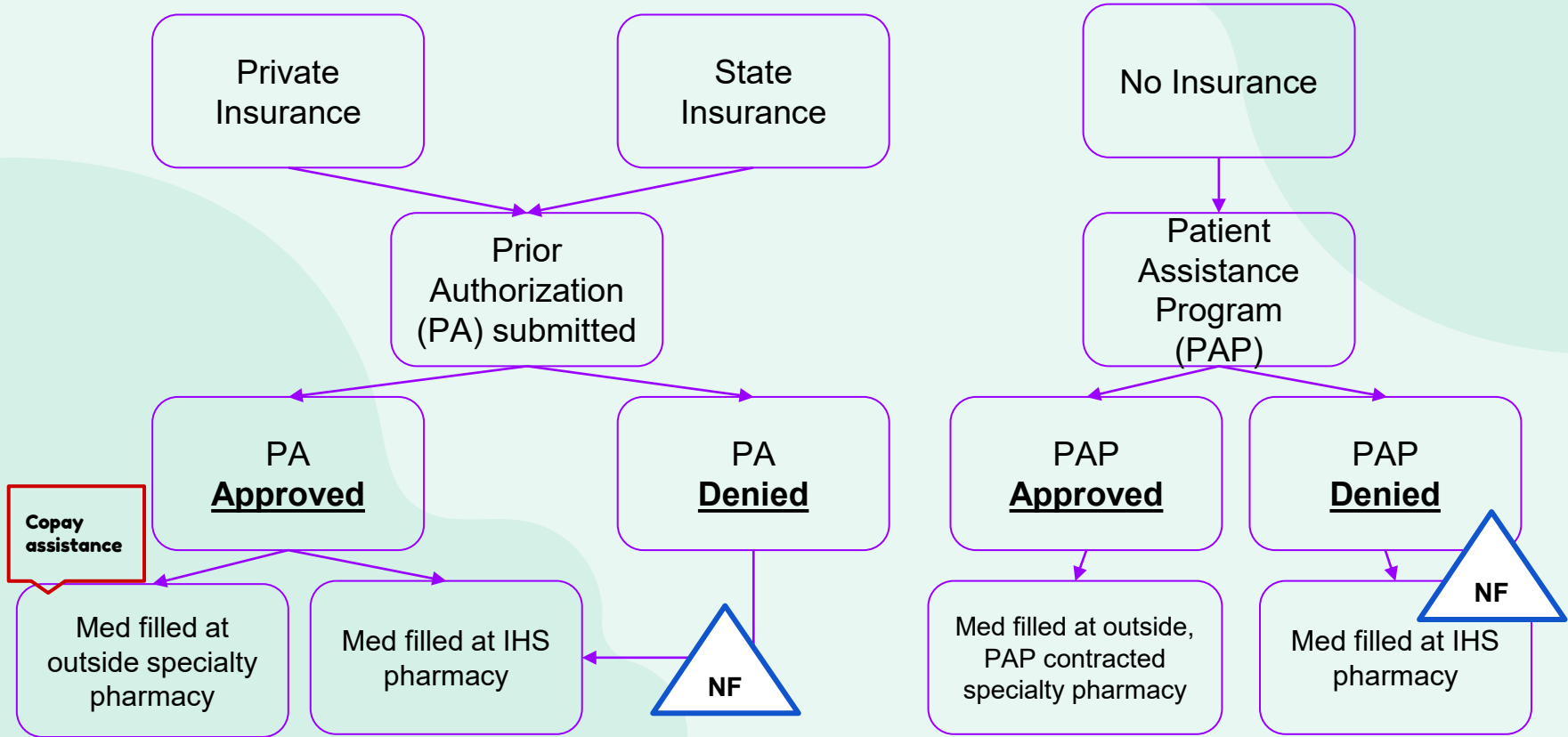
Etanercept Biosimilars and Costs

Generic	Proprietary Name	Manufacturer	Approval Date	Cost (\$/pen)	Commercially Available?
Etanercept	Enbrel	Amgen	11/02/1998	171.85	Y
Etanercept-szsz	Erelzi	Sandoz	8/30/2016	N/A	N
Etanercept-ykro	Eticovo	Samsung Bioepis	4/25/2019	N/A	N

Rituximab Biosimilars and Costs

Generic	Proprietary Name	Manufacturer	Approval Date	Cost (\$/10mg/mL)	Commercially Available?
Rituximab	Rituxan	Genentech	11/26/1997	61.89	Y
Rituximab-pvvr	Ruxience	Pfizer	7/23/2019	10.19	Y
Rituximab-abbs	Truxima	Celltrion / Teva	11/28/2018	41.21	Y

Waysto Pay for Biologics



Useful Resources

covermymeds®

Welcome back!

Log into your CoverMyMeds account to create new, manage existing and access pharmacy-initiated prior authorization requests for all medications and plans.

Need help? [Visit our support page.](#)

The screenshot shows the NeedyMeds website homepage. At the top right, there is a "HELPLINE (800)" link. The main header features the NeedyMeds logo and the tagline "Find help with the cost of medicine". Below the header is a navigation menu with links for Home, Healthcare Savings, Education, Getting Started, Services, News, and Blog. The main content area includes a search bar for drug names, a "Drug Search" button, and several service tiles: "Drug Pricing Calculator" (with a search button), "Get Your NeedyMeds Drug Discount Card" (with a red arrow pointing down), "Send a family member or friend a NeedyMeds Drug Discount Card", "NeedyMeds BeMedWise Patient Information and Education", and "SafeNeedleDisposal.org Be sharp about sharps." On the right side, there is a section titled "How You Can Help" featuring a video player with the text "IMAGINE THAT THERE'S No NeedyMeds" and a play button. Below the video is a link to the "Upcoming Webinar Schedule". At the bottom right, there is a statistic: "Over \$318,815,063.02 Saved With NeedyMeds Drug Card" and a section titled "Let Us Know How We're Doing" with a testimonial and a "QUESTIONS? TOP-RATED NON-PROFIT" badge.



THANKYOU!

Do you have any questions?

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