

Small Patients, Big Advances: Biologics in Pediatric Dermatology

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Disclosure Statement

- Financial Relationships: I have no relevant financial relationships with ineligible companies to disclose.
- Off-Label / Investigational Uses: I do not intend to discuss any unapproved or off-label uses of drugs or medical devices during this presentation.



Objectives

By the end of this presentation, participants will be able to:

- Recognize biologics that are used to treat pediatric skin conditions
- Assess the impact of biologics on the treatment of pediatric patients
- Evaluate mechanisms and safety considerations for biologic therapies in pediatric dermatology





Common Skin Disorders

- Atopic dermatitis (AD)
- Psoriasis
- Hidradenitis suppurativa (HS)
- Alopecia





Common Biologics in Dermatology

- **Atopic dermatitis (AD)**
 - Dupilumab (Dupixent), lebrikizumab-ibkz (Ebglyss), nemolizumab-ilto (Nemluvio), tralokinumab (Adbry), abrocitinib (Cibinqo), upadacitinib (Rinvoq)
- **Psoriasis**
 - Etanercept (Enbrel), guselkumab (Tremfya), ixekizumab (Taltz), adalimumab (Humira), risankizumab (Skyrizi), secukinumab (Cosentyx), ustekinumab (Stelara), upadacitinib (Rinvoq)
- **Hidradenitis suppurativa (HS)**
 - Adalimumab (Humira), secukinumab (Cosentyx)
- **Alopecia**
 - Ritlecitinib (Litfulo)

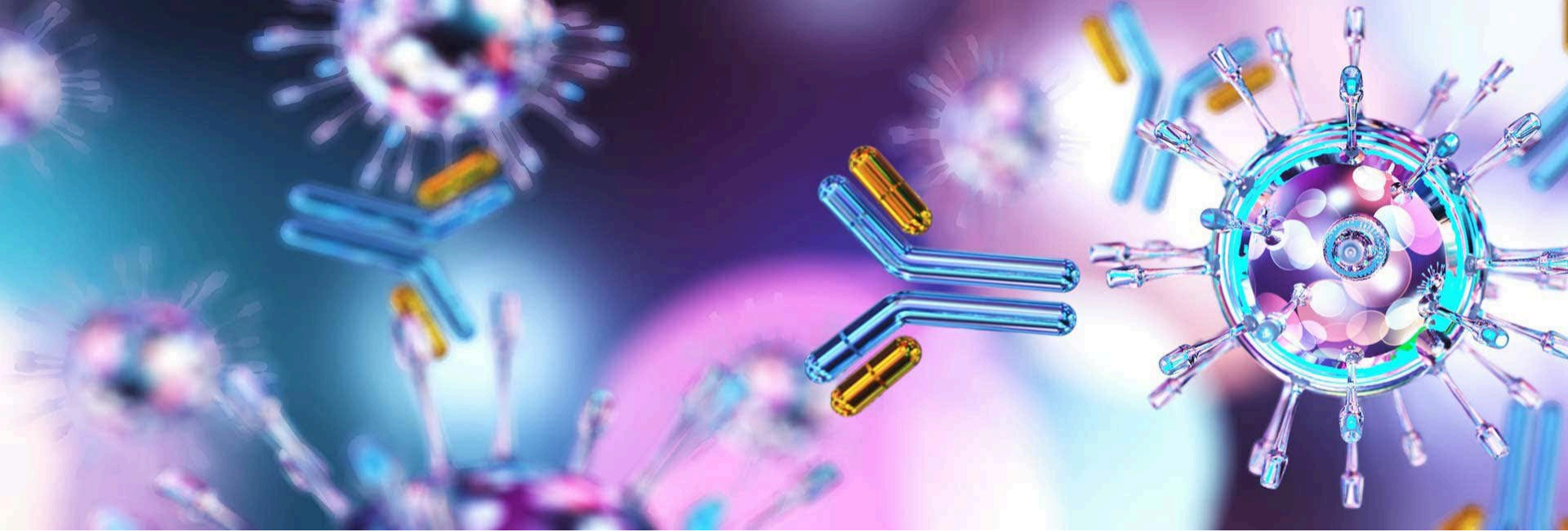




Why Is Pediatric Dermatology Different?

- **Chronic disease presenting early on in life**
- **Impacts quality of life**
 - School
 - Extracurricular activities
 - Social stigma
 - Self-esteem
- **Unique challenges**
 - Weight-based dosing
 - Needle phobia
 - Routine vaccinations
 - Limited clinical data
 - Insurance/access barriers





BIOLOGIC REVIEW



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Common Biologics in Dermatology

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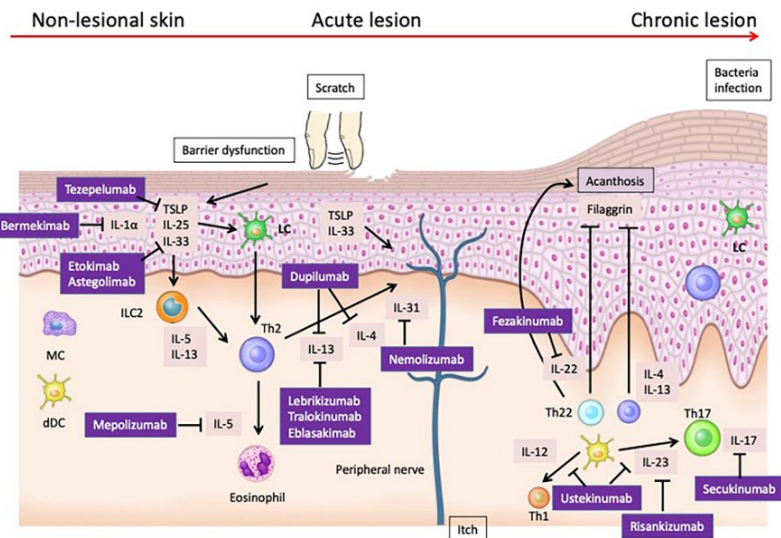
*Including all biosimilars



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Interleukin Antagonists

dupilumab (Dupixent), guselkumab (Tremfya), ixekizumab (Taltz), lebrikizumab-ibkz (Ebglyss), nemolizumab-ilto (Nemluvio), tralokinumab (Adbry), risankizumab (Skyrizi), secukinumab (Cosentyx), ustekinumab (Stelara)



Mechanisms

- **Dupixent:** Inhibits interleukin-4 (IL-4) and interleukin-13 (IL-13)
- **Tremfya/Skyrizi:** Inhibits IL-23 signaling
- **Taltz/Cosentyx:** Inhibits interaction with the IL-17 receptor
- **Ebglyss/Adbry:** Inhibits the bioactivity of IL-13
- **Nemluvio:** Inhibits the bioactivity of IL-31
- **Stelara:** Binds to p40 protein subunit, inhibiting the bioactivity of IL-12 and IL-23



Interleukin Antagonists

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Common Side Effects

- Various dermatologic and hypersensitivity reactions
- Injection site reactions
- Ocular surface disorders (Dupixent)
 - Conjunctivitis, blepharitis, keratitis, eye pruritus, and dry eye syndrome
- Arthralgia and myalgia
- "Flu-like" symptoms





Interleukin Antagonists

dupilumab (Dupixent), guselkumab (Tremfya), ixekizumab (Taltz), lebrikizumab-ibkz (Ebglyss), nemolizumab-ilto (Nemluvio), tralokinumab (Adbry), risankizumab (Skyrizi), secukinumab (Cosentyx), ustekinumab (Stelara)

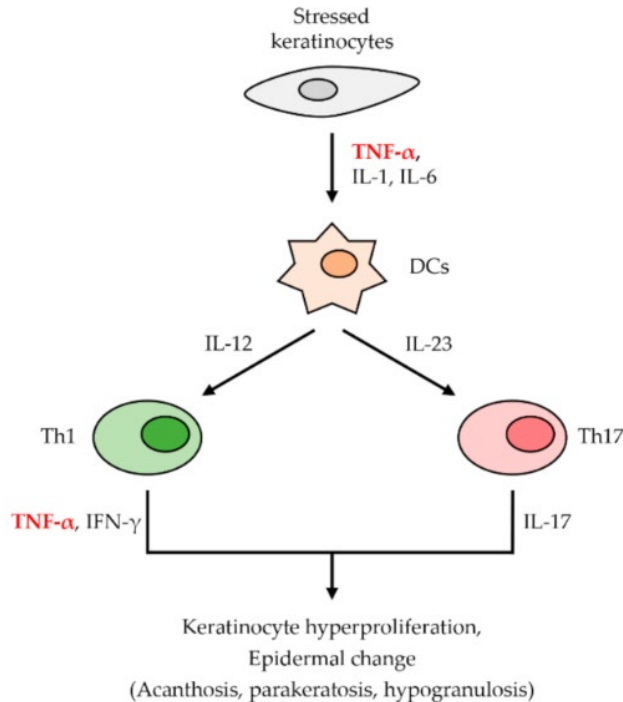
Clinical Considerations

- Serious infections (including herpes zoster, fungal, and opportunistic infections)
- TB reactivation risk
 - QuantiFERON-TB Gold Plus required prior to therapy initiation
- Increased risk of hepatotoxicity
- Patient's comorbid conditions



Tumor Necrosis Factor Alpha (TNF- α) Inhibitors

Adalimumab (Humira), Etanercept (Enbrel)



Mechanism

- Monoclonal antibody that binds to human TNF- α
- Interferes with binding to TNF- α receptor sites and subsequent cytokine-driven inflammatory processes

Common Side Effects

- Dermatologic and hypersensitivity reactions
- Injection site reactions
- Upper respiratory tract infection
- Arthralgia and myalgia

Tumor Necrosis Factor Alpha (TNF- α) Inhibitors

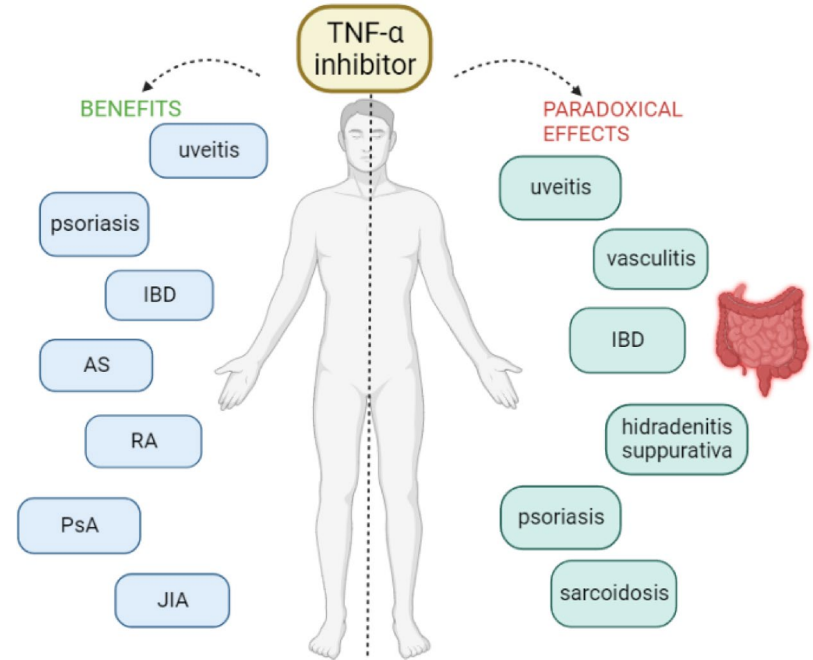
Adalimumab (Humira), Etanercept (Enbrel)

Black Box Warnings (BBW)

- Serious infections (bacterial, fungal and opportunistic pathogens)
- Increased risk of malignancy
- Hepatitis B reactivation
- TB reactivation risk
 - QuantiFERON-TB Gold Plus required prior to therapy initiation

Clinical Considerations

- Cytopenias/pancytopenia
- Appearance of other autoimmune reactions (paradoxical effect)



Janus Kinase (JAK) Inhibitors

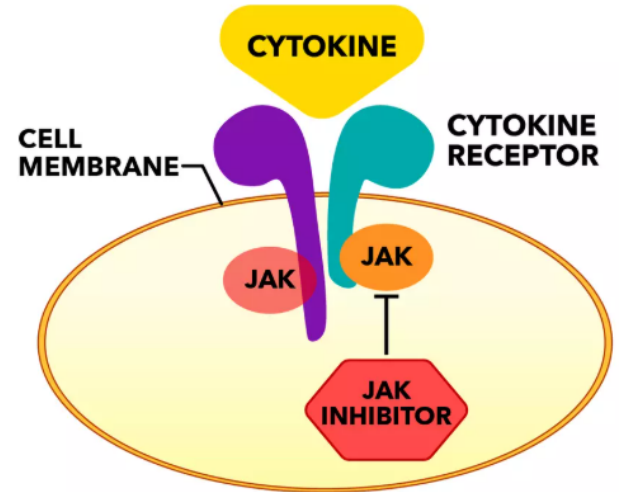
Ritlecitinib (Litfulo), Upadacitinib (Rinvoq), Abrocitinib (Cibinqo)

Mechanism

- Prevents immune cells from triggering inflammatory responses

Common Side Effects

- Elevated cholesterol
- Headache
- Nausea/vomiting
- New/worsening acne
- Rash/urticaria



JAK inhibitors block JAK enzymes from initiating an inflammatory pathway that can lead to symptoms of psoriasis and psoriatic arthritis.



Janus Kinase (JAK) Inhibitors

ritlecitinib (Litfulo), upadacitinib (Rinvoq), abrocitinib (Cibinqo)

Black Box Warning (BBW)

- Higher rate of all-cause mortality
- Major adverse cardiovascular events (MACE)
- Increased risk for malignancy
- Serious infections (bacterial, fungal and opportunistic pathogens)
- Thrombosis (DVT, PE)

Clinical Considerations

- May cause GI perforation
- Risk of hematologic toxicity (anemia, neutropenia)
- Elevated liver enzymes
- TB reactivation risk
 - QuantiFERON-TB Gold Plus required prior to therapy initiation



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If there are all these risks with biologic therapies, why are we using them in our pediatric patients?

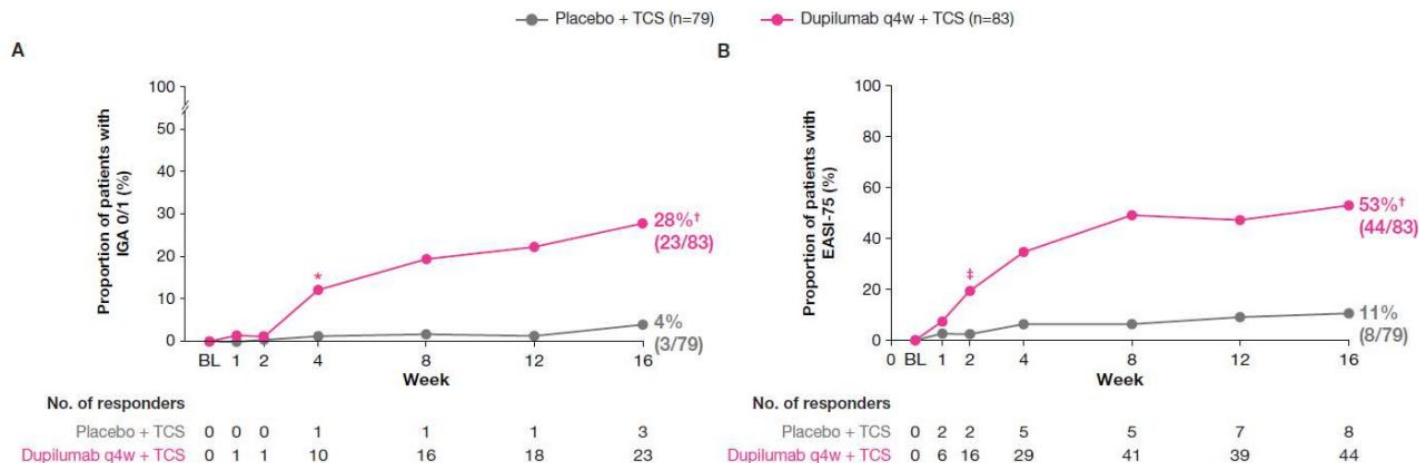


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Why Biologics in Pediatrics?

Significant benefits demonstrated in pediatric-specific clinical studies

- LIBERTY AD PRESCHOOL*: Phase III trial evaluating the efficacy and safety of dupilumab in infants and young children aged 6 months to 6 years with moderate-to-severe atopic dermatitis



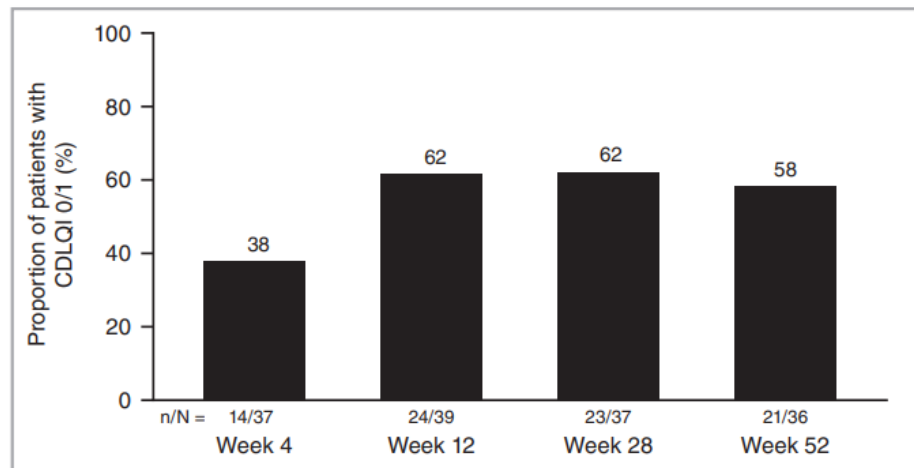
*<https://pubmed.ncbi.nlm.nih.gov/36116481/>



Why Biologics in Pediatrics?

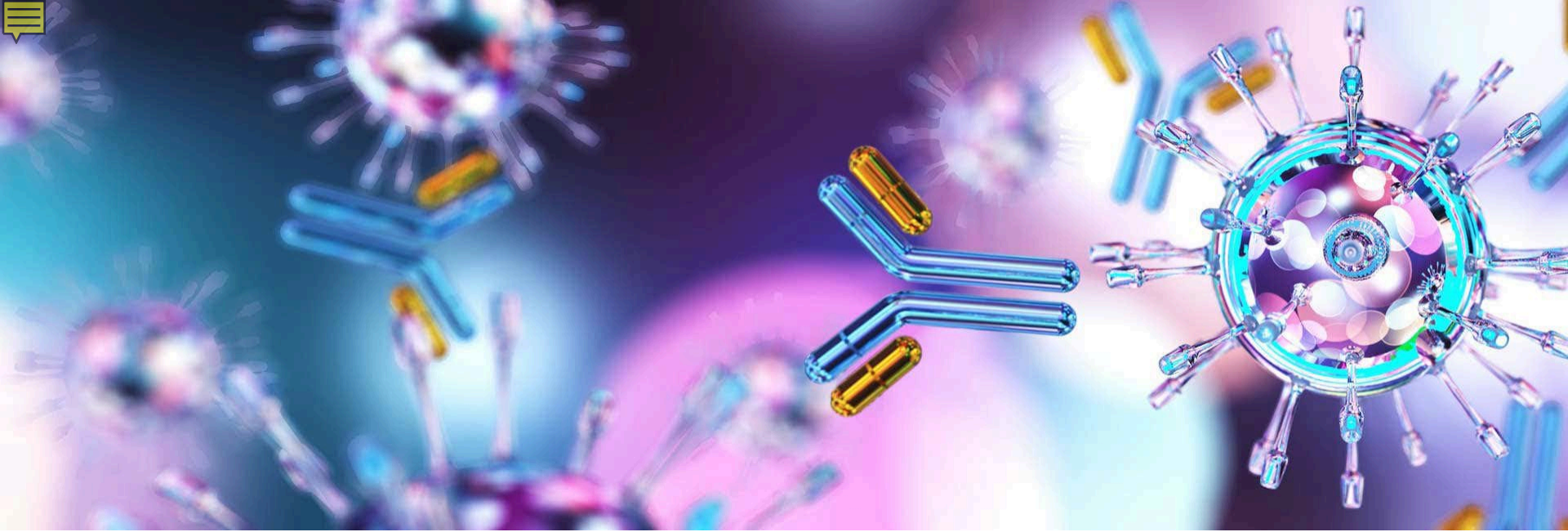
CADMUS Jr.*: Phase III trial evaluating the efficacy and safety of ustekinumab in patients aged ≥ 6 to < 12 years of age with moderate-to-severe plaque psoriasis

- 84% achieved PASI-75
- 64% achieved PASI-90
- Mean Children's Dermatology Life Quality Index improved by 6.3 points at week 12



*<https://pubmed.ncbi.nlm.nih.gov/32173852/>





BIOLOGIC MANAGEMENT IN DIFFERENT HEALTHCARE SETTINGS



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The 4 Rules of Biologic Management

ACTIVE INFECTION
HOLD

LIVE VACCINES
CONTRAINDICATED

MAJOR SURGERY
HOLD

UNEXPLAINED
SYSTEMIC
SYMPTOMS
EVALUATE



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#1 - Active Infection

- Higher risk of infections due to decreased immune response
- Opportunistic infections
 - Tuberculosis
 - Fungal
 - Histoplasmosis
 - Coccidiomycosis
 - Pneumocystis Jirovecii (PJP)
 - Herpes Zoster
 - Viral
- Reasons to hold biologics:
 - Fever
 - Antibiotics
 - Moderate-severe viral illness (i.e. influenza, covid)
- When to resume:
 - Fever-free at least 24 hours
 - Completion of antibiotic therapy
 - Clinical resolution of symptoms





#2 - Live Vaccines



Inactivated vaccines are safe to administer while on biologics



Live vaccines should be avoided (if possible)



Discontinue the biologic 4 weeks prior to receiving live vaccines and for 4 weeks after receiving the live vaccines



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CDC Vaccination Schedule

Vaccine and other immunizing agents	Birth	1 mo	2 mos	4 mos	6 mos	9 mos	12 mos	15 mos	18 mos	19–23 mos	2–3 yrs	4–6 yrs	7–10 yrs	11–12 yrs	13–15 yrs	16 yrs	17–18 yrs			
Respiratory syncytial virus (RSV-mAb [Nirsevimab])	1 dose depending on maternal RSV vaccination status (See Notes)					1 dose (8 through 19 months), See Notes														
Hepatitis B (HepB)	1st dose	← 2nd dose →			← 3rd dose →															
Rotavirus (RV): RV1 (2-dose series), RV5 (3-dose series)	★		1st dose	2nd dose	See Notes															
Diphtheria, tetanus, acellular pertussis (DTaP <7 yrs)			1st dose	2nd dose	3rd dose		← 4th dose →				5th dose									
Haemophilus influenzae type b (Hib)			1st dose	2nd dose	See Notes		← 3rd or 4th dose (See Notes) →													
Pneumococcal conjugate (PCV15, PCV20)			1st dose	2nd dose	3rd dose		← 4th dose →													
Inactivated poliovirus (IPV)			1st dose	2nd dose	← 3rd dose →							4th dose						See Notes		
COVID-19 (1vCOV-mRNA, 1vCOV-aPS)					See Notes															
Influenza (IIV3, cclIV3)					1 or 2 doses annually										1 dose annually					
Influenza (LAIV3)	★	or										1 or 2 doses annually		or				1 dose annually		
Measles, mumps, rubella (MMR)	★				See Notes	← 1st dose →					2nd dose									
Varicella (VAR)	★						← 1st dose →				2nd dose									
Hepatitis A (HepA)					See Notes	2-dose series (See Notes)														
Tetanus, diphtheria, acellular pertussis (Tdap ≥7 yrs)														1 dose						
Human papillomavirus (HPV)															See Notes					
Meningococcal (MenACWY-CRM ≥2 mos, MenACWY-TT ≥2years)		See Notes															1st dose		2nd dose	
Meningococcal B (MenB-4C, MenB-FHbp)															See Notes					
Respiratory syncytial virus vaccine (RSV [Abrysvo])															Seasonal administration during pregnancy (See Notes)					





#3 - Surgery & Procedures

MINOR

- Continue biologic without interruption
- Hold biologic if high risk of poor healing or local infection

MAJOR

- Stop biologic before operation (one full dosing cycle)
- Hold biologic until wound shows signs of healing with no infection



#4 - Unexplained Systemic Signs & Symptoms

- "Red flags" of opportunistic infections
 - Persistent, unexplained fever
 - Night sweats
 - Weight loss
- Severity may be underestimated due to blunted immune response
- Patient evaluation
 - When was last dose of biologic given? How long have you been on biologics? When did these new symptoms begin?
 - Broaden clinical workup
- Hold biologic until further evaluation and lab/imaging results are completed





PATIENT CASES



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Case Example #1

A.H. is a 15-year-old female with a history of plaque psoriasis that presents to her primary care provider. She is febrile with a temperature of 102 degrees, weakness, malaise, and chills. Her POC test confirms that she is positive with Influenza. She currently takes Enbrel injections for her plaque psoriasis as well as Vtama cream, clobetasol ointment, and calcipotriene ointment. Her next dose of Enbrel is due tomorrow.

Would you advise A.H. to continue her home therapy as directed? Why or why not?





Case Example #2

K.E. is a 4-year-old female presenting to her pediatrician's office in October for her annual well-visit. While updating the patient's medical history, you note that K.E. was seen by dermatology and rheumatology in the summer and was started on Humira for her moderate-severe psoriasis and JIA. The last dose of Humira was taken 1 week ago. K.E. is due for the following vaccinations: DTaP, Influenza, & MMR. K.E.'s mom states she would like the least amount of injections possible and prefers vaccines that are needle-free (if available).

Which of the above vaccinations can K.E. receive at today's visit?

If K.E. cannot receive any of these vaccinations, why not? What does she need to do and when can she come back to receive them?





Case Example #3

J.T. is a 4 year-old-male with a history of atopic dermatitis. He presents to the Emergency Department with complaints of pain and soreness in his legs. He has not had any fever and has not had any injuries that mom knows of. His mother reports that he is not playing as much as he usually does and often just wants to rest. She is concerned with the pain and cannot explain the cause. Upon reviewing J.T.'s medication list, he is prescribed betamethasone cream, mupirocin cream, Dupixent, Vanicream, and cetirizine. Mom has not given J.T. any acetaminophen or ibuprofen for his pain.

What are some possible causes of J.T.'s pain?

Assuming all labs and imaging are WNL, what are some recommendations that you can provide?



Biologic Resources

The Purple Book

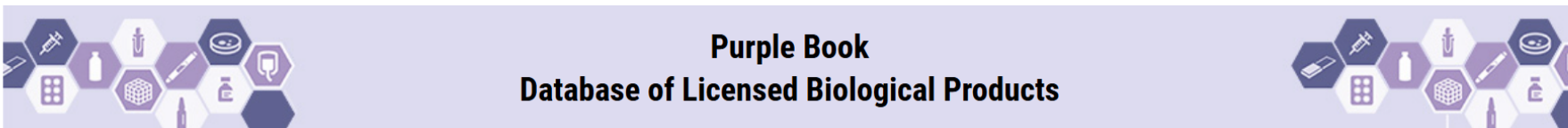
- <https://purplebooksearch.fda.gov>
- All FDA-approved biological products

Treatment guidelines & consensus statements

Specialty pharmacists 😊



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Summary

- Many inflammatory pathways can be targeted by biologics
- Biologics are effective treatment options for pediatric patients
- Treatment/Management should be individualized
- Biologic therapy may impact provision of healthcare outside of the prescriber's office



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