



More Than Skin Deep: *Pedi Derm Update* *2026*

Keri Wallace, MD, FAAP
September 30, 2026



Disclosures



- I have no conflicts of interest to disclose
- I may be discussing off-label use of medications
- I am not a pediatric dermatologist...

The plan...



- Review recently-approved topical therapies for pediatric skin conditions
- Discuss new(er) systemic therapies and their side effects
- Share clinical tips and tricks

In the end...

- Gain familiarity with the latest FDA-approved topical medications
- Have a better understanding of the uses and side effects of systemic medications used in pediatric dermatology
- Add tools to your toolbox to manage common skin problems in children



And so it goes..

- Atopic dermatitis
- Acne vulgaris
- Molluscum contagiosum
- Psoriasis
- Seborrheic dermatitis
- Vitiligo
- Alopecia areata

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Atopic Dermatitis

Itching to know what's new??

It's been a long time coming, but...

FDA approval of topical therapies for atopic dermatitis in children

1952: Topical steroids...



2000: Tacrolimus

2001: Pimecrolimus



Dec 2016: Crisabarole

Sept 2021: Ruxolitinib

July 2024: Roflumilast

July 2025: Tapinarof

Feb 2026: Difamilast

FDA-approved topical treatments for AD in kids



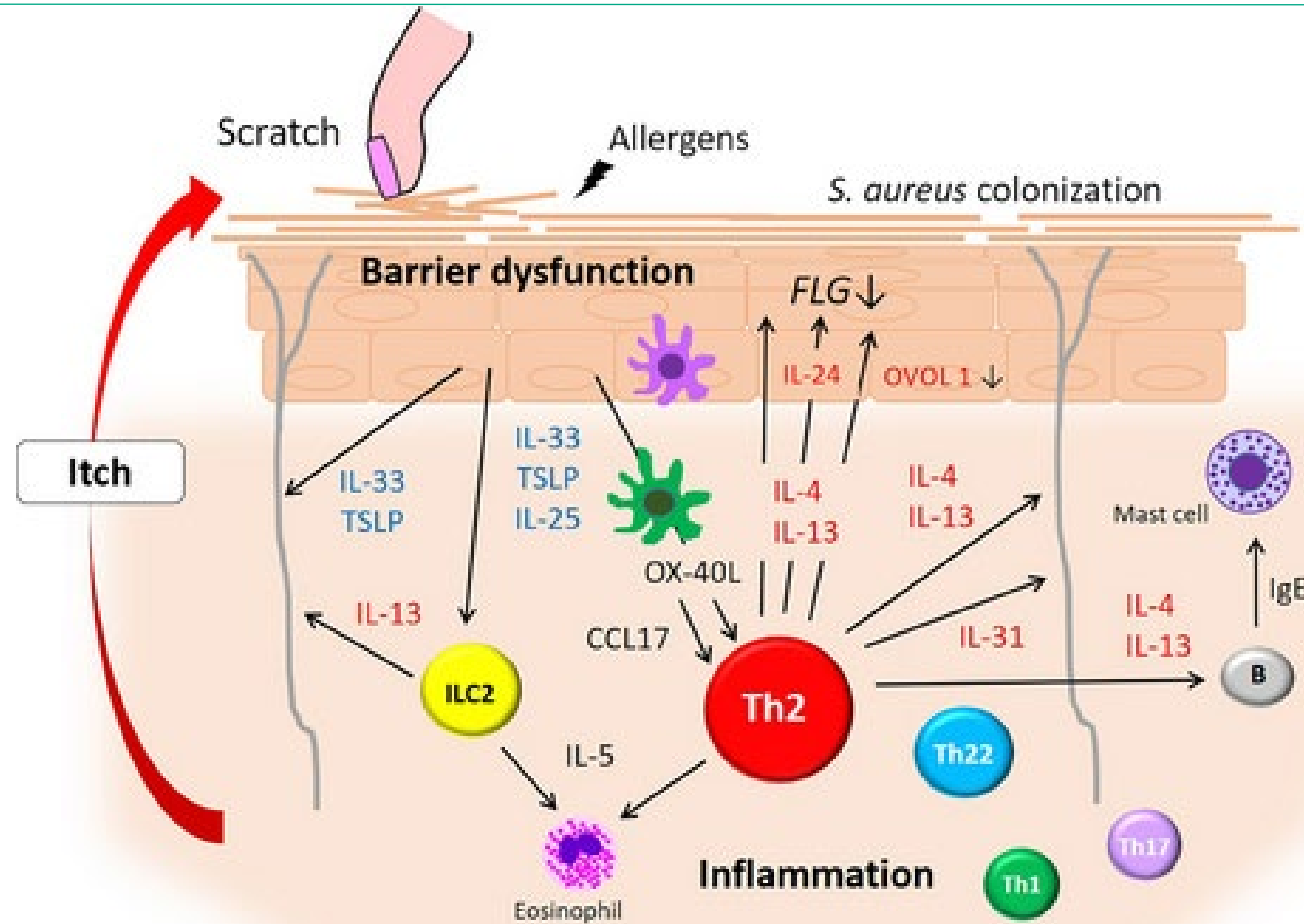
Class	Medication(s)
Steroids	Desonide Fluocinolone acetonide Fluticasone propionate Hydrocortisone acetate Hydrocortisone butyrate Mometasone furoate Triamcinolone acetonide
Calcineurin inhibitors (TCIs)	Tacrolimus ointment Pimecrolimus cream
Phosphodiesterase 4 (PDE4) inhibitors	Crisabarole ointment Roflumilast cream Difamilast ointment
Janus kinase (JAK) inhibitor	Ruxolitinib cream
Aryl hydrocarbon receptor agonist	Tapinarof cream

FDA-approved topical treatments for AD in kids



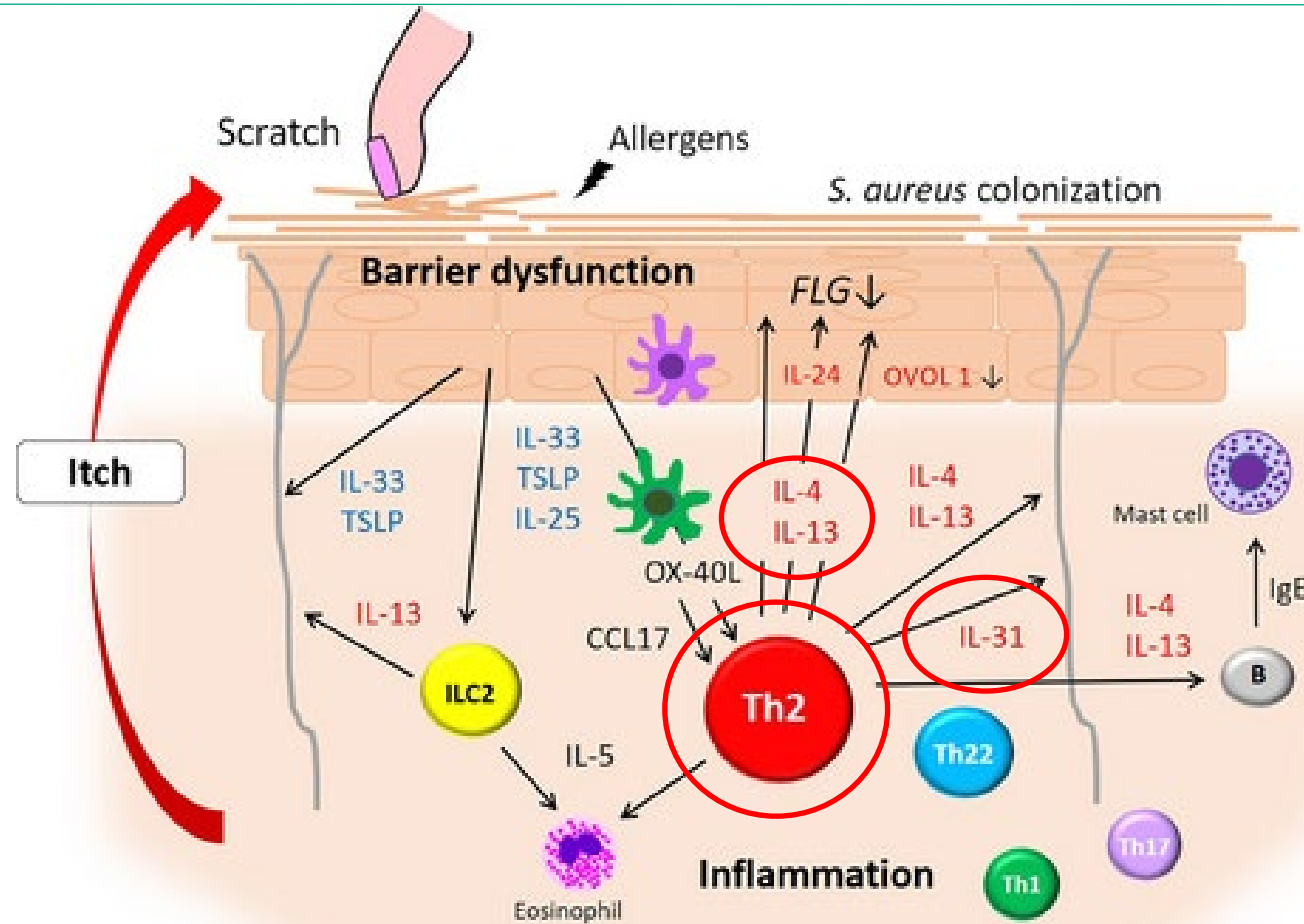
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Janus kinase (JAK) inhibitor	Ruxolitinib cream
Aryl hydrocarbon receptor agonist	Tapinarof cream

Atopic Dermatitis



Nakahara, Takeshi, et al. "Basics and Recent Advances in the Pathophysiology of Atopic Dermatitis." *Journal of Dermatology*, vol. 48, no. 2, 2021, pp. 130–39, <https://doi.org/10.1111/1346-8138.15664>.

Atopic Dermatitis



Nakahara, Takeshi, et al. "Basics and Recent Advances in the Pathophysiology of Atopic Dermatitis." *Journal of Dermatology*, vol. 48, no. 2, 2021, pp. 130–39, <https://doi.org/10.1111/1346-8138.15664>.

Class: Topical calcineurin inhibitors (TCIs)

1) **Tacrolimus** (Protopic ®) ointment

- 0.03%
- 0.1%

2) **Pimecrolimus** (Elidel ®) 1% cream



Advantages - good insurance coverage, generic available. Less expensive than newer therapeutics. 25 years of safety data

Disadvantages - Black box warning. FDA indication is “short-term and non-continuous chronic treatment”. May cause stinging/burning on inflamed skin.

Paller, Amy S., et al. “Tacrolimus Ointment Is More Effective than Pimecrolimus Cream with a Similar Safety Profile in the Treatment of Atopic Dermatitis: Results from 3 Randomized, Comparative Studies.” *Journal of the American Academy of Dermatology*, vol. 52, no. 5, 2005, pp. 810–22

Devasenapathy N, et al. “Cancer risk with topical calcineurin inhibitors, pimecrolimus and tacrolimus, for atopic dermatitis: a systematic review and meta-analysis.” *Lancet Child and Adolesc Health*. 2023 Jan;7(1):13-25

Class: Phosphodiesterase-4 (PDE4) Inhibitors

1) **Crisabarole** (Eucrisa™) 2% ointment

- Approved ≥ 3 mo
- BID application
- Patents start expiring 2027



2) **Roflumilast** (Zoryve®) 0.05% and 0.15% cream

- Approved ≥ 2 yo
- Once daily application
- Cream formulation



3) **Difamilast** (Adquey®) 0.1% ointment

- Approved ≥ 2 yo
- BID application
- PDE4B selectivity



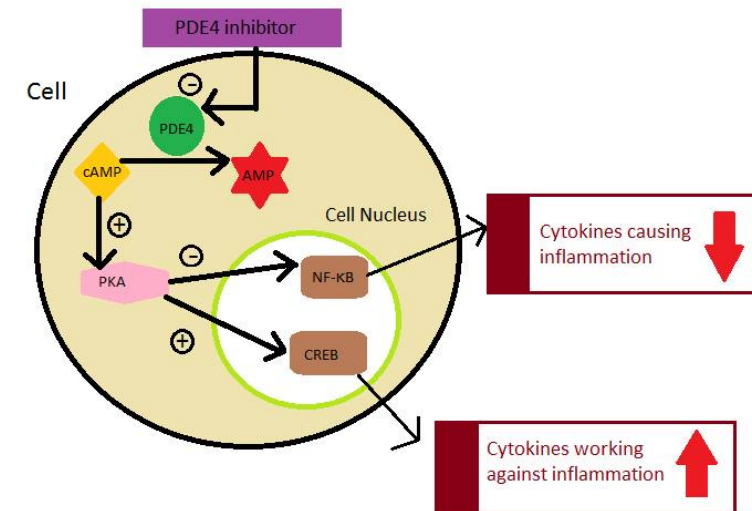
Class: Phosphodiesterase-4 (PDE4) Inhibitors

Advantages -

- NO black box warning. Safe.
- Continuous. Longterm use acceptable.

Disadvantages –

- Limited insurance coverage
- Expensive:
 - Eucrisa ~\$800/tube
 - Zoryve ~\$1100/tube
 - Adquey ??? (not yet available)



Side effects: Significant stinging and burning (esp thin skin and inflamed skin)

Efficacy:

- Week 4: ~ 30-45% clear/almost clear
- Treatment effect over vehicle relatively small



What makes it unique:

- Approved down to 3 *mo*
- Can be used long term
- Patents start expiring 2027



dermnetnz.org/topics/hand-dermatitis-images

Paller AS et al. Efficacy and safety of crisabarole ointment, a novel, nonsteroidal phosphodiesterase 4 (PDE4) inhibitor for the topical treatment of atopic dermatitis (AD) in children and adults. *A Am Acad Dermatol*. 2016 Sep;75(3): 494-503

Roflumilast (Zoryve ®)

Side effects: Generally well-tolerated (1.5% report stinging/burning).

Efficacy:

- Itch improvement in first week
- Week 4: ~ 30% clear/almost clear

What makes it unique:

- Cream formulation, once daily
- No restrictions on application site or BSA



Simpson, Eric L., et al. "Roflumilast Cream, 0.15%, for Atopic Dermatitis in Adults and Children: INTEGUMENT-1 and INTEGUMENT-2 Randomized Clinical Trials." *Archives of Dermatology* (1960), vol. 160, no. 11, 2024, pp. 1161–70

Difamilast (Adquey®)



Side effects: Generally well-tolerated.

- Increase in nasopharyngitis (6%)
- No reported burning/stinging with application (<1%)

Efficacy:

- Itch improvement in first week
- Week 4: ~ 40-50% clear/almost clear

What makes it unique:

- PDE4B selectivity

Freitas E, Torres T. Difamilast for the treatment of atopic dermatitis. *J Int Med Res.* 2023 Jun;51(6):3000605231169445

Class: Janus kinase (JAK) inhibitor

1) **Ruxolitinib** (Opzelura™) 1.5% cream

- Approved for ≥ 2 yo (Nov 2025)
- BID application



Advantages - Very powerful, works quickly. Minimal stinging/burning.

Disadvantages –

- *Expensive* (~\$2300 for 60 gram tube). Limited insurance coverage.
- Can only use on $<20\%$ BSA in AD. Only use prn after 8 weeks
- Black box warning



Opzelura[™]

(ruxolitinib) cream 1.5%

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use OPZELURA cream safely and effectively. See full prescribing information for OPZELURA cream.

OPZELURA[™] (ruxolitinib) cream, for topical use
Initial U.S. Approval: 2011

WARNING: SERIOUS INFECTIONS, MORTALITY, MALIGNANCY, MAJOR ADVERSE CARDIOVASCULAR EVENTS (MACE), AND THROMBOSIS

See full prescribing information for complete boxed warning.

- Serious infections leading to hospitalization or death, including tuberculosis and bacterial, invasive fungal, viral, and other opportunistic infections, have occurred in patients receiving Janus kinase inhibitors for inflammatory conditions. (5.1)
- Higher rate of all-cause mortality, including sudden cardiovascular death have been observed in patients treated with Janus kinase inhibitors for inflammatory conditions. (5.2)
- Lymphoma and other malignancies have been observed in patients treated with Janus kinase inhibitors for inflammatory conditions. (5.3)
- Higher rate of MACE (including cardiovascular death, myocardial infarction, and stroke) has been observed in patients treated with Janus kinase inhibitors for inflammatory conditions. (5.4)
- Thrombosis, including deep venous thrombosis, pulmonary embolism, and arterial thrombosis, some fatal, have occurred in patients treated with Janus kinase inhibitors for inflammatory conditions. (5.5)

It's me. Hi. I'm the problem, it's me...

- Tofacitinib (Xeljanz ®) – treatment of RA in adults (2011)
- Post-marketing data:
 - Increase r/o MI and stroke
 - Increased r/o serious infection
 - Increased r/o malignancy
 - Increase r/o all-cause mortality

2021 → Black box warning for all JAK inhibitors



Topical ruxolitinib safety data



- Papp, Kim, et al. “Long-Term Safety and Disease Control with Ruxolitinib Cream in Atopic Dermatitis: Results from Two Phase 3 Studies.” *Journal of the American Academy of Dermatology*, vol. 88, no. 5, **2023**, pp. 1008–16
- Eichenfield, Lawrence F., et al. “Efficacy, Safety, and Long-Term Disease Control of Ruxolitinib Cream Among Adolescents with Atopic Dermatitis: Pooled Results from Two Randomized Phase 3 Studies.” *American Journal of Clinical Dermatology*, vol. 25, no. 4, **2024**, pp. 669–83
- Hu, Wilson, et al. “Real-World Use of Ruxolitinib Cream: Safety Analysis at 1 Year.” *American Journal of Clinical Dermatology*, vol. 25, no. 2, **2024**, pp. 327–32

Class: Aryl hydrocarbon receptor agonist

1) **Tapinarof** (Vtama ®) 1% cream

- Approved for ≥ 2 yo in July 2025
- Once daily application



Advantages: Safe (no systemic absorption), NO black box warning.

Disadvantages: Expensive (\$1800 per 60 gram tube), limited insurance coverage

Side effects: Generally well-tolerated (3.5% stinging/burning)

Efficacy:

- Quite effective. 45% were clear/almost clear by week 8

What makes it unique:

- No GI absorption

Silverberg, Jonathan I., et al. "Tapinarof Cream 1% Once Daily: Significant Efficacy in the Treatment of Moderate to Severe Atopic Dermatitis in Adults and Children down to 2 Years of Age in the Pivotal Phase 3 ADORING Trials." *Journal of the American Academy of Dermatology*, vol. 91, no. 3, 2024, pp. 457–65

Hot off the press!



- American Academy of Dermatology 2026

Davis DMR et al. **“Guidelines of care for the management of atopic dermatitis in pediatric patients.”** *J Am Acad Dermatol.* 2026 Apr 7:S0190-9622(26)00343-9

You can't always get what you want... with topical therapy



Systemic therapies for AD in children

Drug class	Pros	Cons
Methotrexate	Inexpensive Long-term experience Oral administration	Not-FDA approved Broader-spectrum immunosuppression Side effects (teratogenic) Lab monitoring Slow onset of action
Cyclosporine	Inexpensive Effective Oral administration	Not-FDA approved Broader spectrum immunosuppression Side effects Lab monitoring Drug interactions
Biologics	FDA-approved No black box No labs needed Targeted immunomodulation	Injections q2-4 wks Slower onset of action
JAK inhibitors	FDA-approved Oral administration Quick onset of action Very effective	Black box warning Lab monitoring

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FDA-approved systemic Rx for AD in kids

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FDA-approved systemic treatments pedi AD

Class	Medication
Biologics	Dupilumab Lebrikizumab Nemolizumab Tralokinumab
JAK inhibitors	Abrocitinib Upadacitinib

Class: Systemic biologics

What makes them unique:

- Only available as injection
- No screening labs
- No black box warning

Efficacy:

- Slower onset of action but effective



NKOTB(ish): Dupilumab

- Approved **6 mo and older**
- IL4 and IL13 blockade
- Approved for:
 - Asthma
 - Eosinophilic esophagitis
 - Chronic spontaneous urticaria
 - Chronic rhinosinusitis with nasal polyps
- SQ injection q2wk or q4 wks

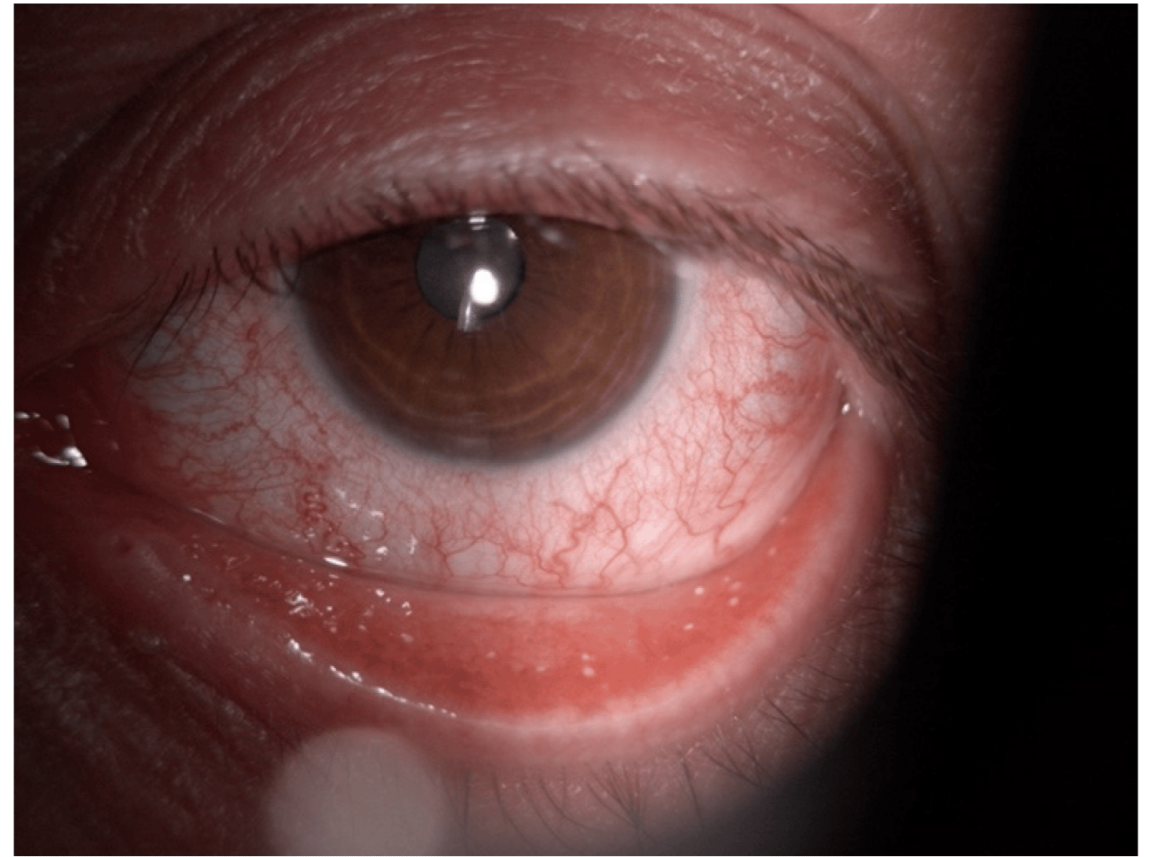
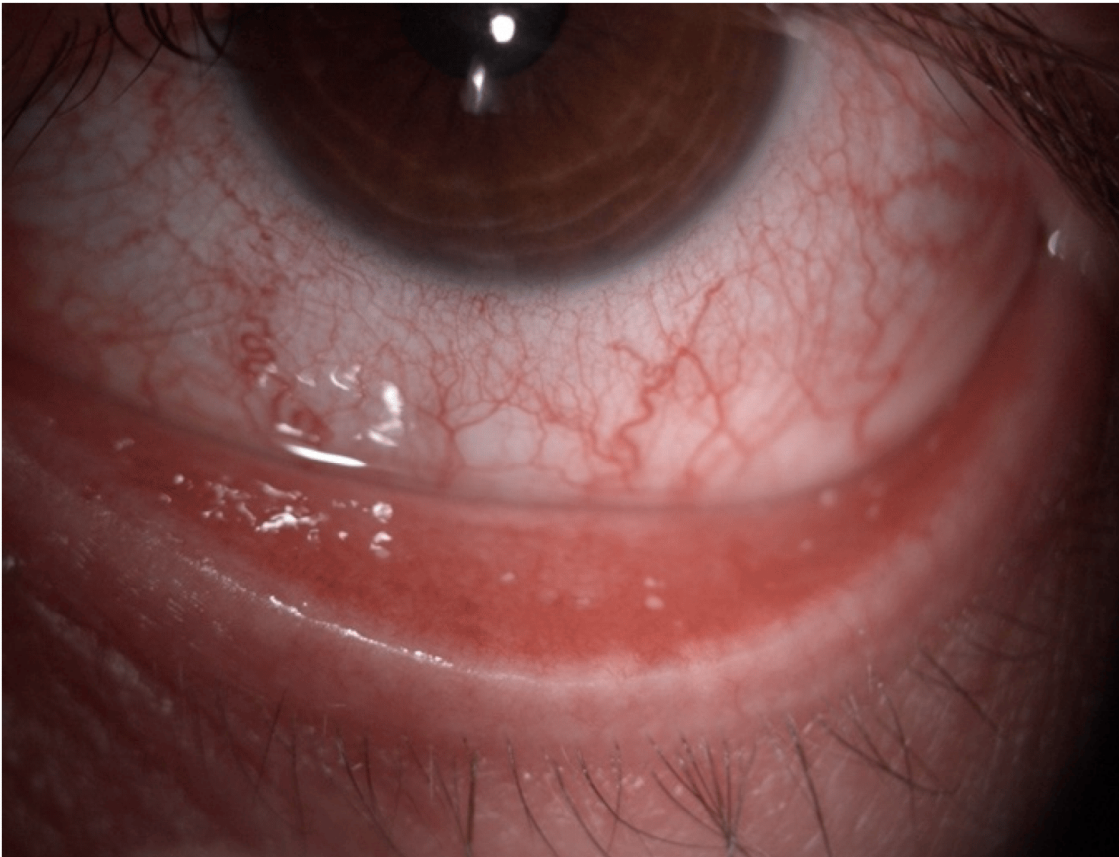


Sernicola, Alvise, et al. "Dupilumab as Therapeutic Option in Polysensitized Atopic Dermatitis Patients Suffering from Food Allergy." *Nutrients*, vol. 16, no. 16, 2024

Maurer, Marcus, et al. "Dupilumab in Patients with Chronic Spontaneous Urticaria (LIBERTY-CSU CUPID): Two Randomized, Double-Blind, Placebo-Controlled, Phase 3 Trials." *Journal of Allergy and Clinical Immunology*, vol. 154, no. 1, 2024, pp. 184–94 pp. 2797

Dupilumab side effects

Conjunctivitis, blepharitis, keratitis, dry eye, ocular pruritus



Facial dermatitis



Samia A M, Cuervo-Pardo L, Montanez-Wiscovich M E, et al. (2022). Dupilumab-Associated Head and Neck Dermatitis With Ocular Involvement in a Ten-Year-Old With Atopic Dermatitis: A Case Report and Review of the Literature. *Cureus* 14(7): e27170. doi:10.7759/cureus.27170.

Dupilumab and live vaccines

- Give all the vaccines possible BEFORE starting
- Package insert advised avoiding live vaccines in patients on dupilumab due to *lack of adequate data not* due to documented safety concerns
- Emerging evidence supports the safety and efficacy of live vaccine administration with dupilumab therapy



Dupilumab and live vaccines



Wechsler ME, et al. Preclinical and clinical experience with dupilumab on the correlates of live attenuated vaccines. *J Allergy Clin Immunol Global* **2022**

Lieberman JA, et al. A systematic review and expert Delphi Consensus recommendation on the use of vaccines in patients receiving dupilumab: A position paper of the American College of Allergy, Asthma and Immunology. *Ann Allergy Asthma Immunol.* **2024** Sep;133(3):286-294

Siegfried, Elaine C., et al. "A Case Series of Live Attenuated Vaccine Administration in Dupilumab-treated Children with Atopic Dermatitis." *Pediatric Dermatology*, vol. 41, no. 2, **2024**, pp. 204–09

Bruess GES, Barry KK, Olsen GM, et al. Evaluating outcomes of live-attenuated vaccine administration in pediatric patients on dupilumab for atopic dermatitis. *Pediatric Dermatology.* **2026**;43(2):330-332.

Dupilumab and live vaccines

- Current outbreak of measles



- Increasing number of children <18 yo on dupilumab for atopic dermatitis and asthma

Pedi Derm consensus: It is reasonable to give live, attenuated vaccines to children being treated with dupilumab. Consider stopping Dupilumab *one month before* and resumed *one month after* administration of live attenuated vaccines.

Beyond Dupilumab... the other biologics



- **Tralokinumab** – approved in 2023 for **≥12 yo.** IL 13 antagonist.
- **Nemolizumab** – approved in 2024 for **≥12 yo.** IL-31 antagonist. **Can be eventually spaced out to q8 wks.**
- **Lebrikizumab** – approved in 2024 for **≥12 yo.** IL-13 antagonist. **No facial dermatitis or conjunctivitis.**

Class: Systemic JAK inhibitors for AD



1) **Upadacitinib (Rinvoq)** – Approved for ≥ 12 yo

- Most patients who failed dupilumab will improve on upadacitinib

2) **Abrocitinib (Cibinqo)**– Approved for ≥ 12 yo

- Also works well on patients who don't do well with biologics.

Thyssen, Jacob P., et al. "Efficacy and Safety of Upadacitinib versus Dupilumab Treatment for Moderate-to-Severe Atopic Dermatitis in Four Body Regions: Analysis from the Heads Up Study." *Dermatology (Basel)*, vol. 241, no. 1, 2024, pp. 10–18

Systemic JAK inhibitors

What makes them unique:

- Oral tablets
- Need screening labs
- Black box warning

Side effects:

- Higher level of immunosuppression
- Acne (“JAKne”)
- Headache

Efficacy:

- Highly effective
- Work quickly





Acne

Making zit simple...

New topical therapy – what's zit about...



Class	Medication(s)
Retinoid	Trifarotene cream
Antibiotic	Minocycline foam
Antiandrogen	Clascoterone cream
Fixed combination	Tretinoin/benzoyl peroxide cream Clindamycin/adapalene/benzoyl peroxide gel

Class: Topical retinoid

1) Trifarotene (Aklief®) – 0.005% cream

- Approved 2019 for ≥ 9 yo
- Selectively targets retinoic acid receptor gamma

Advantages – Photostable. Less irritating (?). Pump

Disadvantages – Limited insurance coverage. Cost (~\$800/45g).



Class: Topical antibiotic

1) Topical minocycline foam (Amzeeq ®) – 4% cream

- Approved 2019 for ≥ 9 yo
- Once daily application

Advantages – Limited systemic absorption
Not photosensitizing. Pump dispenser.

Disadvantages – Does not contain BP.
Limited insurance coverage. Cost (~\$550/30g).



Class: Topical antiandrogen

1) **Clascoterone (Winlevi®) – 1% cream.**

- Approved August 2020 for ≥ 12 yo
- Inhibits binding of DHT to androgen receptor $\rightarrow \downarrow \downarrow$ sebum production
- BID application

Advantages – Good for hormonal acne

Disadvantages – BID application. Limited insurance coverage.
Cost (~\$600/60g).



Class: Fixed combination

1) Tretinoin 0.1%/benzoyl peroxide 3% cream (Twynéo®)

- Approved for ages ≥ 9 yo
- Once daily application

Advantages – Pump. Don't inactivate each other.
Slow release of active ingredients → better tolerance (?)

Disadvantages – Limited insurance coverage. Cost
(~\$750/30g).



Class: Fixed combination

1) Clindamycin 1.2%/adapalene 0.15%/benzoyl peroxide 3.1% gel (Cabtreo™)

- Approved 10/2023 for ≥ 12 yo
- Once daily application

Advantages – Pump. Easy. Effective (75% lesion reduction @ 12 wk)

Disadvantages – Limited insurance coverage. Cost (~\$1100/50g).



Eichenfield, Lawrence F., et al. "Triple-combination Clindamycin Phosphate 1.2%/Benzoyl Peroxide 3.1%/Adapalene 0.15% Gel for Moderate-to-severe Acne in Children and Adolescents: Randomized Phase 2 Study." *Pediatric Dermatology*, vol. 40, no. 3, 2023, pp. 452–59



Molluscum Contagiosum

A bumpy ride...

Molluscum contagiosum

- **Common:** 10-20% of children
- **Bothersome:**
 - 28% reported moderate impact on QOL
 - 10% large impact on QOL
- **Contagious:**
 - Intra-household transmission 41%
- **Takes a long time to go away:** average duration to resolution is 13 months
 - 30% not resolved by 18 mo
 - 13 % not resolved by 24 mo

A close-up of Harry Potter, played by Daniel Radcliffe, wearing his signature round glasses and a Gryffindor house robe. He is pointing his wand directly at the viewer with a serious expression. The background is a dark, swirling teal color.

Molluscum Contagiosum

OTC Preparations

- 2021 Analysis of OTC preparations used to treat MC
- **No** efficacy or safety data



FDA-approved treatment for molluscum

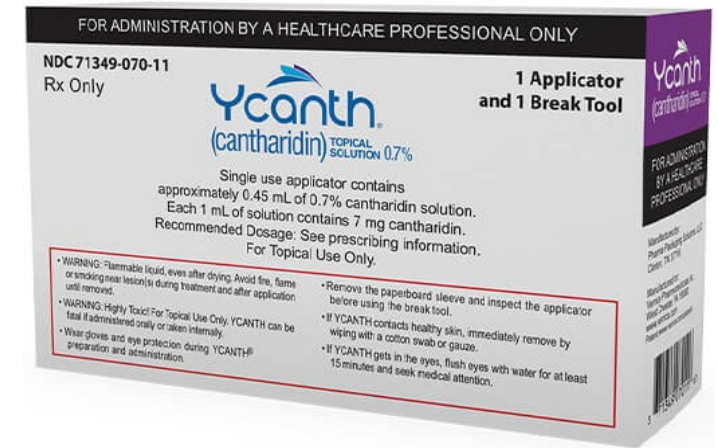


Class	Medication
Topical vesicant	Cantharidin + device
Topical nitric oxide releasing agent	Berdazimer hydrogel

Class: Topical vesicant

1) Cantharidin 0.7% + device (YCANTH®)

- FDA approved 2023 for use in children ≥ 2 yo
- Blister beetle extract, *Cantharis vesicatoris*
- Apply in office → wash off in (no more than) 24 hours



Advantages – painless application, effective

Disadvantages: blistering, r/o infection, needs careful patient education, COST (~\$725)



Class: Nitric oxide releasing agent

1) Berdazimer sodium 10.3% + hydrogel (Zelsuvmi™)

- FDA approved 2024 for ages ≥ 12 mo
- Releases nitric oxide (NO) $\rightarrow$ promotes localized innate immune response

Advantages – At home use, once daily application

Disadvantages – Need to mix 2 gels.

Expensive (\$700/carton)

Herbert AA, et al. J Am Acad Dermatol 2020 887-894

Browning JC et al. JAMA Dermatol 2022; 158 (8) 871-878





Psoriasis

Clearing things up...

Recent FDA-approvals for pediatric psoriasis



Class	Medication(s)
Biologics	Etanercept Guselcumab Ixekizumab Sekukinumab Spesolimab Ustekinumab
Systemic PDE4 antagonist	Apremilast
Systemic oral peptide	Icotrokinra
Topical PDE4 antagonist	Roflumilast

Recent FDA-approvals for pediatric psoriasis



Class	Medication(s)
Biologics	Etanercept Guselcumab Ixekizumab Sekukinumab Spesolimab Ustekinumab
Systemic PDE4 antagonist	Apremilast
Systemic oral peptide	Icotrokinra
Topical PDE4 antagonist	Roflumilast

Class: Topical PDE4 inhibitor

1) **Roflumilast** – (Zoryve ®) 0.3% cream (for psoriasis)

- Approved 2023 for ≥ 6 yo
- Once daily application



Advantages – Non-steroidal

Disadvantages – Cost (~\$1100/60g)

Two (indications) are better than one

Roflumilast cream (Zoryve ®)

	Atopic dermatitis	Psoriasis
Strength	0.05% / 0.15% cream	0.3% cream
Age	2-5 yo / $\geq$ 6 yo	$\geq$ 6 yo
Application frequency	Once daily	Once daily
Tube size	60 g	60 g
FDA approval date	Oct 2025 / July 2024	October 2023



THREE (indications) are better than TWO

Roflumilast (Zoryve ®)

	Atopic dermatitis	Psoriasis	Scalp seb derm and psoriasis
Strength	0.05% / 0.15% cream	0.3% cream	0.3% foam
Age	2-5 yo / ≥ 6 yo	≥ 6 yo	≥ 9 yo
Application frequency	Once daily	Once daily	Once daily
Tube size	60 g	60 g	60 g
FDA approval date	Oct 2025 / July 2024	October 2023	December 2023





Vitiligo

Shedding some light...

FDA-approved treatment for vitiligo in kids



Class	Medication
Topical JAK inhibitor	Ruxolitinib cream

Two (indications) are better than one

Ruxolitinib cream (Opzelura ®)

	Atopic Dermatitis	Vitiligo
Strength	1.5% cream	1.5% cream
Age	≥ 2 yo	≥ 12 yo
Application frequency	BID	BID
BSA	≤ 20%	<10% BSA
Usage	Non-continuous	Continuous
FDA approval date	September 2021	July 2022





Alopecia areata

Hairy situations...

FDA-approved treatment for AA in kids



Class	Medication
Systemic JAK inhibitor	Ritlecitinib

Ritlecitinib (Litfulo®)

The first and (so far) ONLY medication FDA-approved for the treatment of alopecia areata in children

Class: JAK inhibitor

Dosing: 50 mg po once daily

Approved for: Severe AA in children ≥ 12 yo



Welcome to the (2020's, FDA-approved) jungle...



Atopic dermatitis:

- 5 new non-steroidal topical creams
- 4 systemic biologics
- 2 systemic JAK inhibitors

Acne:

- Topical anti-androgen cream
- Topical antibiotic foam
- Topical retinoid cream
- 2 topical fixed-combination products

Molluscum:

- 1 new in-office treatment
- 1 new at-home treatment

Psoriasis:

- Topical non-steroidal cream
- Topical non-steroidal foam

Seborrheic dermatitis:

- Topical non-steroidal foam

Vitiligo:

- Topical non-steroidal cream

Alopecia Areata:

- Systemic JAK inhibitor



Thank you!!!



Email: kwallace@connecticutchildrens.org

