Using Managed Care to Minimize the Burden of Moderate-to-Severe Atopic Dermatitis in Pediatric and Adult Patients

FRIDAY, APRIL 16, 2021

This activity is co-provided by Ultimate Medical Academy/Complete Conference Management (CCM) and AMEDCO.
This activity is supported by an educational grant from Sanofi Genzyme and Regeneron Pharmaceuticals, Inc.

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AGENDA

I. Atopic Dermatitis (AD): An Overview

a. Epidemiology, incidence, and prevalence of AD in adults and children
b. Pathophysiology of AD
- Epithelial barrier dysfunction
- Immune dysregulation
- The role of type 2 inflammation in the pathogenesis of AD

c. Quality of life, psychosocial, and developmental impact of AD

IV. Management of Atopic Dermatitis

a. Measuring disease severity
b. Guideline-recommended management of AD
c. MOAs of approved and investigational agents for the treatment of AD
d. Clinical trial data on the efficacy and safety of:
    a. Systemic agents
    b. Topical therapies
e. Patient-specific factors in treatment selection
f. Developing individualized treatment plans

III. The Managed Care of AD

a. Determining when treatment intensification is warranted
b. Non-adherence to effective therapy regimens
c. The economic burden of disease
    a. Direct and indirect healthcare costs
    b. Cost-benefit analyses of treatment options
d. Including quality-of-life issues in treatment selection
e. Reducing polypharmacy when appropriate
f. Assessing for drug-drug interactions

V. Case Studies – Brief drug utilization review cases of adult and pediatric patients with moderate-to-severe AD

VI. Conclusions

VI. Q&A

April 16, 2020

Using Managed Care to Minimize the Burden of Moderate-to-Severe Atopic Dermatitis in Pediatric and Adult Patients

FACULTY

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PROGRAM OVERVIEW
This case-based activity will cover the underlying causes of atopic dermatitis along with current and emerging systemic agents as part of the overall treatment plan.

TARGET AUDIENCE
This activity is intended for managed care pharmacists, physicians, and other healthcare professionals involved in the management of patients with moderate-to-severe atopic dermatitis.

Learning Objectives
- Recognize patient-specific factors that influence the selection of therapies for the management of moderate-to-severe atopic dermatitis, including comorbidities, adherence barriers, disease severity, and quality-of-life issues
- Evaluate clinical trial data on the efficacy and safety of systemic and topical treatments for the management of moderate-to-severe atopic dermatitis
- Identify strategies to manage healthcare costs while improving quality of life for patients with atopic dermatitis
- Develop treatment plans that apply evidence-based medication use strategies to enhance outcomes in patients with moderate-to-severe atopic dermatitis

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Purpose: This program would be beneficial for nurses involved in the care of patients with atopic dermatitis. **CNE Credits:** 1.0 ANCC Contact Hour.

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Geoff Wall, PharmD has nothing to disclose.

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CNE Content Review

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Using Managed Care to Minimize the Burden of Moderate-to-Severe Atopic Dermatitis in Pediatric and Adult Patients - Live
April 16, 2021
Online

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Objectives - After Attending This Program You Should Be Able To
1. Recognize patient-specific factors that influence the selection of therapies for the management of moderate-to-severe atopic dermatitis, including comorbidities, adherence barriers, disease severity, and quality of life issues.
2. Evaluate clinical trial data on the efficacy and safety of systemic and topical treatments for the management of moderate-to-severe atopic dermatitis.
3. Identify strategies to manage health care costs while improving quality of life for patients with atopic dermatitis.

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Scott McGee-Plys	NA
Geoffrey C. Wall	Speaker Bureau: Janssen Pharmaceuticals and Tetraphase Pharmaceuticals.
Lauren Welch	NA
Ashley Whitehurst	NA

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3. Complete the post-test, click the provided link to go to the online evaluation site.
4. Evaluate the meeting, click the provided link to open your credit certificate.
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Disclosures

- **Peter Lio, MD** has served on the advisory board for the National Eczema Association, Modernizing Medicine, Johnson & Johnson, DermTap Inc., IntraDerm Pharmaceuticals, Regeneron, Sanofi US Services, Realm Therapeutics, Menlo Therapeutics, Syncere Skin Systems, DermVeda, GPower Inc., UCB, Altus Labs, Dermavant Sciences, Micreos Human Health B.V., Verrica Pharmaceuticals Inc., Arbonne, Yobee Care Inc., and Bodewell. Dr. Lio is a stockholder in Modernizing Medicine, LearnHealth/LearnSkin, and Medable. He has been a speaker for Pierre Fabre Dermatologie, Regeneron, Pfizer, and La Roche-Posay. He has been an investigator for La Fondation pour la Dermatite Atopique (Foundation for Atopic Dermatitis), AOBiome LLC, Regeneron, AbbVie, and National Eczema Association. He has been a consultant for Exeltis, Therplex, Odeza LLC, L'Oreal USA Inc., Franklin BioScience, AbbVie, Kiniksa Pharmaceuticals, Eli Lilly and Co., Unilever, Dermira, TopMD, Amyris Inc., Leo Pharma, and Burt's Bees.
- **Geoffrey Wall, PharmD, FCCP, BCPS** has nothing to disclose.
- During this lecture, use of medications for both FDA-approved and non-approved indications may be discussed.

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- Develop treatment plans that apply evidence-based medication use strategies to enhance outcomes in patients with AD

Atopic Dermatitis: Features and Diagnosis

Peter A. Lio, MD

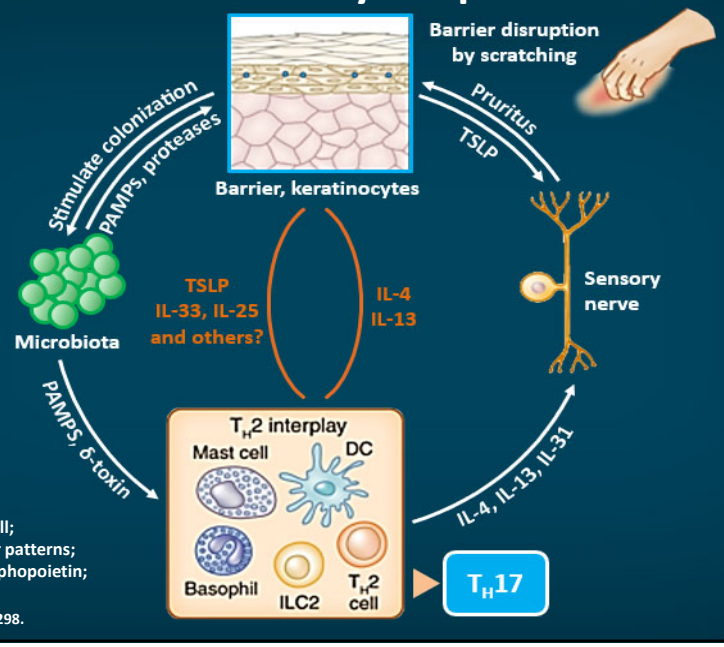
Features of Atopic Dermatitis (AD)

AD is a chronic, pruritic, inflammatory skin disease that typically involves:

- Childhood onset
- Familial occurrence
- Eczematous change
  - Erythema
  - Induration, papulation
  - Excoriation
  - Lichenification
- Characteristic distribution
- Intermittent flares
- Associated skin conditions (minor diagnostic criteria)
- Skin infections
- Associated morbidities

Siegfried EC, Hebert AA. *J Clin Med.* 2015;4:884-917. Ring J, et al. *J Eur Acad Dermatol Venereol.* 2012;26:1045-1060.

The Inflammatory Loop in AD



IL = interleukin; ILC = innate lymphoid cell; PAMPs = pathogen-associated molecular patterns; T_H = T helper; TSLP = thymic stromal lymphopoietin; DC = dendritic cell

Dainichi T, et al. *Nat Immunol*. 2018;19:1286-1298.

Atopic Dermatitis: Diagnostic Features

Features to be considered in diagnosing patients with AD

- **ESSENTIAL FEATURES**; must be present:
  - Pruritus
  - Eczema (acute, subacute, chronic):
    - Typical morphology and age-specific patterns*
    - Chronic or relapsing history

  Patterns include:
  1) facial, neck, and extensor involvement in infants and children;
  2) current or prior flexural lesions in any age group;
  3) sparing of groin and axillary regions.

- **IMPORTANT FEATURES**; seen in most cases, adding support to the diagnosis:
  - Early age of onset
  - Atopy
    - Personal and/or family history
    - IgE reactivity
  - Xerosis

- **ASSOCIATED FEATURES** ; these clinical associations help to suggest the diagnosis of AD but are too non-specific to be used for defining or detecting AD for research and epidemiologic studies:
  - Atypical vascular responses (e.g., facial pallor, white dermographism, delayed blanch response)
  - Keratosis pilaris / pityriasis alba / hyperlinear palms / ichthyosis
  - Ocular / periorbital changes
  - Other regional findings (e.g., perioral changes / periauricular lesions)
  - Perifollicular accentuation / lichenification / prurigo lesions

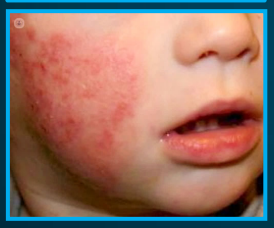
- **EXCLUSIONARY CONDITIONS;** it should be noted that a diagnosis of AD depends on excluding conditions such as:
  - scabies
  - seborrheic dermatitis
  - contact dermatitis (irritant or allergic)
  - ichthyoses
  - cutaneous T-cell lymphoma
  - psoriasis
  - photosensitivity dermatoses
  - immune deficiency diseases
  - erythroderma of other causes

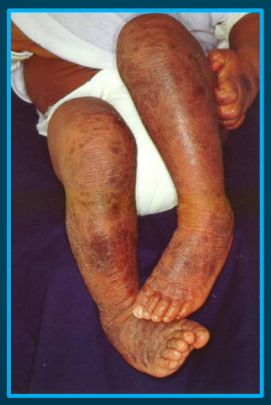
Eichenfield LF, et al. *J Am Acad Dermatol.* 2003;49:1088-1095. Eichenfield LF, et al. *J Am Acad Dermatol.* 2014;70:338-351.

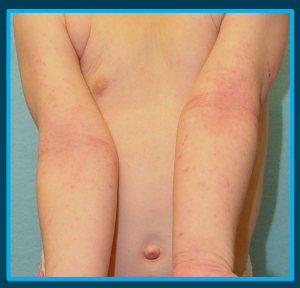
Classic AD Distribution Changes With Age

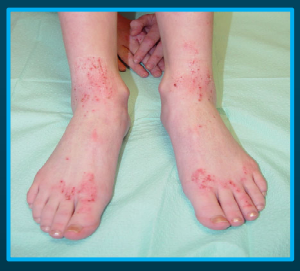
Infants: face, extensor extremities

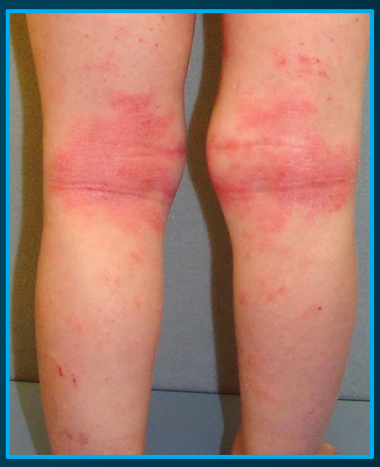
Children: wrists, ankles, antecubital and popliteal fossae





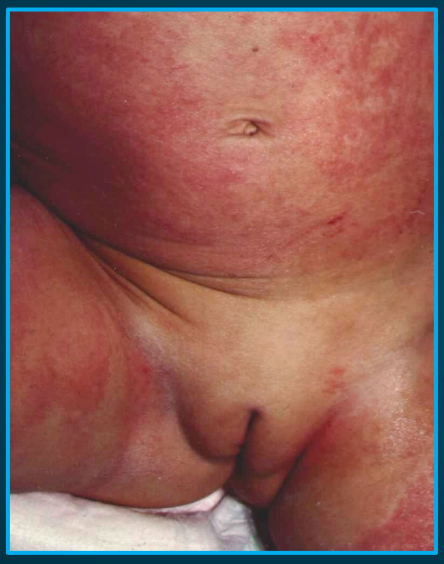


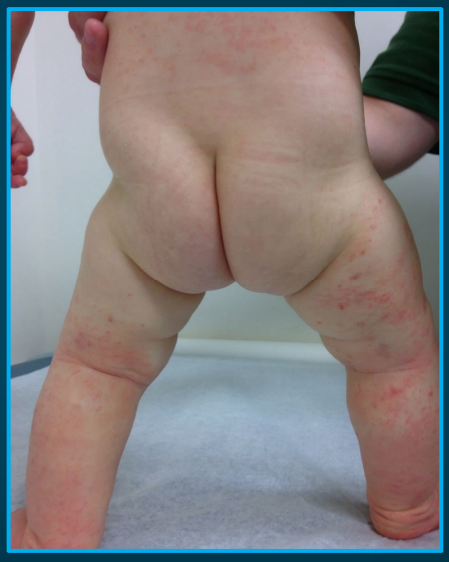




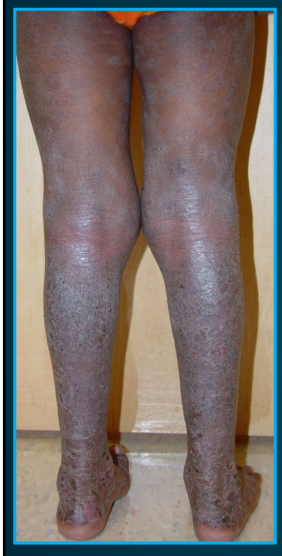
AD across the lifespan (https://atopicdermatitis.net/across-lifespan). Accessed January 26, 2021.

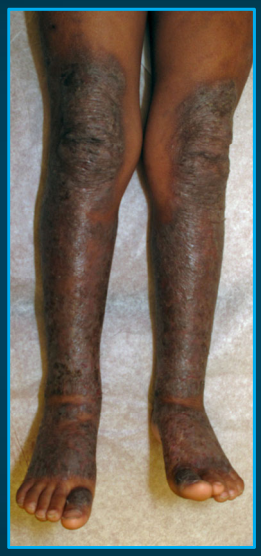
Diaper-Area Sparing: A Diagnostic and Therapeutic Feature

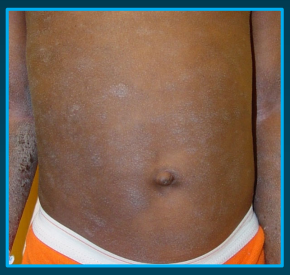


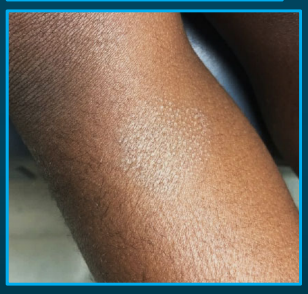


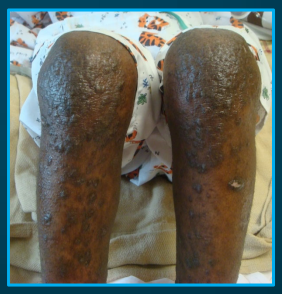
More Common Features in Skin of Color











- Follicular/papular and nummular morphology
- Obscured erythema
- Prominent lichenification
- Dyspigmentation

Boguniewicz M, et al. *J Allergy Clin Immunol Pract.* 2017;5:1519-1531. Poladian K, et al. *Cutis.* 2019;104:164-168. Siegfried EC, Hebert AA. *J Clin Med.* 2015;4:884-917.

Phenotypic Mimics

Otherwise healthy

- **Pityriasis alba**
- **Keratosis pilaris**
- **Ichthyosis vulgaris**
- Lichen simplex chronicus
- Contact dermatitis
- Psoriasiform overlap
- Seborrheic dermatitis
- Tinea
- Scabies

Unhealthy

- Immune deficiencies
- Nutritional deficiencies
- Cutaneous T-cell lymphoma
- Genodermatoses

Siegfried EC, Hebert AA. *J Clin Med.* 2015;4:884-917. Wine SJ, Steinberg S. *Can Fam Physician.* 1972;18:65-66. Purohit MP. Lichen simplex chronicus. DoveMed. 2018 (www.dovemed.com/diseases-conditions/lichen-simplex-chronicus). Fields D. NEWS Medical. 2019 (www.news-medical.net/health/Types-of-Genodermatoses.aspx). All URLs accessed January 26, 2021.

Patient Impact

Please click here to watch a brief animation looking at the 5 I's and patient-centered treatment

Associated Morbidities

Atopic	Others[1,2,6,7]
• **Allergic rhinitis** (≈50% prevalence)[1] • **Allergic conjunctivitis**[2] • **Asthma** (≈22%-30% prevalence)[1,3,4] • **Primary eosinophilic gastrointestinal disorders**[2] • **Food allergy**[5]	• **Mental/behavioral health** • **Skin infections** • **Allergic contact dermatitis** • **Immune deficiency** • **Cataracts**

1. Whiteley J, et al. *Curr Med Res Opin.* 2016;32:1645-1651. 2. Silverberg JI. *Cutis.* 2019;104:142-143. 3. Silverberg JI, Hanifin JM. *J Allergy Clin Immunol.* 2013;132:1132-1138.
4. Wang D, Beck LA. *Am J Clin Dermatol.* 2016;17:425-443. 5. Greenhawt M. *Allergy Asthma Proc.* 2010;31:392-297. 6. Silverberg NB. *Cutis.* 2016;97:408-412.
7. De Benedetto A, et al. *J Invest Dermatol.* 2009;129:14-30.

Management

Standard Treatment Strategies: 5 "I"s

Impaired skin barrier function

Ointment emollient, wet wraps, ambient humidity

Itch (and scratching)

Non-sedating antihistamines for urticarial component, N-acetylcysteine*

Interrupted sleep

Short-term sedating antihistamines, sleep hygiene

Inflammation

- Bleach baths
- Avoid topical allergens
- TCSs/calcineurin inhibitors/ crisaborole
- Systemic anti-inflammatory medication

Infection/risk
(*Strep, HSV, molluscum, tinea*)

- Bleach baths
- Surveillance testing
- Appropriate antimicrobial medication

**N-acetylcysteine not FDA approved for AD.*

FDA = US Food and Drug Administration; HSV = herpes simplex virus; TCS = topical corticosteroid.

Original concept acknowledgement to Dr. Margaret Lee and Dr. Lisa Shen. Lio PA, et al. *J Allergy Clin Immunol Pract.* 2014;2:361-369. Janeczek M, et al. *J Clin Aesthet Dermatol.* 2019;12:20-26.

Assessment of Disease Severity

- Validated AD-specific severity scales
  - **SCORAD** (**SCOR**ing **A**topic **D**ermatitis index): includes extent, sleep, and itch
  - **EASI** (**E**czema **A**rea and **S**everity **I**ndex): includes extent
  - **IGA** (**I**nvestigator's **G**lobal **A**ssessment): simple 0- to 5-point scale
- Modified forms used in clinical trials
- SCORAD and EASI are too cumbersome for clinical practice
- IGA is simple, useful, and may be required for insurance authorization

Siegfried EC, et al. *Pediatr Dermatol*. 2018;35:303-322. Chopra R, et al. *Br J Dermatol*. 2017;177:1316-1321. Brunk D. *Dermatol News*. 2020 (www.mdedge.com/dermatology/article/220713/atopic-dermatitis/expert-discusses-her-approach-using-systemic-agents). Accessed January 26, 2021. Silverberg JI, et al. *Br J Dermatol*. 2019;181:80-87.

AD Severity Informs *Customized* Stepped Therapy

	MILD	MODERATE	SEVERE
Maintenance	**Skin care** Daily bath (bleach optional) Liberal, frequent moisturizer use **Trigger avoidance** Irritants, potential topical allergens, low ambient humidity **Consider comorbidities**	**Add bleach baths, wet wraps** **Maintenance TCI or crisaborole** • Up to twice daily • Monitor quantities **Intermittent TCS** • Medium potency • 15 days/month • Monitor quantities	**Specialist referral** **Consider comorbidities** **Short-term aggressive treatment** • Wet wraps • Hospitalization **Phototherapy** **Systemic immunosuppressants** • Cyclosporine A* • Methotrexate* • Mycophenolate mofetil* • Azathioprine* **Dupilumab**
Flare	**TCS** • Low-to-medium potency • PRN up to 15 days/month • Monitor quantities	**TCS** • Medium-to-high potency • Consider complicating factors	**Other considerations** • Nonadherence • Infection • Misdiagnosis • Contact allergy

PRN = as needed; TCI = topical calcineurin inhibitor.

**Not FDA approved for AD.*

Adapted from Boguniewicz M, et al. *Ann Allergy Asthma Immunol*. 2018;120:10-22.e2.

Emollient Options

- Affordability
- Tactile acceptance
- Low allergenicity
- Options
  - Non-allergenic: plain petroleum jelly, plain mineral oil (beware tocopherol), Vanicream™ Moisturizing Ointment (formerly Vaniply™ Ointment)
  - Physiologic lipids (eg, CeraVe®, EpiCeram®); equimolar ratio of ceramides, cholesterol, fatty acids for benefit
  - pH <5 (A-Mantle™)
  - Colloidal oatmeal (Aveeno®)
  - Prescription skin-barrier devices (Hylatopic ®, Mimyx ®, Atopiclair ®)
- Wet wraps

Elias PM, et al. *Skin Pharmacol Physiol.* 2019;32:1-7. Dhandha MM, Siegfried EC. *Skin.* 2017;1:48-51 (www.jofskin.org/index.php/skin/article/download/4/pdf). URLs accessed January 26, 2021. Cincinnati Childrens. (https://www.cincinnatichildrens.org/health/e/eczema). Accessed January 26, 2021.

Safe and Effective Use of Topical Medications in Children

How much, how often, how to monitor?

Medication	Quantity	Frequency	Possible Safety Monitoring	Prescribing Guideline
Corticosteroids	15-60 g/month (based on age/body site/potency)	15 days/month	AM cortisol	Potency and age group specific
Calcineurin inhibitors	100-200 g/month; Supplied in 30- to 100-g tubes	BID	Tacrolimus peak	≥2 years*
PDE-4 inhibitors	100-200 g/month; Supplied in 60- to 100-g tubes	BID	—	≥3 months

Refer to individual medication prescribing information for approved indications and guidelines for treatment.

*Tacrolimus 0.03% is indicated for children 2-15 years; 0.1% is indicated for adults.

AM = morning; BID = twice daily; PDE-4 = phosphodiesterase-4.

Carr WW. *Paediatr Drugs.* 2013;15:303-310. Eichenfield LF, et al. *J Am Acad Dermatol.* 2014;71:116-132. Schwartz RA. Pediatric atopic dermatitis medication. Medscape. 2020 (https://emedicine.medscape.com/article/911574-medication). Accessed January 26, 2021. Pharmacist's Letter. 2012 (http://snapaprn.org/docs/SNAP%20Comparison%20of%20Topical%20Steroids.pdf). Accessed January 26, 2021. National Eczema Society. Factsheet. 2019 (https://eczema.org/wp-content/uploads/Topical-steroids-Sep-19-1.pdf). Accessed January 26, 2021.

Optimizing Long-Term Control

Address only intermittent flares

Prescription antibiotics, potent TCS, and prednisone

Yields alternating roller-coaster improvement and flares

Practice daily skin care

Use adequate amounts of topical medication

Recognize and avoid triggers

Maintains control

Wollenberg A, et al. *J Eur Acad Dermatol Venereol.* 2016;30:729-747. Torrelo A, et al. *Actas Dermosifiliogr.* 2013;104:409-417. Thaci D, et al. *J Eur Acad Dermatol Venereol.* 2010;24:1040-1046. Sidbury R, et al. *J Am Acad Dermatol.* 2014;71:1218-1233.

New and Targeted Therapy

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Drake University College of Pharmacy and Health Sciences
Internal Medicine Clinical Pharmacist
Iowa Methodist Medical Center
Des Moines, IA

General Therapeutics

- Identify and eliminate triggering factors
  - Avoidance of common irritants, eg, soaps/detergents/wool/occlusive fabrics
  - Potential contact allergens, eg, fragrance, preservatives, botanicals
  - Recommend control of temperature and humidity
  - Consider possible allergy triggers (other than foods) with skin tests, although skin tests (and allergy patch tests) are poorly predictive of triggering factors
  - Allergen immunotherapy
    - Selected patients with aeroallergen sensitivity—may worsen AD
- Phototherapy
  - Narrowband UVB most commonly used due to low-risk profile, relative efficacy, availability, and clinician experience
  - Incidence of adverse events considered to be low; most common are actinic damage, local erythema/tenderness, pruritus, burning, and stinging.
  - Rarely used because of poor accessibility and often poorly tolerated, especially for acute AD
  - Home phototherapy is a consideration for patients with poor adherence.

Schneider L et al. *J Allergy Clin Immunol*. 2013;131:295-299.e1-27. Sidbury R et al. *J Am Acad Dermatol.* 2014;71:327-349.

Atopic Dermatitis: Current Treatment Options
Considerations for Treatment

- Majority of patients with mild AD can expect to obtain clinical improvement and disease control with use of emollients, conventional topical therapies (TCS and/or TCI), and environmental and/or occupational modifications, when necessary.
- These interventions may not be sufficient for patients with moderate-to-severe or difficult-to-control disease.

Sidbury R et al. *J Am Acad Dermatol.* 2014;71:327-349. Wollenberg A et al. *J Eur Acad Dermatol Venereol.* 2016;30:729-747. Saeki H et al. *J Dermatol.* 2016;43:1117-1145.

Skin Hydration

- Bathing followed by immediate application of emollient
- Emollient
  - Use generously—no danger from "excess use"
  - Lotions vs creams vs oils vs ointments
- General recommendations are:
  - Warm (not hot) water
  - Bath is better than shower
  - 5–10 minutes
  - Neutral/low pH, hypoallergenic, fragrance-free non-soap cleansers preferred
- Bleach baths are now standard of maintenance care for pediatric moderate-to-severe AD.

Schneider L et al. *J Allergy Clin Immunol*. 2013;131:295-299.e1-27. Eichenfield LF et al. *J Am Acad Dermatol*. 2014;71:116-132.

Topical Corticosteroids

- TCS recommended if symptoms are not controlled by moisturizers alone
- Low-potency
  - Maintenance therapy to prevent exacerbations
- Intermediate- and high-potency (halogenated)
  - Exacerbations for short period or proactive therapy
- Ultra-high-potency
  - No more than 1–2 weeks
  - Non-facial, non-skinfold areas
- Potent, fluorinated corticosteroids should not be used beyond a few days on mucous membranes, face, eyelids, genitalia, and intertriginous areas or in young infants.

Schneider L et al. *J Allergy Clin Immunol*. 2013;131:295-299.e1-27. Eichenfield LF et al. *J Am Acad Dermatol*. 2014;71:116-132.

Are You Dispensing Enough?

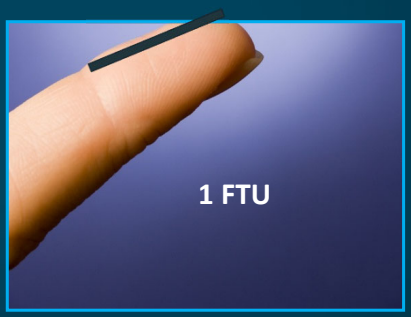
Estimates for Quick Memorization	
Recommended amount per dose	
Total BSA of a 5 month old	5 g
Total BSA of a 5–10 year old	10 g
Total BSA of a 20 year old	20 g
Do the math...	
5 mo 100% BSA = 5 g x 2 = 10 g x 14 days = 140 gm	
7 yo 100% BSA = 10 g x 2 = 20 g x 14 days = 280 gm	

BSA = body surface area

Question: Show of Hands

For dosing topical medications, a “finger tip unit” is equal to about how much medication?

1. 10 mg
2. 1/2 gm
3. 1 gm
4. 2 gm

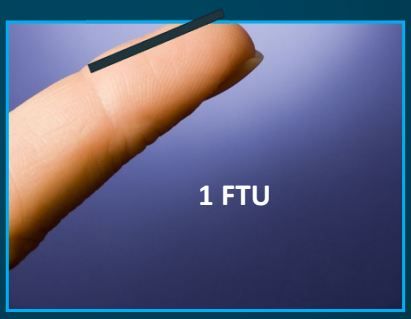


FTU = finger-tip unit.

Dosing of Topical Medications

- FTU (finger-tip unit) = ½ gm
- Distal finger of adult…DIP crease to tip
- 2 FTUs = 1 gram
- 1 FTU covers 2 adult hands and fingers

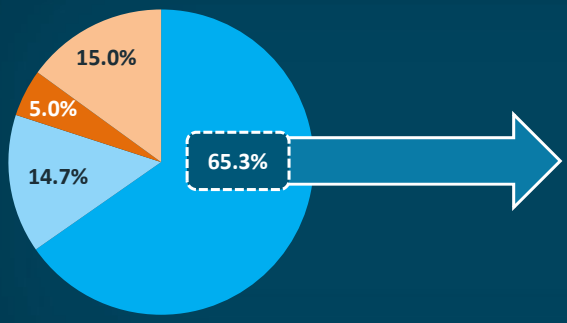
Most topicals have a tube with an orifice ~5 mm



DIP = distal interphalangeal (joint).
Long CC, et al. *Clin Exp Dermatol*. 1991;16(6):444-7.

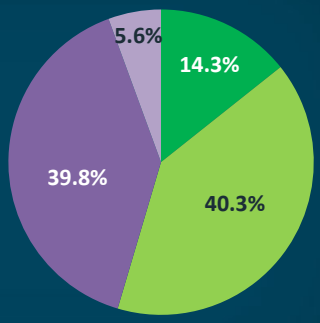
Knowledge of FTU: Japanese Survey of Pharmacists

Are you aware of FTU?



- Very familiar with FTU AND able to explain to patients
- Heard of it, but not enough to explain
- Heard of it, but know very little about it
- Never heard of it

If so, do you explain FTU when prescribing 1st time steroid in AD?



- Always
- Usually
- Not very often
- Never

Oishi N, et al. *Drug Discov Ther*. 2019;13(3):128-32.

"Soak and Smear" of Topical Steroids

Soak-and-smear regimen

- **Soak** in a bath with plain water (no soap) for 10 min at night (or BID)
- Then, **smear** on the topical steroid (usually triamcinolone 0.1% ointment) immediately *without drying*
- After skin is improved, stop soaks but continue the topical steroid at night

BID = twice a day.

Gutman AB et al. *Arch Dermatol*. 2005;141:1556-1559.

Topical Calcineurin Inhibitors

- TCIs include pimecrolimus cream 1%; tacrolimus 0.03% and 0.1% ointment
- Block production of proinflammatory cytokines and other inflammatory mediators[1,2]
- Advantages of TCIs vs TCS[2]
  - For face, anogenital, skin folds, or other sensitive areas
  - No atrophogenic properties; can reverse steroid-induced atrophy
  - Steroid-sparing: reduce overall TCS when used for maintenance

1. Schneider L et al. *J Allergy Clin Immunol*. 2013;131:295-299.e1-27. 2. Eichenfield LF et al. *J Am Acad Dermatol*. 2014;71:116-132.

Topical Calcineurin Inhibitors (continued)

- 2–3x/week "proactive" application is effective in preventing recurrence.[1,2]
- Local adverse effects, such as stinging and burning, are most common[1,2] and primarily occur when applied to acutely inflamed lesions.
- Although increased risk of malignancy is not observed[3], black box warning for theoretical risk persists and requires reassuring the patient when it is prescribed.

1. Schneider L et al. *J Allergy Clin Immunol*. 2013;131:295-299.e1-27. 2. Eichenfield LF et al. *J Am Acad Dermatol*. 2014;71:116-132. 3. Siegfried EC et al. *BMC Pediatr*. 2016;16:75.

Please click here to watch a brief animation exploring current and emerging agents for AD

Dupilumab

- A human monoclonal antibody against IL-4 receptor α
- Inhibits signaling of IL-4 and IL-13
- FDA approved for moderate-to-severe AD in adults in March 2017, for aged ≥12 years in 2019, and for aged ≥6 years in 2020
- Also FDA approved for moderate-to-severe eosinophilic asthma (≥12 years) and for add-on maintenance therapy for CRSwNP (adults)
- SC injection every 2 or 4 weeks, based on patient weight

CRSwNP = chronic rhinosinusitis with nasal polyposis; SC = subcutaneous.

Dupilumab (Dupixent®) PI 2020 (https://www.regeneron.com/sites/default/files/Dupixent_FPI.pdf). Press release. May 26, 2020 (https://www.prnewswire.com/news-releases/fda-approves-dupixent-dupilumab-as-first-biologic-medicine-for-children-aged-6-to-11-years-with-moderate-to-severe-atopic-dermatitis-301065273.html). All URLs accessed January 21, 2021.

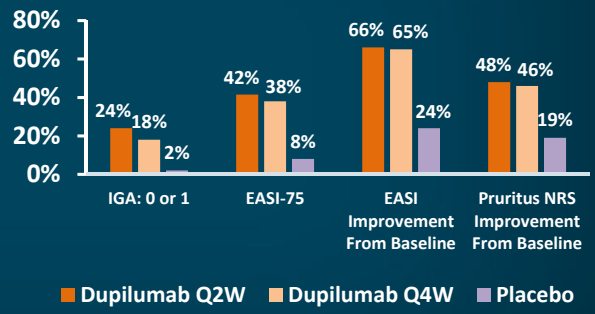
Dupilumab: Select Clinical Trials in Pediatric Patients

Phase 3 Trial (Jul 2020)[1]
- 16-week trial in 251 patients aged 12-17 years
- Dupilumab 200 or 300 mg Q2W
- Dupilumab 300 mg Q4W
- Placebo

Phase 3 Trial (Nov 2020)[2]
- 16-week trial of 367 patients aged 6-11 years with concomitant TCS
- 67%-70% achieved EASI 75 (27% PBO)
- 31%-33% achieved IGA 0/1 (11% PBO)
- 51%-58% achieved ≥4-pt itch reduction (12% PBO)

Additional Trials
- Case series (6 patients; 7-15 years): efficacy/safety over 8.5 months[3]
- Phase 3 open-label extension (6 months - 17 yrs): underway[4]
- Phase 2 and 3 (6 months-6 years): underway

Dupilumab vs Placebo: Clinical Endpoints

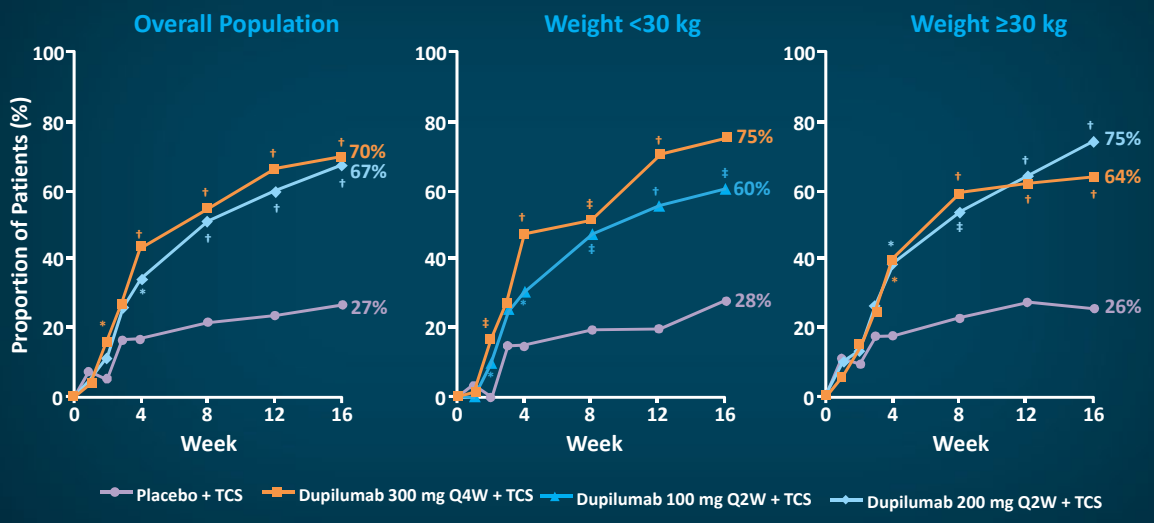


All *P*< .001 vs placebo; dupilumab is FDA approved for moderate-to-severe AD in patients aged ≥6 years.

NRS = Numeric Rating Scale; Q2W = every 2 weeks; Q4W = every 4 weeks; PBO = placebo.

1. Simpson E, et al. *JAMA Dermatol*. 2020;156(1):44-56. 2. Paller A, et al. JAAD. 2020;83(5):1282-93. 3. Treister AD, et al. *Pediatr Dermatol*. 2019;36:85-88. 4. https://clinicaltrials.gov/ct2/show/NCT02612454

Proportions of Children Aged 6-11 Years Achieving EASI-75



*$P \leq .05$; †$P \leq .0001$; ‡$P \leq .001$ vs placebo + TCS.

Paller AS, et al. *J Am Acad Dermatol*. 2020;83:1282-93.

Dupilumab: Safety

- It appears much safer than conventional immunosuppressants, but other potential considerations include:
  - Conjunctivitis in up to 10% of patients[1]
    - Higher rates in those with higher baseline AD severity and/or history of conjunctivitis
    - Mostly mild to moderate
    - In dupilumab trials in other type 2 diseases (eg, asthma, CRSwNP), incidence similar to placebo
  - Head/neck erythema[2,3]
  - Injection site reaction/systemic reactions
  - Cost may be a factor
  - Injection

1. Dupilumab prescribing information. Available at: https://www.regeneron.com/sites/default/files/Dupixent_FPI.pdf. 2. de Beer F, et al. *JAAD Case Rep*. 2019;5:888-891. 3. de Wijs L, et al. *Br J Dermatol*. 2020;183:745-749.

Does Dose Reduction Maintain Efficacy?

Worm et al, 2020:

- 422 adult patients responding to dupilumab, and continuing *once weekly or once every 2 weeks* maintained optimal efficacy
- EASI 75:
  - Negligible changes with above dosing regimens (−0.06%; $P < .001$ vs placebo)
  - Dose-dependent worsening with other doses (Q4wks: −3.84%; Q8wks: −6.84%)
- Adverse events: 70.7% weekly or Q2wks; 73.6% Q4wks; 75.0% Q8wks; 81.7% placebo.
- Similar conjunctivitis rates
- Antidrug antibody incidence lower with more frequent regimens (weekly: 1.2%; Q2wks: 4.3%; Q4wks: 6.0%; Q8wks: 11.7%; PBO: 11.3%)

Worm M, et al. *JAMA Dermatol*. 2020;156(2):131-43.

Cost Utility of Dupilumab

- Lifetime Markov model from a US payer perspective
  - Used EASI 50, 70, and 90 versus no response and assumed lifetime costs of dupilumab at $509 K
  - Dupilumab provided an additional 1.91 quality-adjusted life years (QALYs) over remaining lifetime of patient, leading to an incremental cost-effectiveness ratio (ICER) of $124,500. ICER was lower for patients with severe atopic dermatitis ($95,800).
  - Below the usual willingness to pay threshold of $150 K, but close in moderate AD
- Compare with lifetime societal costs of AD
  - One US study found just direct costs and health-care utilization of severe AD to be almost $24K yearly.

Zimmerman M et al. *J Drugs Dermatol.* 2018;17:750-756. Eckert L et al. *J Am Acad Dermatol.* 2018;78:54-61.e1.

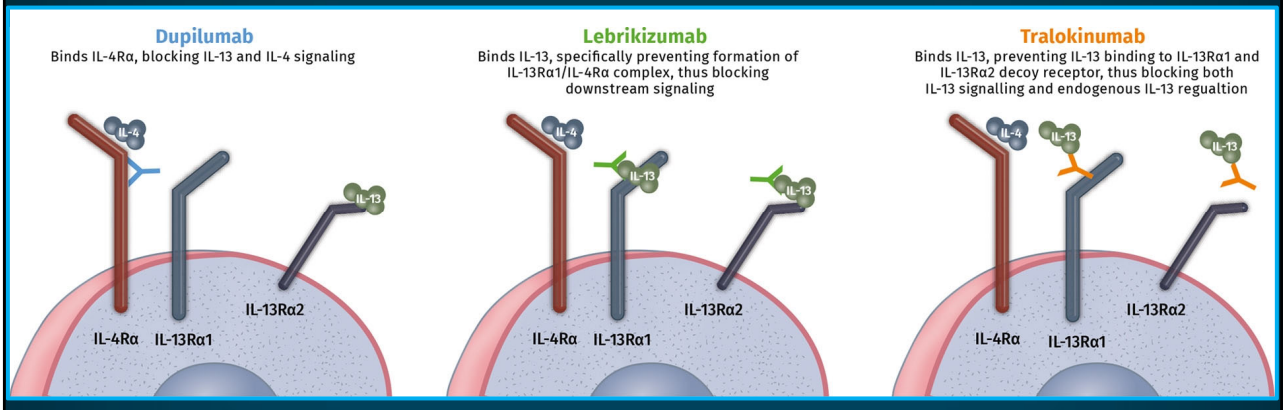
Pipeline: Selected Agents

Drug	Target
TOPICAL	
Delgocitinib	JAK1, JAK2, JAK3, and TYK2
E6005	PDE-4
OPA-15406	PDE-4
Ruxolitinib	JAK1 and JAK2
Tapinarof	AHR ligand
ORAL	
Abrocitinib	JAK1
ASN002	JAK
Baricitinib	JAK1 and JAK2
Upadacitinib	JAK1
SYSTEMIC INJECTION	
Lebrikizumab	IL-13
Nemolizumab	IL-31
Tralokinumab	IL-13

AHR = aryl hydrocarbon receptor; TYK2 = tyrosine kinase 2.

National Eczema Association. Eczema treatments (https://nationaleczema.org/research/eczema-treatment-research). Accessed January 26, 2021. Vakharia PP, Silverberg JI. *Lancet Child Adolesc Health*. 2019;3:343-353.

Not Identical Mechanisms



Lebrikizumab does not prevent binding to Rα2 → no increased levels of IL-13

Tralokinumab prevents the binding to Rα2 → thus increased total IL-13 levels

What does this mean?

We don't know!

Rα = receptor α.

Moyle M, et al. *Exp Dermatol*. 2019;28:756-768.

Emerging Agent: Tralokinumab (Anti–IL-13)

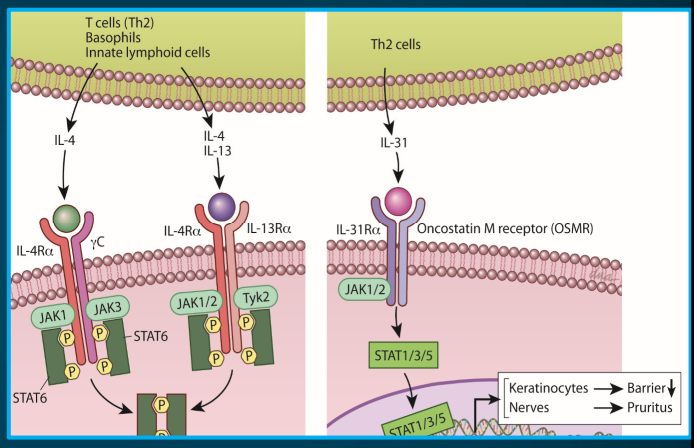
Study	Treatment	IGA 0/1 Response at Week 16	EASI-75 Response at Week 16
ECZTRA 1[1]	Tralokinumab	16%	25%
	Placebo	7%	13%
	Placebo-adjusted response	**9%**	**12%**
ECZTRA 2[1]	Tralokinumab	22%	33%
	Placebo	11%	11%
	Placebo-adjusted response	**11%**	**22%**
ECZTRA 3[2]	Tralokinumab	39%	56%
	Placebo	26%	36%
	Placebo-adjusted response	**13%**	**20%**

- ECZTRA 1/2: 51%-60% maintained response over 52 weeks
- ECZTRA 3: 78%-93% maintained response over 32 weeks

1. Wollenberg A, et al. *Br J Dermatol*. 2020;Sep 30. doi:10.1111/bjd.19574. 2. Silverberg JI, et al. *Br J Dermatol*. 2020 Sep 30. doi:10.1111/bjd.19573.

Janus-Associated Kinase (JAK)

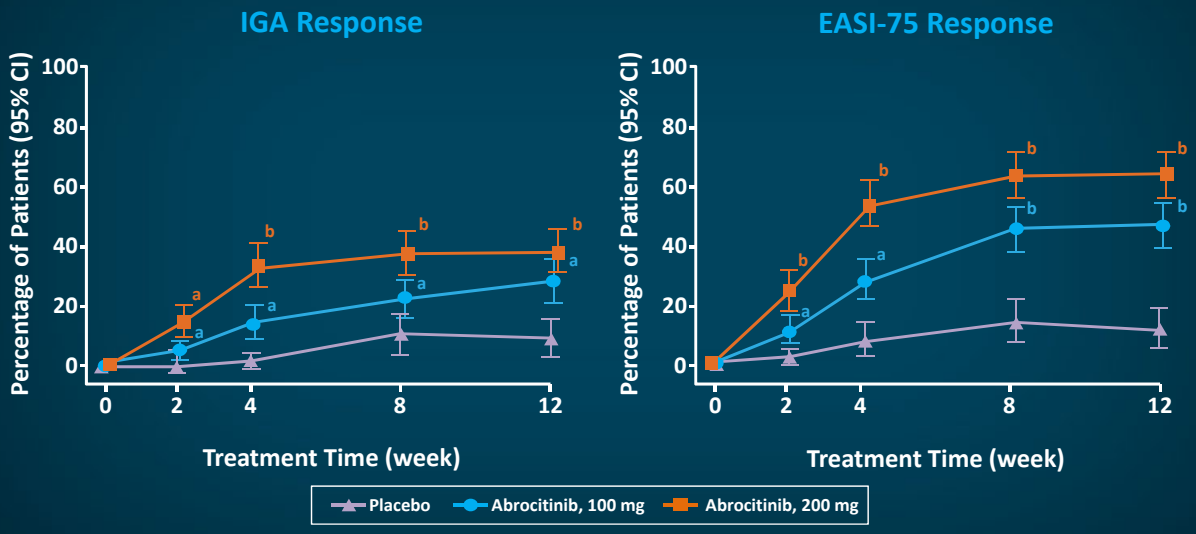
- The JAK-STAT pathway is a conserved master regulator of immunity and myeloproliferation
- JAK inhibitors are used to treat several hematologic and inflammatory diseases
- Small molecules (including JAK inhibitors) show improvement in AD disease scores, patient-reported outcomes, and QoL



STAT = signal transducer and activator of transcription. QoL = quality of life

Cotter DG, et al. *J Am Acad Dermatol*. 2018;78(3 suppl 1):S53-S62. Mobasher P, et al. *J Dermatolog Treat*. 2019;30:550-557. Paller AS, et al. *J Allergy Clin Immunol*. 2017;140:633-643.

Abrocitinib

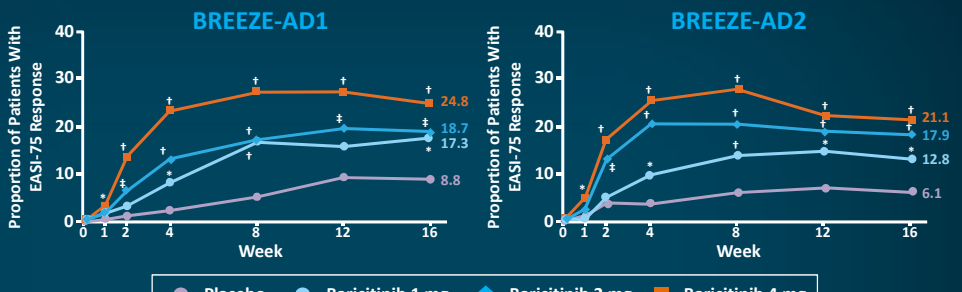


[a]*P*<.05; [b]*P*<.001 vs placebo.

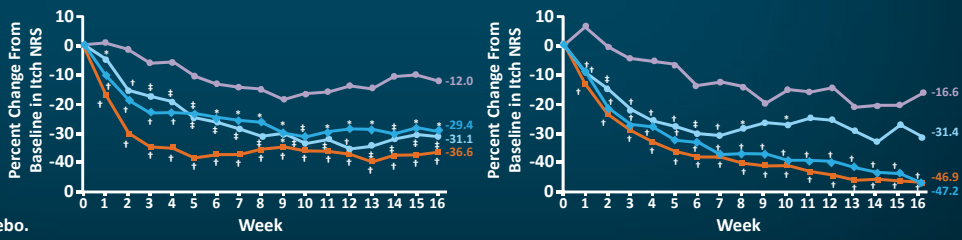
Silverberg JI, et al. *JAMA Dermatol*. 2020;156:863-873.

Baricitinib: BREEZE-AD1/AD2

EASI-75 Response



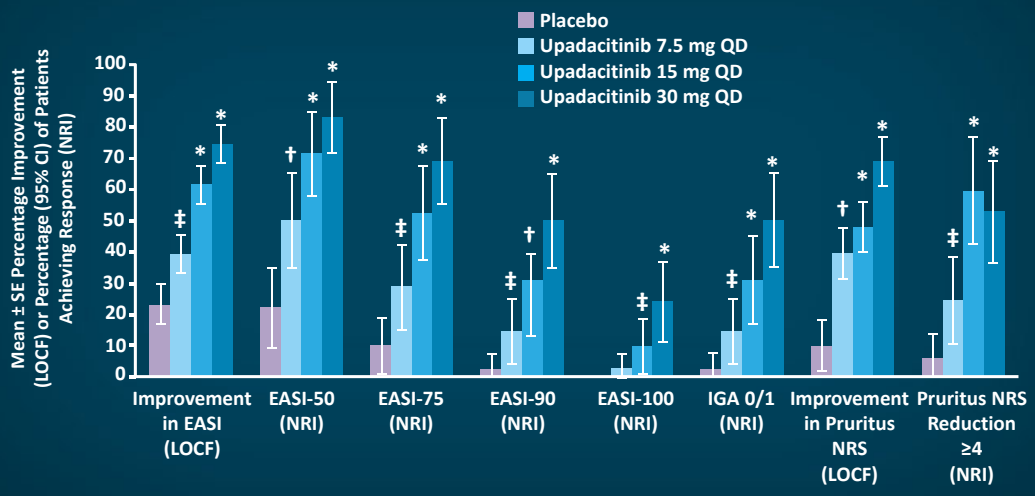
% Change From Baseline: Itch NRS



*P≤ .05; †P≤ .001; ‡P≤ .01 vs placebo.

Simpson EL, et al. *Br J Dermatol*. 2020;183:242-255.

Upadacitinib: Outcomes at Week 16 in Adults



*$P \leq .001$; †$P \leq .01$; ‡$P \leq .05$ for upadacitinib vs placebo.

LOCF = last observation carried forward; NRI = nonresponder imputation; QD = daily; SE = standard error.

Guttman-Yassky E, et al. *J Allergy Clin Immunol*. 2020;145:877-884.

JAK Inhibitors: Key Adverse Events

≥3% (any dose) and >Placebo

- **Abrocitinib**[1]
  - Nausea, nasopharyngitis, headache, URTI, dermatitis atopic, acne, vomiting, upper abdominal pain, elevated CPK, folliculitis, thrombocytopenia
- **Baricitinib**[2]
  - Nasopharyngitis, headache, diarrhea, herpes simplex, URTI, influenza, oral herpes, UTI, folliculitis
- **Upadacitinib**[3]
  - URTI, AD worsening, acne, headache, nasopharyngitis, elevated CPK, nausea, diarrhea, influenza, oropharyngeal pain
- Serious AE's were rare, similar to placebo, and usually unrelated to treatment

URTI = upper respiratory tract infection; CPK = creatinine phosphokinase; UTI = urinary tract infection

1. Silverberg J, et al. *JAMA Dermatol*. 2020;156(8):873. 2. Bieber T, et al. JEADV. 2021;35:476-85. 3. Guttman-Yassky E, et al. *J Allergy Clin Immunol*. 2020;145:877-884.

JAK Inhibitors: Topical

- **Delgocitinib**
  - Dose ranging (0.25-3% ointment) twice daily vs vehicle vs tacrolimus 0.1% x 4 weeks
  - All doses > vehicle in EASI (73% vs 12% in 3% group)
  - Tacrolimus = 62% reduction
  - No serious adverse events
- **Ruxolitinub**
  - Phase 2 randomized, dose-ranging, vehicle- and active-controlled study to evaluate safety and efficacy in adult patients
    - 1.5% twice daily group > vehicle in EASI (71.6% improvement at 4 weeks) and noninferior to triamcinolone cream 0.1%
  - Phase 1 study in children ages 2-7 and two phase 3 studies in patients ≥12 (TruE-AD1 and TruE-AD2) are underway

Nakagawa H, et al. *Br J Dermatol*. 2018;178(2):428-432. Bissonnette R. *Br J Dermatol*. 2018;178(2):321.

Atopic Dermatitis: Adherence

- Lack of adherence can result in poor disease control, worse clinical outcomes, and lack of medication efficacy.
- Studies show worse clinical outcomes in patients with severe disease.
- Poor adherence may be misconstrued as a poor treatment response.
- Medication cost and side effects (“steroid-phobia”) are listed as most important reasons for nonadherence in certain populations.
- Poor compliance can also result from:
  - Time constraints
  - Unclear or difficult-to-follow instructions
  - Alternative health beliefs
- Majority of studies on adherence in AD have focused on pediatric population and parental or caregiver's experience in AD.
- Limited information is available on the issues of nonadherence and causes for nonadherence in adults with AD.

Bass AM et al. *J Clin Med.* 2015;4:231-242. Snyder A et al. *Cutis.* 2015;96:397-401. Ellis RM et al. *Pediatr Dermatol.* 2011;28:242-244. Smith SD et al. *Med J Aust.* 2013;199:467-469.

Atopic Dermatitis: Strategies for Improving Adherence

- Frequent follow-up appointments
- Educational patient workshops
- Written eczema actions plans
- Electronic reminders (eg, email, text messages) can also improve medication adherence and self-care behaviors leading to improved clinical outcomes.

Bass AM et al. *J Clin Med.* 2015;4:231-242. Shi VY et al. *JAMA Dermatol.* 2013;149:481-483. Pena-Robichaux V et al. *Dermatol Res Pract.* 2010;2010.

Role of the Pharmacist

- Access to medications
  - Facilitate PAs or patient-assistance programs when applicable
  - Specialty vs community home for meds?
- Assess economic impact of medications
  - Can patient afford copay? Does this affect adherence
- Counsel on OTC and herbals
  - Use of OTC topical products and antihistamines is high
  - Other topical product selection
- Assess safety: ADRs of systemic medications and DDIs
- Counsel to avoid "steroid phobia"

OTC = over-the-counter; ADR = adverse drug reaction; DDI = drug/drug interaction.

Thandar Y et al. *Br J Dermatol.* 2017;176:330-343.

Pharmacists and Education

- Patient and family education
  - Chronic nature of disease, exacerbating factors, and efficacy and safety of treatments
  - Demonstrate skin care techniques
  - Provide written treatment plan
  - Refer to other healthcare providers as needed
  - Advise patients of support organizations

- Patient and family quality of life is often impaired.
  - Additional treatment may be needed for itching, behavioral disorders, and sleep disturbances.

Schneider L et al. *J Allergy Clin Immunol*. 2013;131:295-299.e.1-27.

Team-Based Approach

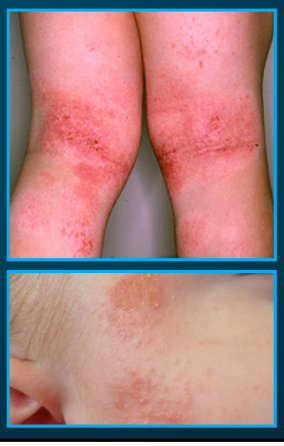
- Incorporating primary care providers, allergy/immunology physicians, and pulmonologists can improve and streamline care for patients with severe disease.
- Pharmacists, nurses, and dietitians can provide support and patient education.
  - They can also facilitate frequent check-ins with patients to improve adherence to the treatment regimen.

Case Study

Peter A. Lio, MD
Clinical Assistant Professor, Dermatology and Pediatrics
Northwestern University Feinberg School of Medicine
Medical Dermatology Associates of Chicago
Chicago, IL

Case Study

A 3-year-old child comes to your clinic after several months of experiencing an itchy rash on the neck, face, upper back, antecubital fossae, upper and lower legs with predilection for popliteal fossae. Treatments tried so far include essential oils without improvement.



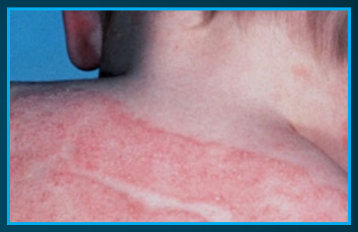
The next best step in treatment would be:

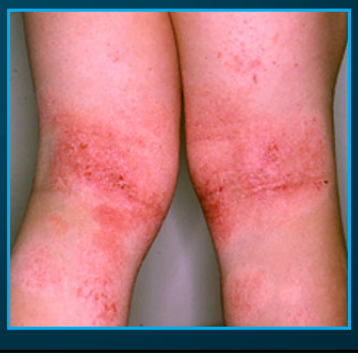
A) Emollient barrier cream
B) Topical therapy, emollient, and gentle skin care
C) Oral corticosteroids
D) Systemic therapy
E) Referral for allergy testing

Photos: National Eczema Association

Atopic Dermatitis

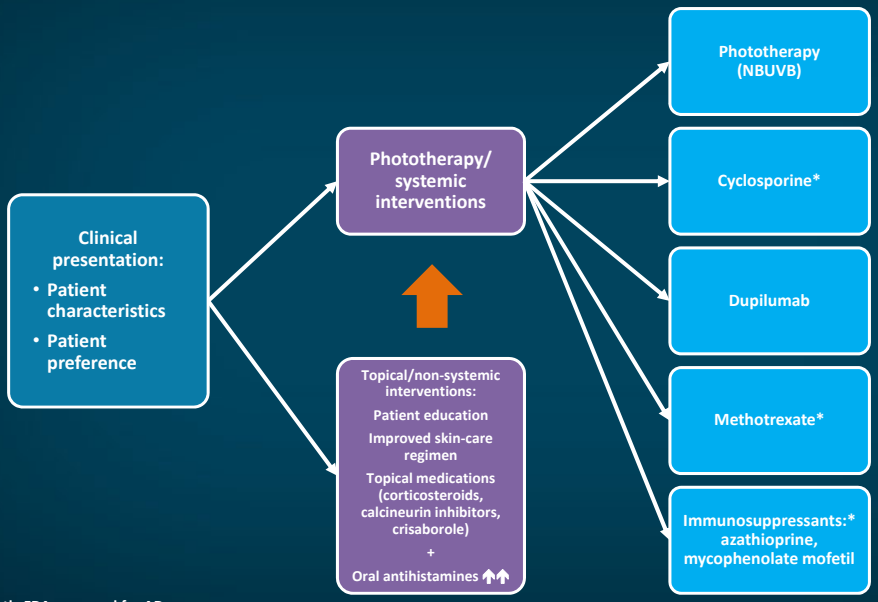
- Gentle skin care—avoid irritants (fragrance, etc)
- Emollient to replace defective barrier—twice daily
- Topical therapy: TCSs, topical calcineurin inhibitors, etc.
- ± Bleach baths, topical antibiotics
- Oral corticosteroids can lead to AD flares upon treatment withdrawal





Photos: National Eczema Association

Management and Treatment Decisions



*Not currently FDA approved for AD

Conclusions

- AD is a chronic disease with a significant impact on QoL
- A **pro**active approach is more effective than **re**active treatment
- Proactive treatment is stepwise and based on severity
- Management can be ***difficult*** and potentially complicated by conflicting messages from different care-team members (clinicians and family)
- **Adherence** is **key** to successful therapy
- Evolving biomarkers and targeted treatments promise to revolutionize treatment

Thank You!

Using Managed Care to Minimize the Burden of Moderate-to-Severe Atopic Dermatitis in Pediatric and Adult Patients

YOUTUBE VIRTUAL ANIMATIONS

ATOPIC DERMATITIS PATIENT FACTORS: https://youtu.be/dq_LngHSPFI

ATOPIC DERMATITIS PATHOLOGY: https://youtu.be/X6w3OZEIMLA

Use your device's QR code scanner to view this 360° content in the **YOUTUBE APP!**

Using Managed Care to Minimize the Burden of Moderate-to-Severe Atopic Dermatitis in Pediatric and Adult Patients

Please visit the **Atopic Dermatitis Thrive Initiative**, which includes online CME offerings for clinicians and patients, toolkits, and a calendar of upcoming educational activities.

Build your own complimentary poster for the office!

Supplement your course learning. It's fast and easy.

We'll ship it to you directly free of charge

Using Managed Care to Minimize the Burden of Moderate-to-Severe Atopic Dermatitis in Pediatric and Adult Patients

For more information and additional resources please visit

https://atopicdermatitis.posterprogram.com

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