The Future is Clear: Treatment Options for Atopic Dermatitis and the Role of Specialty Pharmacy in Dermatology

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Disclosure Statement

- Alexis Mod, PharmD has no relevant financial relationship(s) with ineligible companies to disclose.
 and
- None of the planners for this activity have relevant financial relationships with ineligible companies to disclose.

Learning Objectives

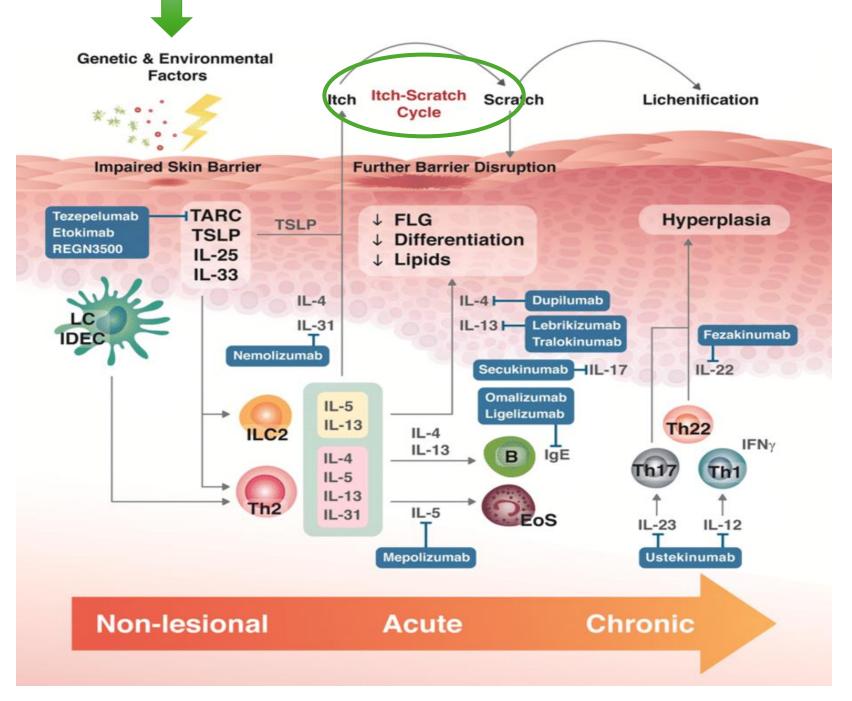
At the completion of this activity, the participant will be able to:

- 1. Discuss the background and disease burden of atopic dermatitis
- 2. Review the American Academy of Dermatology 2023 guidelines for the treatment of atopic dermatitis and apply these guidelines to a patient case
- 3. Evaluate the efficacy and safety study outcomes of recently approved therapies and provide key counseling points
- 4. Describe the role of specialty pharmacy and specialty pharmacist in the outpatient dermatology setting

Atopic Dermatitis (AD)

- Chronic, pruritic inflammatory skin disease
- Occurs most frequently in children, but also affects many adults

Risk Factors	Triggers
 Family history of atopy IgE reactivity Genetic mutations FLG gene African American Urban living 	 Irritants (detergents, soaps, fragrances, cosmetics) Extreme temperatures Environmental allergens (dust mites, pollen, mold) Water hardness Food allergens Clothing (wool, polyester) Emotional stress Skin infections



Clinical Manifestations and Diagnosis

- Essential Features
 - Pruritus
 - Eczema
- Important Features
 - Early age of onset
 - Atopy (personal/family history)
 - Xerosis







Disease Burden

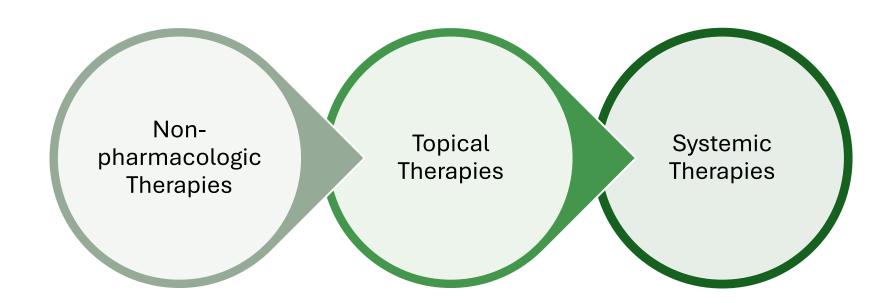
- Associated comorbidities
 - Allergic conditions
 - Immunemediated conditions
 - Mental health and substance use
 - Cardiovascular/ metabolic diseases
 - Bone health
 - Skin infections



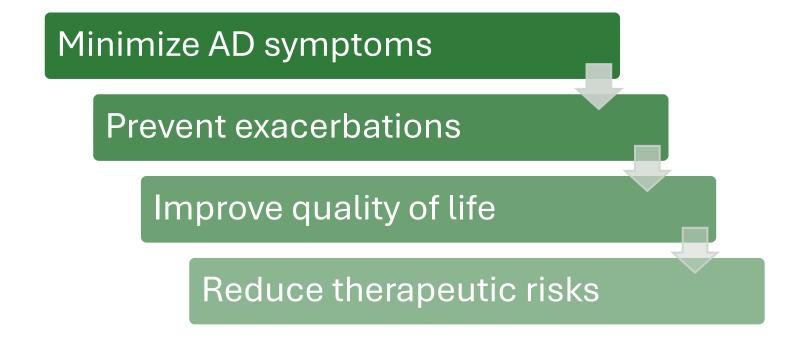


Total annual cost of \$5.3 billion in 2015

American Academy of Dermatology (AAD) 2023 Guidelines in Adults



Goals of Therapy



Outcome Measures in Clinical Practice

- Body surface area (BSA)
- Physician's Global Assessment (PGA) Scale
- Pruritus Numerical Rating Scale (NRS)

Score	Morphological Description No inflammatory signs of atopic dermatitis (no erythema, no induration/papulation, no lichenification, no oozing/crusting). Post-inflammatory hyperpigmentation and/or hypopigmentation may be present.			
0 – Clear				
1 – Almost clear	Barely perceptible erythema, barely perceptible induration/papulation, and/or minimal lichenification. No oozing or crusting.			
2 – Mild	Slight but definite erythema (pink), slight but definite induration/papulation, and/or slight but definite lichenification. No oozing or crusting.			
3 – Moderate Clearly perceptible erythema (dull red), clearly perceptible induration/papul clearly perceptible lichenification. Oozing and crusting may be present.				
4 – Severe	Marked erythema (deep or bright red), marked induration/papulation, and/or marked lichenification. Disease is widespread in extent. Oozing or crusting may be present.			

1.) On scale from 0 (no itch) to 10 (worst imaginable itch)			
how was your itch, on average, within the past 24 hours? Ple	ase select one number.		
0 1 2 3 4 5 6 7	8 9 10		
how was your worst itch in the past 24 hours? Please select of	ane number		
now was your worst nen in the past 24 nours. Flease select o	ne number.		
0 1 2 3 4 5 6 7	8 9 10		

Validity of Outcomes Measures. CADTH. 2018.

Outcome Measures in Clinical Trials

- Investigator's Global Assessment (IGA) Scale
- Eczema Area and Severity Index (EASI) Scale

Eczema Area and Severity Index (EASI)

- Body regions
 - Head/neck
 - Upper limbs
 - Trunk
- Lower limbs
- Scoring of areas of Involvement in each anatomical region (Area)

0	. 1	2	3	4	5	6
No eruption	<10%	10%-29%	30-49%	50-69%	70-89%	90-100%

Calculation of Intensity

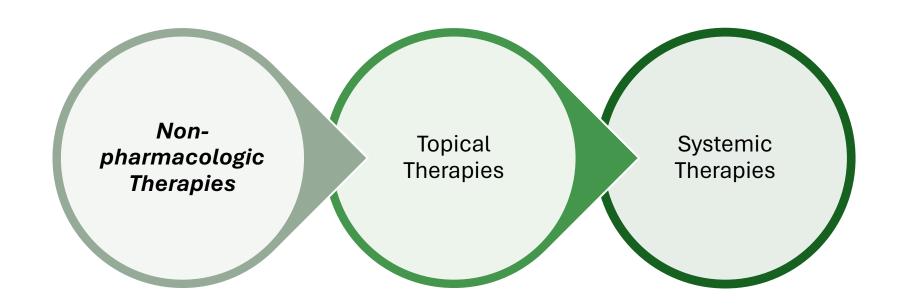
Criteria	0	1	2	3
Erythema (E)	None	Faintly detectable erythema, very light pink	Dull red, clearly distinguishable	Deep, dark red
Infiltration/Papulation (I)	None	Barely perceptible elevation	Clearly perceptible elevation	Extensive elevation
Excoriation (Ex)	None	Scant evidence of excoriation No erosion or crust	Several linear mark, some erosion or crust	Many erosive and/or crusty lesions
Lichenification (L)	None	Light thickening of skin discernable only by touch	Definite thickening of skin with exaggerated markings and markings and visible criss-cross pattern	Thickened Indurated skin and visible exaggerated criss-cross pattern

Calculations

(E+I+Ex+L) x Area x 0.1	(In children 0-7 years (E+ I + Ex + L) \times Area \times 0.2)	
(E+I+Ex+L) x Area x 0.2		
(E+I+Ex+L) x Area x 0.3		
(E+I+Ex+L) x Area x 0.4	(In children 0-7 years (E+ 1 + Ex + L) x Area x 0.3)	
Sum of the above four body	areas	Total score =
	(E+I+Ex+L) x Area x 0.2 (E+I+Ex+L) x Area x 0.3 (E+I+Ex+L) x Area x 0.4	(E+I+Ex+L) x Area x 0.2

Validity of Outcomes Measures. CADTH. 2018.

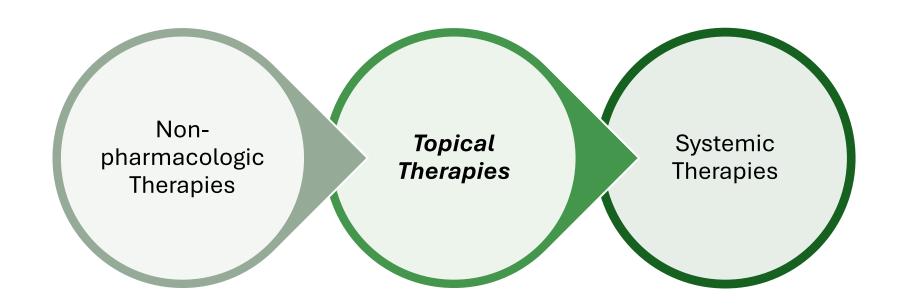
American Academy of Dermatology (AAD) 2023 Guidelines in Adults



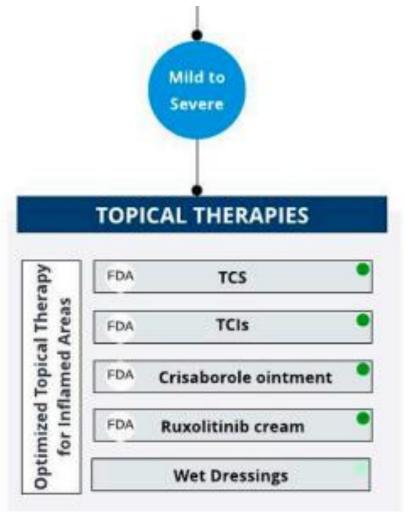
Non-pharmacologic Therapies and Lifestyle Changes

- Maintain skin hydration
- Bathing
- Avoid triggers
- Limit emotional stress
- Avoid scratching
- Basic wound care to limit skin infections

American Academy of Dermatology 2023 Guidelines in Adults



Guideline Recommendations: Topical Therapies



Recommend AGAINST: topical antimicrobials, antihistamines and antiseptics

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Topical Corticosteroids (TCS)

- Recommended for all disease severities
 - Intermittent use of medium potency TCS as maintenance therapy (2 times/week)
- Greater caution on thin skin sites and compromised skin barrier
- Low incidence of AE
 - Cutaneous most common (stretch marks, hair loss, acne, skin atrophy)
- "Steroid phobia"

Table IV. Relative potencies of topical corticosteroids

Class	Drug	Dosage form(s)	Strength (%)
I. Very high potency	Augmented betamethasone	Ointment	0.05
, , , ,	dipropionate		
	Clobetasol propionate	Cream, foam, and ointment	0.05
	Diflorasone diacetate	Ointment	0.05
	Halobetasol propionate	Cream, ointment	0.05
II. High potency	Amcinonide	Cream, lotion, and ointment	0.1
	Augmented betamethasone dipropionate	Cream	0.05
	Betamethasone dipropionate	Cream, foam, ointment, and solution	0.05
	Desoximetasone	Cream, ointment	0.25
	Desoximetasone	Gel	0.05
	Diflorasone diacetate	Cream	0.05
	Fluocinonide	Cream, gel, ointment, and solution	0.05
	Halcinonide	Cream ointment	0.1
	Mometasone furoate	Ointment	0.1
	Triamcinolone acetonide	Cream, ointment	0.5
III-IV. Medium potency	Betamethasone valerate	Cream, foam, lotion, and ointment	0.1
	Clocortolone pivalate	Cream	0.1
	Desoximetasone	Cream	0.05
	Fluocinolone acetonide	Cream, ointment	0.025
	Flurandrenolide	Cream, ointment	0.05
	Fluticasone propionate	Cream	0.05
	Fluticasone propionate	Ointment	0.005
	Mometasone furoate	Cream	0.1
	Triamcinolone acetonide	Cream, ointment	0.1
V. Lower-medium potency	Hydrocortisone butyrate	Cream, ointment, and solution	0.1
	Hydrocortisone probutate	Cream	0.1
	Hydrocortisone valerate	Cream, ointment	0.2
	Prednicarbate	Cream	0.1
VI. Low potency	Alclometasone dipropionate	Cream, ointment	0.05
	Desonide	Cream, gel, foam, and ointment	0.05
	Fluocinolone acetonide	Cream, solution	0.01
VII. Lowest potency	Dexamethasone	Cream	0.1
	Hydrocortisone	Cream, lotion, ointment, and solution	0.25, 0.5, 1
	Hydrocortisone acetate	Cream, ointment	0.5-1

natol 2023 https://doi.org/10.1.20

Topical Calcineurin Inhibitors (TCI)

- Twice daily dosing
- Tacrolimus
 - Recommended for all disease severities
 - **0.03**% **ointment:** ≥ 2 y.o.
 - **0.1% ointment:** ≥ 16 y.o.
 - Tacrolimus may cause more initial local irritation than pimecrolimus
- Pimecrolimus
 - Recommended for mild-moderate AD
 - 1% cream: ≥ 2 y.o.
- BBW: rare cases of malignancy (skin cancer, lymphoma)
- No routine laboratory monitoring required

Box 1. Clinical situations in which topical calcineurin inhibitors may be preferable to topical steroids

Recalcitrance to steroids
Sensitive areas (eg, face, anogenital, skin folds)
Steroid-induced atrophy
Long-term uninterrupted topical steroid use

Crisaborole (Eucrisa™)

- Phosphodiesterase 4 (PDE4) inhibitor
- FDA Approval:
 - Mild-moderate AD in adults and children ≥ 2 years old: December 2016
 - Extended indication to infants ≥ 3 months old: March 2020
- Twice daily dosing
- Adverse Reactions: application site pain, urticaria





Ruxolitinib (Opzelura™)

- Janus kinase (JAK) inhibitor
- FDA Approval:
 - Mild-moderate AD in adults and patients ≥12 years of age: September 2021
- Twice daily until signs/symptoms resolve
 - Max 20% BSA, 60 g per week or 100 g per 2 weeks
- Warnings/Precautions: hematologic toxicity, lipid abnormalities, malignancies, cardiovascular events and thrombosis
- Adverse Reactions:
 - Application site reactions: pruritus, erythema, acne
 - Headache, nasopharyngitis, urinary tract infection

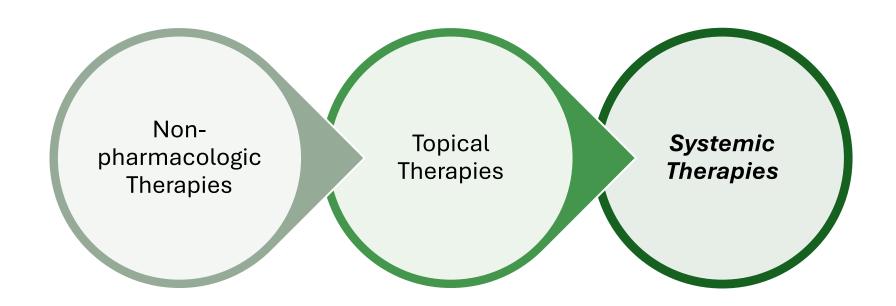


Pricing (AWP):

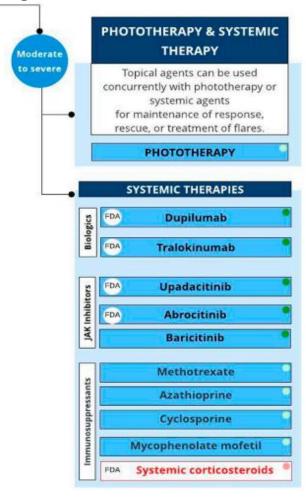
1.5% (per gram): \$40.90

• Package size: 60 g (cream)

American Academy of Dermatology (AAD) 2023 Guidelines in Adults



Guideline Recommendations: Systemic Therapies



- Immunosuppressants
 - Not considered first-line treatments
 - Lower evidence, serious adverse effects, lab monitoring, off-label use
 - Systemic corticosteroids
 - May be considered if no other options available or bridge to other long-term therapies

21 Davis DMR. et al. J Am Acad Dermatol, 2024 Feb;90(2):43-56.

Phototherapy

- Narrowband UVB most commonly used
- In office or at home
 - Accessibility and cost concerns
- AE: sunburn-like reactions, risk of skin cancer (PUVA)

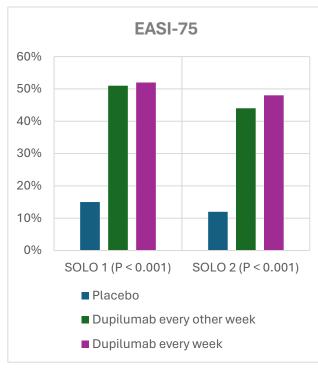




- Mechanism of Action:
 - Human monoclonal antibody specifically targets IL-4Ra
- FDA Approval:
 - Moderate-severe AD:
 - Adults (≥ 18 y.o.): March 2017
 - Adolescents (12 to 17 y.o.): March 2019
 - Children (6 to 11 y.o.): May 2020
 - Infants and children (6 months to 5 y.o.): June 2022
- Favored as first-line systemic agent
- SOLO1 and SOLO2:
 - Two identically designed phase III, placebo-controlled (1:1:1), double-blind studies
 - Primary Endpoint at week 16:
 - IGA success
 - Secondary Endpoints at week 16:
 - EASI-75

SOLO1 and SOLO2







Simpson EL, at el. N Engl J Med. 2016.

Labeled Indications:

 Atopic dermatitis, asthma, rhinosinusitis with nasal polyposis, eosinophilic esophagitis, prurigo nodularis

Administration:

Subcutaneous injection

Warnings/Precautions:

- Hypersensitivity
- Conjunctivitis and keratitis
- Arthralgia
- Parasitic infections

Adverse Effects:

- Injection site reaction, antibody development
- No routine lab monitoring needed
- Avoid live vaccines

Adult Dosing: ≥ 18 years

Initial: 600 mg (2 x 300 mg SC injections)

Maintenance: 300 mg SC once every other

week

Pediatric Dosing: Children ≥ 6 years and Adolescents ≤ 17 years

15 to < 30 kg:	Initial: 600 mg once (2 x 300 mg SC injections) Maintenance: 300 mg every 4 weeks
30 to < 60 kg:	Initial: 400 mg once (2 x 200 mg injections) Maintenance: 200 mg every other week
> 60 kg:	Initial: 600 mg once (2 x 300 mg injections) Maintenance: 300 mg every other week
_	30 kg: 30 to < 60 kg:

Pediatric Dosing: Infants ≥ 6 months and Children < 6 years

5 to < 15 kg: 200 mg every 4 weeks

15 to < 30 kg: 300 mg every 4 weeks

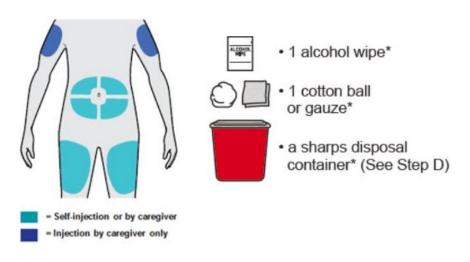
Remove from Refrigerator:

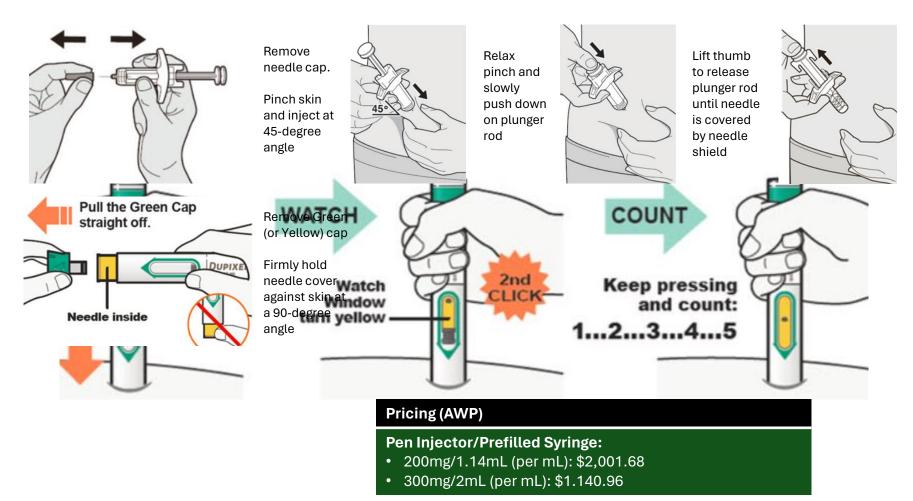
- Allow to warm to room temperature
 - 30 minutes prior to injection (200 mg)
 - 45 minutes prior to injection (300 mg)
- Max 14 days at room temperature

Preferred Injection Sites:

- Thigh
- Stomach
- Outer area of upper arm (caregivers only)



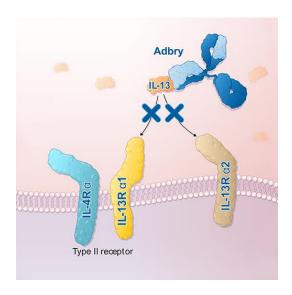




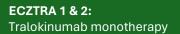
Dupixent.. Sanofi and Regeneron Pharmaceuticals. 2021.

Tralokinumab (Adbry™)

- Mechanism of Action:
 - Human IgG4 monoclonal antibody binds to IL-13
- FDA Approval:
 - Moderate-severe AD
 - Adults (≥ 18 y.o.): December 28, 2021
- ECZTRA 1, 2, and 3:
 - Randomized, double-blind, placebo-controlled phase III trials
 - Co-primary Endpoints at week 16:
 - IGA success
 - EASI-75
 - Secondary Endpoint at week 16:
 - Itch NRS

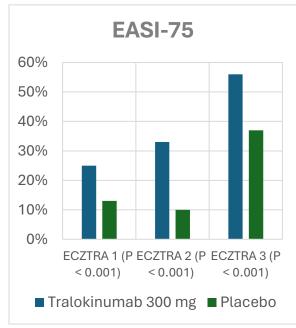


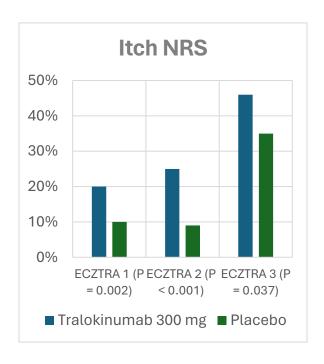
ECZTRA 1, 2 & 3



ECZTRA 3: Tralokinumab + TCS







Tralokinumab (Adbry™)

Dosing/Administration:

- Initial 600 mg SC on Day 0, then 300 mg SC every other week
 - Allow to warm to room temperature 30 minutes prior to injection
 - Max 14 days at room temperature

Warnings/Precautions:

- Hypersensitivity
- Conjunctivitis & keratitis
- Parasitic infection

Adverse Effects:

- Upper respiratory tract infection, conjunctivitis, injection site reaction
- No routine lab monitoring needed
- Avoid live vaccines
- · Limited distribution drug



Pricing (AWP)

Prefilled Syringe:

• 150 mg/mL (per mL): \$1,151.71

Upadacitinib (Rinvoq™)

FDA Approval:

- Refractory, moderate-severe AD
 - Adults and adolescents (≥12 y.o. weighing ≥40kg): January 14, 2022

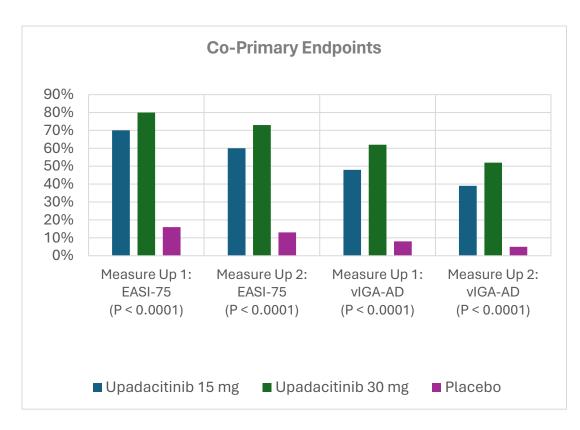
Measure Up 1 & Measure Up 2:

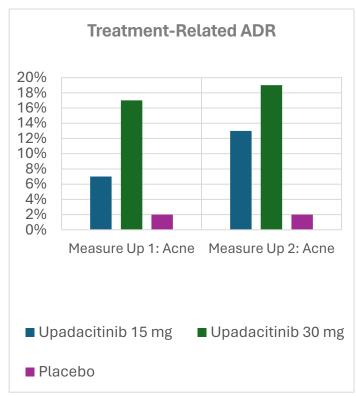
- Replicate phase III, multicenter, randomized (1:1:1), double-blind, placebocontrolled trials
- Co-primary Endpoints at week 16:
 - EASI-75
 - vIGA-AD success

Heads Up:

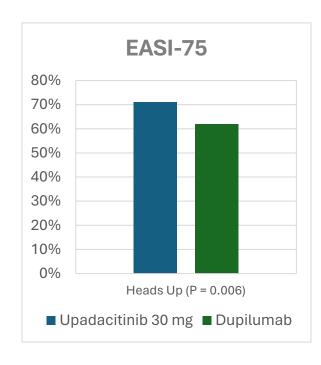
- Head-to-head, phase IIIb, multicenter, randomized (1:1), double-blind, doubledummy, active-controlled trial
- Primary Endpoint at week 16:
 - EASI-75
- Key Secondary Endpoint at week 16:
 - EASI-100

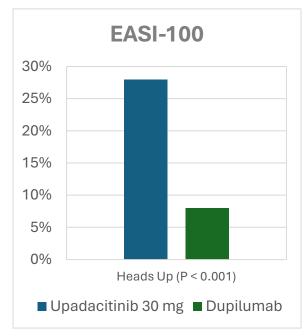
Measure Up 1 & Measure Up 2

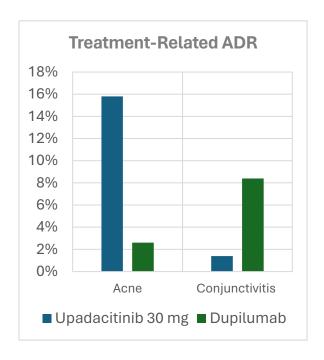




Heads Up







Upadacitinib (Rinvoq™)

Labeled Indications:

- Atopic dermatitis, psoriatic arthritis, rheumatoid arthritis, ankylosing spondylitis, ulcerative colitis
- Dosing/Administration: 15 mg or 30 mg once daily
- Metabolism: Substrate of CYP2D6 (minor), CYP3A4 (major)
- U.S. Boxed Warnings:
 - Serious infections
 - Malignancies
 - Mortality, thrombosis, and major adverse cardiovascular effects

Warnings:

 Hypersensitivity, GI perforations, laboratory abnormalities, embryo-fetal toxicity

Adverse Effects:

Upper respiratory tract infections, headache, acne vulgaris

Lab monitoring

- CBC w/ diff, LFTs, lipids, viral hepatitis, TB, pregnancy status
- Avoid live vaccines



Pricing (AWP)

15 mg and 30 mg (per tablet): \$257.25

Abrocitinib (Cibinqo™)

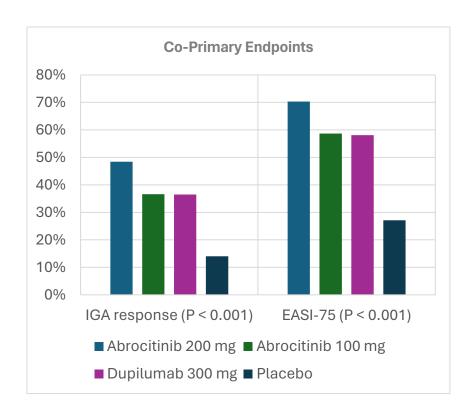
FDA Approval:

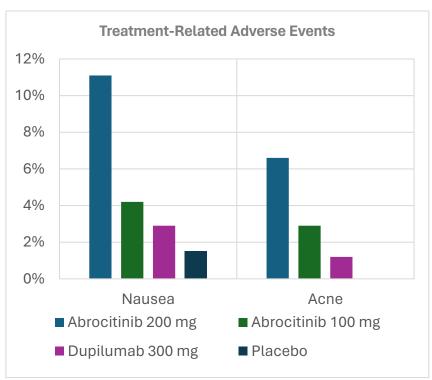
- Refractory, moderate-severe AD
 - Adults (≥ 18 y.o.): January 14, 2022

JADE COMPARE:

- A phase III, multicenter, randomized (2:2:2:1), double-blind, placebo-controlled trial
- Co-primary Endpoints at week 12:
 - IGA response
 - EASI-75

JADE COMPARE





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Abrocitinib (Cibinqo™)

- · Labeled Indications: Atopic dermatitis
- Dosing/Administration: 100 mg or 200 mg once daily
 - 50 mg once daily in moderate-severe renal impairment, use with strong CYP2C19 inhibitors, or suspected poor metabolizers of CYP2C19
- Metabolism: Substrate of CYP2C19 and CYP2C9
- Contraindication: Antiplatelet therapies except for lowdose aspirin (≤81 mg daily) during the first 3 months of treatment
- U.S. Boxed Warnings:
 - Serious infections
 - Malignancies
 - Mortality, thrombosis, and major adverse cardiovascular effects
- Warnings: laboratory abnormalities
- Adverse Effects:
 - Nasopharyngitis, nausea, headaches, acne vulgaris
- Lab monitoring
 - CBC w/ diff, LFTs, lipids, viral hepatitis, TB, pregnancy status
- Avoid live vaccines



Pricing (AWP)

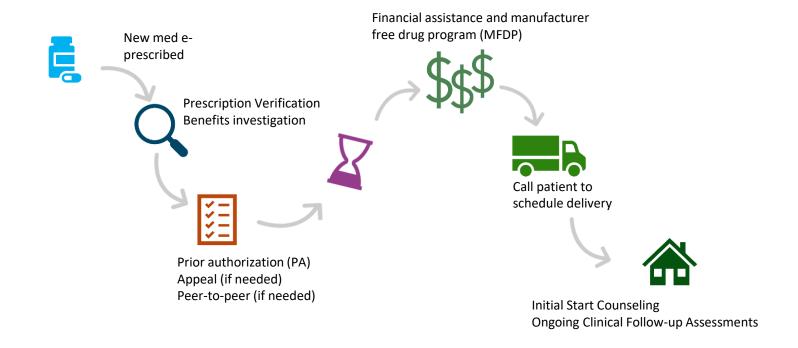
50 mg, 100 mg and 200 mg (per tablet): \$222.69

Baricitinib (Olumiant®)

- Mechanism of Action: Oral JAK 1/2 inhibitor
- U.S. labeled indications: Rheumatoid arthritis (RA), alopecia areata
 - Approved in 40+ countries for moderate-severe AD in adults
 - BREEZE-AD1 & BREEZE-AD2 studies demonstrated safety and efficacy
 - Current Status
 - FDA and manufacturer have not come to agreement on the indicated population (last update 01/2022)

Role of Specialty Pharmacy and Specialty Pharmacist in Dermatology

Specialty Pharmacy Process



Support Services

- Benefits investigation
- Prior authorization submission
- Financial assistance
 - Manufacturer copay cards (commercial insurance)
 - Manufacturer financial assistance programs
 - Bridge programs
 - Free drug programs
 - Internal foundation benefit
- Proactive outreach to schedule medication delivery

Role of Specialty Pharmacist

- Collaborative practice agreement
 - Therapy selection
 - Laboratory monitoring
 - Prescription reroutes/clarifications
- Robust initial education
 - Disease state, dosing, administration, missed doses, storage and disposal, warnings, side effects, reproductive considerations, goals of therapy, efficacy timeline
- Routine reassessment of therapy efficacy and safety
- Appeal or peer-to-peer assistance
- Patient care coordination
 - Scheduling in office injection training
 - Transitions of care
- Drug information resources for providers, clinical staff and patients

Summary

- AD is a chronic, inflammatory condition typically seen in children, but symptoms can persist into adulthood.
- Non-pharmacologic and topical therapies are the mainstay of treatment for all disease severities. However, patient with moderate to severe or refractory AD may require systemic treatment.
- Recently approved systemic therapies greatly expanded the treatment options for moderate-severe atopic dermatitis patients and have been added into the updated AAD guideline recommendations for 2023.
- Specialty pharmacy services are vital in ensuring dermatology patients have access to, are able to afford, and are properly educated on specialty medications when prescribed by their provider.

KH is a 20-year old female who presents to the dermatology clinic for evaluation of dry, itchy, and scaly skin on her face, hands, and legs. She was diagnosed with atopic dermatitis when she was a child, but hasn't had symptoms in several years. She has noticed an increase in her symptoms in the last year since going to college in Minnesota.

PMH	FH	Medications
Allergic rhinitis	Asthma – mother	Loratadine 10mg PO QD
Depression Atopic dermatitis	DM Type II – father	Escitalopram 10 mg PO QD

After her appointment, KH has been diagnosed with moderate atopic dermatitis. She is interested in learning more about lifestyle modifications to help her symptoms. Which of the following would **NOT** be an appropriate non-pharmacologic recommendation for a patient with AD?

- a) Maintaining skin hydration is important for all AD patients
- b) Avoid known triggers as much as possible
- c) Scratching is fine and won't make AD worse
- d)Apply moisturizers soon after bathing

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- b) Avoid known triggers as much as possible
- c) Scratching is fine and won't make AD worse
- d)Apply moisturizers soon after bathing

During her initial appointment, the dermatologist prescribes triamcinolone 0.1% cream and tacrolimus 1% ointment. Which of the following statements are **TRUE** regarding TCS and TCI therapies? (**Select all that apply**)

- a) Both strengths of topical tacrolimus are FDA-approved for patients of all ages
- b) Topical steroids can cause cutaneous side effects
- c) "Steroid phobia" among AD patients is common and can lead to noncompliance
- d)Topical steroids are always preferred over topical calcineurin inhibitors

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KH follow-ups with her dermatologist 3 months after her initial appointment. Despite using topical medications daily and implementing lifestyle modifications, she has only seen mild improvement in her symptoms and she continues to develop new eczema patches. According to the 2023 AAD guidelines for the treatment of atopic dermatitis, which systemic treatment option is considered by many clinicians to be "first-line" for adult patients with AD?

- a) Abrocitinib
- b)Dupilumab
- c) Methotrexate
- d)Upadacitinib

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- a) Abrocitinib
- b)Dupilumab
- c) Methotrexate
- d)Upadacitinib

KH has been prescribed Dupixent[™] and she is scheduled to receive her first delivery from your specialty pharmacy today. You contact her to complete initial fill education. KH notes that she heard about Opzelura[™] (ruxolitinib) from a commercial on TV and wants some more information. Which of the following would **NOT** be an appropriate counseling point for topical ruxolitinib?

- a) Topical ruxolitinib should not be used on more than 20% body surface area
- b) Topical ruxolitinib does not have same BBW as oral JAK inhibitors
- c) Application site reactions are the most common side effects
- d)Topical ruxolitinib is FDA approved for mild-moderate atopic dermatitis

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- a) Topical ruxolitinib should not be used on more than 20% body surface area
- b)Topical ruxolitinib does not have same BBW as oral JAK inhibitors
- c) Application site reactions are the most common side effects
- d)Topical ruxolitinib is recommend in the 2023 AAD guidelines for mild-moderate atopic dermatitis

You are a clinical pharmacist contacting KH to check-in on her Dupixent™ therapy. She has been established on therapy for about 1 year. She has had significant improvement in her atopic dermatitis symptoms on Dupixent™ and is very pleased with her response. She is concerned about what other systemic treatment options are available if she were to lose response to Dupixent™. What would you tell KH?

- a) Oral JAK inhibitors require more routine lab monitoring and have more potential safety concerns than dupilumab
- b) Tralokinumab can be dispensed by any specialty pharmacy
- c)The higher dose of upadacitinib was shown to be superior to dupliumab in a head-to-head trial
- d)All of the above
- e) A and C

You are a clinical pharmacist contacting KH to check-in on her Dupixent[™] therapy. She has been established on therapy for about 1 year. She has had significant improvement in her atopic dermatitis symptoms on Dupixent[™] and is very pleased with her response. She is concerned about what other systemic treatment options are available if she were to lose response to Dupixent[™]. What would you tell KH?

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