# Achieving Appropriate Access for the Treatment of

# Atopic Dermatitis

## MEDICAL AND PHARMACY MANAGEMENT STRATEGIES

FOR MANAGED CARE AND PAYER PROFESSIONALS

Jointly provided by:

National Eczema Association

PIM Postgraduate Institute for Medicine
Professional Excellence in Medical Education

Impact Education LLC

This program is supported by independent educational grants from Incyte Corporation, Pfizer Inc., Sanofi Genzyme and Regeneron Pharmaceuticals, Inc.

# Agenda

| | |
|---|---|
| 6:30 PM | Pre-Activity Learning Assessment and Opening Comments<br>**Michael Zeglinski, RPh** |
| 6:35 PM | Clinical Update on the Evolving AD Treatment Paradigm<br>**Peter Lio, MD** |
| 6:55 PM | Evidenced-based Decision Making in a Cost Conscience Environment<br>**Michael Zeglinski, RPh** |
| 7:15 PM | Medical and Pharmacy Management Strategies to Enhance AD Patient Outcomes (case-based discussion)<br>**Neil Minkoff, MD** |
| 7:35 PM | Faculty Discussion and Audience Q&A Session<br>**Michele Guadalupe, MPH; Peter Lio, MD; Neil Minkoff, MD; Michael Zeglinski, RPh** |
| 7:55 PM | Key Takeaways and Closing Comments; Post-Activity Assessment and Evaluation |
| 8:00 PM | Adjournment |

# Learning Objectives

- Explore the spectrum of clinical, economic, and humanistic burden of AD
- Review clinical data from recently approved and emerging AD therapies
- Evaluate benefit design strategies that can contribute to appropriate access and utilization, while simultaneously managing costs and improving treatment outcomes
- Assess the benefits of multidisciplinary care in AD patients

# *Clinical Update on the Evolving AD Treatment Paradigm*

**Peter Lio, MD**

Clinical Assistant Professor of Dermatology and Pediatrics

Northwestern University Feinberg School of Medicine

Founding Director

Chicago Integrative Eczema Center

# Learning Objectives

- Explore the spectrum of clinical and humanistic burden of atopic dermatitis (AD)
- Review clinical data from recently approved and emerging AD therapies

# Prevalence and Burden of AD

## Prevalence

- 9.6 million children
  - 33% with moderate-to-severe disease
- 16.5 million adults
  - 40% with moderate-to-severe disease

## Presentation & Symptoms

- Rash
- Severe pruritus
- Pain
- Sleep disturbance

## Comorbidities

- Atopic
- Non-Atopic

## Quality of Life

- Anxiety
- Depression
- Other mental health disorders
- Poor QoL
- Impaired social activity
- Decreased professional productivity

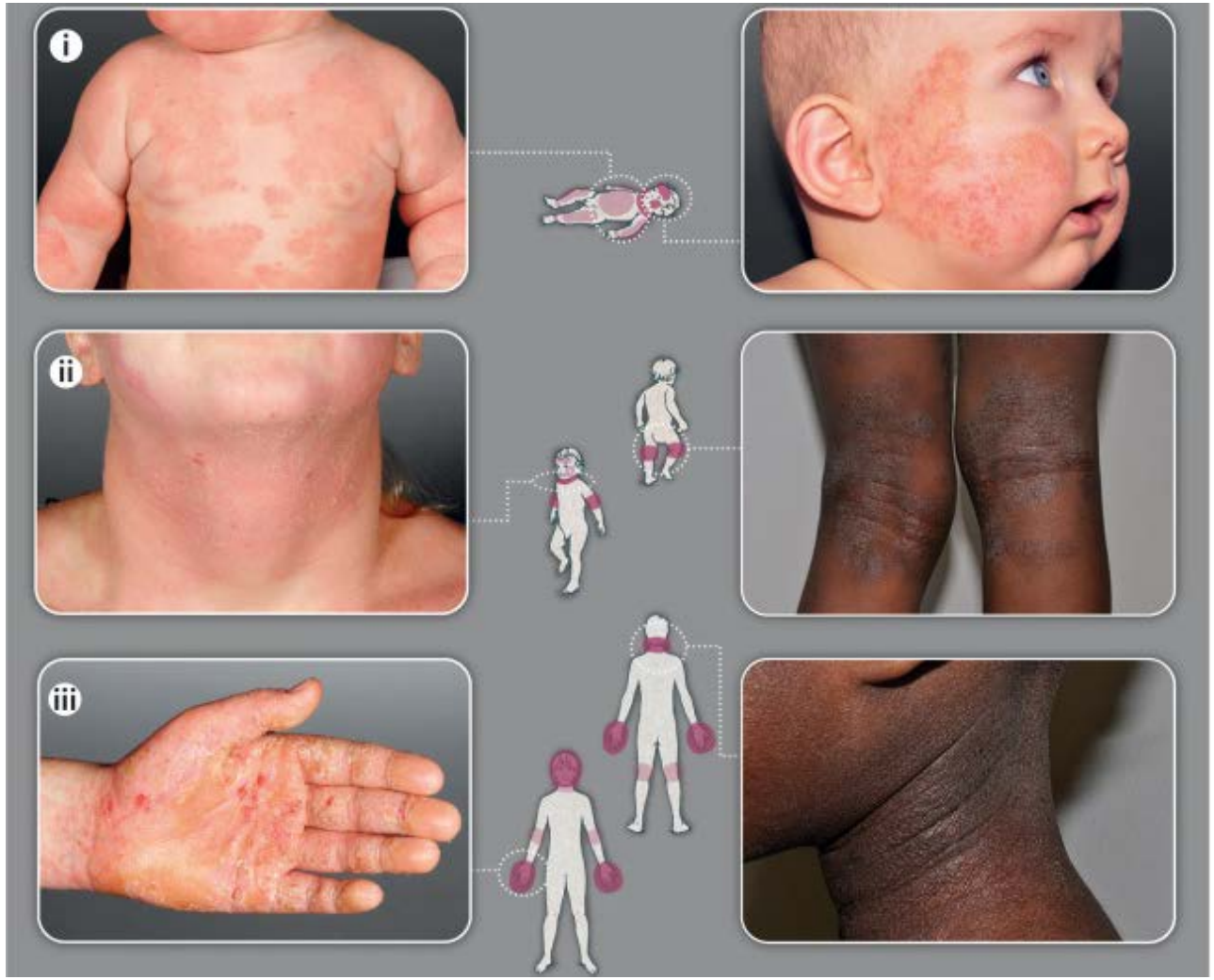
Simpson E, et al. *EMJ*. 2019;4:14-23; Eczema Stats. National Eczema Association. https://nationaleczema.org/research/eczema-facts. Accessed February 2022; Silverberg JI, Simpson EL. *Dermatitis*. 2014;25:107-114; Chiesa Fuxench ZC, et al. *J Invest Dermatol*. 2019;139:583-590.

# AD Shows an Age-Related Distribution in Infants, Children, and Adults

**Infants (age ~0-24 months)**
- Lesions typically involve the face, cheeks, and trunk

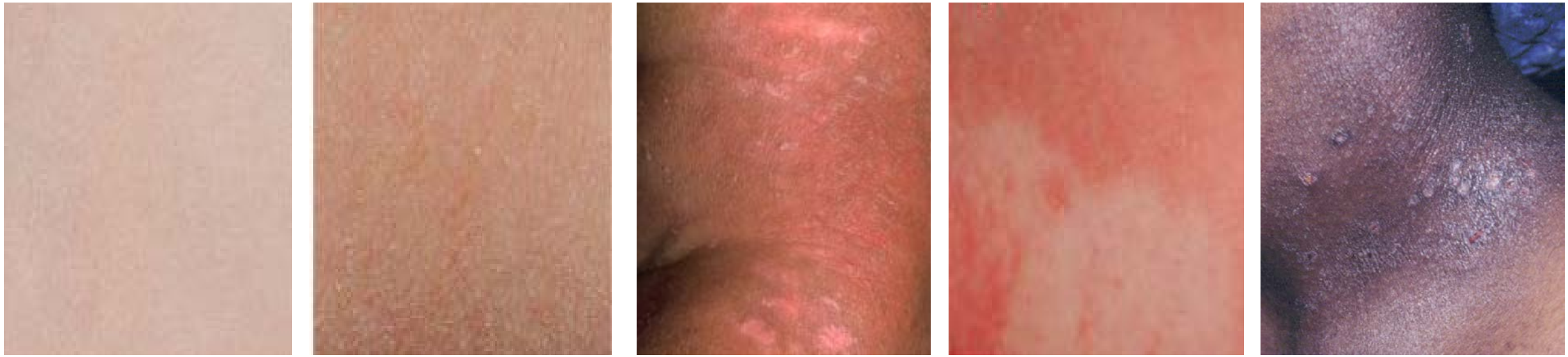
**Children (age ~2-16 years)**
- Lesions typically involve hands, eyelids, and flexures

**Adults (age ~16+ years)**
- Lesions typically involve the hands, upper trunk, shoulders, and scalp



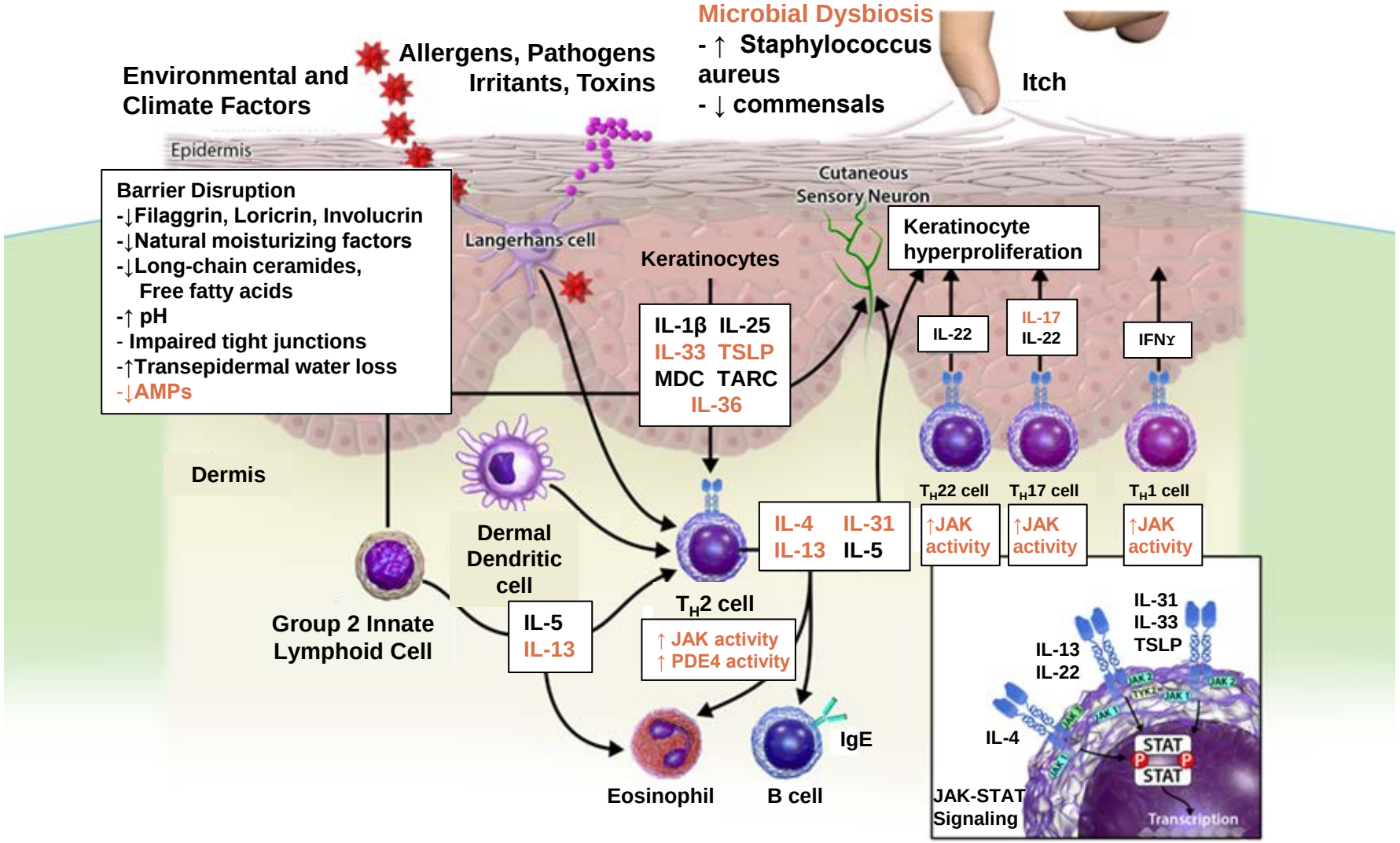

Langan SM, et al. *Lancet* 2020;396:345–360.

# AD is a Clinically Heterogenous Disease



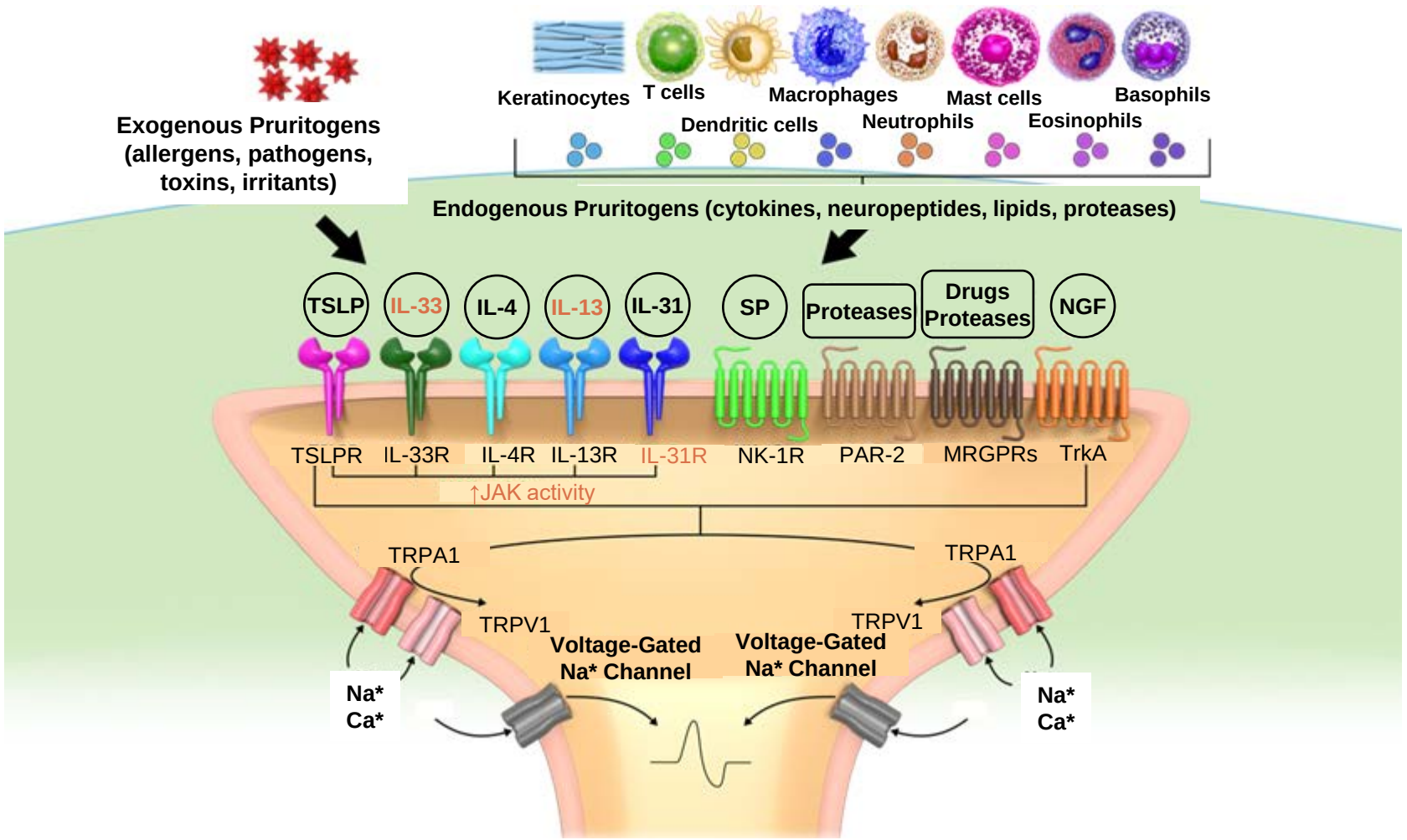

Weidinger S, Novak N. *Lancet*. 2016;387:1109-1122.

# Multiple Cytokines are Involved in the Immunopathology of AD




Puar N, et al. *Ann Allergy Asthma Immunol*. 2021;126:21-31.

# Cutaneous Itch is Highly Prevalent in AD

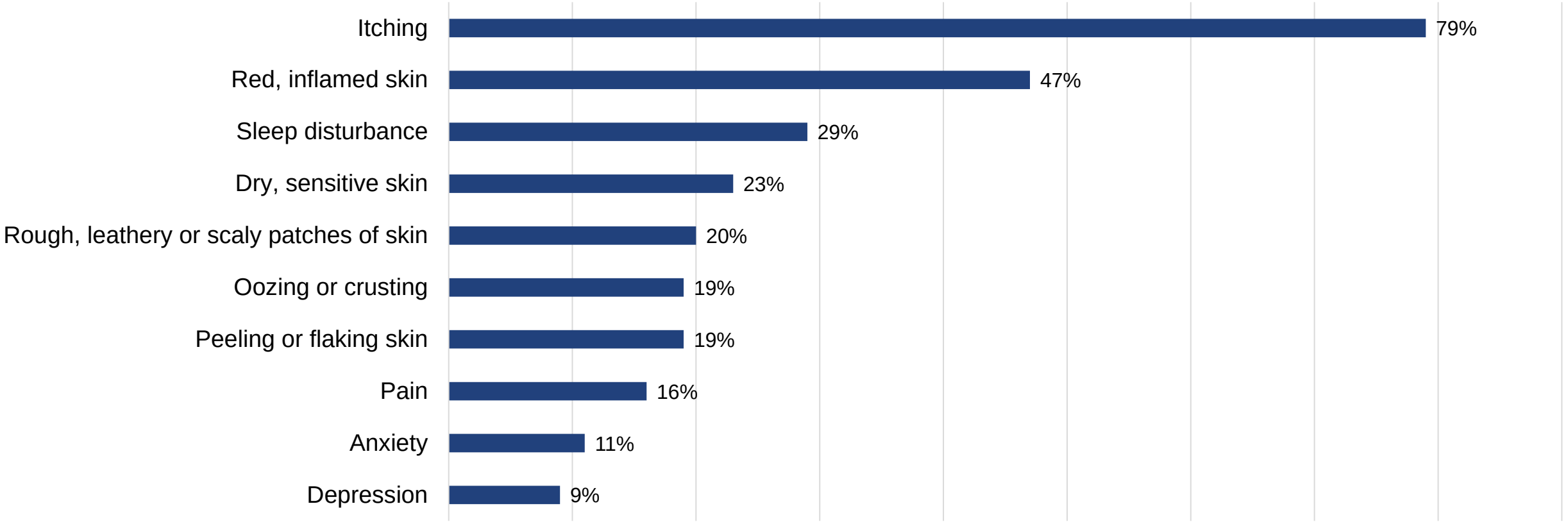



Puar N, et al. *Ann Allergy Asthma Immunol*. 2021;126(1):21-31.

# Patients Report Itch is the Most Burdensome Symptom of AD

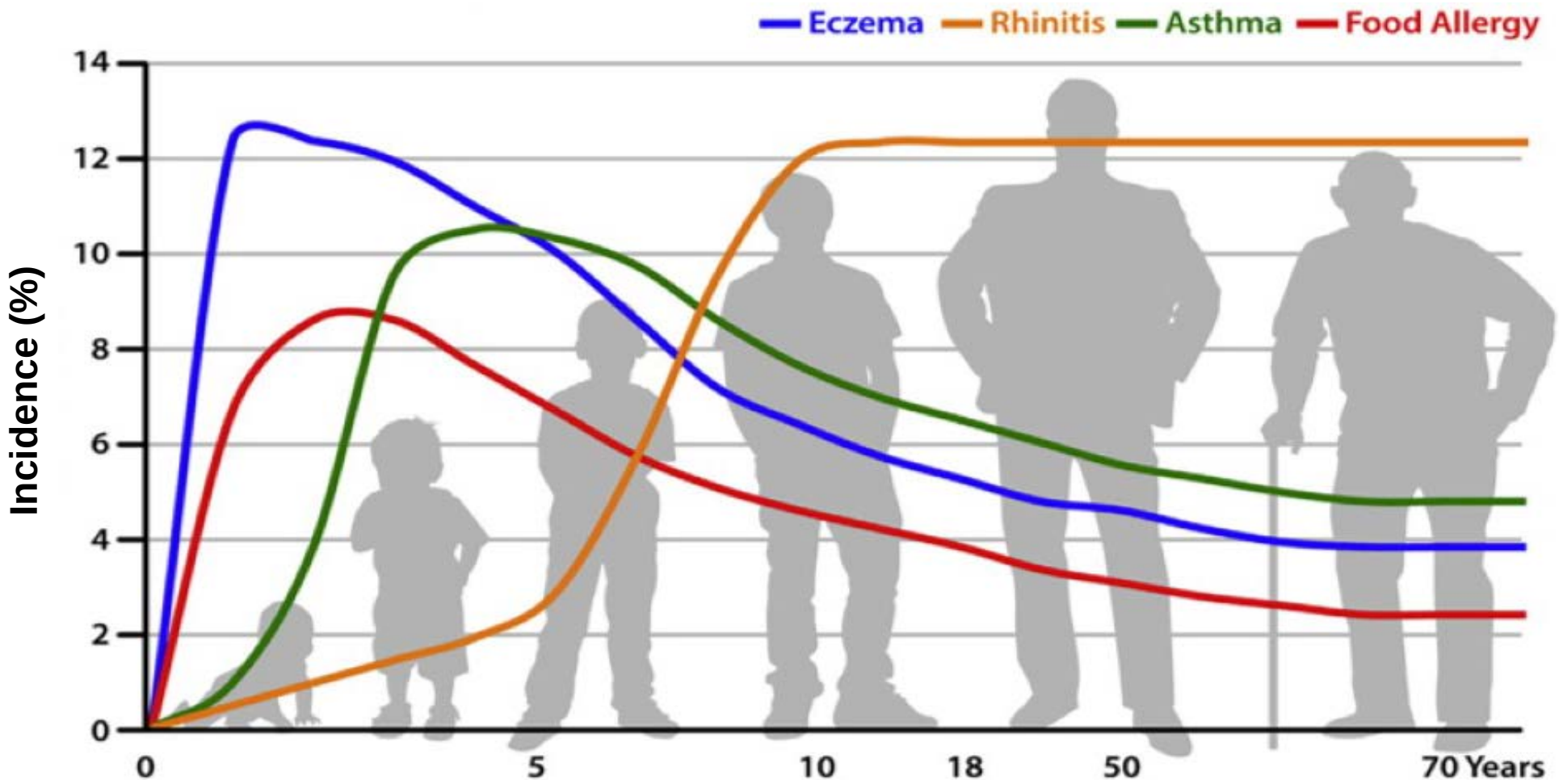
**Symptoms of Greatest Burden**

Patients were asked which three symptoms have been the most problematic.




More Than Skin Deep. “Understanding the Lived Experience of Eczema.” Published 2020. http://www.morethanskindeep-eczema.org/uploads/1/2/5/3/125377765/mtsd_report_-_digital_file.pdf. Accessed February 2022.

# AD is Typically Accompanied by Atopic Comorbidities




Leung WF, et al. *J Allergy Clin Immunol*. 2019;143:894-913.

# AD is a Clinical Diagnosis

- There are no established biomarkers for diagnosis and/or severity assessment
- Diagnosis is based on the patient's history, characteristic clinical findings, and exclusion of other dermatoses
- Diagnostic guidelines are published by both the AAD and the AAAAI/ACAAI
  - AAD guidelines distinguish atopy as an important, but not required feature for the diagnosis of AD
  - AAAI/ACAAI guidelines assert the necessity of an atopic history

AAD=American Academy of Dermatology

AAAI/ACAAI= American Academy of Allergy, Asthma & Immunology/American College of Allergy, Asthma & Immunology

Eichenfield LF, et al. *J Am Acad Dermatol*. 2014;70(2):338-351; Schneider L, et al. *J Allergy Clin Immunol*. 2013;131(2):295-299.e1-27.

# Assessing AD Severity Can Be Challenging

- Despite availability of >20 AD severity scales, there is no “gold standard”
- Common severity assessment tools used in research settings:
  - Scoring Atopic Dermatitis index (SCORAD)*
  - Eczema Area and Severity Index (EASI)*
  - Patient-Oriented Eczema Measure (POEM)*
  - Investigator’s Global Assessment (IGA)

*established minimal clinically important difference

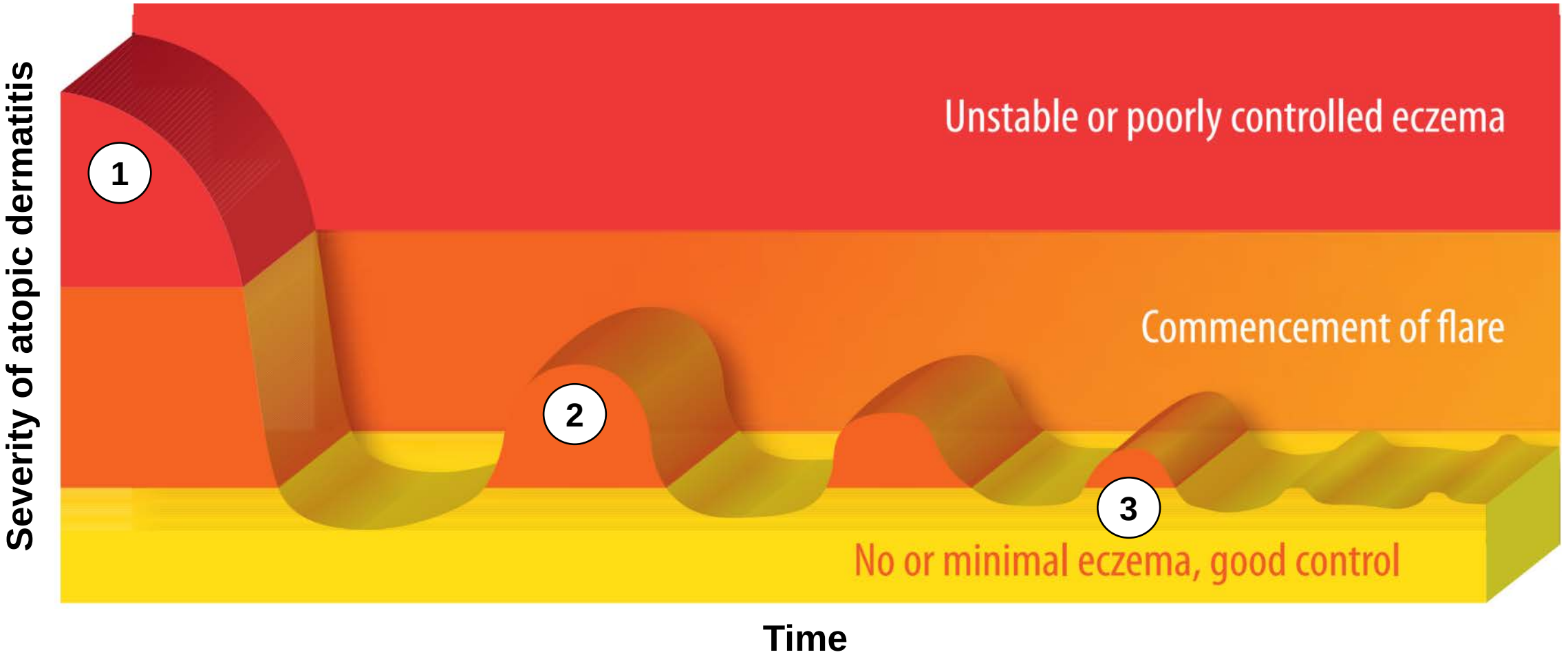
Eichenfield LF, et al. *J Am Acad Dermatol*. 2014;70:338-351.

# Clinical Features That Influence Disease Severity

- Body surface area and/or locations involved
- Disease duration
- Thickness of skin lesions
- Duration and intensity of pruritus
- Impact on quality of life and activities of daily living

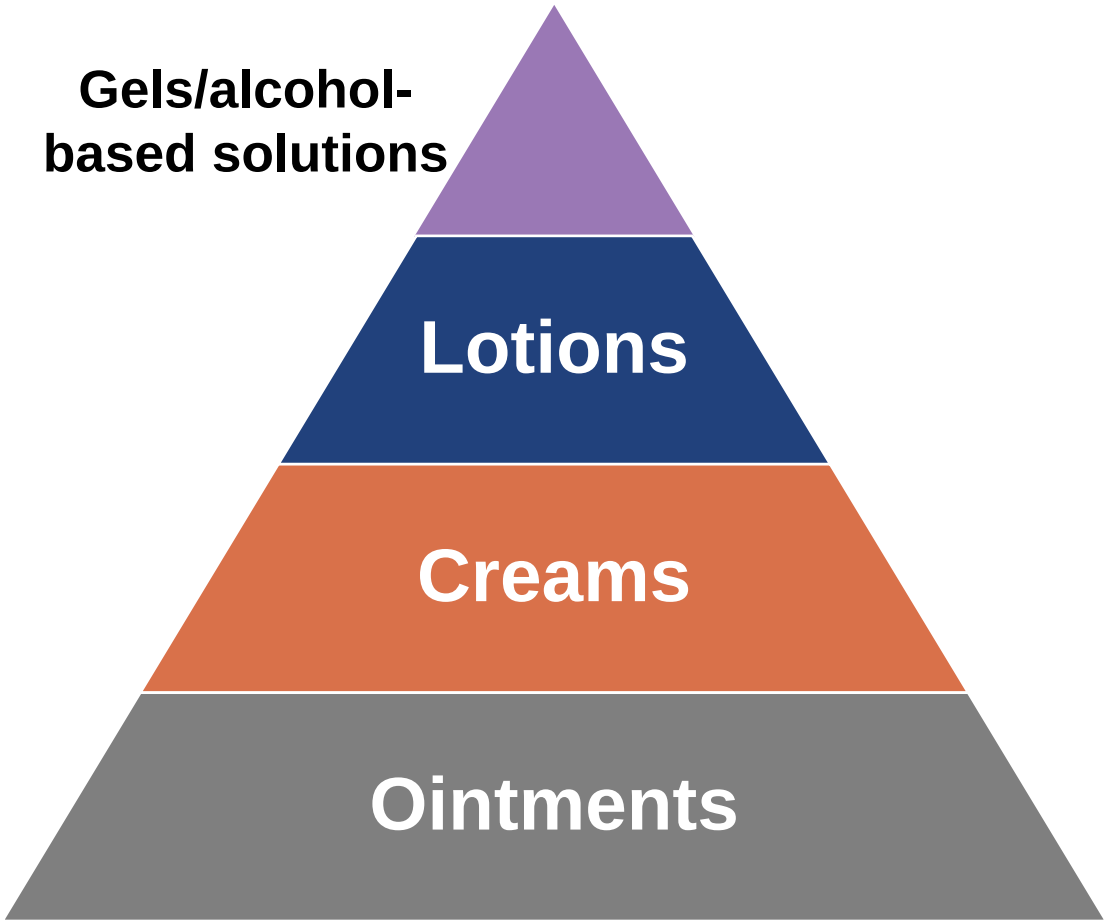
Eichenfield LF, et al. *J Am Acad Dermatol*. 2014;70:338-351.

# Management of AD Has Historically Focused on Symptom Relief




Rubel D, et al. *J Dermatol*. 2013;40:160-171.

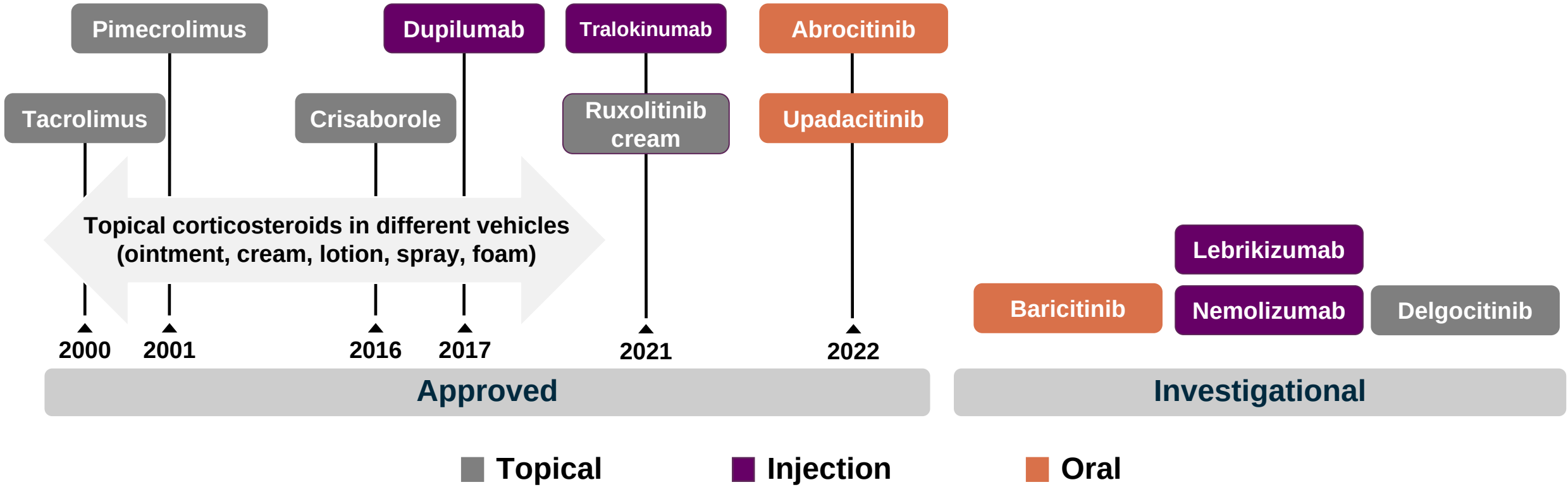
# Moisturizers Remain the Foundation of Therapy




- Moisturizers are used to combat xerosis and transepidermal water loss
  - **Emollients** lubricate and soften skin
  - **Occlusive agents** prevent evaporation of water
  - **Humectants** attract and hold water
- Data defining the optimal amount or frequency of application is lacking
  - Generally thought that liberal and frequent reapplication is necessary
- AAD guidelines encourage incorporating patient preference when selecting a moisturizer

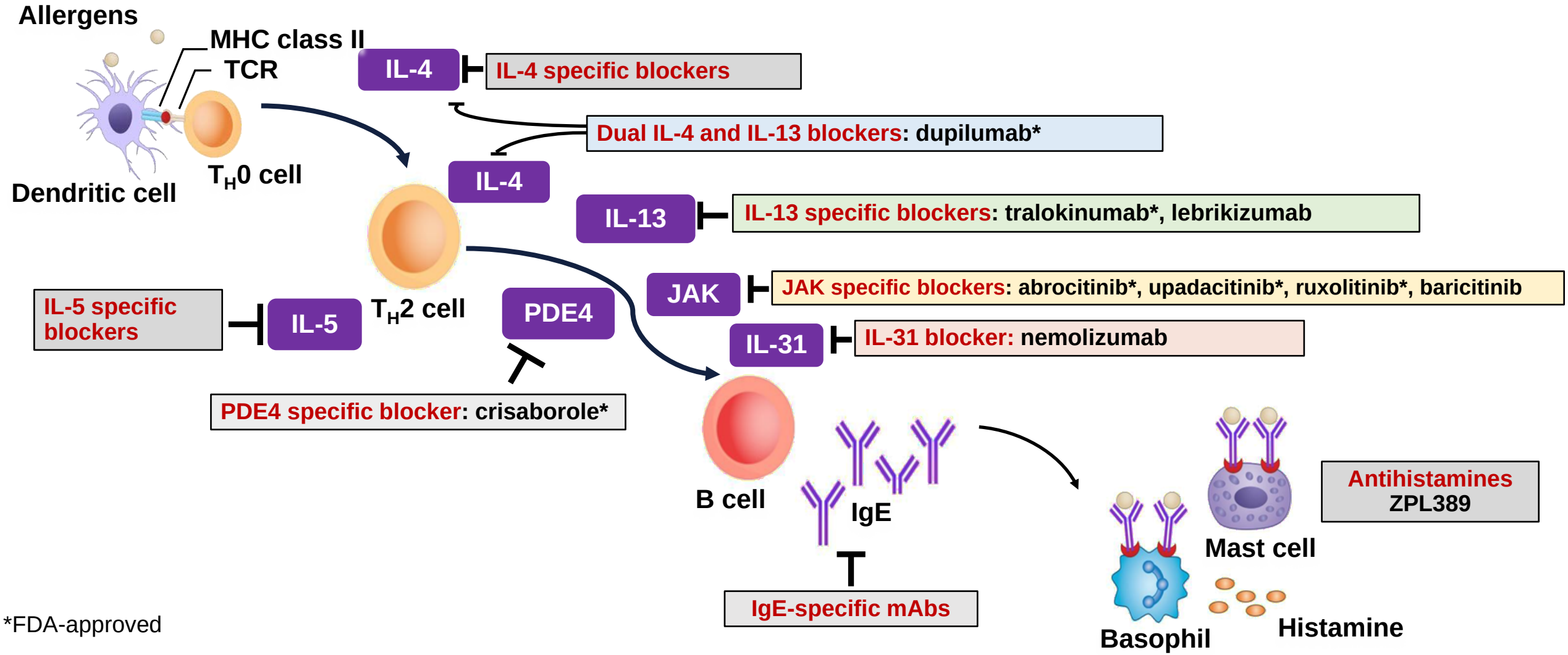
Eichenfield LF, et al. *J Am Acad Dermatol*. 2014;70:338-351.

# AD Treatment is Evolving Rapidly




Puar N, et al. *Ann Allergy Asthma Immunol*. 2021;126:21-31.

# Newer Therapies Target Specific Steps Integral to AD Pathology




*FDA-approved

Adapted from Gandhi NA, et al. *Nat Rev Drug Discov*. 2016;15:35–50; Langan SM, et al. *Lancet*. 2020;396:345-360.

# Targeted Therapies Approved for the Treatment of AD

| Approved Therapy | Target | Route of Administration | Approval Date | Indication |
|---|---|---|---|---|
| **Crisaborole 2% ointment** | PDE-4 | Topical | 2016 | Patients ≥3 months of age with mild-to-moderate AD |
| **Dupilumab** | IL-4 | Subcutaneous | 2017 | Patients ≥6 years old with moderate-to-severe AD |
| **Ruxolitinib cream** | JAK1/2 | Topical | 2021 | Short-term, non-continuous use in patients ≥12 years of age with mild-to-moderate AD |
| **Tralokinumab** | IL-13 | Subcutaneous | 2021 | Adult patients with moderate-to-severe AD |
| **Abrocitinib** | JAK 1 | Oral | 2022 | Adult patients with moderate to severe AD not adequately controlled |
| **Upadacitinib** | JAK 1 | Oral | 2022 | Patients ≥12 years of age with refractory moderate to severe AD not adequately controlled |

Eucrisa [package insert]. New York, NY: Pfizer Labs, Inc; 2020; Dupixent [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc; 2021; Opzelura [package insert]. Wilmington, DE: Incyte Corp, Inc; 2021. Adbry [package insert]. Madison, NJ: Leo Pharma; 2021; Cibninqo [package insert]. New York, NY: Pfizer, Inc.; 2022; Rinvoq [package insert]. N. Chicago, IL: Abbvie Inc.; 2022.

# Agents in Late Phase Development Offer the Potential for Greater Disease Control and Symptom Relief

| Novel Therapy | Target | Route of Administration | Status |
|---|---|---|---|
| **Lebrikizumab** | IL-13 | Subcutaneous | Phase 3 (Fast Track) |
| **Nemolizumab** | IL-31 receptor A | Subcutaneous | Phase 3 (breakthrough therapy) |
| **Baricitinib** | JAK 1/2 | Oral | BLA submitted (decision delayed) |
| **Delgocitinib** | JAK 1/2/3 and TYK | Topical ointment | Phase 3 (Fast Track) |
| **Difamilast** | PDE4 inhibitor | Topical ointment | Phase 3 |

IL=interleukin; JAK= Janus kinase; TYK=tyrosine kinase; PDE4=phosphodiesterase-4.

Puar N, et al. *Ann Allergy Asthma Immunol*. 2021(1);126:21-31; Comparison Trial of OPA-15406 Ointment in Pediatric Patients With Atopic Dermatitis. ClinicalTrials.gov identifier: NCT03911401. Updated January 25, 2021. Accessed March 2022. https://clinicaltrials.gov/ct2/show/NCT03911401

# Treatment Approach: Initiate Therapy Early to Reduce Disease Burden

**Early and effective AD treatment contributes to:**

- **Itch reduction**
- **Sleep improvement**
- **Positive impact on mental health**
- **Slowed disease progression**
- **Enhanced skin clearing**

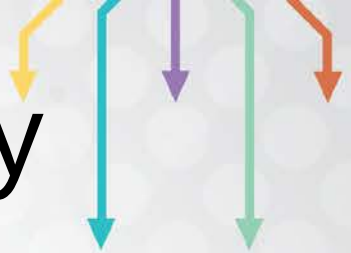
Simpson EL, et al. *EMJ*. 2019;4:14-23; Wollenberg A, et al. *J Eur Acad Dermatol*. 2018;32:657-682.

# Improving Disease Control

- Traditionally, AD has been treated reactively, adjusting treatment in response to symptoms
- Accumulating evidence suggests AD is a chronic systemic disease active even when symptoms are absent
- Approaches to improving disease control while minimizing treatment-related AEs include
  - Matching therapy to disease severity
  - Preventive therapy
  - Scheduled intermittent therapy
  - Alternating therapy
  - Minimizing drug exposure
    - Minimizing exposure may also reduce cost of care for patients and payers

Feldman SR, et al. *Am Health Drug Benefits*. 2019;12:83-93; Eichenfield LF, et al. *J Am Acad Dermatol*. 2014;71:116-132.

# Align AD Treatment with Disease Severity



**Re-assess AD Control Every 4–8 weeks**

| | NON-LESIONAL | MILD | MODERATE | MODERATE-to-SEVERE |
|---|---|---|---|---|
| Maintenance | **Basic Management**<br>• Skin care<br>• Trigger avoidance | **Basic Management**<br>• Skin care<br>• Antiseptic measures<br>• Trigger avoidance | **Basic Management & Topical Anti-Inflammatory Medication**<br>• Maintenance TCS, ***or***<br>• Maintenance TCI, ***or***<br>• Crisaborole 2%[1] ***or***<br>• Ruxolitinib cream[2] | **Basic Management/Referral to AD Specialist**<br>• Phototherapy<br>• Dupilumab[3]<br>• Immunosuppressants[4]<br>• Topical corticosteroids[5]<br>• Tralokinumab[6]<br>• Oral JAK inhibitors[7] (abrocitinib; upadacitinib)<br>• Consider acute treatment to gain control<br>  • Wet wrap therapy<br>  • Short-term hospitalization |
| Acute | • Apply TCS (low to medium potency) to inflamed skin | • Apply TCS (medium to high potency) to inflamed skin<br>• If not resolved in 7 days, consider:<br>  • Nonadherence, infection, misdiagnosis or contact allergy<br>  • Referral to AD specialist/step-up treatment | | |

[1]Approved for patients at least 2 years old with mild to moderate AD; [2]Approved for Short-term, non-continuous use in patients ≥12 years of age with mild-to-moderate AD; [3]Approved for patients at least 6 years old with moderate to severe AD; [4]Not approved by the Food and Drug Administration to treat AD; [5]Approved by the FDA to treat AD but not recommended for long-term maintenance; [6]Approved for adult patients with moderate-to-severe AD; [7]Approved by the FDA for patients ≥12 years of age with refractory, moderate to severe AD not adequately controlled with other systemic drugs (eg, biologics) or when those therapies are inadvisable.

TCS=topical corticosteroids; TCI=topical calcineurin inhibitors; JAK=Janus kinase

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

# Who is a Good Candidate for Systemic Therapy?*

**If aggressive topical therapy is not achieving adequate control of the disease**

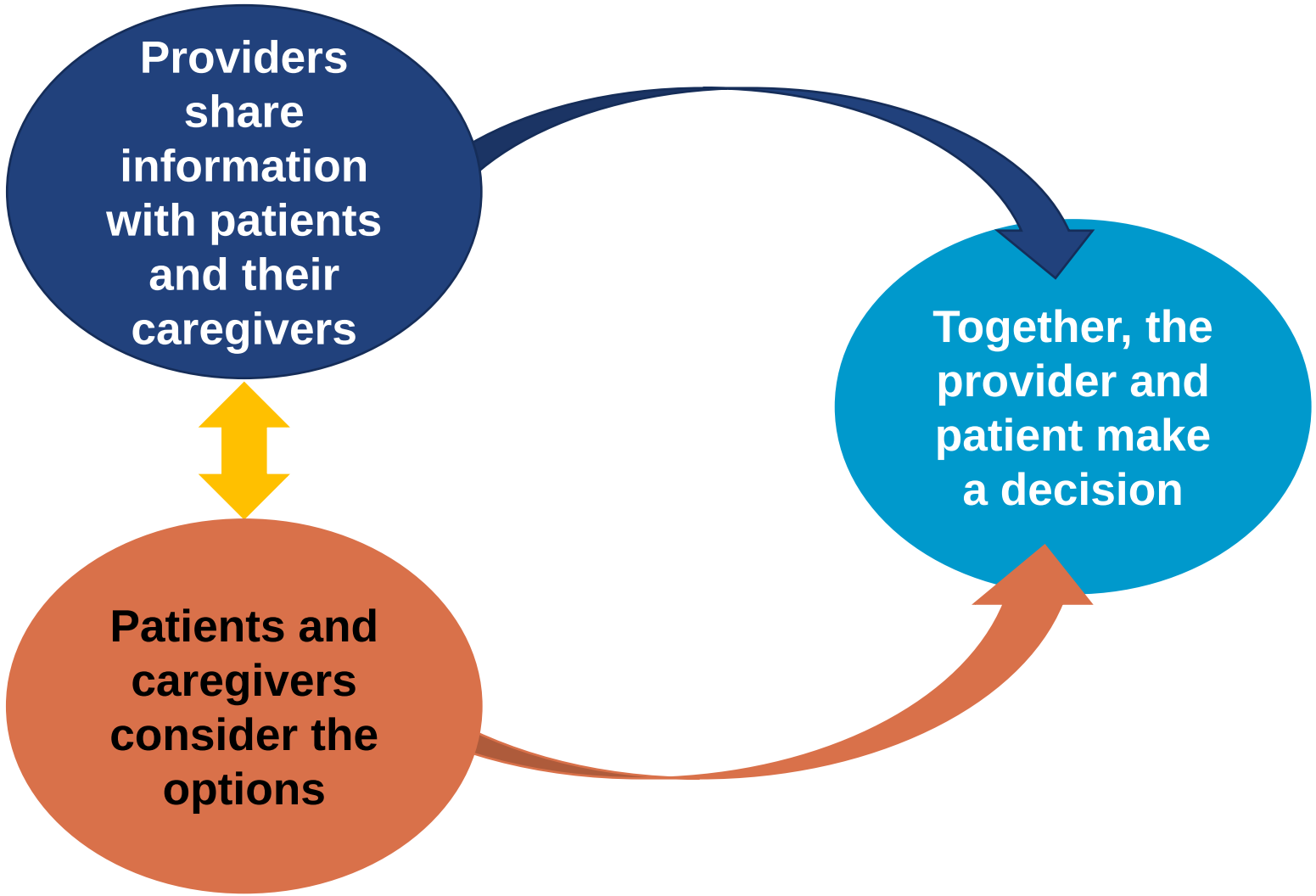
***AND***

- Adequate education delivered
- Infection addressed
- Large impact on QoL
- Diagnosis reconsidered (e.g., cutaneous T-cell lymphoma or allergic contact dermatitis)
- Consider phototherapy

*International Eczema Council Panel Recommendations

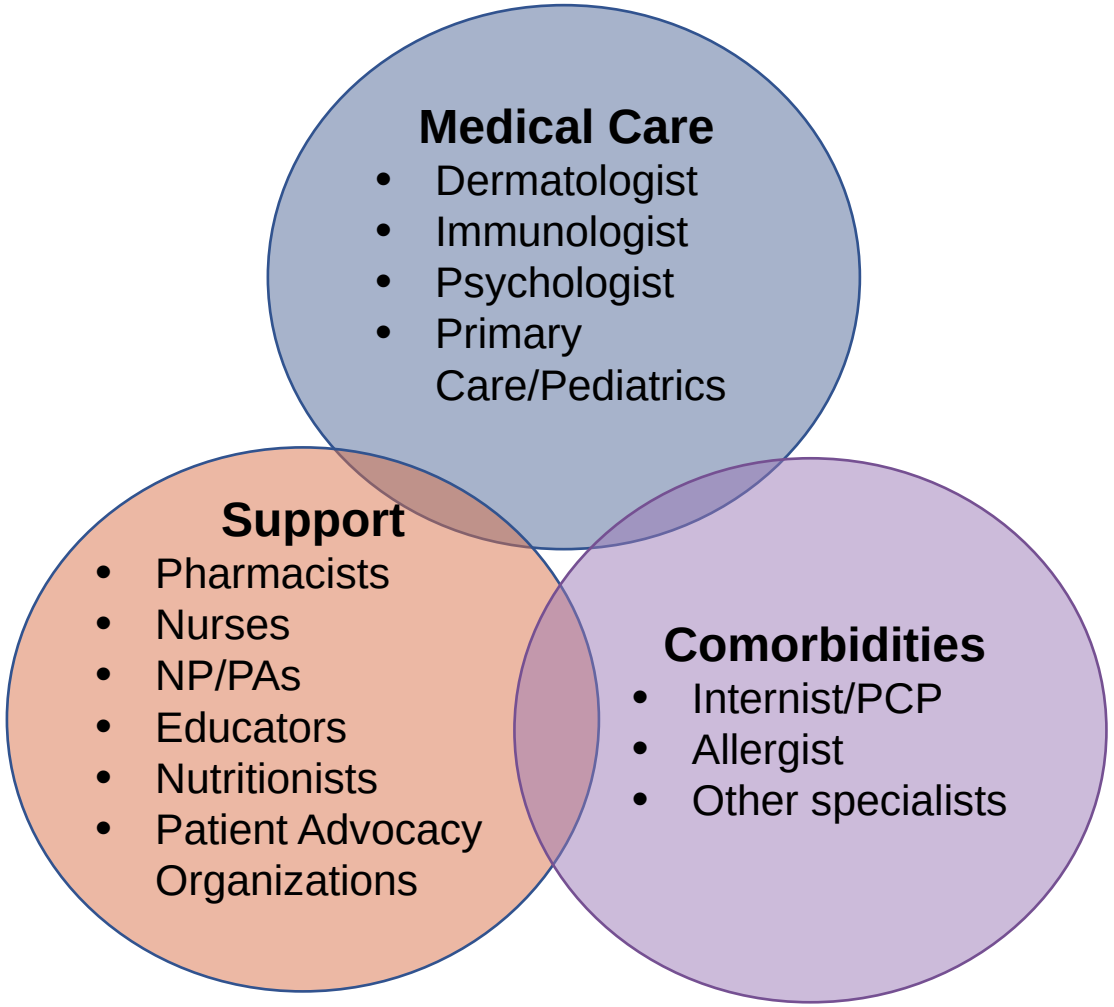
Simpson EL, et al. *J Am Acad Dermatol*. 2017;77:623-633.

# Include the Patient in Treatment Decision Making




LeBovidge J, et al. *Semin Cutan Med Surg*. 2017;36:131-136.

# Multidisciplinary Care May Improve AD Treatment Outcomes




- Effective multidisciplinary care targets the biological, psychological, and behavioral factors that influence disease control
  - It is particularly important in the presence of comorbidities
- Beneficial effects include:
  - Reduced disease severity
  - Improved adherence to therapy
  - Enhanced quality of life

LeBovidge JS, et al. *J Allergy Clin Immunol*. 2016;138:325-334.

# Summary

- AD is a chronic systemic disease that is active even when symptoms are absent
- Strategies to improve disease control include treatment optimization, shared decision making, treating comorbid disease, and utilizing multidisciplinary care
- Early treatment can establish disease control and reduce the overall burden of AD
- Patients with AD and comorbid disease may benefit from multidisciplinary care

# *Evidence-Based Decision Making in a Cost-Conscious Environment*

**Michael Zeglinski, RPh**
Sr. Vice President and CEO
Optum Specialty Pharmacy

# Learning Objective

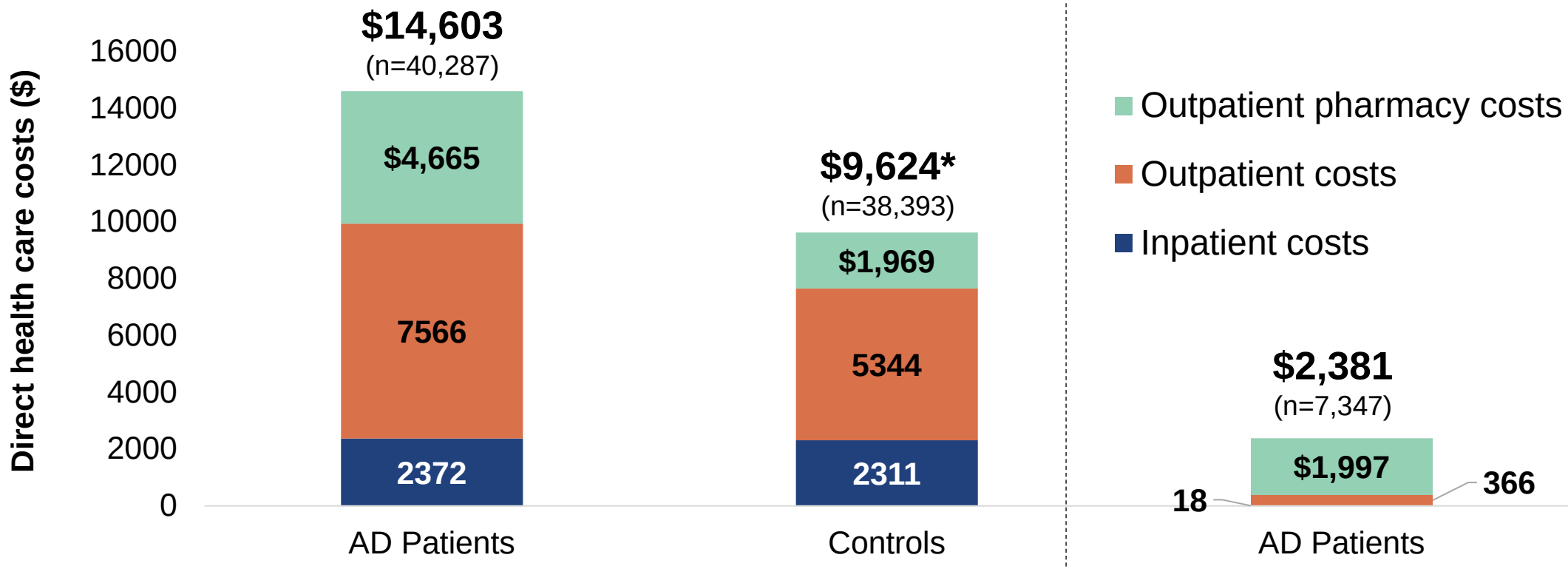
- Evaluate benefit design strategies that can contribute to appropriate access and utilization, while simultaneously managing costs and improving treatment outcomes

# AD Presents Many Challenges to Patients, Providers, and Payers

- The atopic dermatitis (AD) clinical phenotype is highly heterogeneous
  - It is a chronic condition associated with a substantial impact on a patient's qualify of life (QoL) and has a considerable economic burden
- Despite this heterogeneity, AD is largely considered a single disease and is usually treated as such
- AD diagnosis is hampered by a lack of objective diagnostic criteria
- Current management guidelines do not incorporate recent clinical advances, such as the targeting of specific underlying inflammatory processes
- Treatment guidelines for atopic dermatitis are limited in their broad applicability to individual patient scenarios
- Novel treatments can provide additional therapeutic options for patients, but can carry a high cost

Feldman SR, et al. *Am Health Drug Benefits*. 2019;12:83-93.

# All-Cause and AD-Related Health Care Costs Are Higher For Adult Patients vs. Controls



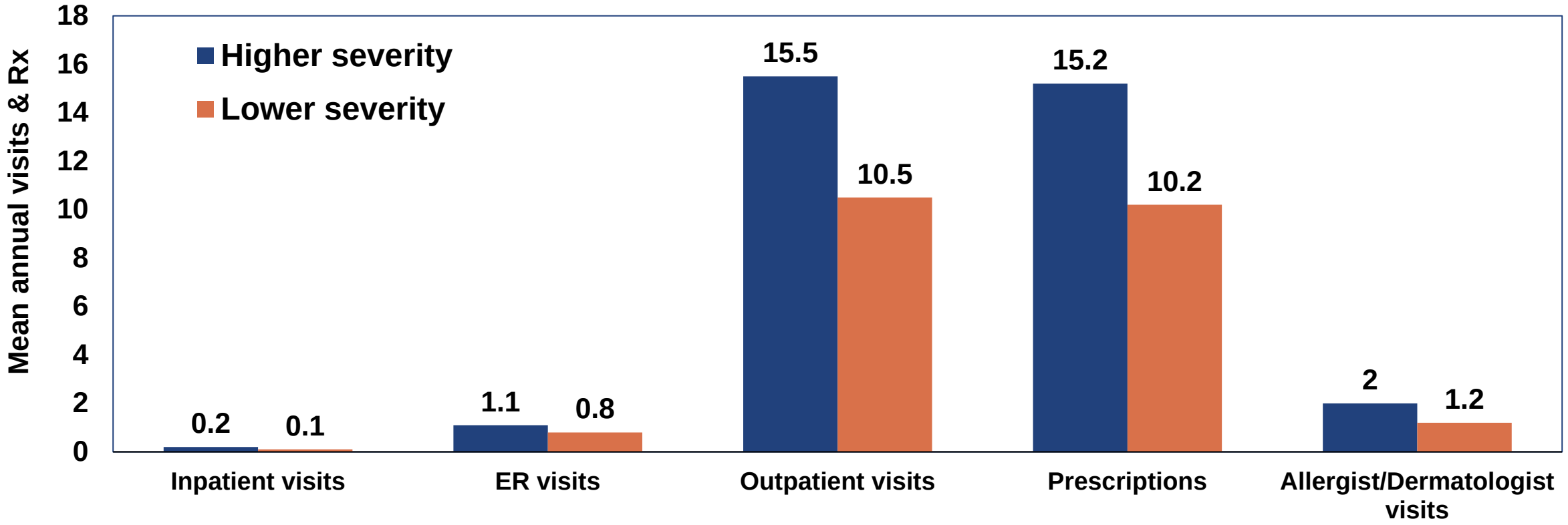

*p<0.001 vs. AD patients

Retrospective cohort study of adults with atopic dermatitis in 2018. Costs are in 2018 US dollars. Inpatient costs included hospitalizations. Outpatient costs included emergency department visits, outpatient office visits, and other outpatient services such as phototherapy service and office-administered medications. Outpatient pharmacy costs included all prescriptions filled in an outpatient pharmacy setting.

Manjelievskaia J, et al. *J Manag Care Spec Pharm*. 2021;27:1416-1425.

# More Severe AD Associated with Increased Use of Health Care Resources

**Mean annual number of per patient healthcare visits & prescriptions stratified by AD severity in a Commercial population†**

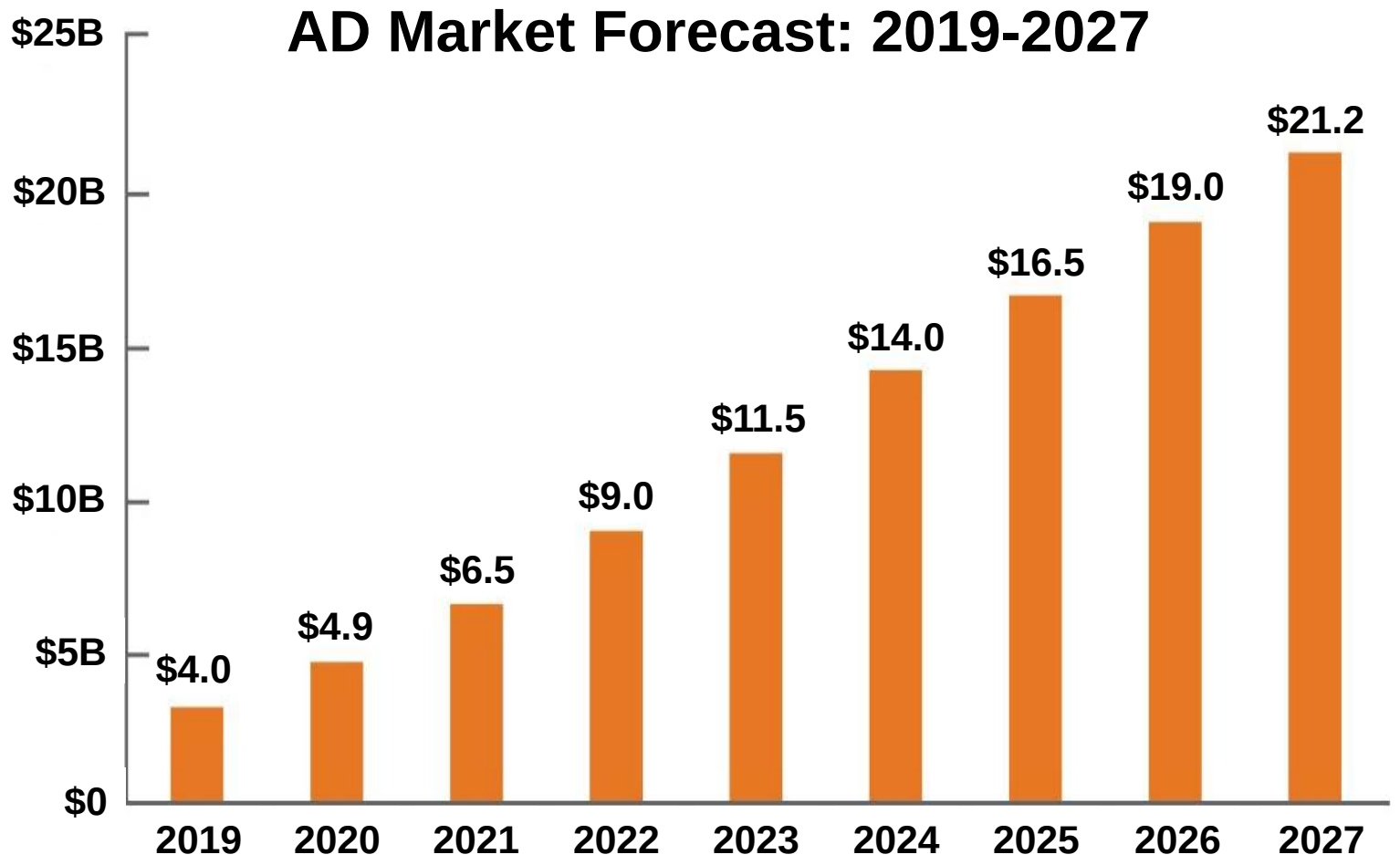



†Data extracted from Optum Health claims data from 2010-2015 (pre-dupilumab); n=83,106

Shrestha S, et al. *Adv Ther.* 2017;34:1989-2006.

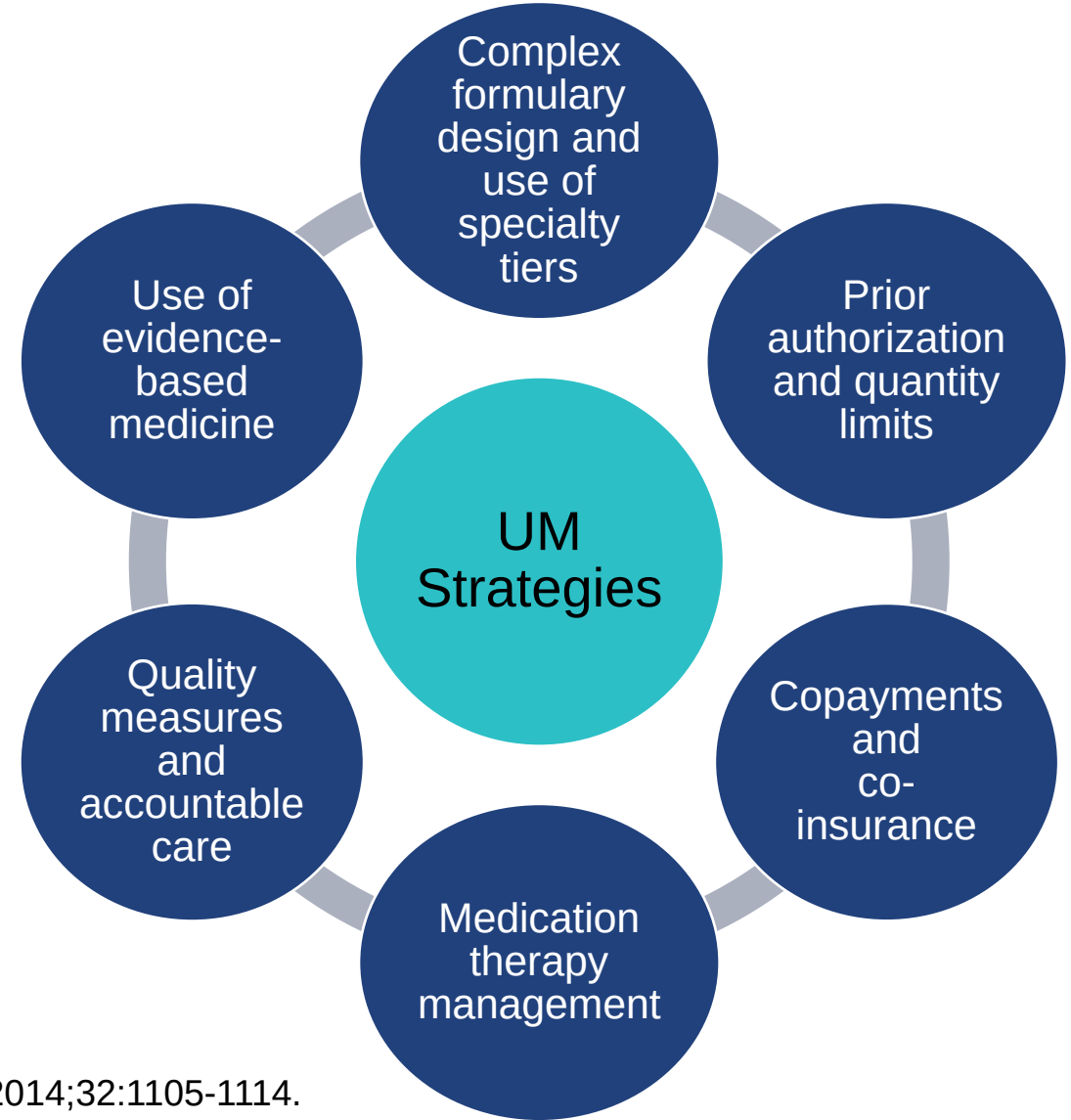
# AD Drug Spend Expected to Rise as Safe and Effective Agents Continue to be Approved

- According to the World Health Organization, AD affected more than 300 million people globally
- The global AD market is projected to show a compound annual growth rate of 24.1% between 2020 and 2027
  - The total value of the AD market is expected to exceed $19B by the end of the forecast period




Atopic Dermatitis Market. Fact.MR website. Published March 2020. Accessed March 2022. https://www.factmr.com/report/4603/atopic-dermatitis-market. Accessed February 2022

# Rising Demand for Effective Therapies is Driving the Increase in AD Cost of Care




Patel BN, Audet PR. *Pharmacoeconomics*. 2014;32:1105-1114.

# Progressive Approach to Utilization Management

## Traditional UM

- Generics first
- Day-one UM control
- Use aligned with guidelines
- Prior authorization
- Step therapy
- Quantity limits
- Differential cost sharing

## Criteria beyond traditional UM

- Enhanced clinical criteria with additional required documentation
- Quantity limits at the time of PA approval
- Shortened duration of approval
- Medical director review

- Earlier identification and increased clinical support
- Advanced utilization oversight
- Advanced analytics
- Improved digital outreach

Fredell J.CVS Health Payor Solutions. Published July 28, 2020. Accessed March 2022. https://payorsolutions.cvshealth.com/insights/utilization-management-for-a-changing-specialty-landscape

# What are the Criteria that Determine Eligibility for Targeted AD Therapy?

**1**

- Confirmed diagnosis of moderate-to-severe AD made by a dermatologist along with documentation of drugs tried and failed
- Clear documentation of moderate-to-severe disease using a validated assessment tool
- Assessment of related comorbidities or exacerbating factors that could contribute to AD (e.g., asthma, nasal polyps, aspirin sensitivity, etc.)

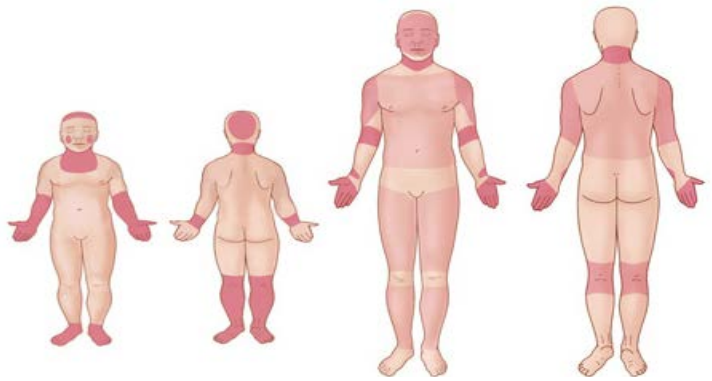
← **Confirmed diagnosis by a specialist**
**Do plans require BSA measurement?**

← **Accurate assessment of disease severity**

Dupixent (dupilumab). Aetna. http://www.aetna.com/products/rxnonmedicare/data/2017/MUSC/Dupixent.html. Accessed February 2022.
Dupilumab (Dupixent). Western Health Advantage. https://www.westernhealth.com/provider/prior-authorization-criteria/dupilumab-dupixent. Accessed February 2022.

# AD Severity Assessment: Research vs. Clinical Tools

- Tools commonly used in clinical trials:
  - Scoring Atopic Dermatitis index (SCORAD)
  - Eczema Area and Severity Index (EASI)
  - Patient-Oriented Eczema Measure (POEM)
  - Investigator's Global Assessment (IGA)



- A "gold standard" scale for use in clinical practice has not been identified
- Measuring severity in clinical practice:
  - Duration of disease
  - Thickness of skin lesions
  - Duration and intensity of pruritus
  - Body surface area (BSA) involved
  - Location of eczema
  - Impact on quality of life (sleep, school/work, social life, mental health, etc.)

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

# What are the Criteria that Determine Eligibility for Targeted AD Therapy?

**Documentation of uncontrolled AD despite use of multiple prior therapies**

**2**

- Refractory to daily topicals including
  - ≥1 medium to very high potency topical corticosteroid (>1 month), *AND*
  - ≥1 topical calcineurin inhibitor (>6 weeks)

    *AND*
  - ≥1 oral DMARD (e.g., cyclosporine)

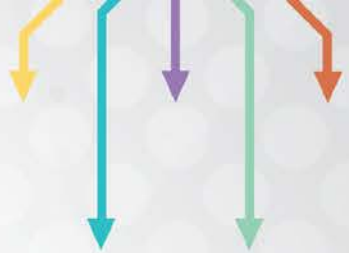
Dupixent (dupilumab). Aetna. http://www.aetna.com/products/rxnonmedicare/data/2017/MUSC/Dupixent.html. Accessed February 2022.
Dupilumab (Dupixent). Western Health Advantage. https://www.westernhealth.com/provider/prior-authorization-criteria/dupilumab-dupixent. Accessed February 2022.

# Use of Treatment Guidelines to Deliver Evidence-Based Care

- Current AD treatment guidelines do not incorporate recent clinical advances and lack recommendations on use of novel agents
- Providers and payers must assess the available evidence in order to incorporate newer agents into current treatment paradigms
- With clear evidence-based guidance lacking, payers often rely on the use of prior authorization (PA) or other UM tools to control access to new agents

Feldman SR, et al. *Am Health Drug Benefits*. 2019;12:83-93.

# Step Therapy Algorithm for AD



| | NON-LESIONAL | MILD | MODERATE | MODERATE-to-SEVERE |
|---|---|---|---|---|
| Maintenance | **Basic Management**<br>• Skin care<br>• Trigger avoidance | **Basic Management**<br>• Skin care<br>• Antiseptic measures<br>• Trigger avoidance | **Basic Management & Topical Anti-Inflammatory Medication**<br>• Maintenance TCS, ***or***<br>• Maintenance TCI, ***or***<br>• Crisaborole 2%[1] ***or***<br>• Ruxolitinib cream[2] | **Basic Management/Referral to AD Specialist**<br>• Phototherapy<br>• Dupilumab[3]<br>• Immunosuppressants[4]<br>• Topical corticosteroids[5]<br>• Tralokinumab[6]<br>• Oral JAK inhibitors[7] (abrocitinib; upadacitinib)<br>• Consider acute treatment to gain control<br>  • Wet wrap therapy<br>  • Short-term hospitalization |
| Acute | • Apply TCS (low to medium potency) to inflamed skin | • Apply TCS (medium to high potency) to inflamed skin<br>• If not resolved in 7 days, consider:<br>  • Nonadherence, infection, misdiagnosis or contact allergy<br>  • Referral to AD specialist/step-up treatment | | |

[1]Approved for patients at least 2 years old with mild to moderate AD; [2]Approved for Short-term, non-continuous use in patients ≥12 years of age with mild-to-moderate AD; [3]Approved for patients at least 6 years old with moderate to severe AD; [4]Not approved by the Food and Drug Administration to treat AD; [5]Approved by the FDA to treat AD but not recommended for long-term maintenance; [6]Approved for adult patients with moderate-to-severe AD; [7]Approved by the FDA for patients ≥12 years of age with refractory, moderate to severe AD not adequately controlled with other systemic drugs (eg, biologics) or when those therapies are inadvisable.

TCS=topical corticosteroids; TCI=topical calcineurin inhibitors; JAK=Janus kinase

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

# What are the Criteria that Determine Eligibility for Targeted AD Therapy?

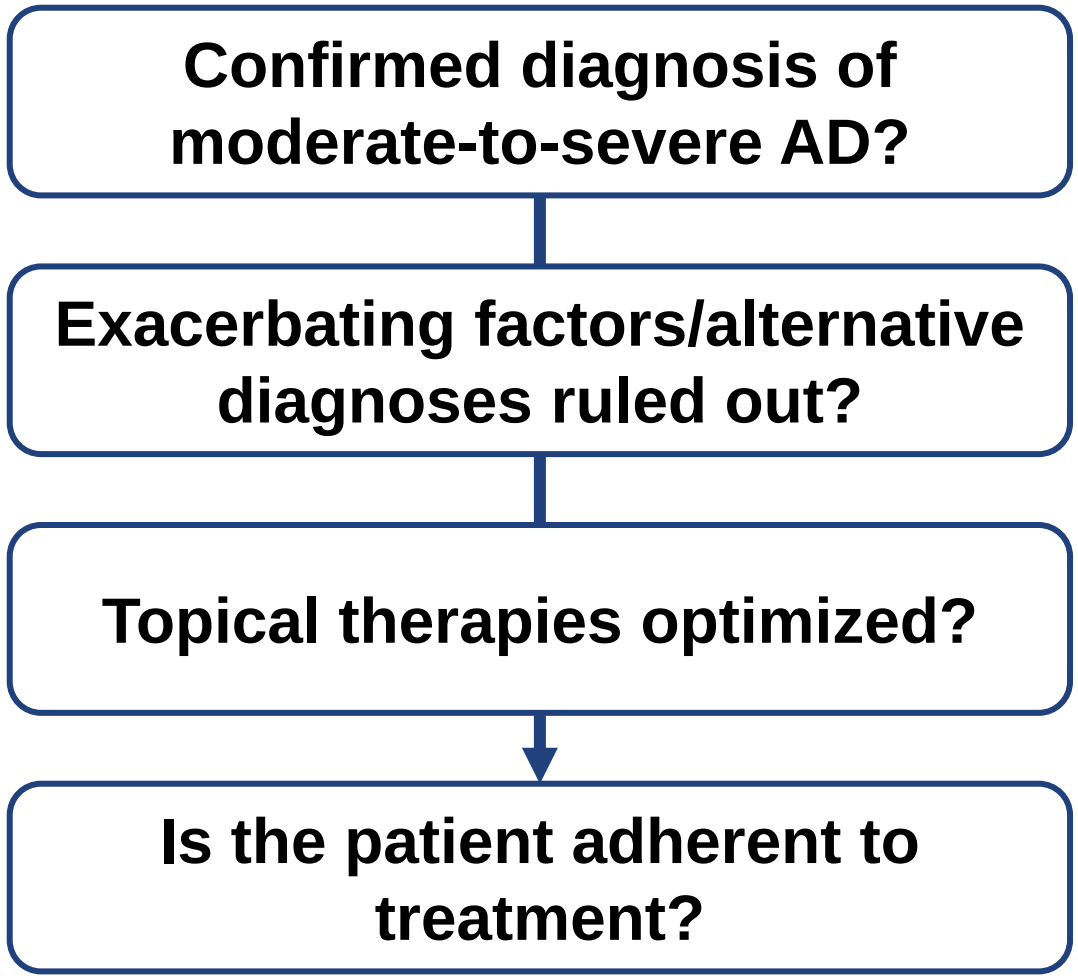
**Duration of approval** ⟶

**3**

- Reauthorization after 4 months if all 3 criteria are met
  - Clinical reduction in BSA affected
  - Clinical reduction in pruritus and flares
  - Improvement of ≥ 2 IGA points

Dupixent (dupilumab). Aetna. http://www.aetna.com/products/rxnonmedicare/data/2017/MUSC/Dupixent.html. Accessed February 2022.
Dupilumab (Dupixent). Western Health Advantage. https://www.westernhealth.com/provider/prior-authorization-criteria/dupilumab-dupixent. Accessed February 2022.

# Summary of the Characteristics of Patients Who Are Good Candidates for Targeted AD Therapy

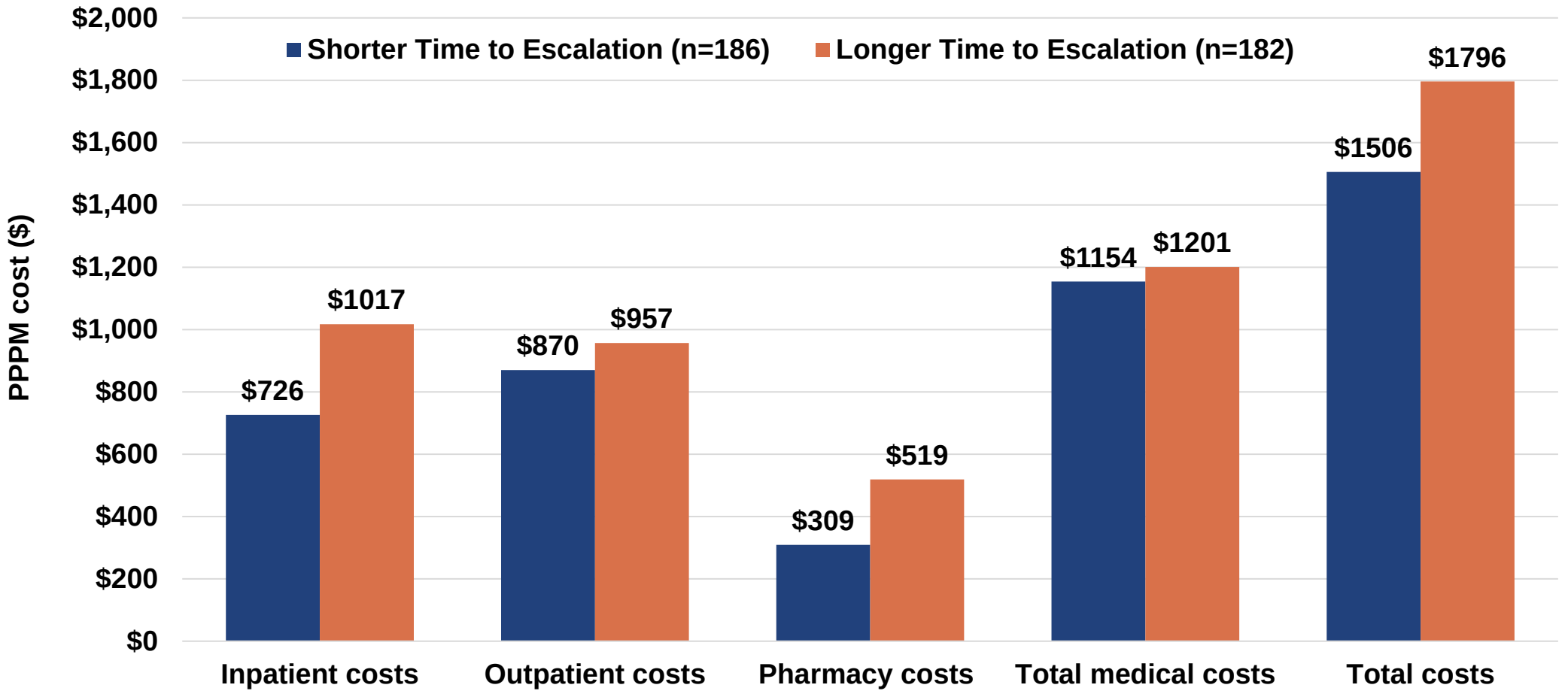



## Characteristics

- Itch that disrupts sleep
- Significant body surface area involvement (≥10%)
- Impaired quality of life
- Low risk for opportunistic infection

Simpson EL, et al. *J Am Acad Dermatol*. 2017;77:623-633; Lynde CCW, et al. *J Cutan Med Surg*. 2018;22:78-83.

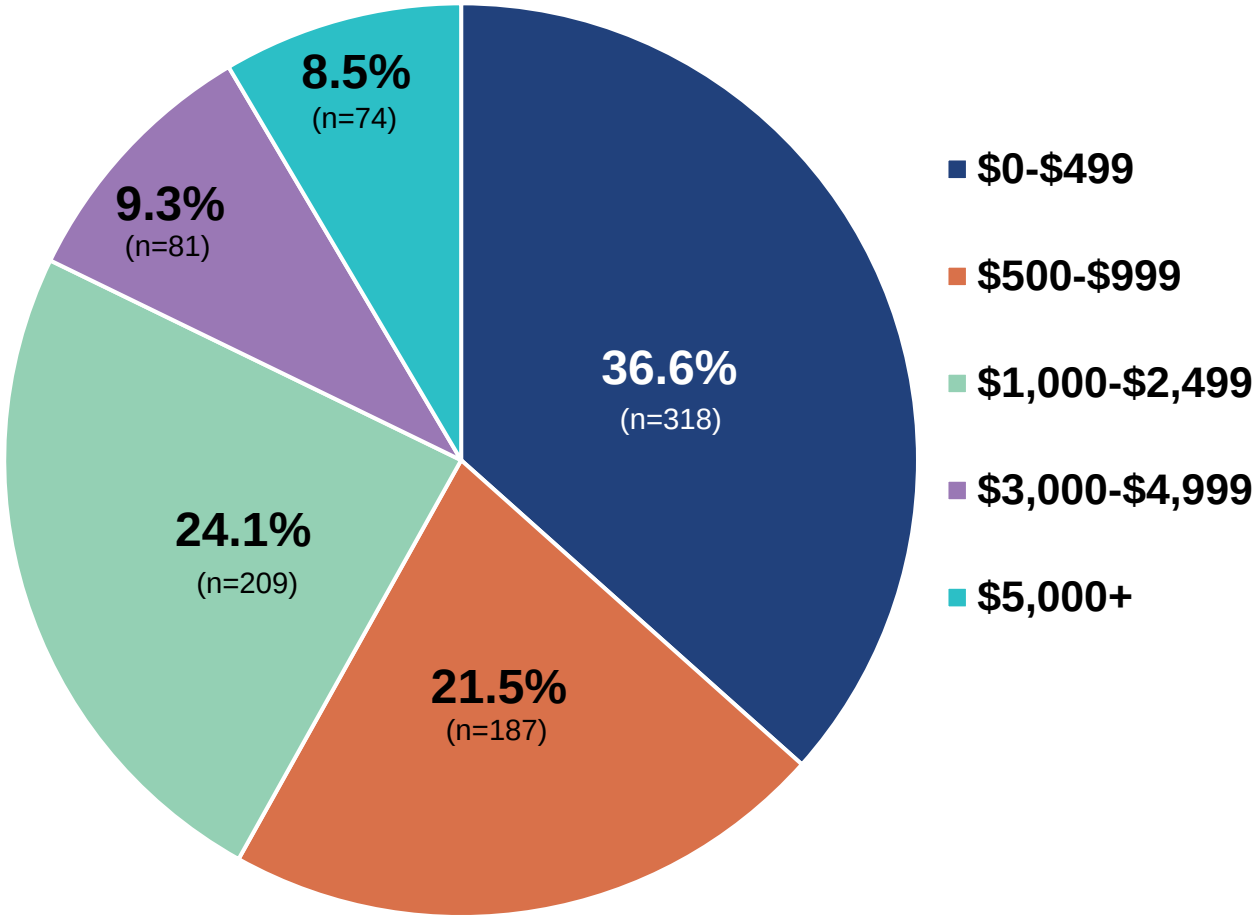
# A Delay in Treatment Escalation is Associated with Higher Costs




*p<0.001 vs. shorter time to escalation.
Data from the Truven Health MarketScan Database; N=368 adult patients with AD treated with topical agents (corticosteroids and calcineurin inhibitors).

Armstrong A, et al. *J Am Acad Dermatol.* 2019;81(supplement 1): AB131.

# Over 40% of AD Patients Incurred Annual OOP Expenses >$1,000

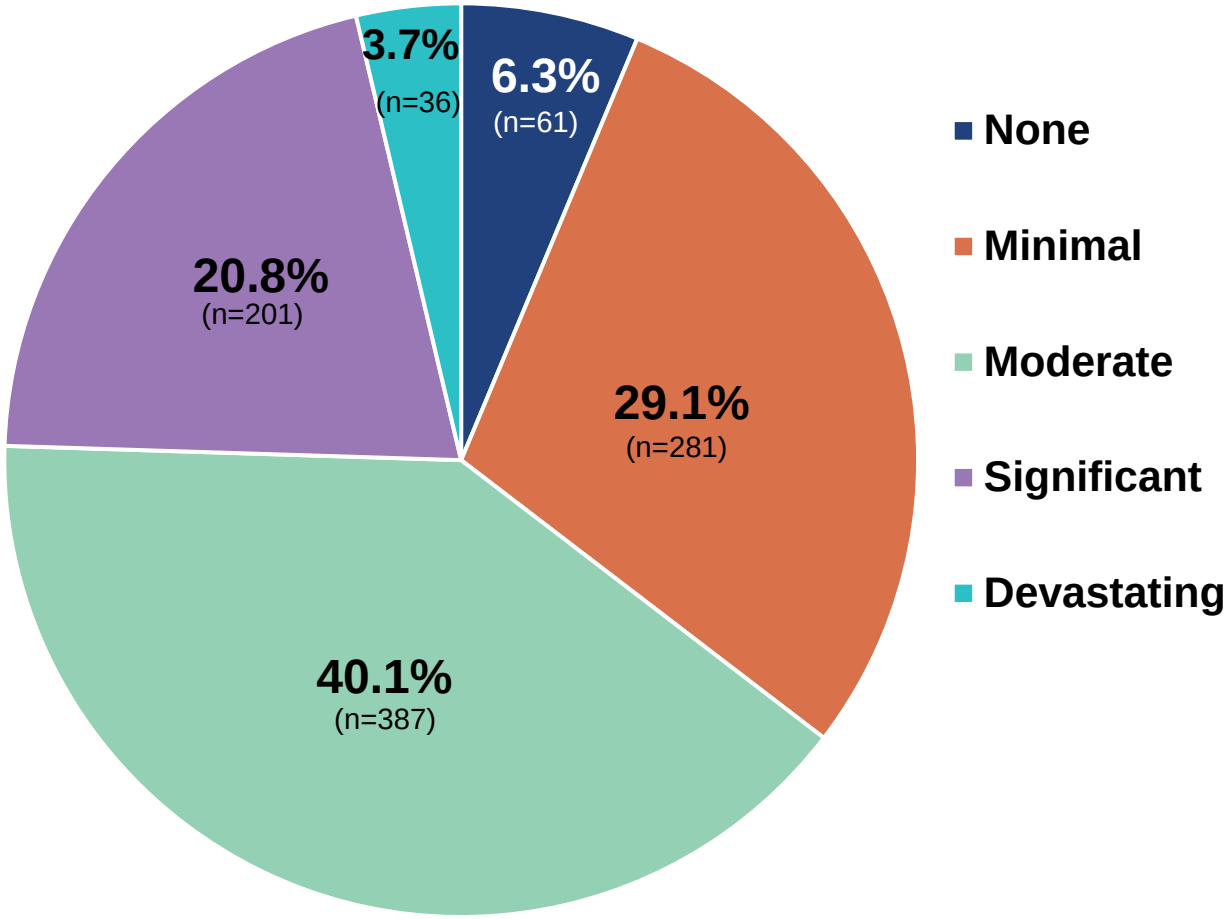



**National Eczema Association survey:**

- 42% of AD patients in the US incurred >$1,000 OOP expenses each year for AD treatments
- 8.5% reported OOP costs >$5,000 per year
- Higher OOP costs were associated with increasing disease severity, increased disease flares, and poorer disease control
- Nearly half (48.6%) reported OOP costs for prescription medications that were not covered by insurance

Begolka WS, et al. *Dermatitis.* 2021;32:S62-S70; Begolka WS, et al. *J Manag Care Spec Pharm*. 2022;28:115-118.

# OOP Expenses Can Have a Significant Impact on Household Finances




- More than half of AD patients (57.5%) are prescribed ≥3 AD medications
- 64.6% of AD patients surveyed OOP expenses had a harmful impact on household finances
- Nearly a quarter of patients reported a “significant” or “devastating” effect of OOP expenses on their household budget

Chovatiya R, et al. *Dermatitis.* 2021; Sep 27. Online ahead of print; Begolka WS, et al. *J Manag Care Spec Pharm*. 2022;28:115-118.

# High Patient OOP Costs Can Have Unintended Consequences

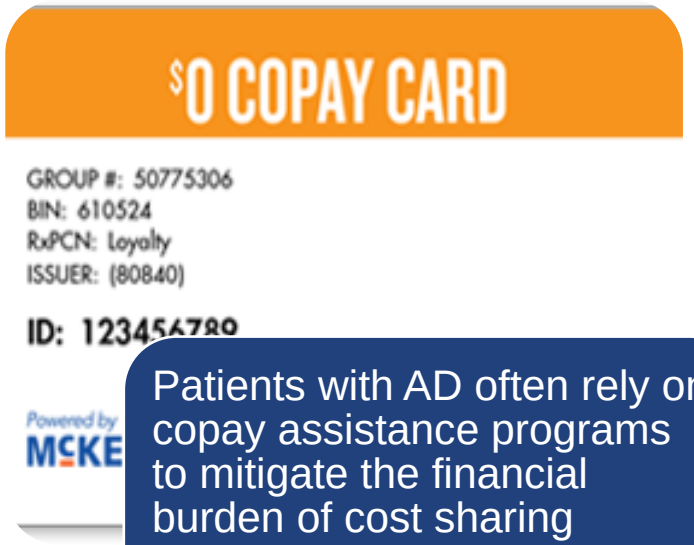
- Delayed initiation or continuation of treatment
- Loss of treatment urgency
- Decreased adherence
- Increased use of medical care
- Diversion of providers away from patient care due to time-consuming processes

Atlas SJ, et al. Institute for Clinical and Economic Review. Published July 9, 2021. https://icer.org/assessment/atopic-dermatitis-2021/#overview. Accessed February 2022.

# Copay Assistance Mitigates Patient Cost Burden, but Accumulator Adjustment Programs Can Reinforce Financial Barriers to Access

Selecting the most appropriate therapeutic approach amidst a growing number of therapeutic options can be a challenge

- Treatment adherence can result in improved Quality of Life and decreased health care utilization




Patients with AD often rely on copay assistance programs to mitigate the financial burden of cost sharing

- A significant proportion of patients now only have high-deductible plan options
- Copay assistance programs are offered by manufacturers of specialty drug products

Copay Accumulator Programs interfere with a vital lifeline for patients with chronic conditions necessitating specialty drugs

- Accumulator adjustment and copay allowance maximization negate the benefits of copay assistance programs and reintroduce financial barriers to care

Sherman BW, et al. *Am J Manag Care*. 2019;25:335-340.

# Summary

- Confirming a diagnosis of AD and staging its severity is complicated by the lack of a “gold standard” test and biomarkers
  - Severity assessment tools used in clinical trials are not widely utilized in clinical practice
- Failure to account for disease heterogeneity and presence of comorbidities can impact disease control and treatment outcomes
- Evidence-based guidelines and UM programs standardize care and control costs but may limit access and care customization
- Collaboration between payers and providers is needed so UM programs do not create a barrier to timely access to appropriate therapy

# *Medical and Pharmacy Management Strategies to Enhance AD Patient Outcomes: A Case-Based Discussion*

**Neil Minkoff, MD**
CMO
Coeus Healthcare

# Learning Objectives

- Review recommendations for assessing the severity of AD
- Identify comorbidities associated with AD
- Assess the benefits of multidisciplinary care in AD patients

# Patient Case

- **Age and personal status:** 20-year-old college student
- **Disease history and diagnosis:** history of moderate-to-severe AD; diagnosed during childhood
  - >10% body surface involvement including shoulders, neck, and arms
  - Experiencing multiple flares (~3/year)
  - Severe itch (7 out of 10)
  - Sleep disturbances 2-3 nights/week
  - Poor quality of life (“AD controls my life”)
- **Comorbidities:** allergy to dairy products
- **Current therapy:** tacrolimus (TCI) 0.1%, moisturizers, and “natural” remedies; adherence to therapy is self-described as “not perfect, but pretty good”
- **Past therapies:** topical corticosteroids (mid- and high potency), pimecrolimus, and cyclosporine

# Current Complaints and Treatment Decision

## Current complaints

- Red, dry and itchy plaques on upper chest, face, and scalp, severe itching, sleep disruption, unable to focus on her course work, reduced quality of life, decreased social interaction
- Topical therapy only provides temporary relief
- Inability to achieve and maintain long-term disease control is frustrating

## Treatment decision

- Confirmed a Dx of moderate-to-severe AD
- Treatment selection criteria:
  - BSA involvement, severe itch, sleep disruption, history of poor disease control with topical prescription therapies, record of good adherence, poor quality of life
- Patient to continue TCI and prescribed dupilumab

# Question to Consider

- What criteria are used to assess AD severity?
- Do payers request this information?

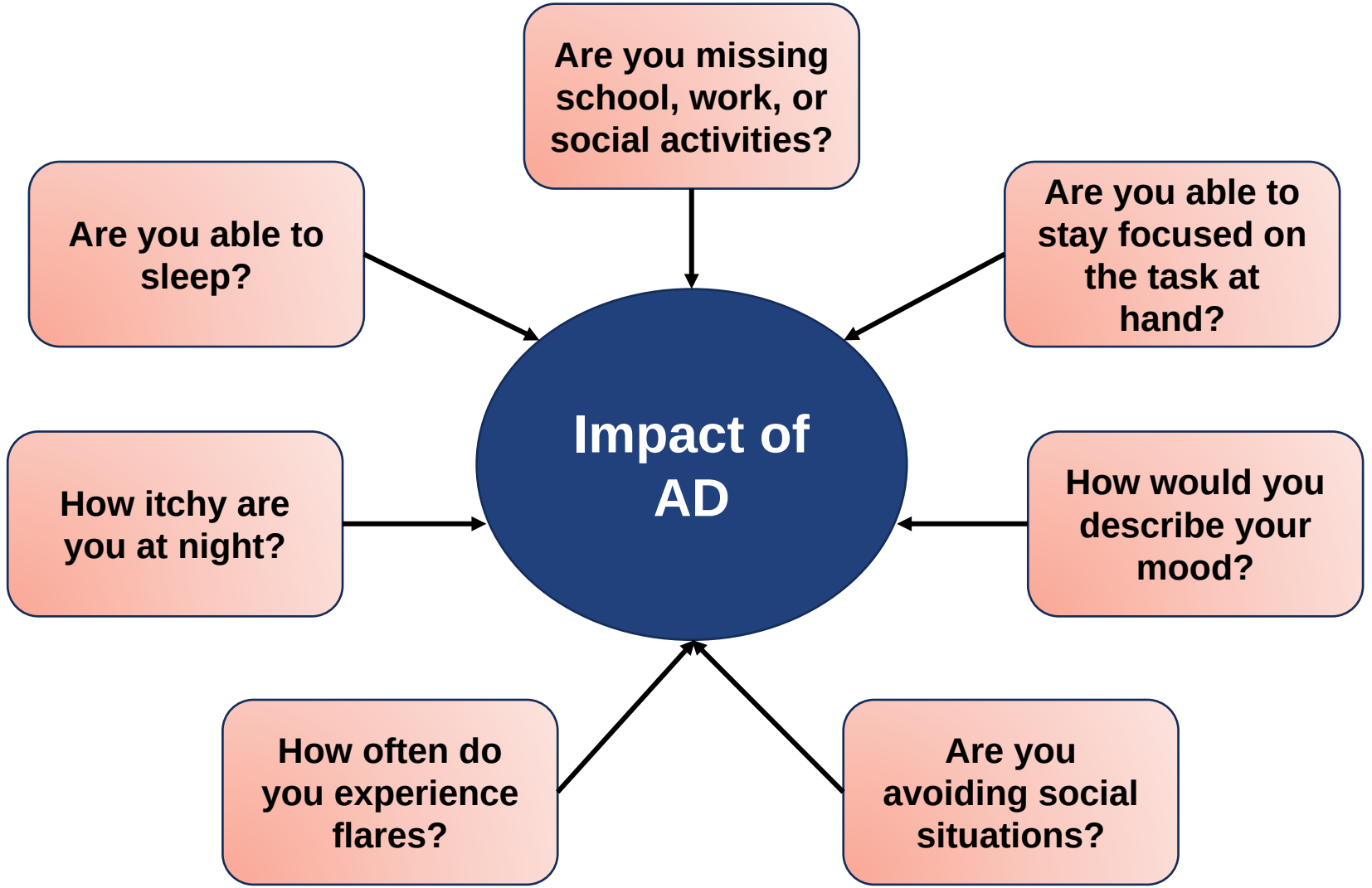
# Recommendations for Assessing Disease Severity

- Commonly assessed based on
  - Body surface area
  - Location, distribution
- Other tools are available but not commonly used in practice
  - EASI, POEM, SCORAD, DLQI
- Best practice: Combine clinical tools with patient interview questions to assess impact of AD on daily functioning and quality of life

DLQI, Dermatology Life Quality Index; EASI, Eczema Area and Severity Index; POEM, Patient-Oriented Eczema Measure; SCORAD, Scoring Atopic Dermatitis

Charman CR, et al. *Arch Dermatol*. 2004;140:1513-1519; Eichenfield LF, et al. *J Am Acad Dermatol*. 2014;70:338-351; Rehal B, et al. *PLoS One*. 2011;6:e17520; Finlay AY, et al. *Clin Exp Dermatol*. 1994;19:210-216.

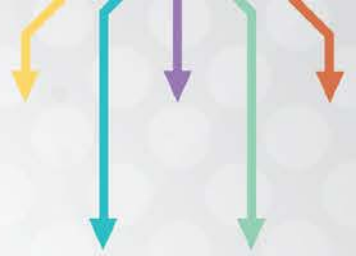
# Assessing Disease Severity: Questions for the Patient



# Question to Consider

- What comorbidities are commonly observed in patients with AD?

# AAD Certainty of Evidence for AD and Comorbid Conditions



### High-Quality Evidence

- Food allergies (diary, nuts, etc.)
- Osteoporosis

### Moderate-Quality Evidence

- Asthma
- Allergic rhinitis
- Alopecia areata
- Urticaria
- Hypertension
- Coronary artery disease
- Peripheral artery disease
- Congestive heart failure
- Thromboembolic diseases
- Obesity
- Dyslipidemia
- Bone fractures
- Skin infection

### Low-Quality Evidence

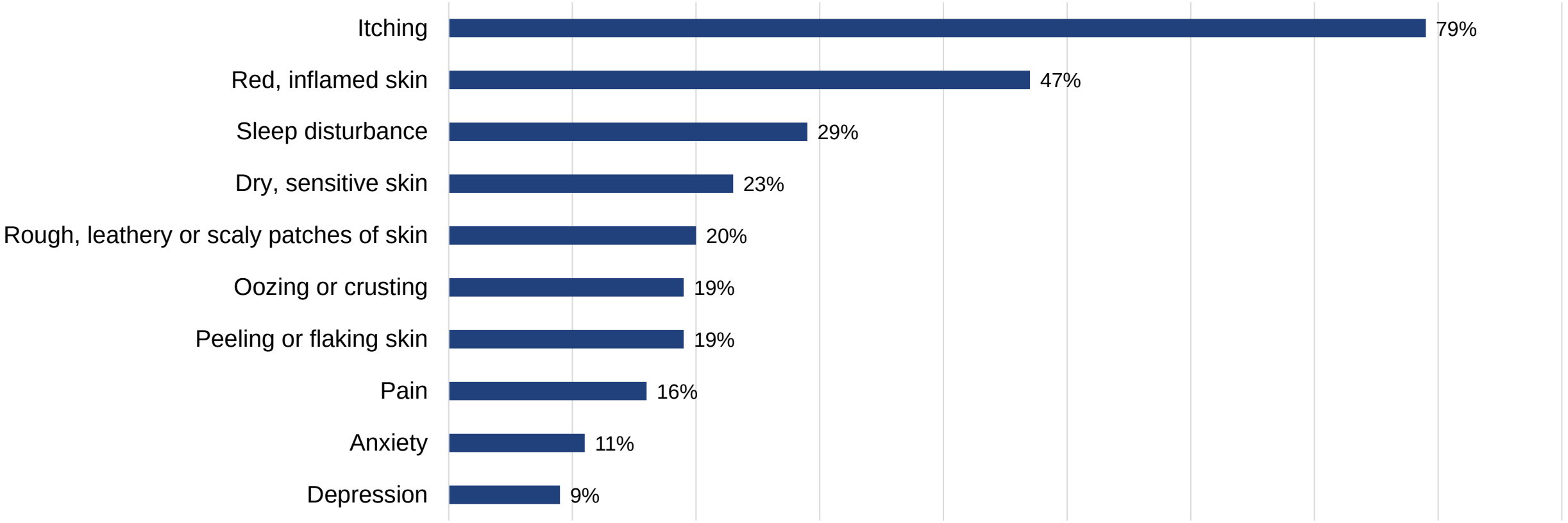
- Allergic conjunctivitis
- Eosinophilic esophagitis
- Myocardial infarction
- Cardiovascular death
- Diabetes

Davis DMR, et al. *J Am Acad Dermatol*. Jan 24:S0190-9622(22)00080-9. doi: 10.1016/j.jaad.2022.01.009. Online ahead of print.

# Patients Report Itch is the Most Burdensome Symptom of AD

**Symptoms of Greatest Burden**

Patients were asked which three symptoms have been the most problematic.



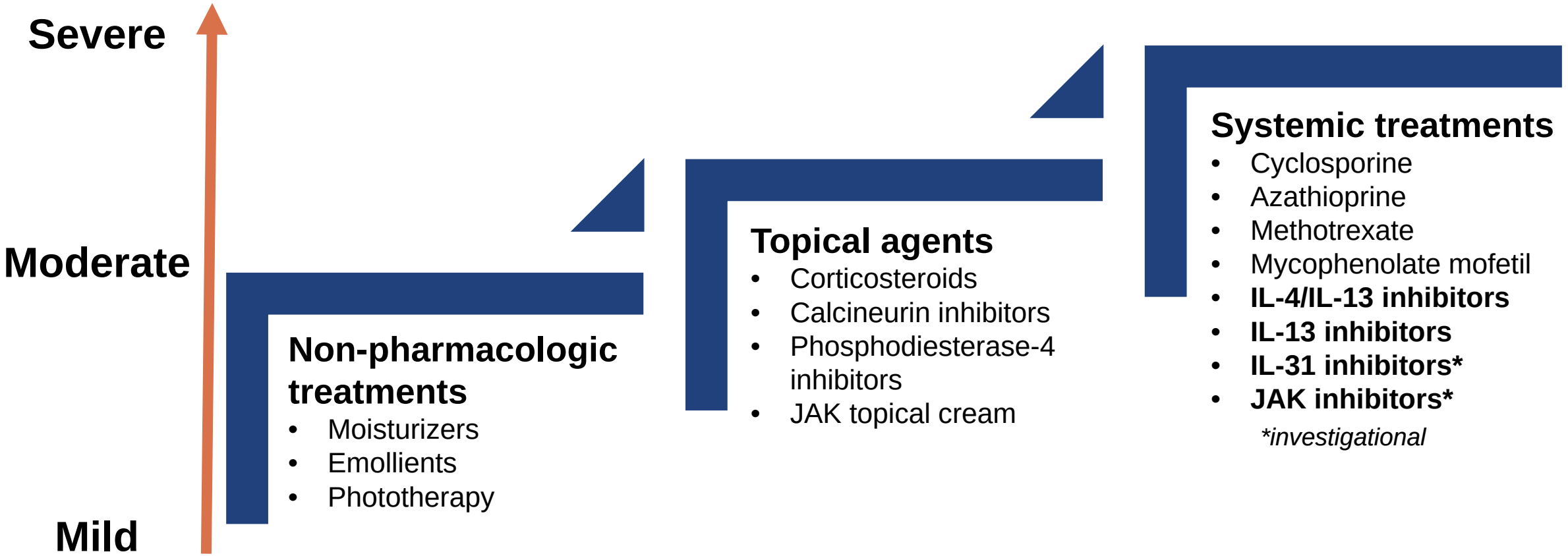

More Than Skin Deep. “Understanding the Lived Experience of Eczema.” Published 2020. http://www.morethanskindeep-eczema.org/uploads/1/2/5/3/125377765/mtsd_report_-_digital_file.pdf. Accessed February 2022.

# Question to Consider

- What is the optimal approach to therapy in this patient?
- How long does it take a patient to ultimate get to their most aggressive therapy?

# AD Step Therapy Algorithm

**Disease Severity**




Boguniewicz M, et al. *J Allergy Clin Immunol Pract*. 2017;5:1519-1531.

# Strategies to Optimize AD Treatment and Outcomes

- Make a **correct diagnosis**
- Determine the disease severity
- Educate the patient about AD and its treatments

- **Choose appropriate and safe** treatment
- Engage in **shared decision making**
- Set realistic treatment goals


- **Tailor the dosing regimen** to match the disease severity
- Employ **multidisciplinary care** to treat comorbid disease
- Escalate and de-escalate treatment to maintain control and as disease progresses

Wollenberg A, et al. *J Eur Acad Dermatol*. 2018;32:657-682.

# Question to Consider

- How can shared decision making influence the AD management strategy in this patient?

# Engage in Shared Decision Making to Set Goals and Make Therapeutic Selections

**Acknowledge the AD burden experienced by the patient**

- Explore the **total impact** of AD on the patient and caregiver

**Recognize the differences between patients**

- Understand that AD affects each patient **differently**

**Discuss preferences and treatment goals**

- Discuss the patient's **expectations** of treatment
- Agree on **treatment goals**
- Discuss **patient preference** for mode of administration, dosing frequency, and overall convenience

**Educate patients about AD treatment options, including newly introduced/emerging therapies**

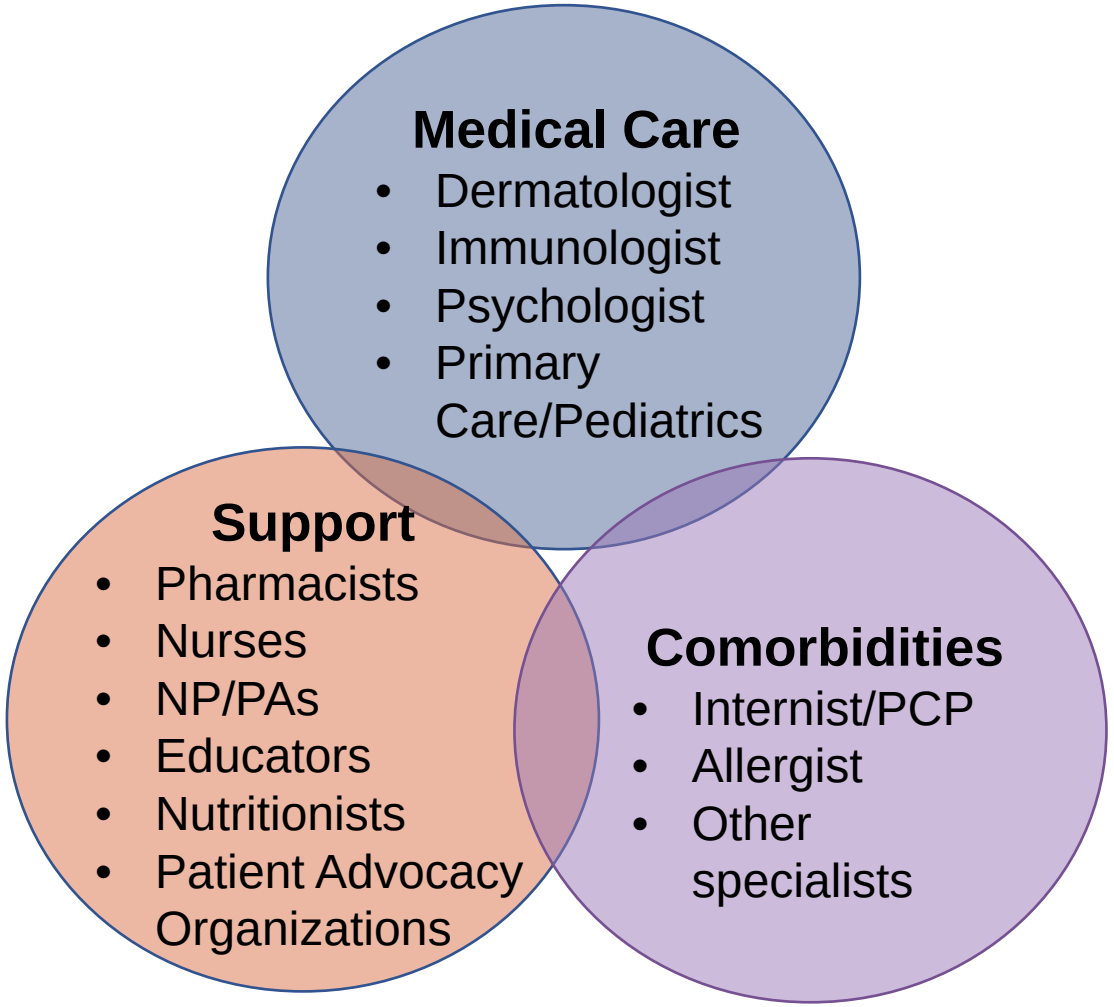
- Discuss with the patient and caregivers about the potential of new therapies to elicit **better treatment outcomes**
- Share knowledge about the **safety** of the new treatments

De Bruin-Weller M, et al. *Acta Derm Venereol*. 2021;101:adv00402.

# Question to Consider

- What might be the benefit of multidisciplinary care in this patient?

# Multidisciplinary Care May Improve AD Treatment Outcomes




- Multidisciplinary care can be used to target biological, psychological, and behavioral factors that affect disease control
- Beneficial effects of multidisciplinary interventions include
  - Reduced disease severity
  - Improved adherence to therapy
  - Enhanced quality of life

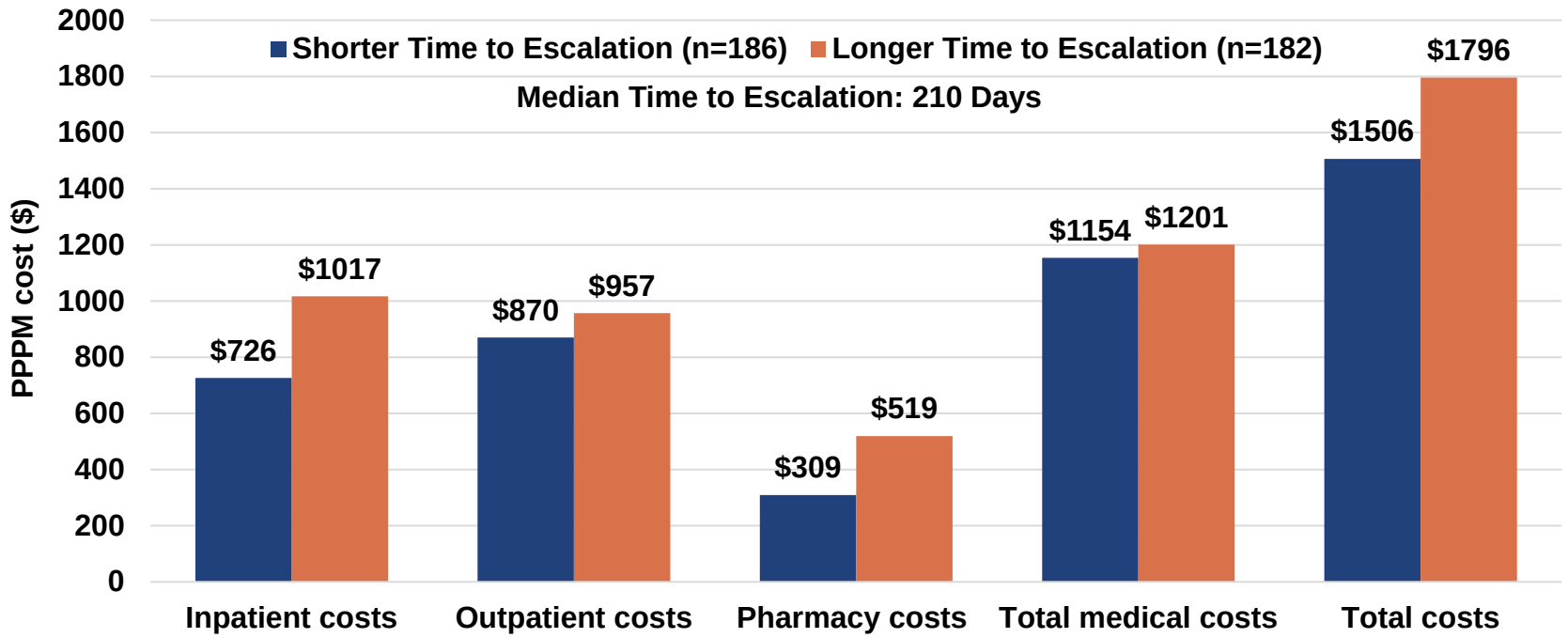
LeBovidge JS, et al. *J Allergy Clin Immunol*. 2016;138:325-334.

# Question to Consider

- How might the implementation of utilization management techniques such as the need to step through multiple therapies, impact treatment outcomes?

# Challenge: Need to Step Through Less Aggressive Therapies

**Stepping through less aggressive therapies can delay access to the prescribed therapy**

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Armstrong A, et al. *J Am Acad Dermatol.* 2019;81(supplement 1): AB131.

# UM Procedures Frequently Lead to Treatment Delays or Denials

- Results of a recent survey of AD patients conducted by the National Eczema Association (NEA) indicated:
  - 50% of AD patients experienced at least one delay or denial in the past 12 months
  - Delays and denials occur in all AD therapeutic categories, but occur most frequently for biologics (31.1%)
  - Prior authorization accounts for 60% of delays and step therapy accounts for 50% of denials
  - Disease flares was the most commonly reported patient-reported impact (18%) due to missed medication doses resulting from delays or denials

Begolka WS, et al. *J Manag Care Spec Pharm*. 2022;28:115-118.

# Summary

- Steps to improve treatment outcomes include
  - Align treatment with disease severity
  - Consider the impact of atopic and non-atopic comorbidities when devising the management strategy
  - Engage the patient in shared decision making
  - Employ multidisciplinary care particularly when the presence of comorbidities increase the complexity of disease management
  - Consider the effect of utilization management on treatment outcomes

# Achieving Appropriate Access for the Treatment of

# Atopic Dermatitis

## MEDICAL AND PHARMACY MANAGEMENT STRATEGIES

FOR MANAGED CARE AND PAYER PROFESSIONALS

Jointly provided by:

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This program is supported by independent educational grants from Incyte Corporation, Pfizer Inc., Sanofi Genzyme and Regeneron Pharmaceuticals, Inc.