

# Pharmaceutical Treatments for Atopic Dermatitis and Other Inflammatory Skin Diseases: Clinical Evidence

*Topic Brief*

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Presented by Beth Shaw, MSc



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## Background and Context (1 of 2)

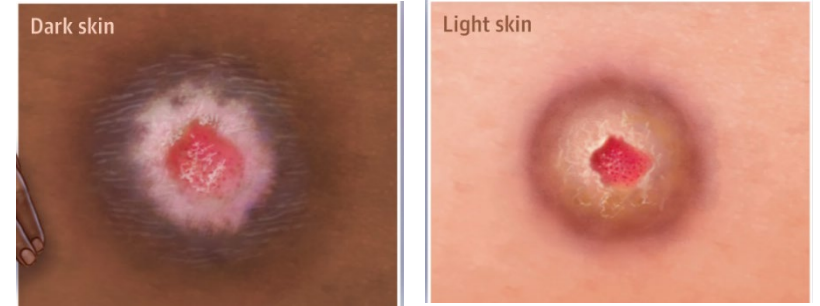
- Atopic dermatitis (AD) affects roughly 7% of adults and 10% of children in the US
- 85% of cases occur before age 5
- Topical treatments such as moisturizers and corticosteroids are first line
- Monoclonal antibodies such as dupilumab and tralokinumab are recommended for moderate-to-severe AD that is resistant to topical treatments



Atopic Dermatitis  
Source. *New Eng J Med.* 352(22)

## Background and Context (2 of 2)

- Prurigo nodularis (PN) is characterized by intensely itchy firm lumps
- Seborrheic dermatitis presents as red or yellowish patches on the scalp, face or chest
- Vitiligo is a loss of pigmentation resulting in smooth white patches on the skin



Source. JAMA Dermatol. 158(3)



Source. dermnetnz.org



Source. clevelandclinic.org

# Previous Systematic Review

## Pharmaceutical Treatments for Atopic Dermatitis: An Update

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Systematic Review

February 2022

# PICOS (1 of 3)

- Populations

- Adults and children with AD, PN, seborrheic dermatitis, or vitiligo

- Interventions

- FDA-approved biologics

- Dupilumab
- Lebrikizumab
- Nemolizumab
- Tralokinumab

- FDA-approved oral JAK inhibitors

- Abrocitinib
- Upadacitinib

## PICOS (2 of 3)

- Interventions (cont.)

- FDA-approved topical therapies

- Crisaborole
    - Pimecrolimus
    - Roflumilast
    - Ruxolitinib
    - Tacrolimus
    - Tapinarof

- Pipeline therapies

- Delgocitinib

- Other therapies used off-label

- Azathioprine
    - Cyclosporine
    - Methotrexate
    - Mycophenolate
    - Omalizumab

## PICOS (3 of 3)

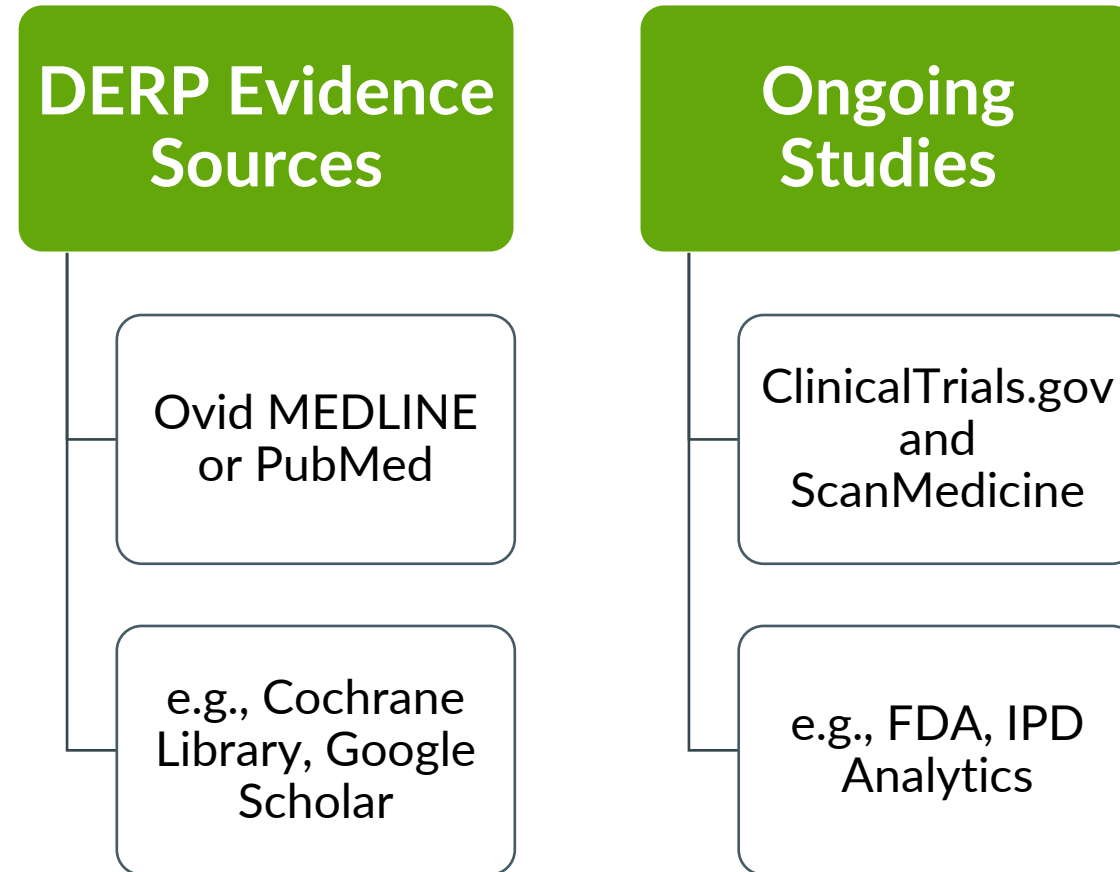
- Comparators
  - Another listed intervention
  - Standard of care
  - Placebo
  - No treatment
- Outcomes
  - Treatment response
  - Symptom severity
  - Adverse events (AEs)
- Study Designs
  - Randomized control trials (RCTs) with a minimum 12 weeks duration
  - Studies from countries ranked *very high* on the United Nations' Human Development Index



# Key Questions

1. Effectiveness of listed interventions
  - a. Variation by patient characteristic (e.g., age, severity of disease)
2. Harms
  - a. Variation by patient characteristic (e.g., age, severity of disease)
3. Characteristics of ongoing studies and selected pipeline agents

# Methods



We included only studies conducted in countries categorized as *very high* on the United Nations Human Development Index

# Findings



# Study Characteristics

**Total**

40 total studies in 49 publications

**Diagnosis**

25 studies in AD

5 studies in PN

1 study in  
SD

9 studies in vitiligo

**Comparator**

32 placebo

3 standard

5 head-to-head

# Atopic Dermatitis



# Study Characteristics: Atopic Dermatitis

Comparators	Number of RCTs	Study Size Range	Total N	Study Duration
Abrocitinib vs. placebo	2	200 to 1,233	1,433	12 to 40 weeks
Baricitinib vs. placebo	1	463	463	52 weeks
Crisaborole vs. placebo	1	270	270	52 weeks
Delgocitinib <sup>a</sup> vs. placebo	5	137 to 920	1,713	16 to 56 weeks
Lebrikizumab vs. placebo	3	211 to 427	1,348	16 to 68 weeks

Note: <sup>a</sup> indicates agent not covered in previous reviews

# Study Characteristics: Atopic Dermatitis

Comparators	Number of RCTs	Study Size Range	Total N	Study Duration
Nemolizumab vs. placebo	2	89 to 941	1,817	16 to 48 weeks
Tapinarof <sup>a</sup> vs. placebo	3	148 to 507	902	12 to 24 weeks
Tralokinumab vs. placebo	2	275 to 289	564	40 to 52 weeks
Upadacitinib vs. placebo	2	272 to 539	811	24 to 76 weeks
<b>Total</b>	<b>21</b> 28 total publications			

Note: <sup>a</sup> indicates agent not covered in previous reviews

# Study Characteristics: Atopic Dermatitis

Comparators	Number of RCTs	Study Size	Study Duration
Abrocitinib vs. dupilumab	1	600	26 weeks
Crisaborole vs. tacrolimus	1	47	12 weeks
Cyclosporin vs. methotrexate	1	103	60 weeks
Upadacitinib vs. dupilumab	1	673	24 weeks
<b>Total</b>	<b>4</b> 4 total publications		



# Study Characteristics: Atopic Dermatitis Outcomes

- Common clinical outcomes
  - Eczema Area and Severity Index (EASI) assessments
  - Use of rescue medication
  - Investigator's Global Assessment
  - Patient Oriented Eczema Measure (POEM)
  - Quality of life (QoL)
  - AEs

# Prurigo Nodularis



# Study Characteristics: Prurigo Nodularis

Comparators	Number of RCTs	Study Size Range	Total N	Study Duration
Dupilumab vs. placebo	1	311	311	24 weeks
Nemolizumab vs. placebo	4	70 to 274	848	12 to 32 weeks
<b>Total</b>	<b>5</b> 7 total publications			

# Study Characteristics: Prurigo Nodularis Outcomes

- Common clinical outcomes
  - Worst Itch-Numeric Rating Scale (WI-NRS)
  - Peak Pruritus Numerical Rating Scale (PP-NRS)
  - Dynamic Pruritus Scale (DPS)
  - Investigator's Global Assessment
  - QoL
  - AEs

# Seborrheic Dermatitis



# Study Characteristics: Seborrheic Dermatitis

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Comparators	Number of RCTs	Study Size	Study Duration
Tacrolimus vs. topical corticosteroids	1	30	12 weeks
<b>Total</b>	<b>1</b> 1 total publications		

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# Study Characteristics: Seborrheic Dermatitis Outcomes

- Common clinical outcomes
  - Seborrhea Area and Severity Index-Face (SASI-F)
  - Severity of lesions at each visit
  - AEs

# Vitiligo





# Study Characteristics: Vitiligo

Comparators	Number of RCTs	Study Size Range	Total N	Study Duration
Methotrexate vs. dexamethasone	1	50	50	24 weeks
Pimecrolimus vs. placebo	1	20	20	36 weeks
Pimecrolimus vs. tacrolimus	2	44 to 46	90	24 weeks
Ruxolitinib vs. placebo	1	157	157	52 weeks
Tacrolimus vs. placebo	3	35 to 42	117	24 to 48 weeks
Tacrolimus vs. clobetasol	1	100	100	24 weeks
<b>Total</b>	<b>9</b> 9 total publications			

# Study Characteristics: Vitiligo Outcomes

- Common clinical outcomes
  - Repigmentation rate
  - Facial Vitiligo Area Scoring Index (F-VASI)
  - Reduction in size of target lesion
  - QoL
  - AEs

## Ongoing Studies (1 of 2)

- We identified 68 ongoing studies evaluating eligible therapies including the following:
  - Atopic dermatitis
    - Abrocitinib: 4 studies
    - Baricitinib: 1 study
    - Delgocitinib: 5 studies
    - Lebrikizumab: 9 studies
    - Methotrexate: 2 studies
    - Roflumilast: 5 studies
    - Ruxolitinib: 8 studies
    - Tacrolimus: 2 studies
    - Tapinarof: 2 studies
    - Tralokinumab: 4 studies
    - Upadacitinib: 5 studies

## Ongoing Studies *(2 of 2)*

- We identified 68 ongoing studies evaluating eligible therapies including the following:
  - Prurigo nodularis
    - Nemolizumab: 2 studies
    - Ruxolitinib: 2 studies
    - Upadacitinib: 1 study
  - Seborrheic dermatitis
    - Roflumilast: 1 studies
    - Ruxolitinib: 1 study
  - Vitiligo
    - Methotrexate: 2 studies
    - Ruxolitinib: 9 studies
    - Upadacitinib: 3 studies

# Questions?



