Article type: From the Academy

Title: Focused update: Guidelines of Care for the Management of Atopic Dermatitis in Adults

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Funding sources: This study was funded in total by internal funds from the American Academy of Dermatology.

Conflicts of Interest: Listed in text.

Supplementary files are available on: To be available via Mendeley

Statement on prior presentation: Contents have not been previously presented.

Manuscript word count: 1918 words [excluding abstract, references, figures, tables, appendix]
Abstract word count: 162
References: 24
Figures: 1

Online Supplementary figures: 0
Tables: 3
Online Supplementary tables: 5

Keywords: atopic dermatitis, eczema, biologic, topical agents, lebrikizumab, nemolizumab, tapinarof, roflumilast

Disclaimer

Adherence to these guidelines will not ensure successful treatment in every situation. Furthermore, these guidelines should not be interpreted as setting a standard of care or be deemed inclusive of all proper methods of care, nor exclusive of other methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding the propriety of any specific therapy must be made by the physician and the patient in light of all the circumstances presented by the individual patient, and the known variability and biologic behavior of the disease. This guideline reflects the best available data at the time the guideline was prepared. The results of future studies may require revisions to the recommendations in this guideline to reflect new data.

Abstract

Background: In 2023 and 2024, the AAD published guidelines on the use of topical and systemic therapies for the management of atopic dermatitis (AD) in adults. Since the publication of these guidelines, several novel therapies have emerged to treat AD.

Objective: To update previous guidelines on the management of AD in adults by providing evidence-based recommendations on the use of additional FDA-approved topical and systemic therapies.

Methods: A multidisciplinary workgroup conducted a systematic review and applied the GRADE approach for assessing the certainty of evidence and formulating and grading recommendations.

Results: The workgroup developed four new recommendations for the management of AD in adults.

Limitations: This analysis is based on the best available evidence at the time it was conducted. Most randomized controlled trials of the considered therapies for AD are of short duration, limiting comparative long-term efficacy and safety conclusions.

Conclusions: The workgroup developed strong recommendations for the use of tapinarof cream, roflumilast cream, lebrikizumab, and nemolizumab with concomitant topical therapy.

Abbreviations Used

AAD: American Academy of Dermatology

AD: Atopic dermatitis

DLQI: Dermatology Life Quality Index

EASI: Eczema Area Severity Index

FDA: U.S Food and Drug Administration

GRADE: Grading of Recommendations, Assessment, Development, and Evaluation

IGA: Investigator Global Assessment

POEM: Patient Oriented Eczema Measure

TCI: Topical calcineurin inhibitor

TCS: Topical corticosteroids

Scope & Objective

In 2023 and early 2024, the American Academy of Dermatology (AAD) published guidelines on the management of atopic dermatitis (AD) in adults with topical and systemic therapies.[1, 2] Recently published evidence and U.S Food and Drug Administration (FDA) approval of novel topical small molecule and biologic therapies necessitated an update of the previous guidance. The focused scope of the present update is to incorporate the evidence specifically and solely addressing the use of tapinarof cream, roflumilast cream, lebrikizumab, and nemolizumab into the AAD's existing guidance on the management of AD in adults. Recommendations for the management of AD in children will be covered in a forthcoming guideline.

The newly developed recommendations for the management of AD in adults are available in **Table I**. A complete list of the current recommendations for the management of AD with topical and systemic therapies is available in **e-Appendix 1** and outlined in **Figure 1**.

Table I. Additional Recommendations for the Management of Atopic Dermatitis in Adults. *AD*, Atopic dermatitis

Recommendation	Strength	Certainty of Evidence	Evidence
For adults with moderate to severe AD, we recommend tapinarof cream	Strong	High	3-5
For adults with mild to moderate AD, we recommend the use of roflumilast 0.15% cream	Strong	High	6, 7
For adults with moderate to severe AD, we recommend lebrikizumab	Strong	High	8-15
For adults with moderate to severe atopic dermatitis, we recommend nemolizumab with concomitant topical therapy	Strong	High	16, 17

Methods

Cognizant of the need for timely updates to clinical guidance when novel evidence that has the potential to inform the revision or development of clinical practice recommendations within the scope of existing, recently published (< 5 years) AAD guidelines becomes available, the AAD's Clinical Guidelines Committee developed a focused update process. For details of the focused update process, see **e-Appendix 2**. Per this process, new evidence and the FDA-approval of

novel topical small molecule and biologic therapies were identified as potentially impacting the current AD guidance resulting in the initiation of this update.

This update is based on a systematic review by an expert workgroup supported by an AAD guidelines staff member with health research methodology expertise and applied the GRADE (Grading of Recommendations, Assessment, Development, and Evaluation) approach for assessing the certainty of the evidence and formulating and grading clinical recommendations. The strength of recommendation indicates the assessed magnitude of the balance of desirable and undesirable consequences of a treatment option. While the certainty of evidence ratings represent the level of confidence the guideline developers placed in the evidence supporting a recommendation (**Table II**).[18-20] For detailed methodology, **see e-Appendix 3**.

Table II. Strength of Recommendation and Certainty of Evidence

Strength of Recommendation	Wording	Implication[18-20]
Strong recommendation *for* the use of an intervention	"We recommend…"	Benefits clearly outweigh risk and burdens; recommendation applies to most patients in most circumstances.
Strong recommendation *against* the use of an intervention	"We recommend against…"	Risk and burden clearly outweigh benefits; recommendation applies to most patients in most circumstances.
Conditional recommendation *for* the use of an intervention	"We conditionally recommend…"	Benefits are closely balanced with risks and burdens; recommendation applies to most patients, but the most appropriate action may differ depending on the patient or other stakeholder values.
Conditional recommendation *against* the use of an intervention	"We conditionally recommend against…"	Risks and burden closely balanced with benefits; recommendation applies to most patients, but the most appropriate action may differ depending on the patient or other stakeholder values
Certainty of Evidence	**Wording**	**Implication[18, 19]**
High	"high certainty evidence"	Very confident that the true effect lies close to that of the estimate of the effect.
Moderate	"moderate certainty evidence"	Moderately confident in the effect estimate; the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low	"low certainty evidence"	Confidence in the effect estimate is limited; the true effect may be substantially different from the estimate of the effect
Very Low	"very low certainty evidence"	The estimate of effect is very uncertain; the true effect may be substantially different from the estimate of effect

New Recommendations

Clinical Questions

This focused update considers new evidence pertaining to the following clinical questions from the previously published guidelines: What are the efficacy and safety of topically applied therapies for AD?[2] and what are the efficacy and safety of systemic therapies for AD?[1] This guidance updates the clinical questions by introducing two new topical and two new systemic therapies and does not update evidence of the topical or systemic therapies considered in the previous guidelines. The previously issued recommendations are considered current for 5 years post-publication or until superseded by another update or full revision of the AD guidelines.

Topical Therapies

Tapinarof

Background

Tapinarof cream 1% is a nonsteroidal, topical aryl hydrocarbon receptor agonist FDA-approved for the treatment of atopic dermatitis in individuals aged two years of age and older in December 2024.[21]

Summary of Evidence and Analysis

A systematic literature search identified two phase II and two phase III randomized, double-blind, vehicle-controlled trials meeting established inclusion criteria.[3-5] The trials collectively included 1,169 participants with moderate to severe AD aged 2 years and older. Evidence on the once-daily use of 1% tapinarof for 8 to 12 weeks was analyzed to support the recommendation.

At 8 weeks, tapinarof 1% cream daily demonstrated statistically significant and clinically meaningful efficacy in the treatment of AD compared with vehicle as assessed via the Validated Investigator Global Assessment scale for AD, ≥75% improvement from baseline is Eczema Area Severity Index (EASI75), and Peak Pruritus Numerical Rating Scale (**e-Table 1**). The most common adverse events (≥5% in any arm) reported at weeks 8 to 12 were folliculitis, headache, and nasopharyngitis and were mild or moderate in severity (**e-Table 1**). No serious treatment-related adverse events were reported across the trials and the rates of discontinuation were low (**e-Table 1**).

Rationale for Recommendation

The Workgroup determined that the overall balance of benefits and potential harms as reported at 8 weeks favors using tapinarof cream for the management of AD and that the certainty of the available short-term evidence is high (**e-Table 1)**.

Reducing symptoms, specifically dermatitis and pruritus, and minimizing therapeutic risks are key goals of AD therapy. The reported clinically meaningful improvements in disease severity and pruritus were considered to be moderate in magnitude. The safety profile suggests tapinarof is well tolerated with limited anticipated adverse effects. The moderate improvement in desirable effects in the absence of substantial risk of undesirable effects favors the use of tapinarof. The Workgroup acknowledges that the current recommendation is based on the available short-term efficacy and safety evidence.

Roflumilast

Background

Roflumilast cream 0.15% is a phosphodiesterase-4 inhibitor approved by the FDA in July of 2024 for the treatment of mild to moderate AD in individuals aged six years and older.[22] While roflumilast cream is also FDA-approved for the management of plaque psoriasis, 0.3% is indicated for the management of that condition.

Summary of Evidence and Analysis

A systematic literature search identified a phase II proof of concept trial and two phase III randomized, double-blind, vehicle-controlled trials meeting established inclusion criteria.[6, 7] The trials collectively included 1,427 participants with mild to moderate AD aged six years and older. Evidence on the once-daily use of roflumilast cream 0.15% for four weeks was analyzed to support the recommendation.

At 4 weeks, significantly more participants achieved Validated Investigator Global Assessment scale for AD scores of 0 or 1 and EASI75 with daily use of roflumilast cream compared with vehicle (**e-Table 2**). A greater percentage of roflumilast- versus vehicle-treated participants also

achieved a 4-point or greater improvement in Worst Itch Numerical score. The most common adverse events reported (≥1% in any arm) were headache, nausea, diarrhea, and vomiting. Application site pain was reported in 1.5% of roflumilast-treated patients compared to 0.7% of vehicle-treated patients. The rates of discontinuation were low and similar across treatment groups (**e-Table 2**).

Rationale for Recommendation

The Workgroup determined that the overall balance of benefits and potential harms as reported at 4 weeks favors using roflumilast cream for the management of AD and that the certainty of the available short-term evidence is high (**e-Table 2)**.

The reported improvements in disease severity and pruritus were considered to be moderate in magnitude and the safety profile suggests roflumilast is well tolerated with limited anticipated adverse effects. The moderate improvement in desirable effects in the absence of substantial risk of undesirable effects favors the use of roflumilast. The Workgroup acknowledges that the current recommendation is based on the available short-term efficacy and safety evidence.

Monoclonal antibodies (biologics)

Lebrikizumab

Lebrikizumab a monoclonal antibody targeting interleukin-13 was FDA-approved for the management of moderate to severe AD in individuals aged 12 years and older in 2024.[23]

Summary of Evidence and Analysis

A systematic literature search identified one phase II and three phase III randomized, double-blind, placebo-controlled trials and a 52-week extension study of lebrikizumab monotherapy that met inclusion criteria.[8, 13-15] Also identified were two randomized, double-blind, placebo-controlled trials of lebrikizumab in combination with topical corticosteroids (TCS).[10, 11]

Collectively, the monotherapy and combination therapy trials included 1,232 and 497 adolescents and adults with moderate to severe AD, respectively. Evidence on the use of lebrikizumab 250mg (500mg loading dose) with or without the use of concomitant TCS every two weeks for 16 weeks was analyzed.

In the monotherapy trials, significantly more participants in the lebrikizumab arm compared to the placebo arm achieved IGA 0/1 with a ≥2-point improvement from baseline, EASI75, and clinically meaningful pruritus improvement (**e-Table 3**). Clinically meaningful improvements in Patient Oriented Eczema Measure (POEM) score and quality of life as assessed via the Dermatology Life Quality Index (DLQI) were also achieved. Similarly, in the combination therapy trials, a greater number of lebrikizumab +TCS- versus placebo +TCS-treated patients achieved the efficacy outcome listed above as well as greater improvement in POEM and DLQI scores (**e-Table 4**).

Worsening of AD (8.9%), conjunctivitis (8.2%), nasopharyngitis (8.2%), allergic conjunctivitis (6.0%), and herpesvirus infection (5.0%) were the most common treatment-emergent adverse events reported over 52-weeks in monotherapy trial participants receiving at least one dose of lebrikizumab (n=806).[8] The frequencies of injection site reactions (2.4%), eosinophilia (1.5%), and anaphylaxis (0%) were low. Discontinuation rates were also low and similar across treatment arms in both the monotherapy and combination therapy trials (**e-Table 3**).

Rationale for Recommendation

Based on high-certainty evidence, the reported improvements in disease severity and pruritus were considered to be large in magnitude with monotherapy. The favorable safety profile suggests lebrikizumab is well tolerated with treatment-emergent adverse effects consisting primarily of mild or moderate events that did not lead to discontinuation. The large improvement

in desirable effects in the absence of substantial risk of undesirable effects favors the use of lebrikizumab.

Nemolizumab

Background

Nemolizumab, a monoclonal antibody targeting the interleukin-31 receptor, was FDA-approved in December 2024 for the management of moderate to severe AD that is inadequately controlled with topical therapies in individuals aged 12 years and older in combination with topical corticosteroids and/or calcineurin inhibitors.[24]

Summary of Evidence and Analysis

A systematic literature search identified one phase II and two phase III randomized, double-blind, placebo-controlled trials that met established inclusion criteria.[16, 17] The treatment arms of the included trials combined nemolizumab with background TCS therapy and the phase III trials allowed for additional therapy with topical calcineurin inhibitors (TCI). Collectively, the trials included 1,256 participants aged 12 years and older with moderate to severe AD. Evidence on the use of nemolizumab 30mg every four weeks + TCS with or without TCI for 16 to 24 weeks was analyzed to support the recommendation.

At 16 to 24 weeks, combination topical therapy and nemolizumab resulted in a significantly greater number of participants achieving clinically meaningful itch reduction, IGA 0/1, and EASI75 compared to placebo and topical therapy (**e-Table 5**). Greater improvements in POEM and DLQI scores were also achieved by nemolizumab- compared to placebo-treated participants. In the phase III trials, adverse events were generally mild or moderate with the most common (≥5% in the nemolizumab arms) being worsening of AD and asthma events.[17]

Injection site reactions or pain occurred in < 1% of the nemolizumab-treated patients. Rates of discontinuation due to adverse events were low and similar across treatment arms (**e-Table 5**).

Rationale for Recommendation

Given the large magnitude of benefits in terms of improvements in disease severity and itch and the favorable safety profile, the Workgroup determined that the overall balance of benefits and potential harms as reported at 16 to 24 weeks favors using nemolizumab in addition to topical TCS and possibly TCI for the management of AD and that the certainty of the available evidence is high.

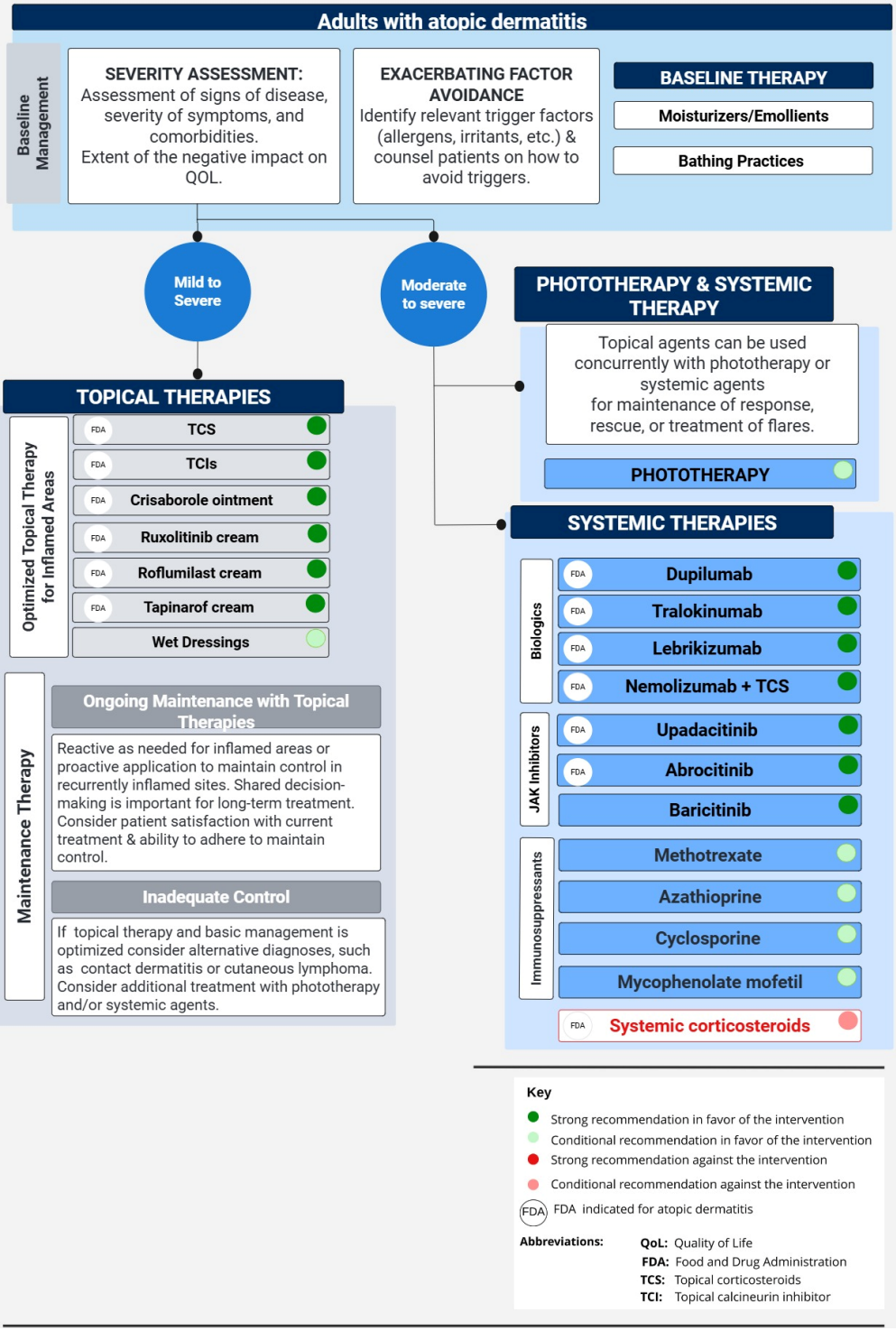
Cost

The Workgroup recognizes that costs for the considered therapies may be prohibitive without adequate insurance coverage and other strongly recommended treatments for AD may be available for a lower cost. Given the available evidence of efficacy and safety, the Workgroup concluded that the use of the recommended therapies is likely acceptable to patients and providers, and cost should be considered during the shared decision-making process.

Conclusion and Research Needs

The Workgroup recommends the use of tapinarof cream, roflumilast cream, lebrikizumab, and nemolizumab with concomitant topical therapy for the management of AD in adults. Additional, long-term efficacy and safety data and data on patient-reported outcomes in real-world settings are needed to provide additional insights into the efficacy, effectiveness, and safety of these therapies for the management of AD. Comparative studies of these medications and available, standard AD therapies would provide an understanding of the role of these therapies in the armamentarium of AD treatments.

Figure 1. Treatment algorithm for adults with atopic dermatitis. *FDA*, U.S. Food and Drug Administration, *TCI*, Topical calcineurin inhibitor, *TCS*, Topical corticosteroids, *QoL*, Quality of life.



Workgroup Members' Disclosures

The information below represents the authors' disclosed relationship with industry during guideline development. Authors (listed alphabetically) with relevant conflicts with respect to this guideline are noted with an asterisk*. In accordance with AAD policy, a minimum 51% of Workgroup members did not have any relevant conflicts of interest.

Participation in one or more of the listed activities below constitutes a relevant conflict:

- service as a member of a speaker bureau, consultant, advisory board, for pharmaceutical companies on atopic dermatitis or atopic dermatitis drugs in development or FDA-approved.
- sponsored research funding or investigator-initiated studies with partial/full funding from pharmaceutical companies on atopic dermatitis or atopic dermatitis drugs in development or FDA-approved

If a potential conflict was noted, the workgroup member recused themselves from the discussion and drafting of recommendations pertinent to the topic area of interest. Complete group consensus was obtained for draft recommendations. Areas where complete consensus was not achieved are shown transparently in the guideline.

Drs. Alikhan, Bercovitch, Davis, Frazer-Green, and Jennifer M. Darr, LCSW, have no relationships to disclose. David E. Cohen*, MD, MPH, serves on the board of directors for Timber and Evommune receiving stock options and/or fees; as a consultant for Asana Biosciences, Ferndale Laboratories, Inc., Novartis, Facilitation of International Dermatology Education, Dermavant Sciences, Leo Pharma, Inc., UCB, and Cosmetic Ingredient Review receiving honoraria and/or stock options. Aaron M. Drucker, MD, ScM receives research grants paid to his institution from the National Eczema Association, Eczema Society of Canada, Canadian Dermatology Foundation, Canadian Institutes for Health Research, US National Institutes of Health, and Physician Services Incorporated Foundation. Lawrence F. Eichenfield*, MD, serves on the board of directors for Verrica Pharmaceuticals, Inc., receiving honoraria and/or stock options; as an investigator for Abbvie, Arcutis, Dermavant, Galderma Laboratories, National Eczema association, Pfizer and Bausch without personal compensation (research grants to institution); as a consultant for Abbvie, Almirall, Amgen, Arcutis, Bausch, Bristol Meyer Squibb, Dermavant, Dermira, Eli Lilly, Forte, Galderma, Incyte, Janssen, Leo Pharma, Novartis, Ortho Dermatologics, Pfizer, Regeneron, and Sanofi Genzyme, honoraria; as an independent contractor for Elsevier, Inc. receiving royalties. Amy S. Paller*, MD, serves as a consultant for Abbvie, Abeona, Almirall, Amagma, Anaptysbio, Arena, Bausch, Bristol Myer Squibb, Dermavant, Dermira, Eli Lilly, Exicure, Forte, Leo, Lifemax, Novartis, Phoenix, Pierre Fabre, Pfizer, Rapt, Regeneron, Sanofi, Sol-Gel, UCB, and Venthera receiving honoraria; as an investigator for Anaptysbio, Eli Lilly, Incyte, Janssen, Krystal Bio, Lenus, Regeneron, and UCB receiving no compensation. Kathryn Schwarzenberger, MD is the founder of Pretel, Inc. and serves as a data safety monitoring board member for Pfizer, Inc. receiving fees. Robert Sidbury*, MD, MPH serves as an advisory board member for Pfizer, Inc. receiving honoraria; as a principal investigator for Regeneron receiving grants and research funding; as an investigator for

Brickell Biotech, Inc., and Galderma USA receiving grants and research funding; as a consultant for Galderma Global and Microes receiving fees or no compensation. Jonathan I. Silverberg*, MD, PhD, MPH, serves as an advisory board member for BioMX, Boehringer Ingelheim, RAPT Therapeutics, Celgene, Ortho Dermatologics, TARGET Pharma, AFYX Therapeutics, Corrona, Inc., Dermira, Pfizer, Inc., Leo Pharma, Inc., and Menlo Therapeutics receiving honoraria and/or fees; as an investigator for DS Pharma, TARGET Pharma, Kiniksa Pharmaceuticals, Ltd., Menlo Therapeutics, GlaxoSmithKline, AbbVie, Leo Pharma, Inc., and Regeneron receiving research funding, honoraria, or no compensation; as a consultant for AOBiome, Bluefin Biomedicine, Bodewell, BiomX, Inc., Galderma Research & Development, LLC., Arena Pharmaceuticals, Dermavant Sciences, Incyte Corporation, DS Biopharma, Sun Pharmaceutical Industries, Ltd., AnaptysBio, Asana Biosciences, LLC., Pfizer, Inc., Glenmark Generics, Inc., Sanofi, Kiniksa Pharmaceuticals, Ltd., GlaxoSmithKlein, Eli Lilly and Company, AbbVie, Regeneron, and Medimmune receiving honoraria or fees; as a speaker for the Fall Clinical Dermatology Conference, Maui Derm, and Regeneron receiving honoraria or fees. Anne Marie Singh, MD, as an advisory board member for Incyte receiving honoraria. Peggy Wu, MD, MPH is an author for UpToDate, Inc receiving honoraria.

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