TV-099-121318-53

SYLLABUS AND COURSE GUIDE

Improving the Quality of Care for Patients with Atopic Dermatitis: *Integrating Measurement-Based Tools Into Your Clinical Practice*

A Free, 90 Minute CME/CNE/ACPE/ABIM Live and On Demand Activity

Premiere Date: Thursday, December 13, 2018

12:00 p.m.–1:30 p.m. ET (live) • "After the Show" live Q&A webcast: 1:02 p.m.–1:30 p.m. ET

4:00 p.m.–5:30 p.m. ET (taped re-air)

Credit Expiration Date: Friday, December 13, 2019

On the Web: www.cmeoutfitters.com/CM28439

FACULTY: Stephen D. Hess, MD, PhD, John J. Russell, MD, Jonathan I. Silverberg, MD, PhD, MPH

MODERATOR: Zelma C. Chiesa Fuxench, MD, MSCE

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INFORMATION FOR PARTICIPANTS

Statement of Need

Attitudes about atopic dermatitis are evolving with the emergence of new and effective treatments. With the average dermatologist having not enjoyed caring for patients with AD for decades, there is little to no consensus in current practice about validated tools to assess and monitor the severity of the diseases and no consistent use of diagnostic or assessment tools. This lack of knowledge and education leads to confusion, poor recognition, and absence of assessment of AD severity.

the use of patient-reported outcomes such as the Patient-Oriented Eczema Measure (POEM) are often underused in clinical practice despite being simple, valid, repeatable, and easy to interpret. The use of tools such as POEM is important to capture the impact of AD on health-related quality of life.

In this CME Outfitters Live and On Demand, expert faculty will discuss diagnostic assessment and measurement of symptom severity in AD including patient-reported outcomes, with the goal of educating clinicians regarding tools for diagnosis and assessment that can be integrated into their clinical practice.

Learning Objectives

At the end of this CE activity, participants should be able to:

- Apply the Hanifin Rajka criteria and/or the American Academy of Dermatology (AAD) criteria to facilitate the diagnosis of AD in clinical practice
- Incorporate the POEM assessment scale into clinical practice to monitor disease severity and response to treatment.
- Document the utilization of clinical assessment tools and results form their use in patients' charts.

The following learning objectives pertain only to those requesting CNE or CPE credit:

- Summarize the Hanifin Rajka criteria and/or the American Academy of Dermatology (AAD) criteria used to diagnose AD.
- Describe the POEM assessment scale for monitoring disease severity and response to treatment.
- Identify the tools and clinical assessment results that should be documented in patients' charts.

Target Audience

Dermatologists, allergists, primary care physicians, physician assistants, nurse practitioners, nurses, and pharmacists who treat patients with atopic dermatitis.

Financial Support

Supported by an educational grant form Sanofi Genzyme and Regeneron Pharmaceuticals.

CREDIT INFORMATION

CME Credit (Physicians)

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CNE Credit (Nurses)

Provider approved by the California Board of Registered Nursing, Provider Number CEP 15510, for 1.5 contact hours.

Note to Nurse Practitioners and Clinical Nurse Specialists: the content of this activity pertains to pharmacology.
Earn up to 1.5 contact hours of pharmacotherapeutic contact hours.

Note to Nurse Practitioners: Nurse practitioners can apply for *AMA PRA Category 1 Credit*™ through the American Academy of Nurse Practitioners (AANP). AANP will accept *AMA PRA Category 1 Credit(s)*™ from organizations accredited by the Accreditation Council for Continuing Medical Education. Nurse practitioners can also apply for credit through their state boards.

CPE Credit (Pharmacists)

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Universal Activity Number: 0376-0000-18-025-H01-P (live presentation)
0376-0000-18-025-H01-P (recorded program)
Activity Type: knowledge-based

ABIM/MOC Credit:

Successful completion of this CME activity, which includes participation in the evaluation component, enables the participant to earn up to 1.5 MOC points in the American Board of Internal Medicine's (ABIM) Maintenance of Certification (MOC) program. Participants will earn MOC points equivalent to the amount of CME credits claimed for the activity. It is the CME activity provider's responsibility to submit participant completion information to ACCME for the purpose of granting ABIM MOC credit.

Learning Formats :
Live activity
Enduring material

MIPS Improvement Activity:

This activity counts towards MIPS Improvement Activity requirements under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). Clinicians should submit their improvement activities by attestation via the CMS Quality Payment Program website.

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Successful completion of this CE activity includes participating in the live or recorded activity, reviewing the course materials, and following the instructions below within 30 days of completion of the activity:

Post-tests, credit request forms, and activity evaluations must be completed online at www.cmeoutfitters.com/TST28439 (requires free account activation), and participants can print their certificate or statement of credit immediately (75% pass rate required). This website supports all browsers except Internet Explorer for Mac. For complete technical requirements and privacy policy, visit www.neurosciencecme.com/technical.asp.

There is no fee for participation in this activity. The estimated time for completion is 90 minutes.
Questions? Please call **877.CME.PROS**.

FACULTY BIOS & DISCLOSURES

Zelma C. Chiesa Fuxench, MD, MSCE (Moderator)

Dr. Chiesa Fuxench is an Assistant Professor of Dermatology with the Department of Dermatology at the University of Pennsylvania School of Medicine. She has a special interest in the diagnosis and management of adult patients with moderate-to-severe atopic dermatitis and is currently spearheading efforts to develop a specialty program focusing on adult patients with this complex disease at University of Pennsylvania. Dr. Chiesa Fuxench has collaborated with the National Eczema Association as well as the Asthma and Allergy Foundation of America and is involved in multiple clinical trials for atopic dermatitis as the principal investigator.

Stephen D. Hess, MD, PhD

Dr. Hess is a board-certified Dermatologist who practices in Philadelphia. He is the owner and medical director of Center City Dermatology, a premier dermatology practice specializing in all aspects of medical, surgical, cosmetic, and aesthetic dermatology. Dr. Hess grew up in Buffalo, NY and completed his undergraduate degree in Biology at Wake Forest University in Winston-Salem, NC. He returned to Buffalo for medical school, where he earned both his MD and a PhD in Immunology. His research focused on the study of tumor immunology and cancer immunotherapy. After graduating medical school, he moved to Philadelphia where he completed his dermatology residency at the University of Pennsylvania. He also did a year of additional fellowship training in Cutaneous Oncology. Dr. Hess has practiced in the Philadelphia area since 2008. He serves as a consultant and speaker for a number of pharmaceutical companies including Janssen (Johnson & Johnson), Pfizer, Celgene, Regeneron / Sanofi-Genzyme, and Sun Pharma. He has a faculty appointment at the University of Pennsylvania where he volunteers his time teaching residents and medical students. Dr. Hess resides in Glen Mills, PA. In his free time, he enjoys skiing, playing and coaching soccer, practicing martial arts, and traveling.

John J. Russell, MD

Dr. Russell is a graduate of Temple University and the Pennsylvania State University College of Medicine. He completed his Family Medicine training at Abington Memorial Hospital, serving as Chief Resident, and joined the faculty in 1993. He has served as Contributing Editor to Patient Care magazine and is a contributor and reviewer for American Family Physician. He has worked on palm- based guidelines for the American Diabetes Association and the Infectious Disease Society of America. He is also co-author of Dermatology Skills in Primary Care set for release in July of 2005. He currently is a contributing Editor for the AAFP's "Learning Link Clinical Update" a twice monthly journal review which also features a twice monthly podcast of the articles. He has written on a variety of topics for articles and textbook chapters. Dr. Russell lectures extensively to primary care physicians on a national level and has won several resident teaching awards. He has been recognized by Philadelphia Magazine as a "Top Doctor"in Family Medicine. His special interests include pediatrics, dermatology, medical history and bioethics.

Improving the Quality of Care for Patients with Atopic Dermatitis: Integrating Measurement-Based Tools Into Your Clinical Practice

Jonathan I. Silverberg, MD, PhD, MPH

Dr. Silverberg is an Associate Professor of Dermatology, Medical Social Sciences and Preventive Medicine at Northwestern University Feinberg School of Medicine in Chicago, IL. He is also founder and Director of Northwestern Medicine's Multidisciplinary Eczema Center, and Director of the patch testing clinic at Northwestern Memorial Hospital. Jonathan received his doctorate in neuroimmunology, medical degree and Master of Public Health degree in biostatistics and epidemiology from the State University of New York Downstate Medical Center, in Brooklyn where he also completed his internship in internal medicine. He completed his residency training in dermatology at St. Luke's-Roosevelt Hospital Center and Beth Israel Medical Centers in New York, NY.

Dr. Silverberg's area of clinical subspecialty is inflammatory skin disease, particularly atopic and contact dermatitis. Dr. Silverberg developed a multidisciplinary atopic dermatitis clinic, including providers from dermatology, allergy and immunology, neurology and sleep medicine. His research interests include drug development, biomarkers, dermato-epidemiology, health services research, patient-reported outcomes, comorbidities and burden of inflammatory skin disease and evidence-based dermatology. His publications include more than 400 peer-reviewed articles, abstracts, books and book chapters. He has also been a local, national and/or international principal investigator for numerous clinical trials for novel treatments in atopic dermatitis and other inflammatory disorders. He has been recognized with several honors, including the Young Leadership Award from the American Dermatological Association in 2017, Teacher of the Year Award in the department of dermatology in 2015, the Outstanding Teacher's Award from the Feinberg School of Medicine in 2016, and the inaugural Rajka Award from the International Society for Atopic Dermatitis in 2014.

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Dr. Chiesa Fuxench discloses that she serves on the Advisory Board for Sanofi Genzyme and Regeneron Pharmaceuticals.

Dr. Hess discloses he is on the Speakers Bureau for Celgene Corporation; Janssen Pharmaceuticals, Inc.; Pfizer Inc.; Sanofi Genzyme and Regeneron Pharmaceuticals; and Sun Pharmaceutical Industries Ltd. He is a consultant for Celgene Corporation; Janssen Pharmaceuticals, Inc.; and Verrica Pharmaceuticals. He is a stock shareholder (directly purchased) for Aclaris Therapeutics, Inc; Celgene Corporation; and Verrica Pharmaceuticals.

Dr. Russell discloses he is on the Speakers Bureau and a consultant for sanofi-aventis U.S. LLC

Dr. Silverberg reports that he receives grants from GlaxoSmithKline and receives research support for Sanofi Genzyme and Regeneron Pharmaceuticals. He is a consultant for AbbVie Inc.; Anaptys Bio, Inc; Asana BioSciences, LLC; Dermavant Sciences, Inc.; Eli Lilly and Company; Incyte Corporation; Galderma; GlaxoSmithKline; Glenmark Pharmaceutical Inc.; Kiniksa Pharmaceuticals; LEO Pharma Inc.; Menlo Therapeutics; Pfizer Inc.; Realm Therapeutics, Inc.; and Sanofi Genzyme and Regeneron Pharmaceuticals .

Jeffrey Helfand, DO (peer reviewer) has no disclosures to report.

Mae Ochoa, RPh (peer reviewer) has no disclosures to report.

Kate Nelson, PhD (planning committee) has no disclosures to report.

Jan Perez (planning committee) has no disclosures to report.

Sharon Tordoff (planning committee) has no disclosures to report.

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Improving the Quality of Care for Patients With Atopic Dermatitis: Integrating Measurement-Based Tools Into Your Clinical Practice

Thursday, December 13, 2018

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AD Referrals From Primary Care[1,2]

- AS was estimated to affect 12.5% of children (age 0-17) in the United States in 2009-2011, an increase of just over 5% since 1997-1999.[1,2]
- Among these patients, the vast majority (~67%) are reported to have mild disease and as such may be adequately managed by their pediatrician or other primary care physician (PCP).[2,3]
- However, the majority of pediatricians refer even their mild patients to dermatologists (~85%) and provide only initial, limited care (81%).[2,4]

1. Jackson KD, et al. *NCHS Data Brief.* 2013;May(121):1-8. 2. Eichenfield L, et al. *Pediatrics.* 2015;136(3):554-565. 3. Silverberg JI, et al. *Pediatr Allergy Immunol.* 2013;24(5):476-486. 4. Saavedra JM, et al. *J Pediatr.* 2013;163(6):1747-1753.

AD in Primary Care

- UK study of AD management in NHS
  - Issues with AD diagnosis not meeting national guideline to confirm diagnosis
  - Large discrepancies in the severity ratings of patients
  - Less than one-half of the patients were using emollients
  - No correlation between severity of disease and potency of topical corticosteroids

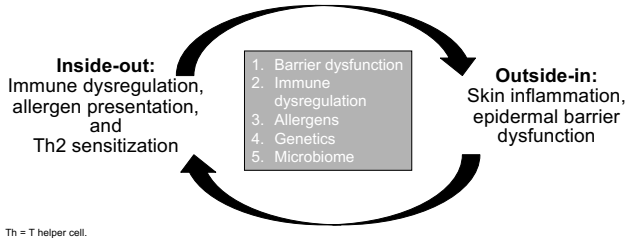
Jacquet L, et al. *BJGP Open.* 2017;1(2):BJGP-2017-00821.

Atopic Dermatitis (AD): Epidemiology[1-5]

- AD is a chronic, pruritic, inflammatory skin disease characterized by periods of acute disease flare
- Prevalence of AD in the United States:
  - Children ~ 20%
  - Adults ~ 3.2% to 10.7% (studies vary)
- Adult-onset AD is considered rarer
  - Occurs more frequently during third decade of life
  - 30% of all cases of AD are in adult population

1. Eichenfield LF, et al. *J Am Acad Dermatol.* 2014;70:338-351.
2. Hanifin JM, et al. *Dermatitis.* 2007;18:82-91.
3. Garmhausen D, et al. *Allergy.* 2013;68:498-506.
4. Silverberg JI, et al. *J Allergy Clin Immunol.* 2013;132:1132-1138.
5. Silverberg JI, et al. *Br J Dermatol.* 2015;173:1400-1404.

Pathogenesis of AD[1-8]

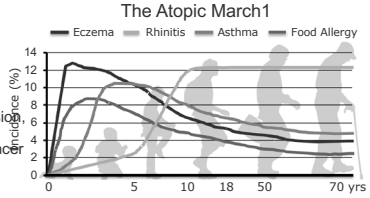


Th = T helper cell.

1. Novak N, et al. *J Allergy Clin Immunol.* 2003;112:252-262. 2. Napolitano M, et al. *G Ital Dermatol Venereol.* 2016;151:403-411. 3. McLean WH. *Br J Dermatol.* 2016;175(suppl 2):4-7. 4. Palmer CN, et al. *Nat Genet.* 2006;38:441-446. 5. Fallon PG, et al. *Nat Genet.* 2009;41:602-608. 6. Paternoster L, et al. *Nat Genet.* 2015;47:1449-1456. 7. Tamari M, et al. *J Dermatol.* 2014;41:213-220. 8. Sasaki T, et al. *J Dermatol Sci.* 2014;76:10-15.

Comorbidities in Adults With AD

- Higher rate of other atopic diseases:[1,2]
  - Nasal allergies/hay fever
  - Bronchial asthma
- Non-atopic diseases:
  - Higher rates of skin infections[3]
  - Sleep disturbances[4]
  - Neuropsychiatric (anxiety, depression, ADD/ASD)[5-9]
  - Other: cardiovascular disease, cancer (e.g., lymphoproliferative malignancies)[10,11]



ASD = autism spectrum disorder.

1. Tran M, Sears M. *Ann Allergy Asthma Immunol.* 2018;120:115-119. 2. Silverberg JI, et al. *J Allergy Clin Immunol.* 2013;132:1132-1138. 3. Czarnowicki T, et al. *J Allergy Clin Immunol.* 2017;139:1723-1734. 4. Jeon C, et al. *Dermatol Ther (Heidelb).* 2017;7:349-364. 5. Sanna L, et al. *J Affect Disord.* 2014;155:261-265. 6. Klokk M, et al. *BMC Dermatol.* 2010;10:3. 7. Dalgard FJ, et al. *J Invest Dermatol.* 2015;135:984-991. 8. Strom MA, et al. *Br J Dermatol.* 2016;175:920-929. 9. Billeci L, et al. *Am J Clin Dermatol.* 2015;16:371-388. 10. Silverwood R, et al. *BMJ.* 2018;361:k1786. 11. Fletcher CL, et al. *Arch Dermatol.* 2004;140:449-454.

AD: Impact on Quality of Life

- Adults with moderate-to-severe AD:[1]
  - 49% experience moderate-to-significant sleep disruption due to itching
  - ~ 82% underwent lifestyle modifications
  - 55% experience decreased confidence
- 14% of adult patients in the ISOLATE study believed that their career progression had been hindered by AD.[2]
- Psychological stress and impaired performance in school and at work[3]
- The aesthetic impact of skin changes can lead to social stress and isolation[3]

1. https://www.prnewswire.com/news-releases/new-survey-reveals-the-widespread-and-serious-impact-of-moderate-to-severe-atopic-dermatitis-on-people-living-with-the-disease-300339444.html; 2. Zuberbier T, et al. *J Allergy Clin Immunol.* 2006;118:226-232. 3. Institute for Clinical and Economic Review, 2017 Final Evidence Report – Atopic Dermatitis.

Learning Objective 1

Apply the Hanifin and Rajka criteria and/or the American Academy of Dermatology (AAD) criteria to facilitate the diagnosis of AD in clinical practice

Diagnosis

- Clinical diagnostic criteria core sets:
  - Hanifin and Rajka criteria[1]
    - 3 of 4 major criteria and 3 of 23 minor criteria must be met
    - Comprehensive, use limited to clinical trials
  - UK Working Party[2]
    - Core set based on Hanifin and Rajka
    - Primarily used in epidemiologic/population-based studies
  - AAD consensus criteria[3]
    - AAD consensus conference (experts in this field)

1. Rudzki E, et al. *Dermatology.* 1994;189:41-46.
2. Williams HC, et al. *Br J Dermatol.* 1996;135:12-17.
3. Eichenfield LF, et al. *J Am Acad Dermatol.* 2014;70:338-351.

Hanifin and Rajka Criteria
Major Criteria

- Major Criteria: Must have ≥3 basic features:
  1. Pruritus
  2. Typical morphology and distribution
     Flexural lichenification in adults
     Facial and extensor eruptions in infants and children
  3. Chronic or chronically relapsing dermatitis
  4. Personal or family history of atopy (asthma, allergic rhinitis, atopic dermatitis)

Tada J. *JMAJ.* 2002;45(11):460-465.

Hanifin and Rajka Criteria
Minor Criteria

- Minor Criteria: Should have ≥ 3 minor features:
  1. Xerosis
  2. Ichthyosis/palmar hyperlinearity, keratosis pilaris
  3. Immediate (type 1) skin-test reactivity
  4. Raised serum IgE
  5. Early age of onset
  6. Tendency toward cutaneous infections (especially *S aureus* and *herpes simplex*), impaired cell-mediated immunity
  7. Tendency toward non-specific hand or foot dermatitis
  8. Nipple eczema
  9. Cheilitis
  10. Recurrent conjunctivitis
  11. Dennie-Morgan infraorbital fold
  12. Keratoconus
  13. Anterior subcapsular cataracts
  14. Orbital darkening
  15. Facial pallor, facial erythema
  16. Pityriasis alba
  17. Anterior neck folds
  18. Itch when sweating
  19. Intolerance to wool and lipid solvents
  20. Perifollicular accentuation
  21. Food intolerance
  22. Course influenced by environmental or emotional factors
  23. White dermographism, delayed blanch

Tada J. *JMAJ.* 2002;45(11):460-465.

UK Working Party Diagnostic Criteria for Atopic Dermatitis

Must have an itchy skin condition plus ≥3:
Onset before age 2 (criterion not used in children under age 4)
History of flexural involvement
History of generally dry skin
Personal history of other atopic diseases (in children under age 4, history of atopic disease in a first-degree relative may be included)
Visible flexural dermatitis

Williams HC, et al. *Br J Dermatol.* 1994;131(3):406-416.

AAD Criteria for Diagnosing AD

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

*Patterns include:

1. *Facial, neck, and extensor involvement in infants and children*
2. *Current or previous flexural lesions in any age group*
3. *Sparing of the groin and axillary regions*

IMPORTANT FEATURES—Seen in most cases, adding support to the diagnosis:
- Early age of onset
- Atopy
  - Personal and/or family history
  - Immunoglobulin E reactivity
- Xerosis

ASSOCIATED FEATURES—These clinical associations help to suggest the diagnosis of atopic dermatitis but are too nonspecific to be used for defining or detecting atopic dermatitis for research and epidemiologic studies:
- Atypical vascular responses (eg, facial pallor, white dermographism, delayed blanch response)
- Keratosis pilaris/pityriasis alba/hyperlinear palms/ichthyosis
- Ocular/periorbital changes
- Other regional findings (eg, perioral changes/periauricular lesions)
- Perifollicular accentuation/lichenification/prurigo lesions

EXCLUSIONARY CONDITIONS—It should be noted that a diagnosis of atopic dermatitis depends on excluding conditions, such as:
- Scabies
- Seborrheic dermatitis
- Contact dermatitis (irritant or allergic)
- Ichthyoses
- Cutaneous T-cell lymphoma
- Psoriasis
- Photosensitivity dermatoses
- Immune deficiency diseases
- Erythroderma of other causes

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

Clinical Manifestations

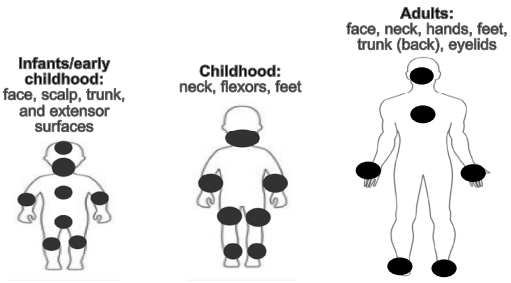


Image courtesy of Dr. Chiesa Fuxench.

Differential Diagnosis

INFANCY	CHILDHOOD	ADULTHOOD
Seborrheic dermatitis	Scabies	Seborrheic dermatitis
Scabies	Contact dermatitis	Contact dermatitis
Immunodeficiency syndromes: • Wiskott-Aldrich syndrome • Hyper-IgE syndrome • Omenn syndrome • Netherton syndrome	Tinea corporis	Scabies
	Tinea versicolor	Insect bites
	Seborrheic dermatitis	Photoallergic or photoirritant dermatitis
	Psoriasis	HIV-related dermatitis
Langerhans cell histiocytosis	Pityriasis lichenoides/PLEVA/PR	Psoriasis
Acrodermatitis enteropathica	CTCL	CTCL
Metabolic disorders		Drug-induced dermatitis

CTCL = cutaneous T-cell lymphoma; PLEVA = pityriasis lichenoides et variioliformis acuta; PR = pityriasis rosea.
Simpson EL, et al. *J Am Acad Dermatol*. 2017;77:623-633.

Learning Objective 2

Incorporate the Patient Oriented Eczema Measure (POEM) assessment scale into clinical practice to monitor disease severity and response to treatment

Assessment of Disease Severity and Clinical Outcomes in AD

- Measures of disease severity:
  - **SCORAD: SCOR**ing **A**topic **D**ermatitis Index
  - **EASI: E**czema **A**rea and **S**everity **I**ndex
  - **IGA: I**nvestigator's **G**lobal **A**ssessment
  - **SASSAD: S**ix **A**rea, **S**ix **S**ign **A**topic **D**ermatitis severity score
  - **TISS: T**hree-**I**tem **S**everity **S**cale
  - **POEM: P**atient **O**riented **E**czema **M**easure
- Measures of impact on quality of life (QoL):
  - ~ 22 different scales for measuring QoL/psychological outcomes in AD
  - Dermatology Life Quality Index
- Symptom specific:
  - **NRS**: Pruritus Numerical Rating Scale

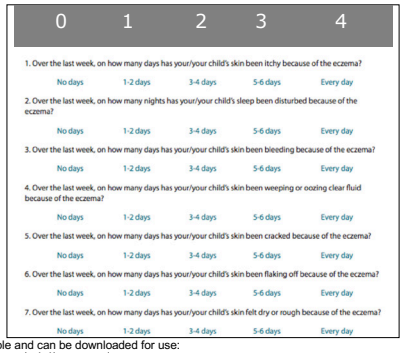
Eichenfield LF, et al. *J Am Acad Dermatol.* 2014;70:338-351.

Assessment of Disease Severity and Clinical Outcomes in AD

- **AAD consensus guidelines for diagnosis of AD:**[1]
  - Pragmatic approach for diagnosis in infants, children, and adults
  - Well-suited for clinical practice
- When practical, use scales to consider disease severity: SCORAD, EASI, POEM[2]
  - **POEM:** measure severity from the *patient perspective*

1. Eichenfield LF, et al. *J Am Acad Dermatol.* 2014;70:338-351.
2. Rehal B, et al. *PLoS one*. 2011;6:e17520.

Patient Oriented Eczema Measure (POEM)[1,2]



0	1	2	3	4

1. Over the last week, on how many days has your/your child's skin been itchy because of the eczema?
No days | 1-2 days | 3-4 days | 5-6 days | Every day

2. Over the last week, on how many nights has your/your child's sleep been disturbed because of the eczema?
No days | 1-2 days | 3-4 days | 5-6 days | Every day

3. Over the last week, on how many days has your/your child's skin been bleeding because of the eczema?
No days | 1-2 days | 3-4 days | 5-6 days | Every day

4. Over the last week, on how many days has your/your child's skin been weeping or oozing clear fluid because of the eczema?
No days | 1-2 days | 3-4 days | 5-6 days | Every day

5. Over the last week, on how many days has your/your child's skin been cracked because of the eczema?
No days | 1-2 days | 3-4 days | 5-6 days | Every day

6. Over the last week, on how many days has your/your child's skin been flaking off because of the eczema?
No days | 1-2 days | 3-4 days | 5-6 days | Every day

7. Over the last week, on how many days has your/your child's skin felt dry or rough because of the eczema?
No days | 1-2 days | 3-4 days | 5-6 days | Every day

1. Charman CR, et al. *Br J Dermatol.* 2013;169(6):1326-1332. 2. Charman CR, et al. *Arch Dermatol.* 2004;140:1513-1519.

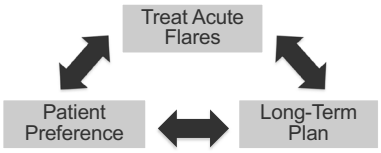
Patient Oriented Eczema Measure (POEM)[1,2]

- What does a POEM score mean?
  - 0-2 = Clear or almost clear
  - 3-7 = Mild eczema
  - 8-16 = Moderate eczema
  - 17-24 = Severe eczema
  - 25-28 = Very severe eczema

1. Charman CR, et al. *Br J Dermatol.* 2013;169(6):1326-1332. 2. Charman CR, et al. *Arch Dermatol.* 2004;140:1513-1519.

Considerations for Treatment

Establishment of an adequate diagnosis and extent of disease severity as well as assessment of the impact of AD on QoL will be critical in determining appropriate treatment plan for our patients.



Goals:

- Decrease the rate of acute flares or disease exacerbations
- Maintain a state in which symptoms are mild with minimal to no impact on QoL

Education is KEY!

- Skin care IS treatment for atopic dermatitis
- Moisturize after bathing, use of emollients
- Understanding patient preference is critical
  - Discuss avoidance of irritants and known triggers
  - Stress importance of adherence
  - Optimize topical therapy (under and over treatment)
  - Address topical steroid phobia
  - Consider structured educational intervention (eczema school)

Simpson EL, et al. *J Am Acad Dermatol.* 2017;77(4):623-633.

Strength of Recommendation for Use of Topical Therapies in the Treatment of AD

Recommendation	Strength of recommendation	Level of evidence	References
Use of moisturizers	A	I	9-16,18-21,26
Bathing and bathing practices	C	III	23,24,26,28,30
Application of moisturizers after bathing	B	II	24,25
Limited use of nonsoap cleansers	C	III	27-30
Against use of bath additives, acidic spring water	C	III	31,32,127
Wet-wrap therapy	B	II	34-41
Use of TCS	A	I	42-46
Consideration of a variety of factors in TCS selection	C	III	49,128,129
Frequency of application	B	II	51-53
Proactive use of TCS for maintenance	B	II	54-56
Need for consideration of side effects with use	A	I	57,58,66
Need for monitoring for cutaneous side effects with potent TCS	B	III	57,58,66
Specific routine monitoring for systemic side effects with TCS not needed	C	III	57,58,63,66
Addressing fears with use	B	III	67-69
Use of TCI	A	I	70,76,81
Use as steroid-sparing agents	A	I	80,83
Off-label use of TCI in those age <2 y	A	I	76,89
Counseling on local reactions with TCI and the preceding use of TCS	B	II	81,85,96
Proactive use of TCI for maintenance	A	I	94,95-99
Concomitant TCS and TCI use	B	II	80,85,100-109
Informing patients regarding theoretical risk of cutaneous viral infections with use	C	III	80,98
Awareness of black-box warning of TCI	C	III	98-101
Routine monitoring of TCI blood levels not needed	A	I	102,103
Against routine use of topical antistaphylococcal treatments	A	I	110-113
Bleach baths and intranasal mupirocin for those with moderate to severe AD and clinical infection	B	II	113
Against use of topical antihistamines	B	II	40,115-117

AD, Atopic dermatitis; TCI, topical calcineurin inhibitors; TCS, topical corticosteroids.

Eichenfield LF, et al. *J Am Acad Dermatol.* 2014;71:116-132.

Role of Proactive Treatment[1-4]

Reactive Approach

Relies on anti-inflammatory therapies administered to active lesions that are then discontinued once visible skin lesions are cleared

Proactive Approach

A combination of predefined, long-term, low-dose, anti-inflammatory treatments applied to previously affected areas of the skin on a regular schedule, in addition to emollients on the entire body

1. Wollenberg A, et al. *J Eur Acad Dermatol Venereol.* 2016;30:729-747. 2. Torrelo A, et al. *Actas Dermosifiliogr.* 2013;104:409-417. 3. Thaci D, et al. *J Eur Acad Dermatol Venereol.* 2010;24:1040-1046. 4. Sidbury R, et al. *J Am Acad Dermatol.* 2014;71:1218-1233.

Systemic Agents in AD (Off-label)

	CsA	AZA	MTX	MPA
Starting dose in adults	5 mg/kg/day	50 mg/day	5 mg/week	MMF 1,000-2,000 mg/day (EC-MPS 1,440 mg/day)
Maintenance dose in adults	2.5-3 mg/kg/day	2-3 mg/kg/day*	Increase to max 25 mg/week	MMF 2,000 mg/day† (EC-MPS 1,440 mg/day)
Starting dose in children	5 mg/kg/day	50 mg/day	10-15 mg/m^2/week	MMF 20-50 mg/kg/day
Maintenance dose in children	2.5-3 mg/kg/day	2-3 mg/kg/day*	Increase by 2.5-5 mg/week to effective dose, taper by 2.5 mg/week to lowest effective dose	MMF increase daily total dose by 500 mg increments every 2-4 weeks

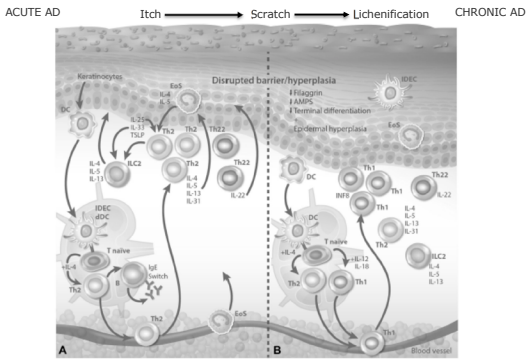
None of these treatments are FDA-approved for AD

AZA = azathioprine; CsA = cyclosporine A; EC-MPS = enteric-coated mycophenolic sodium; MMF = mycophenolate mofetil; MPA = mycophenolic acid; MTX = methotrexate. *TPMT heterozygote 1-1.5 mg/kg/day. †Children 30-50 mg/kg/day.
Wollenberg A, et al. *J Eur Acad Dermatol Venereol*. 2016;30:729-747.

Systemic Agents in AD (Off-label) cont.

	CsA	AZA	MTX	MPA
Decrease in clinical score (%)	54-95	26-39	42-52	55-68
Treatment period in trials (wks)	Max 52	Max 24	Max 24	Max 30
Time to respond (wks)	2	8-12	8-12	8-12
Time to relapse (wks)	< 2	> 12	> 12	> 12
Most important side effects	Serum creatinine ↑ Blood pressure ↑	Hematological Liver enzymes ↑ Gastrointestinal	Hematological Liver enzymes ↑ Gastrointestinal	Hematological Skin infections Gastrointestinal
Pregnancy	Possible	Conflicting data, possible with strict indication	Teratogenic, absolutely contraindicated	Conflicting data, better not to use
Fathering	Possible	Little information, possible with strict indication	Little information, conflicting data, contraindicated	Little information, better not to use

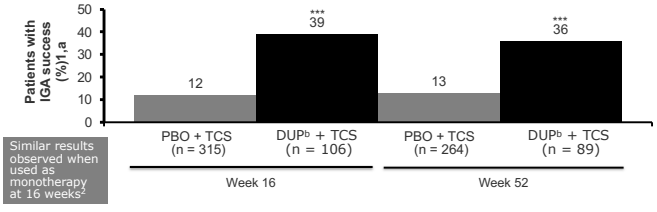
None of these treatments are FDA-approved for AD
Wollenberg A, et al. *J Eur Acad Dermatol Venereol*. 2016;30:729-747.



Gooderham MJ, et al. *J Am Acad Dermatol*. 2018;78:S28-S36.

New Therapeutic Targets: Dupilumab

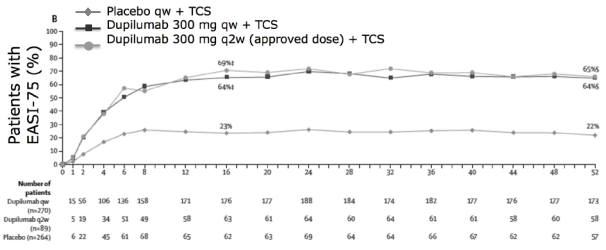
First FDA-approved systemic therapy for adult patients with moderate-to-severe atopic dermatitis



Similar results observed when used as monotherapy at 16 weeks[2]

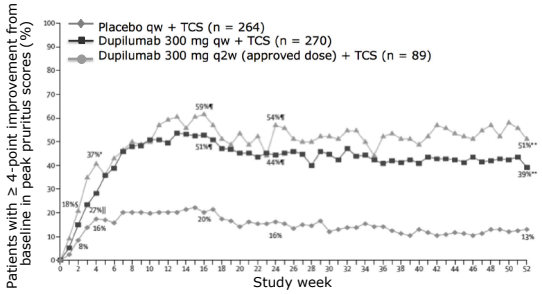
IGA = Investigator's Global Assessment; TCS = topical corticosteroids. [a]Score of 0 or 1 and ≥2-pt improvement from baseline. [b]300 mg q2w (approved dose). ***$p < .0001$ vs. placebo.
1. Blauvelt A, et al. *Lancet*. 2017;389:2287-2303. 2. Simpson E, et al. *N Engl J Med*. 2016;375:2335-2348.

Dupilumab + TCS: Impact on EASI-75



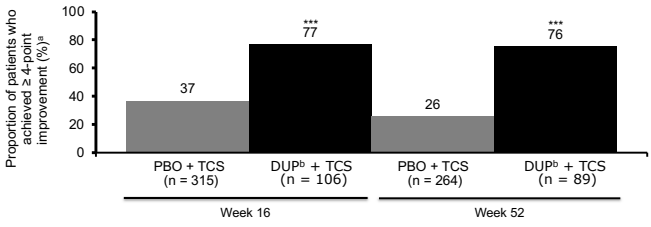
‡p < .0001 vs. PBO + TCS (FAS). §p < .0001 vs. PBO + TCS (FAS-52).
Blauvelt A, et al. *Lancet*. 2017;389:2287-2303.

Dupilumab + TCS Improves Pruritus



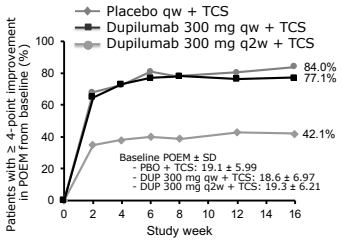
*p < .0001, DUP q2w + TCS vs. PBO + TCS. §p = .0062, DUP q2w + TCS vs. PBO + TCS. ¶p < .0001, DUP q2w + TCS and DUP qw + TCS vs. PBO + TCS. ‖p=.0021, DUP qw + TCS vs. PBO + TCS. **p < .0001, DUP q2w + TCS vs. PBO + TCS and DUP qw + TCS vs. PBO + TCS. Blauvelt A, et al. *Lancet*. 2017;389:2287-2303.

Dupilumab + TCS Improves POEM Scores



aMCID. b300 mg q2w (approved dose). ***p < .0001 vs. placebo.
Blauvelt A, et al. *Lancet*. 2017;389:2287-2303.

Dupilumab + TCS Improves POEM Scores in Patients With Inadequate Response or Intolerance to Cyclosporine



	PBO + TCS (n = 108)	DUP qw + TCS (n = 110)	DUP q2w + TCS (n = 107)
POEM LS mean change from baseline at week 16 ± SE	-4.3 ± .62	-11.4 ± .59***	-11.9 ± .60***

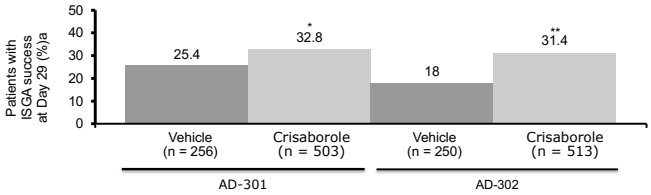
Patients with 4-point improvement in POEM from baseline (%):

- > 70% of patients by week 4 achieve this improvement

***p < .001 vs. PBO + TCS. de Bruin-Weller M, et al. *Br J Dermatol*. 2018;178(5):1083-1101.

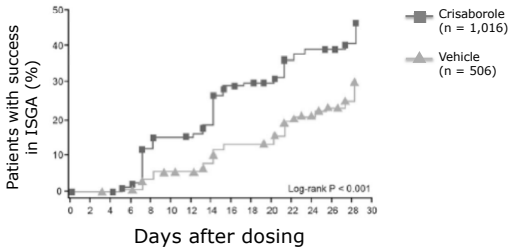
New Therapeutic Targets: Crisaborole

Topical PDE4 inhibitor approved for treatment of mild-to-moderate atopic dermatitis in patients age ≥2



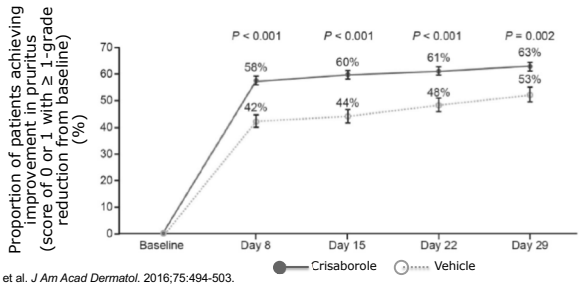
ISGA = Investigator's Static Global Assessment.
[a]Score of 0 or 1 with ≥ 2-grade improvement. *p < .038 vs. vehicle. **p < .001 vs. vehicle.
Paller A, et al. *J Am Acad Dermatol.* 2016;75:494-503.

Crisaborole Effects on ISGA: Pooled Data From AD-301 and AD-302



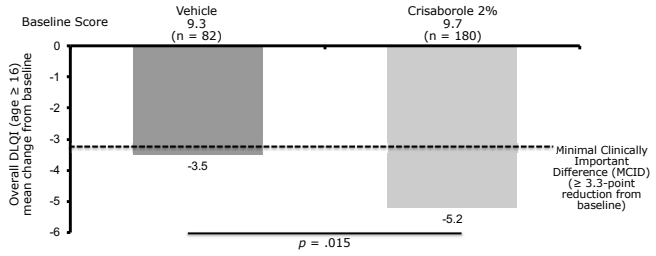
Paller A, et al. *J Am Acad Dermatol.* 2016;75:494-503.

Crisaborole Effects on Pruritus: Pooled Data From AD-301 and AD-302



Paller A, et al. *J Am Acad Dermatol.* 2016;75:494-503.

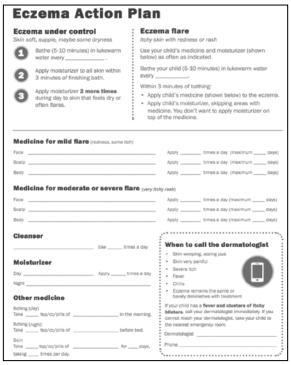
Crisaborole: Impact on QoL



Simpson EL, et al. *Dermatol Ther (Heidelb).* 2018 Oct 22. [Epub ahead of print].

Education is KEY![1-4]

- Engage the patient/ provide written instructions
- Understanding patient preference is **critical**



1. Bass AM, et al. *J Clin Med*. 2015;4:231-242. 2. Snyder A, et al. *Cutis*. 2015;96:397-401. 3. Ellis RM, et al. *Pediatr Dermatol*. 2011;28:242-244. 4. Smith SD, et al. *Med J Aust*. 2013;199:467-469.

Case Presentation: JC

- JC is a 36 y/o man with an itchy, red rash
- ***Duration:*** Has had intermittent symptoms throughout his entire life and feels that they have been getting progressively worse in recent years
- ***Location:*** Rash is primarily located on the neck, arms, legs, and back
- ***Symptoms:*** Extremely itchy, feels as if he cannot stop scratching, results in waking up from sleep almost every night.
- Impact on lifestyle and career choices

Medical History

Medical History

- No history of cancer or serious infection
- No known allergies to foods or other medications
- Non-smoker, alcohol intake (4-5 drinks/week)
- ROS: Denied any constitutional symptoms, negative in detail

Physical Examination

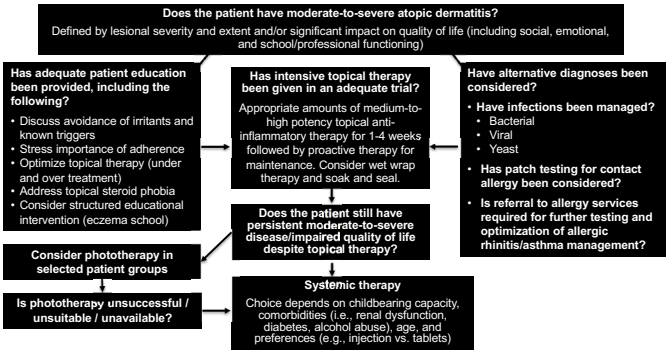
- Presence of multiple, somewhat ill-defined, erythematous patches and plaques with evidence of lichenification and excoriation on the scalp, trunk, arms, and legs

Case Presentation: Assessment of JC's Disease Severity

- EASI Score: 25
- IGA: 4
- Pruritus NRS: > 4
- POEM: 20

Case Presentation: JC's Current Treatments

- Multiple topical corticosteroids, oral/IM steroid injections — X
- Oral antihistamines — X
- Bathes daily, uses a mild soap and white petrolatum as an emollient — √



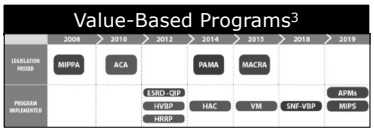
Simpson EL, et al. *J Am Acad Dermatol.* 2017;77(4):623-633.

Learning Objective 3

Document the utilization of clinical assessment tools and results from their use in patients' charts

Value-Based Health Care

- Programs designed to reward health care providers with incentive payments for the quality of care provided[1]
- "Value" is derived from measuring health outcomes against the cost of delivering these outcomes[2]



1. CMS. 2018. https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/Value-Based-Programs.html. 2. NEJM Catalyst. 2017. https://catalyst.nejm.org/what-is-value-based-healthcare/.

Value-Based Health Care[1-3]

- Triple Aim:
  - Enhancing patient experience
  - Improving population health
  - Reducing cost

→

- Quadruple Aim:
  - Enhancing patient experience
  - Improving population health
  - Reducing cost
  - Improving work-life of health care providers

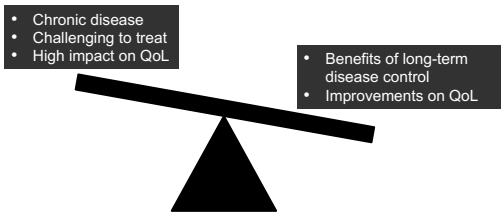
Chronic Illnesses: difficult to treat and represent a major cost in the U.S. health care system

Emerging treatment options are expensive

1. Bodenheimer T, et al. *Ann Fam Med*. 2014;1573-576. 2. Block J. *Value in Health*. 2018;21:380-385.
3. https://catalyst.nejm.org/what-is-value-based-healthcare/.

Cost-Effectiveness of Biologics for AD

- Importance of demonstrating value of health care interventions



Kuznik A, et al. *Dermatol Ther (Heidelb)*. 2017;7:493-505.

Cost-Effectiveness of Biologics for AD

- Biologics for AD: high price tag (~$37,000/year)[1]
- Dupilumab was cost-effective for the treatment of moderate-to-severe AD with a better cost-effectiveness ratio for patients with more severe disease compared to those with moderate disease.[1,2]
- Shown to be an intervention of high value as compared to secukinumab for psoriasis[3]
  - Related to drug efficacy, cost of the intervention, unmet need, and PROs

1. Kuznik A, et al. *Dermatol Ther*. 2017;7:493-505.
2. Zimmerman M, et al. *J Drugs Dermatol*. 2018;17:750-756.
3. Zozaya N, et al. *BioDrugs*. 2018;32:281-291.

Cost Effectiveness and QALY

	Usual Care	Dupilumab	Incremental
Total Costs	$271,461	$466,168	$194,708
Drug Costs	-	$224,372	$224,372
Other Healthcare Cost	$271,461	$241,796	-$29,665
QALYs	14.37	16.28	1.91
Cost per additional QALY			$101,830

QALY = quality adjusted life year
Institute for Clinical and Economic Review, 2017 Final Evidence Report – Atopic Dermatitis

SMART Goals

Specific, **M**easurable, **A**ttainable, **R**elevant, **T**imely

- Primary care should be able to handle 80% of patients with mild-to-moderate AD
- Recognize that untreated disease will progress and should be managed
- Atopic dermatitis is a **chronic** disease, challenging to treat, and often results in **significant** impairments in patient's quality of life

Questions for Faculty?

Use the "Q&A" widget on your screen

OR

E-mail:
questions@cmeoutfitters.com

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3 Things to Do

1. Actively participate in the meeting by **responding to ARS** and/or **asking the faculty questions**
   (It's ok if you miss answering a question or get them wrong, you can still claim MOC)
2. Complete your post-test and evaluation at the conclusion of the webcast
3. Be sure to fill in your **ABIM ID number** and **DOB** (MM/DD) on the evaluation, so we can submit your credit to ABIM.

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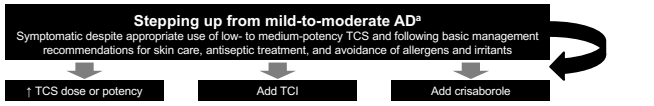
Quality Payment Program (QPP)

How to Claim this Activity as a QPP Improvement Activity

- **Actively participate** by responding to ARS and/or asking the faculty questions
- **Complete activity posttest and evaluation** at the link provided
- Over the next 90 days, **actively work to incorporate improvements** in your clinical practice from this presentation.
- **Complete the follow-up survey** from CME Outfitters in approximately 3 months

CME Outfitters will send you confirmation of your participation to submit to CMS attesting to your completion of a QPP Improvement Activity.

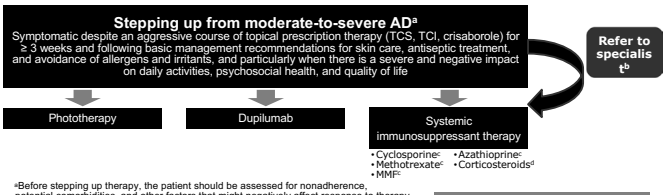
Example of AD Treatment Algorithm: AD Yardstick



3-month therapeutic trial with reassessment at 4-8 weeks

TCI = topical calcineurin inhibitor.
[a]Before stepping up therapy, the patient should be assessed for nonadherence, potential comorbidities, and other factors that might negatively affect response to therapy.
Boguniewicz M, et al. *Ann Allergy Asthma Immunol*. 2018;120:10-22.

Example of AD Treatment Algorithm: AD Yardstick (Cont'd)



[a]Before stepping up therapy, the patient should be assessed for nonadherence, potential comorbidities, and other factors that might negatively affect response to therapy.
[b]Consider for some patients acute treatment to help gain control: wet wrap therapy, hospitalization.
[c]Not FDA-approved for AD.
[d]Approved by the FDA to treat AD but not recommended for long-term maintenance.
Boguniewicz M, et al. *Ann Allergy Asthma Immunol*. 2018;120:10-22.

3-month therapeutic trial with reassessment at 4-8 weeks

This continuing education activity is provided by CME Outfitters

TV-099-121318-53

Attendance Form for Groups

Please complete and FAX to **614.929.3600**

Activity Title and Faculty:

Improving the Quality of Care for Patients with Atopic Dermatitis: Integrating Measurement-Based Tools Into Your Clinical Practice

with Stephen D. Hess, MD, PhD, John J. Russell, MD, Jonathan I. Silverberg, MD, PhD, MPH, and Zelma C. Chiesa Fuxench, MD, MSCE (Moderator)

❑ Office-based ❑ Hospital ❑ Clinic ❑ Managed Care ❑ Small Group Practice (less than 5)
❑ Large Group Practice (more than 5) ❑ Other:

Site/Institution Name: ______________________________

Practice Setting: ______________________________

Address: ______________________________

City: ______________________________ State: ________ ZIP: ______________

Site Coordinator: ______________________ Phone: ______________________

Fax: ______________________ Email: ______________________

Completion Date: __________ We participated in a: ______________________

Attendee Name (please print)	Please Circle Discipline						
______________________	MD	DO	PA	NP	RN	Pharm	Other: __________
______________________	MD	DO	PA	NP	RN	Pharm	Other: __________
______________________	MD	DO	PA	NP	RN	Pharm	Other: __________
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______________________	MD	DO	PA	NP	RN	Pharm	Other: __________

Please FAX completed form to 614.929.3600 and use additional sheets as necessary.
Questions? Call 877.CME.PROS. Thank you for participating in this continuing education activity!