TV-111-032620-45

SYLLABUS AND COURSE GUIDE

Navigating the New Psoriasis Guidelines: Implications for Clinical Practice

A Free, 90-Minute CME/CNE/CPE/MIPS/ABIM MOC/ABP MOC/ Live Webcast Activity

Premiere Date: Thursday, March 26, 2020

12:00 PM - 1:30 PM ET (live)

Credit Expiration Date: Friday, March 26, 2021

www.cmeoutfitters.com/PsOcare

LIVE FACULTY: Analisa Vincent Halpern, MD; Lara Wine Lee, MD, PhD

MODERATOR: Joel M. Gelfand, MD, MSCE

Take advantage of our LIVE Q&A segment during this webcast!

Please click on the **Ask Question** tab and type your question.

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INFORMATION FOR PARTICIPANTS

Statement of Need

The American Academy of Dermatology (AAD) and the National Psoriasis Foundation (NPF) have recently released new joint guidelines that outline best practices for the management of psoriasis (PsO) with biologics, the need for awareness and attention to comorbidities, and guidelines for pediatric PsO treatment. Clinicians must ensure that they are aware of these guidelines and of strategies to incorporate them into clinical practice, including the integration of biologic therapy into treatment plans, the implementation of strategies to manage comorbidities, and the management of pediatric patients with PsO, in alignment with guideline recommendations.

In this interactive CMEO Live and On Demand webcast, leading experts in PsO will utilize clinical cases to illustrate real-life approaches that learners can apply in order to optimize incorporation of these latest recommendations into clinical practice.

Learning Objectives

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

- Integrate biologic therapy into treatment plans for appropriate patients with moderate-to-severe psoriasis (PsO), in accordance with the joint AAD-NPF guidelines.
- Implement strategies to manage comorbidities in patients with PsO, as recommended by the joint AAD-NPF guidelines.
- Apply the joint AAD-NPF guidelines when managing pediatric patients with PsO.

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

- Describe treatment plans for appropriate patients with moderate-to-severe PsO, in accordance with the joint AAD-NPF guidelines.
- Explain strategies to manage comorbidities in patients with PsO, as recommended by the joint AAD-NPF guidelines.
- Identify the joint AAD-NPF guidelines when managing pediatric patients with PsO.

Target Audience

Dermatologists, primary care physicians, physician assistants, nurse practitioners, nurses, and pharmacists

Financial Support

Supported by an educational grant from Novartis Pharmaceuticals Corporation.

CREDIT INFORMATION

CME Credit (Physicians)

CME Outfitters, LLC, is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians. CME Outfitters, LLC, designates this live activity for a maximum of 1.5 *AMA PRA Category 1 Credit(s)™*. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

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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: 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™* 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)

CME Outfitters, LLC, is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. 1.5 contact hours (0.15 CEUs)

Universal Activity Number: Live: 0376-0000-20-007-L01-P; Enduring: 0376-0000-20-007-H01-P
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

ABP MOC Credit

Successful completion of this CME activity, which includes participation in the activity and individual assessment of and feedback to the learner, enables the learner to earn up to 1.5 MOC points in the American Board of Pediatrics' (ABP) Maintenance of Certification (MOC) program. It is the CME activity provider's responsibility to submit learner completion information to ACCME for the purpose of granting ABP MOC credit.

Royal College MOC

Through an agreement between the Accreditation Council for Continuing Medical Education and the Royal College of Physicians and Surgeons of Canada, medical practitioners participating in the Royal College MOC Program may record completion of accredited activities registered under the ACCME's "CME in Support of MOC" program in Section 3 of the Royal College's MOC Program.

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.

CREDIT REQUIREMENTS

Post-tests, credit request forms, and activity evaluations must be completed online (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 https://www.cmeoutfitters.com/privacy-and-confidentiality-policy.

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

Joel M. Gelfand, MD, MSCE (Moderator)

Dr. Gelfand is Professor of Dermatology and Epidemiology (with tenure) at the University of Pennsylvania's Perelman School of Medicine. He is also Vice Chair of Clinical Research, Medical Director of the Dermatology Clinical Studies Unit, and Director of the Psoriasis and Phototherapy Treatment Center. He is a nationally and internationally recognized expert in psoriasis, clinical epidemiology, drug safety, and clinical trials. Dr. Gelfand is the author of over 200 scientific publications, editorials, reviews, and text book chapters (cited over 16,600 times, H index 57) that appear in journals such as *JAMA, BMJ, European Heart Journal, Annals of Rheumatic Disease, JAMA Dermatology, JAAD*, and the *JID*. He is the recipient of the American Skin Association's Psoriasis Achievement Award, PENN's Marjorie Bowman Award, Penn's Department of Biostatistics and Epidemiology's epidemiology teaching award, NPF's inaugural award for scientific achievement, and an elected member of the American Society for Clinical Investigation. He has given over 10 named lectureships and keynote addresses, including the Society for Investigative Dermatology's Eugene M. Farber lecture and the American Academy of Dermatology's Marion B. Sulzberger lecture. He has received grant support from NIH, FDA, PCORI, the Dermatology Foundation, the American Skin Association, the National Psoriasis Foundation, and numerous pharmaceutical companies to support his independent research program. The overarching goal of his research and clinical practice is to improve psoriasis patient outcomes in the skin and joints, while lowering the risk of diabetes, CV disease, and mortality.

Analisa Vincent Halpern, MD

Dr. Halpern is Associate Professor of Medicine in the Division of Dermatology at Cooper University Hospital and Cooper Medical School of Rowan University (CMSRU). For the past decade, she has served as the Director of the Dermatology Residency Program at CMSRU, training hundreds of dermatology and internal medicine residents and medical students. Dr. Halpern earned her Bachelor's degree at Stanford University followed by her MD at the University of Pennsylvania School of Medicine. She is a fellow of the American Academy of Dermatology and a member of the National Psoriasis Foundation, the Pediatric Dermatology Society, and the Association of Professors of Dermatology. She focuses on best practices in complex medical dermatology, including complex psoriasis. Dr. Halpern has devoted her career to practicing and teaching in a severely underserved community, managing difficult cases in an era when practitioners are increasingly asked to do more for patients with less access to quality health care.

Lara Wine Lee, MD, PhD

Dr. Wine Lee is originally from the Washington, DC area. She received her undergraduate degree from Harvard University. She completed the medical scientist training program at the University of Pennsylvania, where she was elected to the Alpha Omega Alpha medical honors society. She completed general pediatrics residency at the Children's Hospital of Philadelphia prior to her dermatology residency at the University of Pennsylvania. She subsequently completed fellowship training in pediatric dermatology at the Children's Hospital of Philadelphia. She joined the dermatology and pediatrics departments at Medical University of South Carolina (MUSC) in 2014.

Dr. Wine Lee is a member of the American Academy of Dermatology, American Academy of Pediatrics, and the Society for Pediatric Dermatology where she serves on the patient and practice advocacy committee. Her interests include general pediatric dermatology with specialty interests in pediatric psoriasis, hemangiomas and vascular anomalies, and genetic skin disorders.

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It is the policy of CME Outfitters, LLC, to ensure independence, balance, objectivity, and scientific rigor and integrity in all of their CE activities. Faculty must disclose to the participants any relationships with commercial companies whose products or devices may be mentioned in faculty presentations, or with the commercial supporter of this CE activity. CME Outfitters, LLC, has evaluated, identified, and attempted to resolve any potential conflicts of interest through a rigorous content validation procedure, use of evidence-based data/research, and a multidisciplinary peer review process. The following information is for participant information only. It is not assumed that these relationships will have a negative impact on the presentations.

Dr. Gelfand reports that he receives grants from AbbVie Inc.; Boehringer Ingelheim; Celgene Corporation; Janssen Biologics, Inc.; Novartis Corporation; Ortho Dermatologics; and Pfizer Inc. He is a consultant for Boehringer Ingelheim; Bristol-Myers Squibb Company; Janssen Biologics, Inc.; NeuroDerm Data and Safety Monitoring Board (DSMB); Novartis Corporation; Pfizer Inc.; Sun Pharmaceutical Industries; and UCB Data and Safety Monitoring Board (DSMB). He receives other financial or material support as a co-patent holder of resiquimod for treatment of cutaneous T-cell lymphoma; and Deputy Editor for the *Journal of Investigative Dermatology*, receiving honoraria from the Society for Investigative Dermatology.

Dr. Halpern has no disclosures to report.

Dr. Wine Lee reports she receives research support from AbbVie Inc.; Amryt Pharma; Castle Creek Pharma; Eli Lilly and Company; Incyte; Mayne Pharma; Regeneron Pharmaceuticals, Inc.; Sanofi; and Trevi Therapeutics. She is a consultant for AbbVie Inc. and Pyramid Biosciences and on the advisory board for Eli Lilly and Company and Regeneron Pharmaceuticals, Inc.

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

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

Poshala Tish Aluwihare, PhD (planning committee) has no disclosures to report.

Susan Perry (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.

Disclosures were obtained from the CME Outfitters, LLC staff: No disclosures to report.

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Activity Slides

The slides that are presented in this activity will be available to download and print out at the CME Outfitters website: **www.cmeoutfitters.com**. Activity slides may also be obtained via fax or email by calling **877.CME.PROS**.

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https://www.cmeoutfitters.com/dermatology-hub/

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The course guide for this activity includes slides, disclosures of faculty financial relationships, and biographical profiles.

View and/or print the course guide from the *Resources* tab.

To Ask a Question

Please click on the *Ask Question* tab and type your question. Please include the faculty member's name if the question is specifically for them.

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Please click on the *Take Note* tab. If you did not enter your email address when you joined the meeting, you will be required to do so for note-taking.

All your notes will be e-mailed to you within 5 business days.

To receive CME/CE credits for this activity, participants must complete the post-test and evaluation online.

Go to the *Evaluations* tab and click on the link to complete the process and print your certificate.

Claim ABIM MOC Credit

3 Things to Do

1. Actively participate in the meeting by **responding to questions** 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

CME for MIPS Improvement Activity

How to Claim this Activity as a CME for MIPS Improvement Activity

- Actively participate by responding to ARS questions and/or asking the faculty questions
- Complete activity post-test 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 CME for MIPS Improvement Activity

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Joel M. Gelfand, MD, MSCE

Professor of Dermatology and Epidemiology
Vice Chair of Clinical Research
Medical Director, Dermatology Clinical Studies Unit
Director, Psoriasis and Phototherapy Treatment Center
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Joel M. Gelfand, MD, MSCE
Disclosures

- ***Research Support:*** AbbVie Inc.; Boehringer Ingelheim; Celgene Corporation; Janssen Biologics, Inc.; Novartis Corporation; Ortho Dermatologics; and Pfizer Inc.
- ***Consultant:*** Boehringer Ingelheim; Bristol-Myers Squibb Company; Janssen Biologics, Inc.; NeuroDerm Data and Safety Monitoring Board (DSMB); Novartis Corporation; Pfizer Inc.; Sun Pharmaceutical Industries; and UCB Data and Safety Monitoring Board (DSMB)
- ***Other Financial or Material Support:*** Co-patent holder of resiquimod for treatment of cutaneous T-cell lymphoma; and Deputy Editor for the Journal of Investigative Dermatology, receiving honoraria from the Society for Investigative Dermatology

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Analisa Vincent Halpern, MD
Disclosures

- Dr. Halpern has no disclosures to report.

CME Outfitters
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Lara Wine Lee, MD, PhD

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Charleston, SC

Lara Wine Lee, MD, PhD

Disclosures

- ***Research Support:*** AbbVie Inc.; Amryt Pharma; Castle Creek Pharma; Eli Lilly and Company; Incyte; Mayne Pharma; Regeneron Pharmaceuticals, Inc.; Sanofi; and Trevi Therapeutics
- ***Consultant:*** AbbVie Inc. and Pyramid Biosciences
- ***Advisory Board:*** Eli Lilly and Company and Regeneron Pharmaceuticals, Inc.

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Navigating the New Psoriasis Guidelines: Implications for Clinical Practice

March 26, 2020

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Learning Objective 1

Integrate biologic therapy into treatment plans for appropriate patients with moderate-to-severe psoriasis (PsO), in accordance with the joint AAD-NPF guidelines.

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Learning Objective 2

Implement strategies to manage comorbidities in patients with PsO, as recommended by the joint AAD-NPF guidelines.

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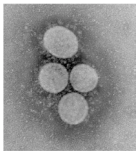
Learning Objective 3

Apply the joint AAD-NPF guidelines when managing pediatric patients with PsO.

COVID-19: Key Facts

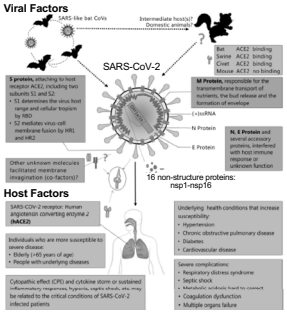


- There are hundreds of coronaviruses
  - Most circulate among animals (pigs, camels, bats, cats)
  - Sometimes jump to humans (SARS 2002-2004) (MERS 2012)
  - COVID-19 caused by SARS-CoV-2[1]
- Spread by respiratory droplets
  - Viable on surfaces for up to 72 hours
- Epidemiology (China)
  - Fever in 44% at admission, cough in 68%, gastrointestinal (GI) symptoms uncommon, no rash
  - Lymphocytopenia in 83%, increased C-reactive protein (CRP) in 61%
  - 15% severe, 5% intensive care unit (ICU), 1.4% died
- Incubation median 5 days, range 2-11.5 days

COVID-19 = coronavirus; MERS = Middle East respiratory syndrome; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
1. van Doremalen N, et al. *New England Journal of Medicine (NEJM) Website*. 2020. https://www.nejm.org/doi/full/10.1056/NEJMc2004973?query=featured_home.
2. Guan W, et al. *NEJM Website*. 2020. https://www.nejm.org/doi/pdf/10.1056/NEJMoa2002032?articleTools=true. 3. Lauer SA, et al. Annals of Internal Medicine Website. 2020. https://annals.org/aim/fullarticle/2762808/incubation-period-coronavirus-disease-2019-covid-19-from-publicly-reported. Image from National Institute of Allergy and Infectious Diseases Website. 2020. https://www.niaid.nih.gov/diseases-conditions/coronaviruses.

Pathophysiology of SARS-CoV-2 Infection

- Binds/enters cells through angiotensin-converting enzyme 2 (ACE2) receptor
- Mainly spreads through the respiratory tract
- Severe outcomes include acute respiratory distress syndrome (ARDS) and cytokine storm
- Cytokines increased: IL-1, IL-2, IL- 4, IL-7, IL-10, IL-12, IL-13, IL-17, granulocyte macrophage colony-stimulating factor (GCSF), macrophage colony-stimulating factor (MCSF), IP-10, MCP-1, MIP-1α, hepatocyte growth factor (HGF), IFN-γ, and TNF-α



Guo YR, et al. *Military Med Res*. 2020;7:11.

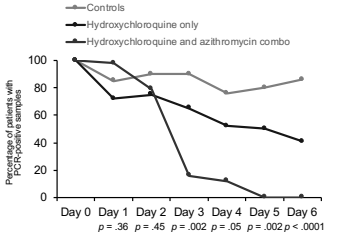
US-Based Studies of Therapeutics for COVID-19

- Nitric oxide gas for SARS
- Hydroxychloroquine
- CD24Fc (immunomodulator)
- Losartan
- Aviptadil (analogue of vasoactive intestinal peptide)
- Remdesivir (antiviral)
- Sarilumab (anti–IL-6)
- Vaccines

ClinicalTrials.gov Website. 2020. https://clinicaltrials.gov/ct2/results?cond=covid-19&term=therapeutics&cntry=US&state=&city=&dist=.

Hydroxychloroquine and Azithromycin as a Treatment of COVID-19: Open-Label, Non-randomized Study

- 26 received hydroxychloroquine (HCQ)
  - 6 dropped from analysis
    - 3 transferred to intensive care unit (ICU)
    - 1 died
    - 1 stopped due to nausea
    - 1 left the hospital
  - 6 had azithromycin added
- 16 controls (patients who refused HCQ, did not) meet criteria, or from other centers)
- Virologic cure ($p < .001$):
  - 70% HCQ
  - 100% HCQ + azithromycin
  - 12.5% control
- Conclusion
  - Weak design invites bias
  - Possible improvement in surrogate endpoint (viral shedding)
  - No evidence of benefit on clinical outcomes
  - Needs testing in clinical trials



Percentage of patients with PCR-positive nasopharyngeal samples from inclusions to day6 post-inclusion in COVID-19 patients treated with hydroxychloroquine only, in COVID-19 patients treated with hydroxychloroquine and azithromycin combo, and in COVID-19 control patients.

Gautret P, et al. *Int J Antimicrob Agents*. In press. 2020.

AAD Guidance on Use of Biologics During COVID-19 Outbreak

- Dermatologists must delicately balance the risk of immunosuppression with the risk of disease flare requiring urgent intervention; patients should not stop biologic therapy without consulting their physicians
- Patients already on biologics
  - Weigh risk vs. benefit on case-by-case basis
    - Age > 60 and major cardiopulmonary comorbidity increase risk
  - Tested positive for COVID-19
    - Discontinue/postpone biologics until recovery
- Patients not on biologics
  - Assess risks/benefits on case-by-case basis

AAD = American Academy of Dermatology.
Biologics and COVID-19. https://assets.cfassets.net/1ny4yciyrqia/PlcgNuD0IpYd9MSOwab47/023ce3cf6eb82cb304b4ad4a8ef50d56/Biologics_and_COVID-19.pdf. March 18, 2020.

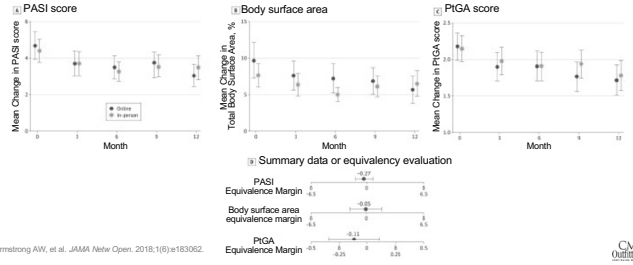
AAD COVID-19 Guidance 3.20.20

- Dermatologists should avoid non-essential in-person visits
- Patients scheduled for non-essential or elective services should be rescheduled or seen via telemedicine
- Essential, urgent, and high acuity cases should still be treated in the office, which may help alleviate an influx of these patients into acute care facilities

AAD Website. 2020. https://marketing.aad.org/acton/rif/32948/s-0854-2003/-f-ctx:689e/q-008c/showPreparedMessage?sid=TV2:JaKJOyAgu.

Online vs. In-Person Care for PsO

An online, collaborative, connected-health model is equivalent to the in-person model in improving PsO clinical outcomes



Armstrong AW, et al. *JAMA Netw Open*. 2018;1(6):e183062.

Clinical Case: James

Patient Characteristics	Family and Social History
• **Sex:** male • **Age:** 52 • **Height and weight:** 5' 10" (177.8 cm), 216 lbs (98 kg) (BMI: 31)	• Father: **PsO** • Mother: **diabetes, hypertension** • Brother: **CD**
History of Present Illness	**Past Medical History**
• **Disease diagnosis:** age 28 • **Sites affected:** scalp, trunk, elbows, knees, genitals, fingernails • **Symptoms:** painful skin, itching resulting in sleep loss, experiences severe embarrassment, swollen hands and feet, back pain/stiffness all developing over last 3-6 months after having well-controlled disease • **Prior treatment:** o Acitretin (stopped when he developed PsA) o Sulfasalazine (stopped due to rash) o Methotrexate (stopped due to increased LFTs)	• **Obesity** (BMI: 31.0) • **PsA** (diagnosed at age 32) • **Hypertension** • **Asthma**
Current Medications	**Laboratory Results**
• On adalimumab 40 mg every 2 weeks for past 2.5 years • Inhaler, as needed	• **Blood pressure:** 160/90 mm Hg • **Hemoglobin A1c:** 6.3%

BMI = body mass index; CD = Crohn's disease; LFTs = liver function tests; PsA = psoriatic arthritis.

Clinical Case: James

Clinical Assessment Results
• **Physician Global Assessment (PGA):** 3 • **Body Surface Area (BSA):** 12% • Affecting most of the scalp, chest, elbows, knees, genitals, fingernail pitting and onycholysis; tender and swollen metacarpal, metatarsal, and proximal interphalangeal joints; diffuse swelling of left third toe
Additional Considerations
• Photoshoot in 1 month • Demanding job with long hours

Selected Pearls from 2019 Joint AAD-NPF Guidelines: Increased Dosing of TNFi

Recommendation Number	Recommendation	Strength of Recommendation
1.3	Etanercept administered at a dose of 50 mg twice weekly is more efficacious than a dose of 50 mg once weekly and may be required for better disease control in some patients	A
2.3	Infliximab is recommended to be administered at a more frequent interval (less than every 8 weeks and as frequently as every 4 weeks during the maintenance phase) and/or at a higher dose up to 10 mg/kg for better disease control in some adult patients	B
3.3	A maintenance dose of adalimumab 40 mg every week is recommended for better disease control in some patients	A

NPF = National Psoriasis Foundation; TNFi = tumor necrosis factor inhibitor.
Menter A, et al. *J Am Acad Dermatol*. 2019;80:1029-1072.

2019 Joint AAD/NPF Guidelines: PsA

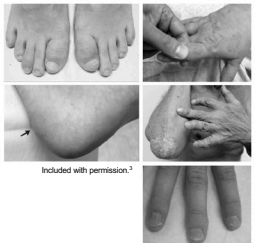
Recommendation Number	Recommendation	Strength of Recommendation
1.1	Patients with PsO should be informed about the association between PsO and PsA	B
1.2	PsA should be considered in all patients with cutaneous PsO	B
1.3	Patients with signs and symptoms suspicious for PsA should be fully evaluated for PsA; initiate appropriate PsA therapy if comfortable with the diagnosis or otherwise consult with a rheumatologist for assessment and management	A

NPF = National Psoriasis Foundation.
Elmets CA, et al. *J Am Acad Dermatol*. 2019;;80(4):1073-1113.

Screening for PsA

Identify symptoms/signs of PsA

- Morning joint stiffness[1,2]
- Joint pain[1,2]
- Swollen and tender joints[1,2]
- Dactylitis and enthesitis[1,2]
- Radiographic changes[2]
  - Consider x-rays of hands/feet if affected
- Consider laboratory testing[1,2,4]
  - Erythrocyte sedimentation rate (ESR)
  - CRP
  - Uric acid
  - Rheumatoid factor
  - Cyclic citrullinated peptide



Included with permission.[3]

Images courtesy of Dr. Joel Gelfand.

1. Mease PJ, Armstrong AW. *Drugs*. 2014;74(4):423-441. 2. Mease P, Goffe BS. *J Am Acad Dermatol*. 2005;52(1):1-19.
3. Ritchlin CT, et al. *N Engl J Med*. 2017;376(10):957-970. 4. Tsuruta N, et al. *J Dermatol*. 2017;44(12):1349-1352.

2019 Joint AAD/NPF Guidelines: PsO and CVD Disease Comorbidity

Recommendation	Strength of Recommendation
CV risk assessment (screening for hypertension [HTN], diabetes mellitus [DM], and hyperlipidemia) according to national guidelines is recommended for all patients with PsO	B*
Consider early and more frequent screening for HTN, DM, and hyperlipidemia in candidates for systemic treatment or phototherapy or who have PsO involving > 10% BSA	B*
Risk score models should be adapted by introducing a 1.5 multiplication factor when the patient meets either: • Disease severity of > 10% BSA • Candidate for systemic treatment or phototherapy	C†
• CV risk management for HTN and dyslipidemia should be carried out according to national guidelines • Target blood pressure and lipid levels are based on risk calculated for PsO • Antihypertensives and statins may be used as in the general population • CV risk management should be performed by a primary care physician, a health care provider experienced in CV risk management, or the dermatologist	C†

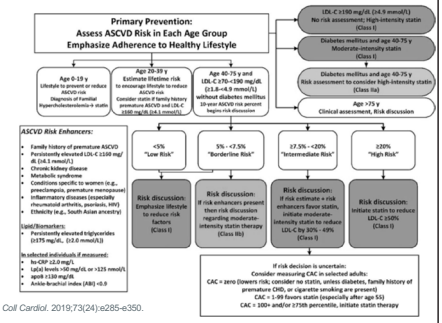
*Clinical recommendation B indicates recommendation based on inconsistent or limited-quality patient-oriented evidence.
†Clinical recommendation C indicates recommendation based on consensus, opinion, case studies, or disease-oriented evidence.
CV = cardiovascular; CVD = CV disease.
Elmets CA, et al. *J Am Acad Dermatol*. 2019;80(4):1073-1113.

ACC/AHA Statin Recommendations for ASCVD

Primary prevention age 40-75, LDL-C ≥ 70 - < 190 mg/dL without diabetes

Borderline 10-Year Risk 5% to < 7.5%

- Risk enhancers present:
  - Family history of ASCVD
  - Chronic kidney disease
  - Metabolic syndrome
  - ***PsO***, ***RA***, ***HIV***
  - Ethnicity
- Discuss moderate-intensity statin



ACC = American College of Cardiology;
ASCVD = atherosclerotic CVD;
AHA = American Heart Association;
HIV = human immunodeficiency virus;
LDL-C = low-density lipoprotein cholesterol.
ACC/AHA Task Force on Clinical Practice Guidelines. *J Am Coll Cardiol*. 2019;73(24):e285-e350.

Impact of Anti-Inflammatory Treatment on CV Events

	CANTOS	CIRT	COLCOT
Drug	Canakinumab IL-1b inhibitor 3 dose groups	MTX Anti-inflammatory Median dose 18.8 mg	Colchicine Blocks microtubules 0.5 mg every day
Sample Size	10,061 Median follow-up 3.7 years	4,786 Median follow-up 2.3 years	4,745 Median follow-up 1.88 years
Major Inc. Criteria	Prior MI and HsCRP ≥ 2 mg/L	Prior MI or multivessel CAD and DM/metabolic syndrome	MI within 30 days
HsCRP Baseline	4.2 mg/L	1.5 mg/L	NA
Biomarker	Reduction in CRP, IL-6	No effect on CRP, IL-6, IL-1b	NA
CV Events	HR: 0.85 95% CI: 0.74, 0.98	HR: 1.01 95% CI: 0.82, 1.25	HR: 0.77 95% CI: 0.61, 0.96
Cancer	Decreased cancer mortality	Increased non–basal cell carcinoma skin cancer	No difference
Infection	Increased risk of death due to infection	Increased risk of non-serious infection	Increased pneumonia serious adverse event

CAD = coronary artery disease; HsCRP = high-sensitivity CRP.
Ridker PM, et al. *N Engl J Med*. 2017;377:1119-1131. Ridker PM, et al. *N Engl J Med*. 2019;380:752-762. Tardif J-C, et al. *N Engl J Med*. 2019;381:2497-2505.

Vascular Inflammation in PsO Trials: Week 12 vs. Placebo Summary

Marker	Adalimumab NCT01553058	Phototherapy NCT01553058	Secukinumab NCT02690701*	Ustekinumab NCT02187172
Aortic vascular inflammation	No change	No change	No change	Reduced
Inflammatory markers	Reduction in CRP, TNF-α, IL-6, GlycA	Reduction in CRP, IL-6	No change	Reduction in VCAM1, IL-2ra
Lipid metabolism	No change	Improved HDL particles	Increased LDL particles	Increased LDL particles
Glucose metabolism	No change	No change	No change	No change

HDL = high-density lipoprotein; VCAM1 = vascular cell adhesion protein 1.
Mehta NN, et al. *Circ Cardiovasc Imaging*. 2018;11(6):e007394. Gelfand JM, et al. *J Invest Dermatol*. 2020;140(1):85-93. Gelfand JM, et al. *J Invest Dermatol*. 2020 Feb 20. pii: S0022-202X(20)30157-3 [Epub ahead of print].

Treatment Options for the Clinical Case: Biologics

	Advantages	Challenges
TNF inhibitors[1-4]	• Good efficacy • Gold standard for PsA • Effective for peripheral and axial disease	• Class warning for demyelinization, tuberculosis (TB), malignancy (including lymphoma), serious infections, and new onset or worsening of congestive heart failure
Ustekinumab, anti–IL-23[1-3]	• Good efficacy • Convenient dosing regimen • Ustekinumab is approved for CD	• TNF inhibitors are recommended over ustekinumab for PsA; ustekinumab not proven to prevent joint destruction • Anti–IL-23s not approved for PsA • Ustekinumab not recommended for axial spondyloarthritis • Ustekinumab approved for PsA but not effective for axial disease
Anti–IL-17[1,3,5]	• Good efficacy • Rapid onset • Secukinumab/ixekizumab approved for PsA • Effective for peripheral and axial disease	• Warning and precaution for patients with a personal history of or active inflammatory bowel disease (IBD) • Brodalumab has black box warning for suicidal ideation • Class effect for mucocutaneous *Candida* infections

1. Menter A, et al. *J Am Acad Dermatol*. 2019;80:1029-1072. 2. Singh JA, et al. *Arthritis Rheumatol*. 2019;71(1):5-32. 3. Sawyer LM, et al. *PLoS ONE*. 2019;14(8):e0220868. 4. Zhu TH, et al. *J Dermatolog Treat*. 2016;27(5):406-413. 5. Rønholt K, Iversen L. *Int J Mol Sci*. 2017;18(11):pii:E2297.

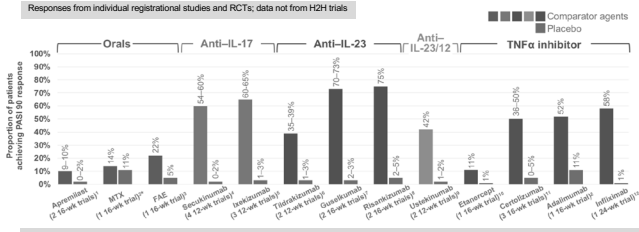
Biologics for PsO*

Biologic	Recommended Initiation Dosing	Recommended Maintenance Dosing	Recommended Dosing Adjustments	Half-Life (approximate, days)
Etanercept	50 mg twice weekly for 12 consecutive weeks	50 mg once weekly	50 mg twice weekly if poor response	3.5
Infliximab	5 mg/kg at weeks 0, 2, and 6	5 mg/kg every 8 weeks	Up to 10 mg/kg and/or as frequent as every 4 weeks if poor response	10
Adalimumab	80 mg at week 0, followed by 40 mg at week 1	40 mg every 2 weeks	40 mg once weekly if poor response	14
Certolizumab	If ≤ 90 kg: 400 mg at weeks 0, 2, and 4; If > 90 kg: 400 mg at week 0	If ≤ 90 kg: 200 mg every other week; If > 90 kg: 400 mg every 2 weeks	Not applicable (NA)	14
Ustekinumab	If ≤ 100 kg: 45 mg at weeks 0 and 4; If > 100 kg: 90 mg at weeks 0 and 4	If ≤ 100 kg: 45 mg every 12 weeks; If > 100 kg: 90 mg every 12 weeks	Up to 90 mg every 12 weeks if ≤ 100 kg or dosing every 8 weeks if poor response	21
Secukinumab	300 mg weekly for 5 consecutive weeks	300 mg every 4 weeks	NA	27
Ixekizumab	160 mg at week 0 followed by 80 mg every 2 weeks for 12 consecutive weeks	80 mg every 4 weeks	NA	13
Brodalumab	210 mg at weeks 0, 1, and 2	210 mg every 2 weeks	NA	11
Guselkumab	100 mg at weeks 0 and 4	100 mg every 8 weeks	NA	18
Tildrakizumab	100 mg at weeks 0 and 4	100 mg every 12 weeks	NA	23
Risankizumab	150 mg at weeks 0 and 4	150 mg every 12 weeks	NA	11

*As of March 2020 and based on joint AAD-NPF guidelines of care for the management and treatment of PsO with biologics.
Menter A, et al. *J Am Acad Dermatol*. 2019;80:1029-1072. Pithadia DJ, et al. *Cutis*. 2019;104(2S):12-16. Package insert for risankizumab. Drugs@FDA Website. https://www.accessdata.fda.gov/scripts/cder/daf/.

PASI 90 Responses of Biologics and Oral Treatments for PsO

Responses from individual registrational studies and RCTs; data not from H2H trials



Data are collected from individual SmPC, USPI, or published RCTs. Trial designs and patient populations are not uniform across studies, and no direct comparisons can be made.

PASI 90 responses of the in-label recommended dose are shown. Percentage above each bar indicates a data range of trials, and the plot is based on the highest PASI 90 response of each agent.

*Methotrexate (MTX) and placebo responses are from head-to-head (H2H) trial of adalimumab versus MTX with a placebo arm.
FAE = fumaric acid esters; RCTs = randomized, controlled trials; SmPC = summary of product characteristics; USPI = U.S. package insert.
1. OTEZLA [SmPC]. Celgene Europa Ltd; 2015. 2. Saurat JH, et al. *Br J Dermatol*. 2008;158(3):558-566. 3. Mrowietz U, et al. *Br J Dermatol*. 2017;176(3):615-623. 4. COSENTYX [SmPC]. Novartis Europharm Limited; 2015. 5. TALTZ [SmPC]. Eli Lilly Nederland BV; 2016. 6. ILUMETRI [SmPC]. SUN Pharmaceuticals Industries Nederland BV; 2018. 7. TREMFYA [SmPC]. Janssen-Cilag International NV; 2017. 8. Package insert for SKYRIZI. North Chicago, IL: AbbVie Inc; 2019. 9. STELARA [SmPC]. Janssen-Cilag International NV; 2017. 10. Papp KA, et al. *Br J Dermatol*. 2005;152(6):1304-1312. 11. Package insert for CIMZIA. Smyrna, GA: UCB, Inc; 2019. 12. REMICADE [SmPC]. Janssen Biologics BV; 2017.

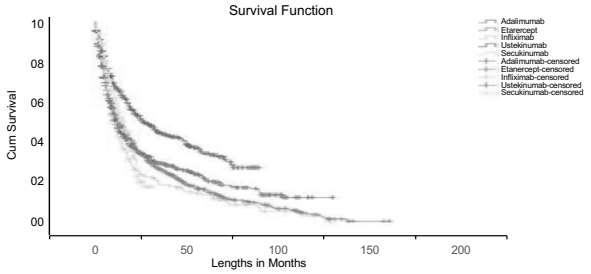
H2H Trials: Biologics in PsO

Week	12		16			48		
	PASI 75		PASI 90			PASI 90		
FIXTURE	**secukinumab***	**77%**	CLEAR	**secukinumab***	**79%**	VOYAGE1	**guselkumab†**	**76.3%**
	etanercept**	44%		ustekinumab‡	58%		adalimumab**	47.9%
reSURFACE2	**tildrakizumab†**	**61%**	UltIMMa-1	**risankizumab†**	**75%**	ECLIPSE	**guselkumab†**	**84%**
	etanercept**	48%		ustekinumab‡	42%		secukinumab*	**70%**
	PASI 90		IMMvent	**risankizumab†**	**72%**			
IXORA-S	**ixekizumab***	**75%**		adalimumab**	47%			
	ustekinumab‡	42%		**risankizumab†**	**74%**			
UNCOVER	**ixekizumab***	**70%**		secukinumab*	66%			
	etanercept**	22%						
	PASI 100							
IXORA-R	**ixekizumab***	**41%**						
	guselkumab†	25%						
AMAGINE2	**brodalumab***	**44%**						
	ustekinumab‡	22%						
AMAGINE3	**brodalumab***	**37%**						
	ustekinumab‡	19%						

*IL-17i; **TNF-i; †IL-23i; ‡IL-23i/L-12i.

Gordon KB, et al. *Lancet*. 2018;392:650-661. Langley RG, et al. *N Engl J Med*. 2014;371:326-338. Reich K, et al. *Lancet*. 2017;390:276-288. Blauvelt A, et al. *J Am Acad Dermatol*. 2017;76:405-417. Reich K, et al. *Br J Dermatol*. 2017;177:1014-1023. Griffiths CE, et al. *Lancet*. 2015;386:541-551. Blauvelt A, et al. *Br J Dermatol*. 2019;10.1111/bjd.18851. Lebwohl M, et al. *N Engl J Med*. 2015;373:1318-1328. Papp KA, et al. *Br J Dermatol*. 2016;175:273-286. Thaçi D, et al. *J Am Acad Dermatol*. 2015;73:400-409. Reich K, et al. *Lancet*. 2019;394:831-839. AbbVie press release. January 14, 2020. https://news.abbvie.com/news/press-releases/new-head-to-head-phase-3-data-show-skyrizi-risankizumab-superior-to-cosentyx-secukinumab-across-primary-and-all-ranked-secondary-endpoints-in-adults-with-moderate-to-severe-plaque-psoriasis-at-52-weeks.htm.

Real-World Effectiveness of Biologic Therapies for Moderate-to-Severe PsO



Shalom G, et al. *J Eur Acad Dermatol Venereol*. 2020. https://doi.org/10.1111/jdv.16205.

Selected Clinically Important Biologic Adverse Events (AEs)

Biologic	Common (> 1%)	Uncommon (0.1%-1%)	Rare (< 0.1%)	Black Box
Adalimumab	Injection site reaction + ANA Elevated alkaline phosphatase, cholesterol	Neutralizing antibodies Serious infections* Allergic reactions Malignancy*	TB, lupus-like syndrome, hypersensitivity, hepatitis B reactivation, demyelinization, CHF Pancytopenia	**Serious infections:** Increased risk of serious infections leading to hospitalization or death, including TB, bacterial sepsis, invasive fungal infections **Malignancy:** lymphoma and other malignancies, some fatal
Etanercept	Injection site reaction + ANA	Serious infections* Malignancy*	TB, lupus-like syndrome, hypersensitivity, hepatitis B reactivation, demyelinization, CHF Pancytopenia	
Infliximab	Infusion reactions + ANA Elevated LFTs Neutralizing antibodies	Hypersensitivity Serious infections* Malignancy*	Severe hepatic injury, TB, lupus-like syndrome, hypersensitivity, hepatitis B reactivation, demyelinization, CHF Pancytopenia	
Certolizumab	Upper respiratory tract infection (URI)	Serious infections* Headache, cardiomyopathy, injection site reactions, cough, lupus, hypersensitivity, herpes infection, Malignancy*	TB, hepatitis B reactivation, demyelinization Pancytopenia	

*Specific warning: serious infection from placebo-controlled period.
ANA = antinuclear antibody; CHF = congestive heart failure.
Package inserts for adalimumab, etanercept, infliximab, and certolizumab. Drugs@FDA Website. https://www.accessdata.fda.gov/scripts/cder/daf/.

Selected Clinically Important Biologic AEs

Biologic	Common (> 1%)	Uncommon (0.1%-1%)	Rare (< 0.1%)	Black Box
Ustekinumab	Infection	Serious infections (0.3%)* Malignancy*	Reversible posterior leukoencephalopathy*	None
Guselkumab	URI	Serious infections (≤ 0.2%)* Increased LFTs Migraine, mucocutaneous candida, urticaria	None	None
Tildrakizumab	URI	Injection site reactions Diarrhea, dizziness Serious infections (≤ 0.3%)*		None
Secukinumab	Nasopharyngitis	Serious infections (0.3%)* Mucocutaneous candida	Exacerbation of IBD*	None
Ixekizumab	Nasopharyngitis, injection site reactions	Serious infections (0.4%)* Mucocutaneous candida	IBD*	None
Brodalumab	Influenza	Arthralgia, headache, neutropenia, mucocutaneous candida Serious infections (0.5%)*	CD*	**Suicidal ideation and behavior:** Evaluate history of depression and suicidal behavior; brodalumab only available through REMS program
Risankizumab	URI	Serious infections (≤ 0.4%)* Headache, fatigue, injection site reactions, tinea infections, folliculitis, urticaria		None

*Specific warning: serious infection from placebo-controlled period. REMS = Risk Evaluation and Mitigation Strategies.
Package inserts for ustekinumab, guselkumab, tildrakizumab, secukinumab, ixekizumab, brodalumab, and risankizumab. Drugs@FDA Website. https://www.accessdata.fda.gov/scripts/cder/daf/.

Considerations for Selecting Treatment for Patients with PsO

++ preferred agents
+ recommended
+/- can be used but controversial
?/+ not enough data
-/+ not preferred but can be used
? mixed
- controversial because there are not enough data
x not recommended

	Comorbidities						
	PsA	CD	Obesity	Cardiovascular	CHF	MS	Lupus
TNF Inhibitor	++	Mostly ++	Mostly +	++	-/+	X	+/-
Anti–IL-23/12	+	++	++	+	++	+	+
Anti–IL-23	?	+	++*	?	++	?/+	?/+
Anti–IL-17	Mostly ++	-	++	?	++	+	?/+
Orals: apremilast and MTX	+	+	**Apremilast:** ++ **MTX:** X	**Apremilast:** ? **MTX:** ++	++	**Apremilast:** ?/+ **MTX:** +	+

*There are not enough data to support the use of risankizumab and mirikizumab in this patient population.
Kaushik SB, Lebwohl MG. *J Am Acad Dermatol.* 2019;80(1):27-40.

Risk of Liver Disease in Patients with Pso/PsA/RA Treated with MTX

	Outcome, HR (95% CI)			
	Mild Liver Disease	Moderate-to-Severe Liver Disease	Cirrhosis	Hospitalization Due to Cirrhosis
RA	1.0 (ref)	1.0 (ref)	1.0 (ref)	1.0 (ref)
PsO	2.22 (1.81-2.72)	1.56 (1.05-2.31)	3.38 (2.44-4.68)	2.25 (1.37-3.69)
PsA	1.27 (1.01-1.60)	0.93 (0.58-1.50)	1.63 (1.10-2.42)	1.17 (0.64-2.16)

Adjusted for sex, age, age^2, average weekly MTX dose, dose^2, smoking and alcohol abuse, diabetes, hyperlipidemia, Charlson index (excluding RA and liver disease), and year of cohort entry

CI = confidence interval; HR = hazard ratio; RA = rheumatoid arthritis.
Wan J, et al. International Conference on Pharmacoepidemiology & Therapeutic Risk Management; 2019. Abstract 15.

Clinical Case: James

Patient Characteristics
- **Sex:** male
- **Age:** 52
- **Height and weight:** 5' 10" (177.8 cm), 216 lbs (98 kg) (BMI: 31)

Family and Social History
- Father: **PsO**
- Mother: **diabetes, hypertension**
- Brother: **CD**

James

History of Present Illness
- **Disease diagnosis:** age 28
- **Sites affected:** scalp, trunk, elbows, knees, genitals, fingernails
- **Symptoms:** painful skin, itching resulting in sleep loss, experiences severe embarrassment, swollen hands and feet, back pain/stiffness all developing over last 3-6 months after having well-controlled disease
- **Prior treatment:**
  - Acitretin (stopped when he developed PsA)
  - Sulfasalazine (stopped due to rash)
  - Methotrexate (stopped due to increased LFTs)

Past Medical History
- **Obesity** (BMI: 31.0)
- **PsA** (diagnosed at age 32)
- **Hypertension**

Clinical Assessment Results
- **PGA:** 3
- **BSA:** 12%
- Affecting most of the scalp, chest, elbows, knees, genitals, fingernail pitting and onycholysis. Tender and swollen metacarpal, metatarsal and proximal interphalangeal joints, diffuse swelling of left third toe

Current Medications
- On adalimumab 40 mg every 2 weeks for past 2.5 years

Laboratory Results
- **Blood pressure:** 160/90 mm Hg
- **Hemoglobin A1c:** 6.3%

Additional Considerations
- Photoshoot in 1 month
- Demanding job with long hours

Clinical Case: Jennifer

Patient Characteristics
- **Sex:** female
- **Age:** 32
- **Height and weight:** 5' 3" (160 cm), 170 lbs (77 kg) (BMI: 30)

Family and Social History
- Paternal grandfather: **PsO**
- Father: passed away at age 52 from **MI**
- Brother: **CD**
- No tobacco, Two glasses of wine/night
- Getting married in 6 months

History of Present Illness
- **Disease onset:** age 15
- **Sites affected:** scalp, arms, legs, nails
- **Symptoms:** mild itching, reports severe embarrassment
- **Modifying factors:** better in the summer, worse with stress
- **Prior treatment:** topical medications only

Past Medical History
- **Obesity** (BMI: 30)
- **Depression**
- History of optic neuritis in college
- Smokes ¼ pack of cigarettes daily
- Two glasses of wine each evening

Current Medications
- Sertraline

Laboratory Results
- **Blood pressure:** 140/90 mm Hg

MI = myocardial infarction.
Meier M, Sheth PB. *Curr Probl Dermatol.* 2009;38:1-20.

Clinical Case: Jennifer

Clinical Assessment Results
• **PGA:** 4 • **BSA:** 5% • **PsO** affecting most of the scalp, forehead, small patches on elbows and knees; fingernails have pitting and onycholysis
Additional Considerations
• N/A

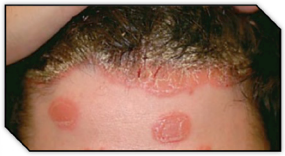


Image from Meier M, Sheth PB. *Curr Probl Dermatol.* 2009;38:1-20.

IPC Consensus Statement about PsO Severity

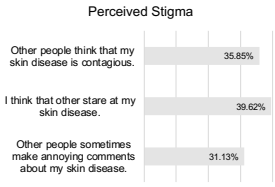
- Patients should be classified as either candidates for topical therapy or systemic therapy (pills, biologics, phototherapy)
- Candidates for systemic therapy must meet at least one of the following criteria:
  1. BSA > 10%
  2. Disease involving special areas
     - Face, palms, soles, genitalia, scalp, or nails
  3. Failure of topical therapy

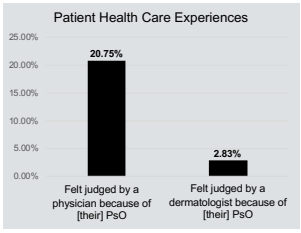
IPC = International Psoriasis Council.

Strober B, et al. *J Am Acad Dermatol.* 2020;82(1):117-122.

Stigma Experienced by Patients With PsO, N = 106

Patients answered questions based on how they thought "others" respond to seeing their psoriatic lesions





Wan MT, et al. *J Invest Dermatol*, 2019;139(Suppl 5):S101.

2019 Joint AAD-NPF Guidelines: Scalp PsO

Monotherapy in adults with moderate-to-severe plaque PsO affecting scalp

Recommendation Number	Recommendation	Strength of Recommendation
1.4, 8.3	Etanercept, guselkumab	A
2.6, 3.6, 5.5, 6.4	Infliximab, adalimumab, secukinumab, ixekizumab	B
4.6	Ustekinumab	C

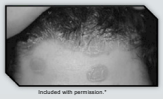
Menter A, et al. *J Am Acad Dermatol.* 2019;80:1029-1072.

Selected Pearls from 2019 Joint AAD-NPF Guidelines: Comorbidities

Recommendation Number	Recommendation	Strength of Recommendation
4.3	PsO patients showing signs or symptoms of anxiety, depression, or suicidal ideation should be referred to an appropriate health care professional for further assessment and management	A
5.4	Patients with PsO who have nicotine or alcohol dependency should be referred to expert health professionals for further assistance	A
6.2	PsO patients found to have concerns for IBD should be referred to their primary care provider or a gastroenterologist for further assessment and management	A

Elmets CA, et al. *J Am Acad Dermatol.* 2019;80(4):1073-1113.

Clinical Case

Patient Characteristics	Family and Social History	
• **Sex:** female • **Age:** 32 • **Height and weight:** 5' 3" (160 cm), 170 lbs (77 kg) (BMI: 30)	• Paternal grandfather: **PsO** • Father: passed away at age 52 from **MI** • Brother: **CD** • No tobacco • Two glasses of wine per night • Getting married in 6 months	**Jennifer**  Included with permission.*
History of Present Illness	**Past Medical History**	**Clinical Assessment Results**
• **Disease onset:** age 15 • **Sites affected:** scalp, arms, legs, nails • **Symptoms:** mild itching, experiences severe embarrassment • **Modifying factors:** better in the summer, worse with stress • **Prior treatment:** topical medications only	• **Obesity** (BMI: 30) • **Depression** • History of optic neuritis in college • Smokes ¼ pack of cigarettes daily • Two glasses of wine each evening	• **PGA:** 4 • **BSA:** 5% • **PsO** affecting most of the scalp, forehead, small patches on elbows and knees; fingernails have pitting and onycholysis
Current Medications	**Laboratory Results**	**Additional Considerations**
• Sertraline	• **Blood pressure:** 140/90 mm Hg	• N/A

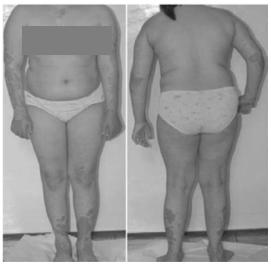
This clinical case is based on a real-life case study; however, the image of PsO is for illustrative purposes only and does not depict an actual patient.
*Meier M, Sheth PB. *Curr Probl Dermatol.* 2009;38:1-20.

Clinical Case: Melissa

Patient Characteristics	Family and Social History
• **Sex:** female • **Age:** 12 • **Height and weight:** 5' 0" (154 cm), 160 lbs (73 kg) (BMI: 31.2)	• Father: **diabetes** • Mother: **hypertension, PsO** • Bullied in school, peers call her names due to weight and malodorous rash • No friends, socially isolated, low self-esteem • Irritable, inattentive at school
History of Present Illness	**Past Medical History**
• **Disease onset:** infancy • **Sites affected:** scalp, palms, soles, trunk • **Symptoms:** pruritic rash, sleep significantly impacted • **Prior treatment:** topicals, phototherapy, MTX	• **Obesity** (BMI: 31.2) • Asthma
Current Medications	**Laboratory Results**
• Inhaled bronchodilator as needed • 1% hydrocortisone ointment twice daily • Etanercept 50 mg weekly	• **Blood pressure:** 130/89 mm Hg

Clinical Case: Melissa

Clinical Assessment Results
• **PGA:** 4 • **BSA:** 18% • Scaly erythematous plaques on the trunk, limbs, and scalp; yellow-brown crusts on palms and soles; subungual hyperkeratosis on fingers
Additional Considerations
▪ N/A



2019 Joint AAD-NPF Guidelines: Pediatric PsO/PsA Recommendations

Recommendation Number	Recommendation	Strength of Recommendation
2.1	Pediatric patients with PsO should be educated about the risk of PsA and its clinical manifestations	C
2.2	Pediatric patients with PsO should be routinely screened for PsA via a thorough history and physical examination	C
2.3	Pediatric patients with PsO who show signs and symptoms of inflammatory arthritis should be referred to a rheumatologist with pediatric expertise, if available, for further evaluation and management	C
2.4	Pediatric PsO patients with PsA should be routinely screened for uveitis by history and physical examination	C
2.5	Pediatric patients with PsO who show signs and symptoms of uveitis should be referred to an ophthalmology specialist for further evaluation and management	C

Menter A, et al. *J Am Acad Dermatol*. 2020;82(1):161-201.

2019 Joint AAD-NPF Guidelines: Pediatric PsO Obesity

Recommendation Number	Recommendation	Strength of Recommendation
3.1	Routinely assess for obesity status	B
3.2	Routinely assess for comorbidities of obesity (independent of PsO)	B

Screening recommendation:

Screen for overweight and obesity yearly using BMI percentile, starting at age 2

Menter A, et al. *J Am Acad Dermatol*. 2020;82(1):161-201; Osier E, et al. *JAMA Dermatol*. 2017;153(7):698-704.

2019 AAD-NPF Guidelines: Pediatric PsO CV Risk Factor Recommendations

- CVD
  - Education
  - Screen
  - Specialist referral
- Dyslipidemia
  - Education
  - Screen according to AAP guidelines
  - Screening frequency
  - Specialist referral
- Hypertension
  - Screen according to AAP guidelines
- Insulin resistance
  - Education
  - Screen
  - Screening frequency
  - Specialist referral

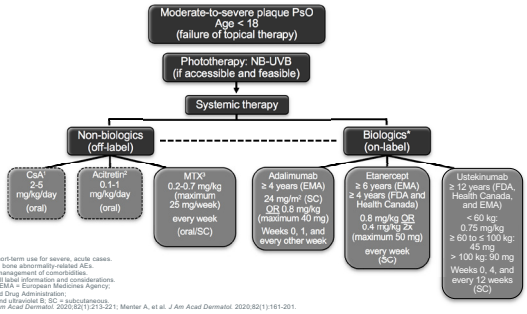
AAP = American Academy of Pediatrics.
Menter A, et al. *J Am Acad Dermatol*. 2020;82(1):161-201.

AAP Screening Recommendations

- Dyslipidemia
  - Universal lipid screening from 9-11 years and 17-21 years
  - Screening recommended in the presence of any additional CV risk factors
  - Recommended lipid screening
    - Fasting lipid panel (total cholesterol: LDL, HDL, and triglycerides)
- Hypertension
  - Screen for hypertension yearly starting at 3 years of age, using age, sex, and height reference charts
- Insulin Resistance
  - With PsO & obesity
    - Fasting glucose every 3 years at puberty or age 10

Expert Panel on Integrated Guidelines for Cardiovascular Health and Risk Reduction in Children and Adolescents. *Pediatrics*. 2011;128(suppl 5):S213-S256.
Osier E, et al. *JAMA Dermatol*. 2017;153(7):698-704.

Management of Pediatric PsO



[1]Consider for fast, short-term use for severe, acute cases.
[2]Lower dose to avoid bone abnormality-related AEs.
[3]Useful for off-label management of comorbidities.
*See reference for full label information and considerations.
CsA = cyclosporine; EMA = European Medicines Agency; FDA = U.S. Food and Drug Administration; NB-UVB = narrowband ultraviolet B; SC = subcutaneous.
Lansang P, et al. *J Am Acad Dermatol.* 2020;82(1):213-221; Menter A, et al. *J Am Acad Dermatol.* 2020;82(1):161-201.

Oral Treatments: Pediatric PsO

	MTX	Cyclosporine	Acitretin
2019 Joint AAD NPF Guidelines Recommendation Strength of Recommendation: B	Recommended as an effective systemic therapy for moderate-to-severe plaque PsO and other PsO subtypes in children	Recommended as an effective systemic therapy for moderate-to-severe plaque PsO in children	Recommended as an effective, non-immunosuppressive systemic therapy for children with extensive guttate or moderate-to-severe (ideally thin plaque) psoriasis vulgaris at a dosage of 0.1 to 1 mg/kg/day
Dosing Regimen	0.2-0.7 mg/kg/week (maximum 25 mg/week)	2-5 mg/kg/day	0.1-1 mg/kg/day
Contraindications	Liver disease, kidney disease, hematologic disorders immunodeficiency, pregnancy	Kidney disease, active infections, hypertension, malignancy, use of phototherapy	Liver disease, kidney disease, hypertriglyceridemia, pregnancy
Adverse Effects	Common: gastrointestinal upset, upper respiratory infections, fatigue, headache Severe: bone marrow suppression, hepatotoxicity	Common: nausea, diarrhea, arthralgia, headache Severe: nephrotoxicity, hepatotoxicity, hypertension, hyperlipidemia, gingival hyperplasia, malignancy	Common: dry skin, dry mouth, cheilitis, stomatitis, gingivitis, taste disturbances Severe: teratogenicity, hyperlipidemia, hepatotoxicity
Baseline Lab Monitoring	CBC, CMP, lipid profile, hepatitis panel	Blood pressure, CBC, CMP, lipid profile, urinalysis	CBC, CMP, lipid profile, pregnancy testing (in females of childbearing age)
FDA-Approved in Pediatric Populations	Treatment of juvenile idiopathic arthritis in patients age > 2 years	Pediatric transplant patients age > 6 months	Safety and efficacy in pediatric patients have not been established

CBC = complete blood count; CMP = comprehensive metabolic panel.
Frantz T, et al. *Children (Basel).* 2019;6(11):125. Menter A, et al. *J Am Acad Dermatol.* 2020;82(1):161-201.

Monitoring for Non-biologics*

Medication†	Baseline	Follow-up	Miscellaneous
MTX Dose range: 0.2-0.7 mg/kg/week Maximum: 25 mg/week	• CBC with differential, platelets • Renal function‡ • Liver function • If at risk: hepatitis A, B, C; HIV, PPD, or other TB tests for latent TB screening‡	• CBC with differential, platelets (5-7 days after initiating therapy) • Renal function‡ • LFTs (monthly for the first 3 months, then every 3 to 6 months) • Annual TB test if at risk‡	• Liver enzymes rise after dose; check labs 4-6 days after the last dose • Liver biopsy often avoided/not indicated in pediatric patients but should be individualized to clinical context • Avoid in children with liver risk factors • Chest radiograph for symptoms
Acitretin Dose range: 0.1-1 mg/kg/d	• CBC • Fasting lipids • Liver function • Pregnancy test (if appropriate)	• Liver function and fasting lipids after 1 month of treatment and with dose increases, then every 1-3 months • Monthly pregnancy test (if appropriate)	Bone imaging based on symptoms and duration of treatment
Cyclosporine Dose range: 2-5 mg/kg/d	• Blood pressure • CBC • Renal function • Liver function • Fasting lipids • Serum magnesium and potassium uric acid • HIV if at risk	• Blood pressure once a week for the first month and at follow-up visits as needed • CBC, serum creatinine, BUN, uric acid, potassium, lipids, and magnesium every 2 weeks for the first month and then at least monthly thereafter	Whole-blood cyclosporine trough level if inadequate clinical response or concomitant use of potentially interacting drugs

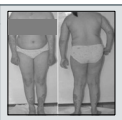
BUN = blood urea nitrogen; LFT, liver function test; PPD = protein derivative test; TB = tuberculosis.
*Some monitoring suggestions are not evidence-based recommendations and are expert consensus. These recommendations may vary based on patient age and specific protocols. Practicing physicians should individualize monitoring protocols according to the clinical context. For all pediatric patients receiving long-term systemic therapy, growth parameters should also be monitored.
†Dosing is based on actual weight.
‡At the discretion of the physician based on the clinical situation/individual risk factors.
Menter A, et al. *J Am Acad Dermatol.* 2020;82(1):161-201.

Pediatric PsO Biologics

Drug	Mechanism of Action	Dosing Schedule
Etanercept	Soluble fusion protein of TNF-α receptor and Fc portion of human IgG	0.8 mg/kg weekly subcutaneous If ≥ 63 kg, 50 mg
Adalimumab	Fully humanized monoclonal IgG antibody targeting TNF-α	24 mg per m^2 subcutaneous or 0.8 mg/kg (maximum, 40 mg) weekly for first 2 weeks and then every 2 weeks
Infliximab (Off-label)	Chimeric monoclonal IgG antibody targeting TNF-α	Intravenous infusions 5 mg/kg at weeks 0, 2, and 6 and then every 8 weeks after
Ustekinumab	Fully human monoclonal antibody targeting the p40 subunit of IL-12 and IL-23	If < 60 kg: 0.75 mg/kg/dose If 60 to ≤ 100 kg: 45 mg If > 100 kg: 90 mg SC, weeks 0 and 4, and then every 12 weeks

Fc = fragment crystallizable; IgG = immunoglobulin G.
Menter A, et al. *J Am Acad Dermatol.* 2020;82(1):161-201.

Clinical Case: Melissa

Patient Characteristics	Family and Social History	
• **Sex:** female • **Age:** 12 • **Height and weight:** 5′ 0″ (154 cm), 160 lbs (73 kg) (BMI: 31.2)	• Father: **diabetes** • Mother: **hypertension, PsO** • Bullied in school, peers call her names due to weight and malodorous rash • No friends, socially isolated, low self-esteem • Irritable, inattentive at school	 Melissa
History of Present Illness	**Past Medical History**	**Clinical Assessment Results**
• **Disease onset:** infancy • **Sites affected:** scalp, palms, soles, trunk • **Symptoms:** pruritic rash, sleep significantly impacted • **Prior treatment:** topicals, phototherapy, MTX	• **Obesity** (BMI: 31.2) • Asthma	• **PGA:** 4 • **BSA:** 8% • Scaly erythematous plaques on the trunk, limbs, and scalp; yellow-brown crusts on palms and soles; subungual hyperkeratosis on fingers
Current Medications	**Laboratory Results**	**Additional Considerations**
• Inhaled bronchodilator as needed • 1% hydrocortisone ointment twice daily • Etanercept 50 mg weekly	• **Blood pressure:** 130/89 mm Hg	▪ N/A

SMART Goals

Specific, Measurable, Attainable, Relevant, Timely

- In accordance with joint AAD-NPF guideline recommendations:
  - Individualize treatment with biologics for moderate-to-severe PsO, tailored to the patient's needs and circumstances
  - Evaluate and appropriately treat patients with PsO for comorbidities
  - Assess disease severity, manage comorbidities, and evaluate safety and effectiveness of therapy in children with PsO

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