

Balancing Cost & Access to Quality Care for Therapeutic Advancements in PSORIASIS

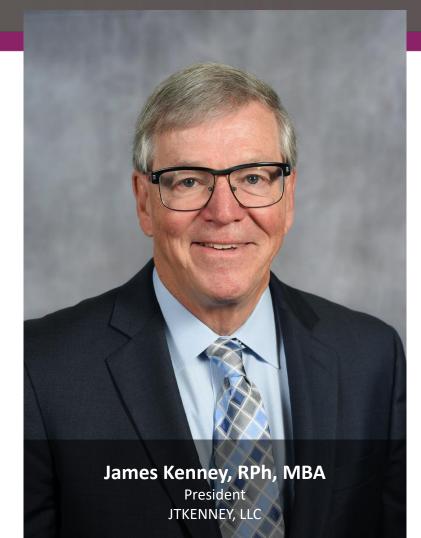


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THIS ACTIVITY IS SUPPORTED BY INDEPENDENT EDUCATIONAL GRANTS FROM ARCUTIS BIOTHERAPEUTICS, INC. AND DERMAVANT SCIENCES, INC.



Welcome

Faculty



Jason Harris Vice President of Government Relations & Advocacy National Psoriasis Foundation



Heather Woolery-Lloyd, MD Director, Skin of Color Division Dr. Phillip Frost Department of Dermatology and Cutaneous Surgery University of Miami Miller School of Medicine

Agenda

5 minutes	Pre-Activity Learning Assessment and Opening Comments	
25 minutes	Clinical Expert Update – Psoriasis Evolving Treatment Landscape Heather Woolery-Lloyd, MD	
20 minutes	Best Practices to Overcome Barriers to Access Optimal Care James Kenney, RPh, MBA, Jason Harris, Heather Woolery-Lloyd, MD	
20 minutes	Patient-Centric Medical and Pharmacy Management Strategies (case-based discussion) James Kenney, RPh, MBA, Jason Harris, Heather Woolery-Lloyd, MD	
15 minutes	Audience Q&A Session	
5 minutes	Key Takeaways and Closing Comments; Post-Activity Assessment and Evaluation	

Learning Objectives

- Assess how emerging and recently approved psoriasis therapies impact disease control and fit into the treatment algorithm
- Recognize how comorbidities, treatment history, and patient preferences can influence therapeutic selection
- Employ timely referral and collaborative, multidisciplinary management for all patients with psoriasis
- Apply strategies to improve and expedite access to high-quality psoriasis care and treatment

Psoriasis: An Immune-Mediated Chronic Relapsing Multisystem Inflammatory Disease

- Occurs in >3% of the US population
- Can affect multiple areas of the body
- Accompanied by significant lifelong clinical, social, and economic burden
- Associated with psoriatic arthritis and other comorbidities resulting in a need for multidisciplinary care
- Comprehensive and collaborative care required for early diagnosis and appropriate treatment



Plaque Psoriasis is the Most Common of the Five Recognized Variants

- Plaque: scaly, erythematous patches, and plaques; can be pruritic; most common affecting ~80% of patients)
- Inverse/flexural: lesions located in skin folds (intertriginous areas)
- **Guttate:** small papules with fine scale
- Erythrodermic: erythema covering nearly the entire body surface area; varying degrees of scaling present
- **Pustular:** clinically apparent pustules
- Other: scalp, inverse



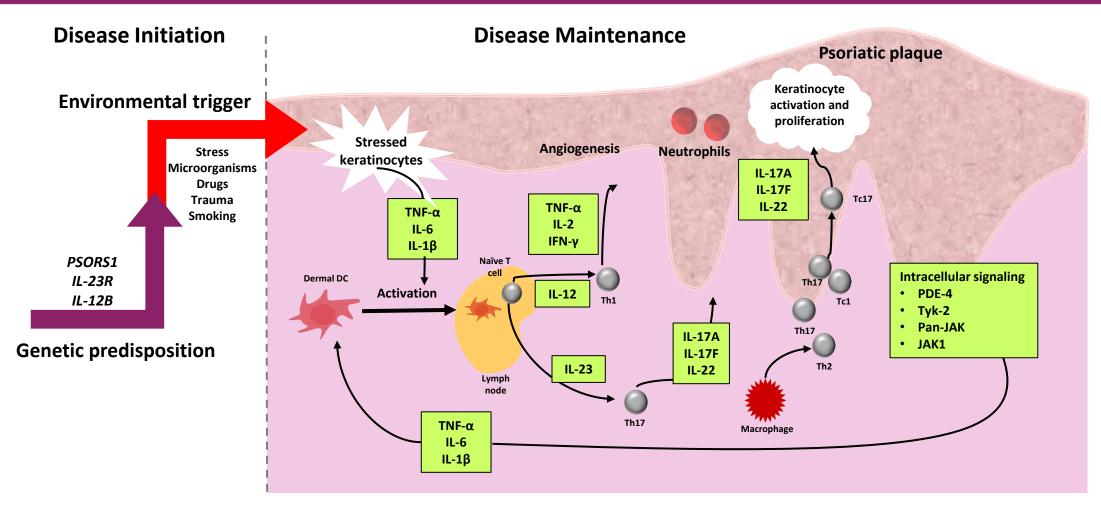
<3% of BSA

3% -10% of BSA

>10% of BSA

About Psoriasis. National Psoriasis Foundation Web site. https://www.psoriasis.org/about-psoriasis/. Accessed August 2023.

Immunopathogenesis of Chronic Plaque Psoriasis



DC=dendritic cell; PSORS1=psoriasis susceptibility 1; IL=interleukin; TNF=tumor necrosis factor; JAK=Janus kinase; Tyk=Tyrosine kinase; PDE=phosphodiesterase. Rendon A, Schakel K. Int J Mol Sci. 2019;20:1475; Griffiths CEM, et al. Lancet. 2021;397:1301-13:15.

Comorbidities Associated with Psoriasis

	Depression/Anxiety	Depression, poor self-esteem, anxiety, low quality of life
	Cardiovascular/Cardiometabolic Disease	 Obesity Vascular inflammation Diabetes Myocardial infarction Stroke Peripheral vascular disease CV mortality
	Gastrointestinal disorders	Inflammatory bowel disease
	Musculoskeletal disorders	Psoriatic arthritis

Early Diagnosis of Psoriasis Remains a Challenge

- Diagnosis often delayed; a prolonged lapse (>1.5 years) between symptom onset and confirmed diagnosis is common
- Clinical diagnosis based on symptoms (e.g., itching, dry skin, rash, skin texture changes)
 - Symptoms often resemble other conditions such as eczema
- Patients typically first seen by non-specialists unfamiliar with psoriasis
- Delayed diagnosis is not uncommon in people with skin of color and/or where access to specialist care is limited
- Benefit of timely diagnosis:
 - Early targeted, individualized treatment
 - Screening for and treatment of comorbidities
 - Improved disease course
 - Reduced cumulative impairment

Abo-Tabik M, et al. Br J Gen Pract. 2022;72:e834-e841.

Approved Treatments for Plaque Psoriasis

Topical Therapy		Oral Therapy		licht	Piologia
Traditional	Recently Approved	Traditional	Recently Approved	Light Therapy	Biologic Therapy
 Moisturizers TCS TCI Vitamin D Tazarotene Anthralin Coal tar 	 Tapinarof Roflumilast Calcipotriene + Betamethasone Dipropionate cream (0.005%/0.064%) 	MethotrexateCyclosporinAcitretin	ApremilastDeucravacitinib	NB-UVBUVB laser	 TNF-a IL-17 IL-17A IL-23 IL-12/13
Mild		Moderate		Severe	
Psoriasis Severity					

TCS=topical corticosteroid; TCI=topical calcineurin inhibitor; NB=narrow band; UVB=ultra-violet B; TNF=tumor necrosis factor; IL=interleukin

Treatment & Care. National Psoriasis Foundation. Updated October 14, 2020. Accessed September 2023. https://www.psoriasis.org/treatment-and-care/

Psoriasis Treatments Currently in Phase 2-3 Development

Therapy	Therapeutic Target	Administration	Status	Notes
Bimekizumab	IL-17A/F	IV	Phase 3	FDA decision expected 3Q 2023
Imsidolimab	IL-36	IV followed by subQ	Phase 3	For generalized pustular psoriasis
JNJ-2113	IL-23R	Oral	Phase 3	First oral IL-23 antagonist
Piclidenoson	A3 AR	Oral	Phase 3	First agent to target adenosine receptors
Brepocitinib	Tyk2/JAK1	Topical	Phase 2	Oral formulation in development for PsA
DC-806	IL-17 receptor	Oral	Phase 2	Recently acquired by Lilly
Izokibep	IL-17A	Sub-Q	Phase 2	Based on trivalent nanobody technology
Orismilast	PDE-4	Oral	Phase 2	Fast track designation
Ropsacitinib	Tyk2/JAK1	Topical	Phase 2	Oral formulation in development for PsA
Sonelokimab	IL-17A/F	Sub-Q	Phase 2	Based on trivalent nanobody technology

TNF=tumor necrosis factor; IL=interleukin; AR=adenosine receptor; PDE-4=phosphodiesterase; TYK=tyrosine kinase; JAK=Janus kinase

Drakos A, Vender R. *Dermatol Ther (Heidelb)*. 2022; 12:2715-2730; Puig L. New and emerging therapies for psoriasis. Presentation at EADV Congress 2023; October 2023; Berlin, Germany; eadvcongress2023.org

Most Patients Will Need Topical Therapy

- Topical therapies are used to treat localized plaques (<10% BSA) as well as to clear residual plaques in patients with more widespread disease
- Topical corticosteroids (TCS) are the mainstay of topical therapy
- Although effective, TCS lose efficacy overtime and have been associated with skin atrophy at the application area
- Tapinarof and roflumilast (approved in 2022) are steroid-free topicals
- These therapies represent new mechanisms, pathways, and delivery systems providing more treatment choices for providers and patients

Forand R. A topical treatment revolution is on the horizon for psoriasis. https://www.healio.com/news/dermatology/20211222/a-topical-treatment-revolution-is-on-thehorizon-for-psoriasis. January 5, 2022. Accessed September 2023.

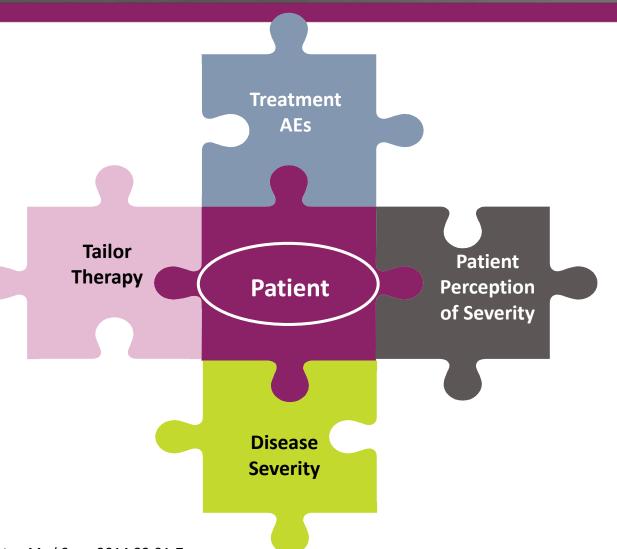
Establish Individualized Treatment Goals

Goals of psoriasis treatment

- Clear the skin
- Minimize adverse events
- Enhance patient quality of life
- Address comorbidities

Individualize therapy using shared decision-making

Consider patient preferences when selecting therapy



Schaarschmidt ML, et al. Arch Dermatol. 2011;147:1285-94; Brezinski EA, Armstrong AW. Semin Cutan Med Surg. 2014;33:91-7.

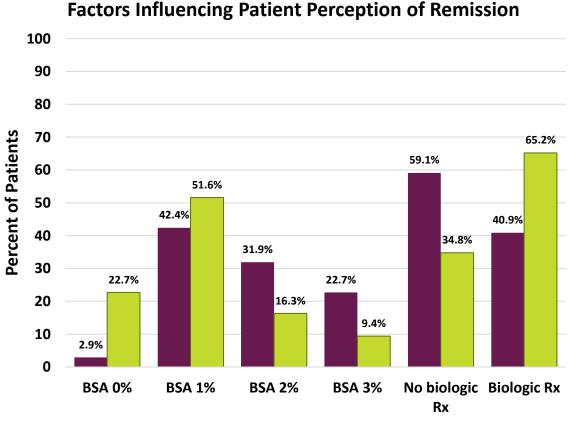
Comorbidities Are Highly Prevalent and Negatively Impact Quality of Life

- Nationwide survey of individuals with psoriasis (n=1570) conducted by the National Psoriasis Foundation
 - Survey results can help identify areas of need and inform providers, researchers, and payers as to the unmet needs of individuals with psoriasis
- >85% of individuals reported having ≥1 relevant comorbidity¹
 - On average, individuals reported having 3 comorbidities
- Presence of even one comorbidity negatively impacts global and disease-specific quality of life (QoL) as well as mental health
 - 33% of respondents exhibited mental health scores suggesting they should seek treatment for their depressive symptoms
- These results suggest the need to treat psoriasis systemically and holistically to optimize patient outcomes

1. Bell S, et al. J Invest Dermatol. 2020;140:S67. Abstract 495; 2. Gondo G, et al. J Invest Dermatol. 2020;140:S67. Abstract 459.

Patient Perception of Psoriasis Remission Not Solely Associated with Body Surface Area (BSA)

- Compared with provider-defined psoriasis remission, patient perceptions of remission are not well understood
- NPF survey results (n=930) suggest factors beyond BSA are associated with patient-reported remission
- Patient-reported remission was independently associated with female sex, lower BSA, less impairment in the DLQI and global QoL, and biologic use



Remission No Remission Yes

Barriers to Effective Psoriasis Care

- Despite numerous effective treatments, undertreatment, and non-treatment is prevalent
- Barriers to effective psoriasis care can include
 - Missed or delayed diagnosis
 - Presence of comorbidities
 - Differences in the patient and physician perspectives on the disease
 - Knowledge gaps/limited availability of qualified care providers
 - Race/ethnicity and lack of culturally sensitive care
 - Lack of established treatment goals
 - Insurance limitations/benefit design policies
 - Patient socioeconomic status/affordability of treatment

Comorbidities Screening Recommendations

Metabolic Disease

- Monitor blood pressure according to national guidelines
- Screen lipids
- Follow up/refer to appropriate specialist (e.g., endocrinology)
- Encourage a healthy diet and lifestyle

Cardiovascular Disease

- Conduct risk assessment as per national guidelines
- Encourage regular follow up with a PCP
- Follow up/refer to appropriate specialist (e.g., cardiology)
- Encourage a healthy diet and lifestyle

Joint Disease

- Assess joint complaints during dermatology exam
- Evaluate for peripheral inflammatory arthritis and other indicators of psoriatic arthritis
- Consult with rheumatology for management

Mental Health

- Assess for signs and symptoms of anxiety and depression
- Refer patient to appropriate specialist (e.g., psychiatry)

Strategies to Improve the Quality of Psoriasis Care

Approach	• collaborative, multi-disciplinary care to ensure appropriate treatment of the skin as well as comorbidities
Realistic Goals	 total skin clearance and reduction of symptoms (most importantly itch) are important to the patient
Early Treatment	 minimize time to appropriate therapy including novel topicals, biologics, or new oral agents
Increase Treatment	 early diagnosis and use of efficacious, safe, and cost- effective therapies
Benefit Design	 ensure access and reimbursement policies keep pace with clinical science and therapeutic advances

Strober BE, et al. Dermatol Ther (Heidelb). 2019;9:5-18.

Patient-Centric Medical and Pharmacy Management Strategies: A Case-Based Discussion

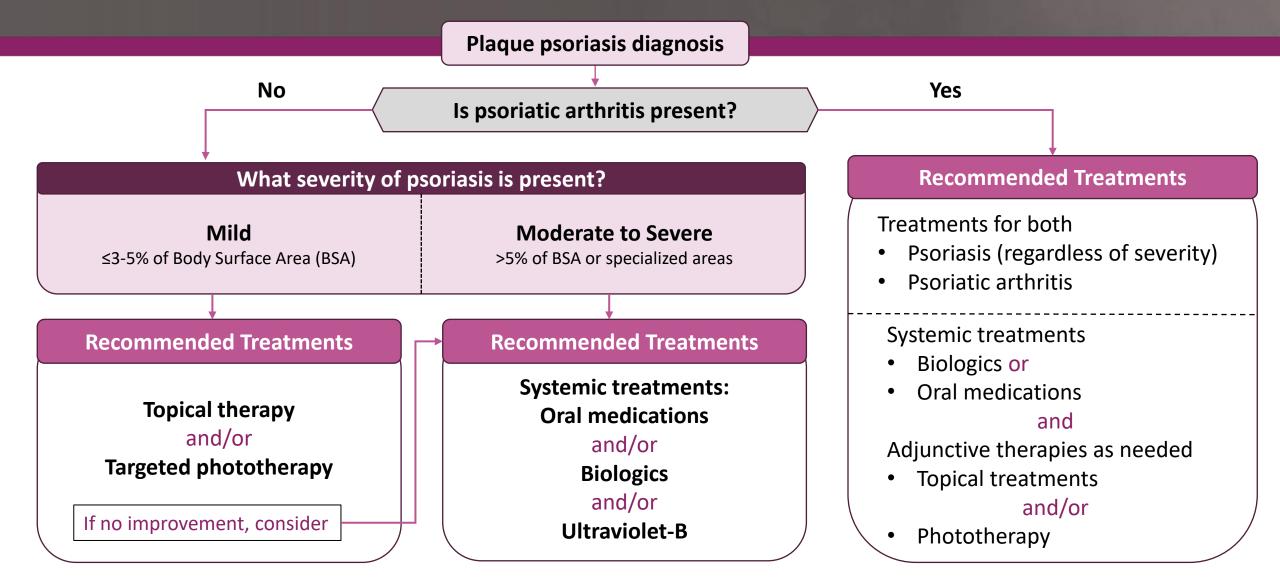
Case Presentation

- Introduction: 57-year-old male with a 12-year history of psoriasis seen in a primary care clinic
- Medical history: hypertension, diabetes, dyslipidemia, obesity (BMI=29)
- **Body surface area (BSA)**: 9% with lesions on the back, wrist, and lower legs
- **Current medications:** OTC moisturizers, diuretics, metformin, statin
- Current complaint: itch, scaling, and morning joint stiffness





Overall Treatment Approach for Plaque Psoriasis



Armstrong AW, Read C. JAMA. 2020;323:1945-1960.

Unmet Needs and Challenges When Treating Psoriasis in Patients with Skin of Color

People with Psoriasis and Skin of Color

Access to Care

- Culture may influence decision to seek care
- Access to medical care and treatment may be limited
- When care is accessible, it may be delayed resulting in more severe disease

Diagnosis

- Differences in prevalence and incidence
- Unfamiliar presentation due to skin pigmentation masking more severe disease, thicker plaques, more scale, greater BSA
- Risk of misdiagnosis
- Presence of comorbidities

Treatment

- Few patients with skin of color in clinical trials
- Cultural-based preferences for treatment modalities
- Differences in clinical response to different treatment modalities
- Complications due to comorbidities

Psoriasis Treatments are Not "One Size Fits All"

Patient Education

Discuss benefits and risks of each treatment option

Assess Patient's Values and Preferences

Route of administration, frequency of dosing, cost concerns (e.g., out-of-pocket costs), etc.

Establish Treatment Goals

Discuss and set treatment expectations and address concerns

Shared Decision-Making

Reach a treatment decision with the patient

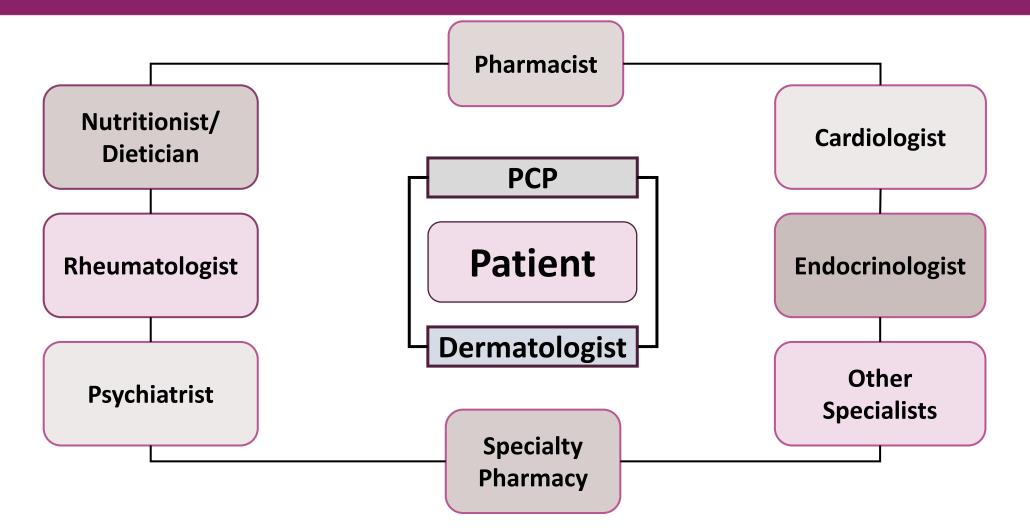
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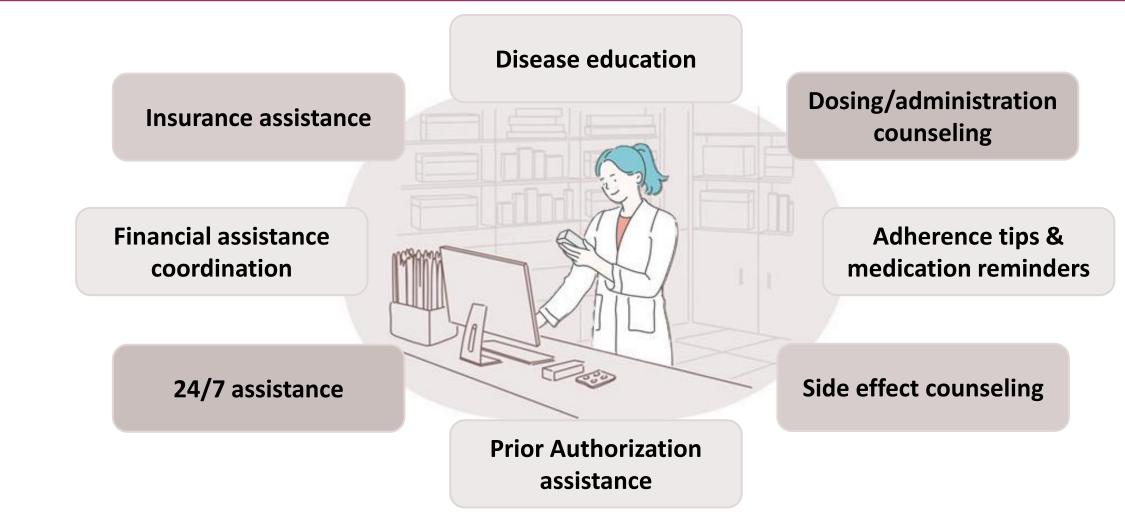




Key Members Psoriasis Multidisciplinary Care Team



Specialty Pharmacy Role in Improving Psoriasis Outcomes



Kibbons AM, et al. Drugs Real World Outcomes. 2020;7:295-305.

Improving Formulary Decision-Making to Ensure Value and Access to Psoriasis Treatment

- AMCP encourages identification of solutions that optimize patients' health outcomes and address barriers to care access
- Potential solutions to be considered:
 - Value
 - Access
 - Affordability
 - Technologies
 - Quality
- Achieving this goal will require:
 - Improving formulary decision-making tools
 - Support for biosimilar adoption
 - Incorporation of the patient voice into formulary decision-making

AMCP strategic priorities—updated winter 2023. Academy of Managed Care Pharmacist. Accessed September 2023. https://www.amcp.org/about/about-amcp/amcp-strategic-priorities

Audience Q&A

Summary and Key Takeaways

- Psoriasis is an immune-mediated, chronic, relapsing multisystem inflammatory disease accompanied by significant lifelong clinical, social, and economic burdens
- Patients often present with multiple comorbidities, which can complicate the diagnosis and long-term management
- Treatment options include topical, oral, light and biologic therapies
 - Several recently approved topical and oral therapies with novel mechanisms of action provide patients and providers with additional safe and effective treatment options
- Despite numerous effective treatments, undertreatment and non-treatment is prevalent, particularly in patients with skin of color
- Both providers and payers can implement strategies to facilitate timely access to innovative psoriasis therapy