CUTANEOUS MEDICINE FOR THE PRACTITIONER

VOL. 86 NO. 3S SEPTEMBER 2010

Optimizing Topical Therapies for Treating Psoriasis:

A Consensus Conference

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CUTANEOUS MEDICINE FOR THE PRACTITIONER VOL. 86 NO. 3S

A SUPPLEMENT TO

Cutis® Cutaneous Medicine for the Practitioner, September 2010, Volume 86 Number 3S

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PUBLISHER: Cutis® (ISSN-0011-4162) (GST #128741063) is published monthly by Quadrant HealthCom Inc., with business offices at 7 Century Dr, Suite 302, Parsippany, NJ 07054-4609; telephone 973-206-3434; fax 973-206-9378.

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SEPTEMBER 2010

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This activity is supported by an educational grant from Galderma Laboratories, LP.

INTENDED AUDIENCE

This activity has been designed to meet the educational needs of physicians, registered nurses, and healthcare providers involved in the management of patients with psoriasis.

STATEMENT OF NEED/PROGRAM OVERVIEW

This article is designed to provide useful tips and to help guide dermatologists through the practical challenges of treating psoriasis patients with topical medications as part of both initial and maintenance therapies.

LEARNING OBJECTIVES

After completing this activity, the participant should be better able to:

- Identify the severity of a patient's psoriatic disease.
- Discuss topical treatment strategies for psoriasis on various areas of the body.
- Select appropriate topical vehicle and dose for different types of psoriasis.
- Explain approaches to improve patient adherence to treatment regimens.
- Outline psoriasis treatment guidelines for different population types.
- Identify strategies for long-term maintenance therapy for psoriasis.

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Optimizing Topical Therapies for Treating Psoriasis: A Consensus Conference

Joshua A. Zeichner, MD; Mark G. Lebwohl, MD; Alan Menter, MD; Jerry Bagel, MD; James Q. Del Rosso, DO; Boni E. Elewski, MD; Steven R. Feldman, MD, PhD; Leon H. Kircik, MD; John Koo, MD; Linda Stein Gold, MD; Emil Tanghetti, MD; for the Psoriasis Process of Care Consensus Panel

In 2010, an expert committee of physicians and researchers in the field of dermatology working together as the Psoriasis Process of Care Consensus Panel developed consensus guidelines for the treatment of psoriasis. As much as possible, the guidelines were evidence based but also included the extensive clinical experience of the dermatologists. Psoriasis is a lifelong disease that requires long-term treatment and 80% of psoriasis patients have mild to moderate disease. Topical therapies play an important role in the treatment of psoriasis, especially in patients with mild to moderate disease. Patients usually start with monotherapy; however, in more severe cases (>10% body surface

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Center, New York, New York. Dr. Menter is from Baylor Research Institute, Dallas, Texas. Dr. Bagel is from Columbia University College of Physicians and Surgeons, New York. Dr. Del Rosso is from Valley Hospital Medical Center, Las Vegas, Nevada. Dr. Elewski is from the University of Alabama School of Medicine, Birmingham. Dr. Feldman is from Wake Forest University School of Medicine. Winston-Salem, North Carolina. Dr. Kircik also is from Indiana University School of Medicine, Indianapolis. Dr. Koo is from the University of California at San Francisco School of Medicine. Dr. Stein Gold is from Henry Ford Health System, Detroit, Michigan. Dr. Tanghetti is from Sacramento, California. Dr. Zeichner is an advisory board member for Promius Pharma. Dr. Lebwohl is a consultant for and has received honoraria from Abbott Laboratories; Allostera Pharma Inc; Amgen Inc; Astellas Pharma Inc; Biosynexus Incorporated; Cambridge Pharma; Can-Fite BioPharma; Celgene Corporation; Centocor Ortho Biotech Inc; DermaGenoma, Inc; DermiPsor Ltd; Ethicon, Inc; Helix BioMedix, Inc; Novartis Pharmaceuticals Corporation; Pfizer Inc; and Stiefel, a GSK company. He also has lectured for and has received honoraria from Ranbaxy Laboratories Ltd. Dr. Menter is an advisory board member, consultant, investigator, and speaker for, and has received grants and honoraria from Abbott Laboratories; Amgen Inc; Astellas Pharma Inc; Centocor Ortho Biotech Inc; and Genentech, Inc. He also is an advisory board member, consultant, investigator, and speaker for, and has received honoraria from Warner Chilcott and Wyeth Pharmaceuticals, and is an investigator for and has received grants from Allergan, Inc; Asubio Pharmaceuticals, Inc; Celgene Corporation; DUSA Pharmaceuticals, area [BSA], severely impaired quality of life [QOL], or recalcitrant psoriatic lesions), multiple treatment modalities may be used as part of combination, sequential, or rotational therapeutic regimens. Main treatment options include topical steroids, systemic therapies, topical vitamin D treatments such as vitamin D₃ ointment, retinoids, phototherapy, and biologic therapies. Other topical therapies include the following steroid-sparing agents: coal tar, anthralin, calcineurin inhibitors, keratolytics, and emollients. Therapeutic considerations also should focus on adherence, improving QOL, and promoting a good patient-physician relationship.

Cutis. 2010;86(suppl 3):5-31.

Inc; Novartis Pharmaceuticals Corporation; Novo Nordisk; Pfizer Inc; Promius Pharma; and Syntrix Biosystems, Inc. Dr. Menter also is a consultant and investigator for and has received grants from Eli Lilly and Company; is an advisory board member, consultant, and speaker for and has received honoraria from Galderma Laboratories, LP; and is a consultant and investigator for and has received grants and honoraria from Stiefel, a GSK company. Dr. Bagel is a consultant and speaker for Abbott Laboratories; Amgen Inc; Centocor Ortho Biotech Inc; Galderma Laboratories, LP; LEO Pharma; The NeoStrata Company, Inc; and Stiefel, a GSK company. Dr. Del Rosso is a consultant and speaker for Coria Laboratories, Ltd; Galderma Laboratories, LP; Intendis, Inc; Medicis Pharmaceutical Corporation; Ranbaxy Laboratories Ltd; and Stiefel, a GSK company. Dr. Elewski is an advisory board member and consultant for Centocor Ortho Biotech Inc; Galderma Laboratories, LP; and Intendis, Inc. She also is a consultant for Novartis Pharmaceuticals Corporation and has received research grants from Abbott Laboratories; Amgen Inc; Centocor Ortho Biotech Inc; Galderma Laboratories, LP; Intendis, Inc; Novartis Pharmaceuticals Corporation; and Novo Nordisk. Dr. Feldman is a consultant and speaker for and has received grant support from Abbott Laboratories; Amgen Inc; Astellas Pharma Inc; Bristol-Myers Squibb Company; Centocor Ortho Biotech Inc; Galderma Laboratories, LP; PharmaDerm; Stiefel, a GSK company; and Warner Chilcott. He also has received grant support from Hoffmann-La Roche Ltd; Ortho-McNeil-Janssen Pharmaceuticals, Inc; and sanofi-aventis. Dr. Feldman also is a consultant for, has received research support from, and has stock options with PhotoMedex, Inc; is a consultant for and has received grant

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ffective use of topical therapies for psoriasis is an art learned from experience. While there Lis a limited number of classes of medications available, there is an increasing number of formulations. Choosing the right vehicle for the right body part is crucial in treating patients with psoriasis. Regimens must be customized to accommodate individual patient preferences, and there is no one correct formula to treat individual patients with psoriasis. To provide guidance, a panel of psoriasis experts gathered to create a road map that can be used in everyday practice, representing different viewpoints based on available data as well as extensive clinical experience. This article is designed to give useful tips and help guide dermatologists through the practical challenges of treating psoriasis patients with topical medications as part of both initial and maintenance therapies

Defining Severity of Psoriasis

Creating a working definition of mild, moderate, and severe psoriasis is a difficult task; there was no consensus among the members of the Psoriasis Process of Care Consensus Panel (hereafter, the panel). However, it was acknowledged that topical therapy is an integral part of the therapeutic regimen, regardless of the severity of disease. In clinical practice, diagnosing psoriasis severity takes into account both subjective and objective measures. Dermatologists must take into account the percentage body surface area (BSA) involved; location, severity, and number of individual lesions; and response to topical therapies, as well as the physical and psychosocial effects of the disease on the patient (Table 1).

Table 1.

Determinants of Psoriasis Severity

- Body surface area (%) involved
- Location of individual lesions
- Severity and number of individual lesions
- Response to topical therapies
- Associated physical disability, including psoriatic arthritis
- Psychosocial side effects/quality-of-life issues

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Figure 1. Approximate representation of 1% of a patient's body surface area.

Psoriasis severity traditionally has been defined by the percentage of BSA involved: mild psoriasis generally is defined as BSA involvement of 3% or less, moderate disease involves 5% to 10% BSA, and severe psoriasis is disease that affects greater than 10% BSA.¹ Most clinical trials evaluating the treatment of severe psoriasis define severe disease as greater than 10% BSA.² In addition, documentation of greater than 10% BSA is required by many insurance plans for patients to qualify to receive some systemic medications, such as a biologic agent. Although this definition of severe psoriasis does not take into account issues of quality of life (QOL), BSA determination is important in the practical management of patients with psoriasis.

The method to determine percentage of BSA must be clarified to avoid variation from one dermatologist to another. There was consensus among members of the panel that the area of a patient's full palm including the fingers and thumb tucked together is an approximate representation of 1% of the patient's BSA (Figure 1). It is important to recognize that the area of the dermatologist's palm does not necessarily correlate with the patient. The total percentage of BSA affected by psoriasis is the sum of the individual areas of psoriasis including the head and neck, trunk, axillae, groin, and upper and lower extremities.

The ability to adequately treat patients with topical agents alone or the need to use systemic medications may be another defining factor for psoriasis severity. For some members of the panel, only patients with involvement of less than 10% BSA are candidates for topical agents alone and, for that reason, their disease should be considered mild. The opposing view, also represented on the panel, is that the BSA percentage should not be used to determine if topical agents can be used alone. In some cases, even a patient with greater than 10% BSA involvement may be adequately treated with only topical medicines, provided that the patient adheres to the suggested topical regimen. Conversely, patients with less than 3% BSA may have resistant or disabling disease requiring systemic treatment. Regardless of the viewpoint, dermatologists should take patient preferences and time available for therapy into consideration when evaluating therapeutic options.

Psoriasis may be characterized as severe depending on the degree of resulting physical disability independent of BSA.³ In some locations, psoriasis can interfere with everyday functioning, even if only a small percentage of BSA is affected. For example, scalp disease has a substantial impact on the QOL of patients. Patients frequently experience pruritus, and thick scale may cover the scalp and extend visibly beyond the hair margin. In addition, the presence of hair makes this area a challenge to treat effectively; overall, patients are dissatisfied with current treatments.^{4,5} Palmoplantar disease may lead to notable problems with daily activities, such as use of the hands and ambulation. Although collectively representing only 4% to 5% of the total BSA, substantial involvement of the palms and soles has to be considered severe disease, frequently requiring the use of systemic therapies.⁶ Intertriginous (flexural) diseases including the genitalia frequently lead to severe symptoms because of secondary maceration and candidiasis, despite limited areas of skin involvement.^{7,8} Patients with concomitant psoriatic arthritis may have severe disease regardless of degree of skin disease, and unlike psoriasis of the skin, psoriatic arthritis may be degenerative and irreversible.⁹

Psoriasis has a remarkable impact on patient QOL that may be affected by disease severity. For some patients, even a single plaque of psoriasis on the elbow may be devastating, while others may have more extensive involvement and be unconcerned. In general, psoriasis has negative effects on the psychological and social dimensions of patients' lives.¹⁰ Several tools have been developed to help evaluate QOL in patients with psoriasis. The Koo-Menter Psoriasis Instrument (KMPI) is designed to include not only the psychosocial aspects of the disease but also its other effects on life such as occupation (Figures 2 and 3).¹¹ The KMPI includes both a patient self-assessment and a physician assessment. In the KMPI, scores for part 1 range from 0 to 120, with higher scores signifying greater impairment of a patient's QOL.

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Part 1: Quality of Life - Please answer eac	h of tl	he foll	owing	ques	tions	as the	y pert	ain to	your	osoria	sis
during the past month. (Circle one numb	er per	quest	ion)			omerch				Very	Much
 How self-conscious do you feel with regard to your psoriasis? 	0	1	2	3	4	5	6	7	8	9	10
How helpless do you feel with regard to your psoriasis?	0	ï	2	3	4	5	6	7	8	9	10
3. How embarrassed do you feel with regard to your psoriasis?	0	1	2	3	4	5	6	7	8	9	10
 How angry or frustrated do you feel with regard to your psoriasis? 	0	Ť.	2	3	4	5	6	7	8	9	10
To what extent does your psoriasis make your appearance unsightly?	0	1	2	3	4	5	6	7	8	9	10
6. How disfiguring is your psoriasis?	0	1	2	3	4	5	6	7	8	9	10
7. How much does your psoriasis impact your overall emotional well-being?	0	1	2	3	4	5	6	7	8	9	10
 Overall, to what extent does your psoriasis interfere with your capacity to enjoy life? 	0	1	2	3	4	5	6	7	8	9	10
How much have each of the following bee (Circle one number per question)	en affe	cted b	y you	r psoi	riasis	luring	the p	oast m	onth?		
	Not	at All			S	omewha	at			Very	Much
9. Itching?	0	1	2	3	4	5	6	7	8	9	10
10. Physical irritation?	0	1	2	3	4	5	6	7	8	9	10
11. Physical pain or soreness?	0	1	2	3	4	5	6	7	8	9	10
·····								7	8	9	10
12. Choice of clothing to conceal psoriasis?	0	1	2	3	4	5	6	<i>'</i>			
12. Choice of clothing to conceal psoriasis?	0	1	2	3	4 Total Qu * (Medic	5 ality-of-Lifi al staff	6 e Score ((to calcu) - 120) Jate)			
12. Choice of clothing to conceal psoriasis?	0	1	2	3 12-iten	4 Total Qu * (Medic n Psoriasis Qu	5 ality-of-Lifi al staff ality of Life Qu	6 e Score ((to calcu) - 120) Ilate)	ryright 2002, 20	003, Allergan,	Inc.
12. Choice of clothing to conceal psoriasis? Part 2:	0	1 Part	2 3 :	3 12-ten	4 Total Que * (Medic	5 al ity-of-Lifi al staff alley of Life Qu	6 e Score ((to calcu) - 120) Ilate)	yright 2002, 20	003, Allergan,	Inc.
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 12. Choice of clothing to conceal psoriasis? Part 2: A. Using the figures below, place an "X" on the parts of your body that <u>currently</u> have psoriasis. 	0	1 Part A. Ha B. Do hip If ye 1 [If ye to-c	2 3: ve you Yes you ha yes how 2 2 2 3: A 2 2 3: 2 3: 2 3: 4: 4: 4: 4: 4: 4: 4: 4: 4: 4	3 13 terr ever be ve swo ve sw	4 Total Qu * (Medic No No Dillen, ter No joints a 3 have ye	5 al staff gnosed	6 e Score ((to calcu with p: stiff jo teted? ((More	soriatic ints (e.c Check c than 4	arthritis g., hanc one box))))))))))))))))))	inc.
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Figure 2. Koo-Menter Psoriasis Instrument patient self-assessment.

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Physician Assessment	Name:		Date:	C
Part 1: Total Quality-of-Life a	assessment score (from part 1 of previous page)			
Part 2: Area of involvement:	% BSA (body surface area)	5.00. 		
Head %	Head: up to 9% of total BSA			
Anterior Trunk	Anterior Trunk: up to 18% Note: Patient's open h with fingers tucked tog	and (from wrist to tips of fingers) jether and thumb tucked to the s) ide	
Posterior Trunk %	Posterior Trunk: up to 18%	1% body surface area		
Right Leg %	Right Leg: up to 18% (includes buttock)			
Left Leg %	Left Leg: up to 18% (includes buttock)			
Both Arms %	Both Arms: up to 18%			
Genitalia %	Genitalia: 1%			
Total BSA %				
Part 3: In terms of psoriasis	severity, does the patient have:		Check	Answer
Plaque, erythrodermic, or pust	tular psoriasis with >10% BSA involvement?		Yes	No
Guttate psoriasis?			Yes	No
ocalized (< 10% BSA) psoria	sis but resistant to optimized attempts at topical therapy	or physically disabling (eg,	Yes	No
_ocalized (< 10% BSA) but se osoriasis)?	rious subtype with possibility of progression (eg, pustula	ar or pre-erythrodermic	Yes	No
Clinical evidence of psoriatic jo nands, wrists, feet, and ankles	oint disease as assessed by physician (e.g., examine IF s, plus patient responses from Part 3 of patient self-asse	, MCP, and MT joints of essment)?	Yes	No
Substantial psychosocial or qu ≥ 50?	ality-of-life impact documented by patient Quality-of-Lif	e self-assessment score of	Yes	No
Part 4: Is phototherapy an o	ption?		Check	Answer
s a suitable phototherapy unit	readily accessible to the patient?		Yes	No
Does the anatomical location	or form of psoriasis (e.g., scalp, inverse, erythrodermic)	preclude phototherapy?	Yes	No
Does the patient have the dedication, time, stamina, or transportation for phototherapy?			Yes	No
Has phototherapy, as monothe	erapy, failed in the past?		Yes	No
s phototherapy contraindicate	ed (eg, photosensitive drugs, history of multiple skin can	cers)?	Yes	No
In your clinical judgement, is phototherapy likely to yield substantial improvement to justify its use before system therapy?				No
Physician/Nurse comments:				
lf at lea che	ist one of the shaded boxes in both Part ecked, then the patient is a candidate for	3 and Part 4 above systemic therapy.	are	

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Figure 3. Koo-Menter Psoriasis Instrument physician assessment. BSA indicates body surface area; IP, interphalangeal; MCP, phalangeal; MT, metatarsal.

	 Over the last week, how itchy, sore, painful, or stinging has your skin been? Very much A lot A little Not at all Over the last week, how embarrassed or self- conscious have you been because of your skin? Very much A lot A little Not at all 	 6. Over the last week, how much has your skin made it difficult for you to do any sport? Very much A lot A little Not at all Not relevant 7. Over the last week, has your skin prevented you from working or studying? Yes No Not relevant
	 3. Over the last week, how much has your skin interfered with you going shopping or looking after your home or garden? Very much A lot A little Not at all Not relevant 4. Over the last week, how much has your skin influenced the clothes you chose to wear? Very much A lot A little 	 8. Over the last week, how much has your skin created problems with your partner or any of your close friends or relatives? A lot A little Not at all 9. Over the last week, how much has your skin caused any sexual difficulties? Very much A lot A little Not at all Not at all Not at all
t	 Not at all Not relevant 5. Over the last week, how much has your skin affected any social or leisure activities? Very much A lot A little Not at all Not relevant 	 10. Over the last week, how much of a problem has the treatment for your skin been, for example by making your home messy or taking up your time? Very much A lot A little Not at all Not relevant

Figure 4. Dermatology Life Quality Index (DLQI). The DLQI is ©AY Finlay, GK Khan April 1992 www .dermatology.org.uk. The DLQI can be used for routine clinical purpose without seeking permission and without charge. For all other uses, please contact dermqol@cardiff.ac.uk. Further information: www.dermatology.org.uk.¹²

The Dermatology Life Quality Index (DLQI), commonly used in clinical trials, is another tool that can evaluate the impact of skin diseases on patient QOL. This 10-item questionnaire assesses both skin diseases and treatment (Figure 4). Most questions are scored on a 4-point Likert scale (0=not at all/not relevant; 1=a little; 2=a lot; 3=very much). The total score ranges from 0 to 30, with higher scores signifying greater impairment of a patient's QOL.¹²

Assessing QOL in patients with psoriasis is of utmost importance. Although many dermatologists may not incorporate the entire KMPI or DLQI into their practice, they may adopt specific questions as they see fit. The DLQI is one important factor included in the rule of tens for current severe psoriasis: BSA involved greater than 10%, psoriasis area and severity index score greater than 10, or DLQI score greater than 10.²

Establishing a Relationship With the Patient

At the patient's first visit to the office, the dermatologist must set the groundwork for a long-term relationship, which includes not only evaluating the patient's skin and QOL but also educating him/ her on the skin condition itself and on what to expect both short term and long term. Patients may have seen many other dermatologists in the past and be frustrated with prior treatments. Much of this frustration may result from a lack of education on the chronic nature of the disease or the proper ways to use medications. Expectations for treatments

Panel Tips: Patient Education

Give patients written handouts

Engage office staff to be available to answer questions and educate patients

- Demonstrate how to apply topical agents and how much to apply
- Encourage patients to join support groups, including the National Psoriasis Foundation

Table 2.

Comorbid Conditions

Comorbid Condition	Prevalence/Comments
Psoriatic arthritis	Affects ≈30% of patients ¹³
Anxiety and depression	24% prevalence ¹⁴
Obesity	Associated with more severe psoriasis; 49% prevalence ¹⁵
Diabetes mellitus	10%-12% prevalence ¹⁶
Hypertension	32% prevalence with mild psoriasis; 40.3% with severe psoriasis 17
Dyslipidemia	Risk ratio is \approx 2-fold that of individuals without psoriasis ¹⁸
Crohn disease	Risk ratio is 1.5- to 2.9-fold that of individuals without psoriasis ¹⁹
CVD	Psoriasis may be a risk factor for developing atherosclerosis and myo- cardial infarction; however, other studies do not detect a connection
	It is clear, however, that patients with psoriasis have a higher risk for many of the comorbidities associated with CVD and screening is warranted ²⁰

Abbreviation: CVD, cardiovascular disease.

must be defined, taking into consideration differences in patient preferences and cultural backgrounds. With an open conversation on treatment options, the patient can become an active participant in developing the treatment regimen, which may improve adherence to therapy.

Patients ideally should be fully examined from head to toe at the initial office visit. When questioning patients about their psoriasis, they may not fully discuss their disease. Due to insecurity or naïveté, patients often do not disclose involvement of the scalp, genital area, or intertriginous skin. Thus to perform a complete and proper physical examination, the patient should be undressed and in a hospital gown. Discovery of psoriasis in the intergluteal skin, for example, will give the dermatologist a complete understanding of the extent of the disease process, leading to a full and sensitive discussion of QOL issues and treatment options, even in patients too embarrassed to bring up the topic themselves.

Psoriasis is a systemic inflammatory condition. All patients should be evaluated for the presence of comorbidities (Table 2), including the metabolic

Panel Tips: Establishing a Good Dermatologist-Patient Relationship

- Speak to patients in a way that shows empathy:
- "I am sure you find this very frustrating."
- Ask questions that patients will see as insightful to their condition:
- "Do you wear long sleeves to cover your visible psoriasis?"
- "Can you wear a black blouse or jacket?"
- "How much itching do you have?"
- "Do you lose sleep because of your psoriasis?"
- "How much does your disease affect your relationships with other people?"
- "Are your sexual experiences affected by your psoriasis?"

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Preferred Vehicles for Different Anatomic Locations					
Anatomic Location	Vehicles				
Scalp	Shampoo, foam, gel, solution, spray				
Male chest/hair-bearing locations	Foam, gel, spray				
Intertriginous areas	Cream, ointment, lotion				
Knees/elbows	Cream, ointment, lotion, spray, foam				
Extensive skin involvement	Spray, foam				
Face	Cream, lotion				
Palms/soles	Ointment, cream, lotion				

Table 3. Preferred Vehicles for Different Anatomic Locations

syndrome X, coronary artery disease, psoriatic arthritis, obesity, and diabetes mellitus.²¹ In addition, the incidence of depression is increased in patients with psoriasis.²² Psoriasis patients may present to the dermatologist before other clinicians because of visible skin lesions; therefore, the dermatologist serves an important role in identifying potentially unrecognized comorbid conditions and should refer patients to the appropriate specialists.

Psoriasis is a chronic disease that requires longterm treatment. The schedule for follow-up visits varied among the experts on the panel. According to one panel member, "You may see a person at baseline, then 1 month later, and then every 3 months. If a patient has problems with adhering to medication, which typically would be a patient with scalp psoriasis who has seen another dermatologist and has failed multiple treatments, I'd bring that patient back to the office in 3 days." Another panel member noted that there is a shortage of medical dermatologists and "We can't dictate how to factor that into visit frequency. There is no single right frequency of visits for all patients." The consensus included frequent early follow-up appointments when possible to evaluate initial response and adherence to application of medicines. After initial control has been obtained, long-term office visits should be less frequent and should be used to reinforce maintenance therapy and readjust regimens to treat psoriasis flares. The frequency of office visits must be tailored to the needs of the individual patient.

Topical Vehicles in the 21st Century

In the 21st century, dermatologists have options for agents to prescribe to their patients and vehicles to select. Choosing the appropriate vehicle depends on several factors, including the application site (Table 3) and patient preferences. Advances in drug formulations have put old drugs into new vehicles with increased efficacy, lower risks for side effects, and greater patient cosmetic acceptability. New vehicles allow for improved delivery of the drug from vehicle into the skin, designed to have specific release characteristics and rates of absorption through the stratum corneum.

The US Food and Drug Administration recognizes 8 different topical formulations consisting of creams; gels; lotions; ointments; pastes; solutions; suspensions; and others, which encompasses various foams, sprays and aerosols, powders, and patches. Technical definitions of the various formulations depend on the chemical makeup of the vehicle and the process by which the vehicle is created. If the product is pourable, then it is broadly categorized as a liquid (eg, lotion, solution) or as a semisolid (eg, cream, ointment). If it is not pourable, it is a nonliquid nonsemisolid formulation or other (eg, foam, spray).²³ Regardless of classification, the consensus of the panel was to prescribe the vehicle that is most acceptable to each individual patient.

New formulations have improved patient adherence to therapy. Gels, for example, historically have been alcohol based and caused drying, stinging, and irritation of the skin. They have been replaced

by newer hydrogels and nonaqueous gels that can be used more widely while minimizing cutaneous side effects. New foam and spray vehicles have been developed with various penetration enhancers that temporarily disrupt the skin barrier to improve absorption of the drug across the stratum corneum. Penetration enhancers include detergents and emulsifiers, which vary from vehicle to vehicle.¹⁴ A new formulation of clobetasol propionate spray 0.05% contains isopropyl myristate that partially dissolves lipids in the stratum corneum to allow for rapid penetration of clobetasol. Ethanolbased foam vehicles dissolve on the skin, leaving a supersaturated solution on the skin that, in combination with propylene glycol, drives penetration of the drug.²⁴ With newer technology, occlusion of a medication is used less frequently.

Generics Versus Brands

All classes of topical medications have generic preparations to decrease cost, regardless of clinical class.²⁵ However, according to the panel, caution is warranted when using generics. According to one panel member, "When you use a generic, you don't know which vehicle you are going to get." Another panel member was concerned that "there may be different mix characteristics, especially if you're remixing." It should be noted, however, that many patients are successfully treated with generic therapies.

Panel Tips: Generic Medications

- Be aware that there is a 20%–25% margin of potency, either up or down, that can affect outcomes
- To better anticipate response, know which vehicle is being used
- If potency is underestimated, the patient may develop cutaneous adverse events

Knowing How Much Topical Medication Is Enough

In addition to choosing the appropriate topical agent, the dermatologist must understand how much of the medicine will be necessary. Not giving patients an adequate amount of medication will prevent them from treating all affected areas for the appropriate period, which will undoubtedly



Figure 5. A fingertip unit, which measures approximately 500 mg and should be enough cream or ointment to cover approximately 1% body surface area for 1 day with twice daily application. Reprinted from Menter et al; American Academy of Dermatology.²⁶ ©2009, with permission from the American Academy of Dermatology.

lead to treatment failure. The percentage of BSA involved varies greatly among patients, as does the amount of medication that is required. The differences in the amount of medication can be large, ranging from approximately 15 g/wk for twice daily treatment of the elbows and knees to 400 g/wk for twice daily treatment of the entire BSA of an average-sized adult.

In the previous section, guidelines were provided to calculate a patient's percentage of BSA affected by psoriasis, which is important to master so that appropriate amounts of topical medications may be dispensed. It is estimated that 0.55 g/d of a cream or ointment is needed to cover 1% BSA for an average-sized adult with a twice daily application. This amount, known as a fingertip unit, can be easily demonstrated to patients; it is the amount of medicine needed to cover a thin film over the volar surface of the first phalanx of the index finger (Figure 5). One fingertip unit measures approximately 500 mg and should be enough cream or ointment to cover approximately 1% BSA for 1 day with twice daily application.²⁶

Dermatologists need to ensure that patients receive enough medication to treat their psoriasis per month and per medication co-payment. Patients will commonly pay the same co-payment for a topical medication regardless of the size of the tube. In addition, the dermatologist may need to provide documentation of the amount of medication required to treat a particular BSA percentage to obtain approval for coverage by the insurance

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plan. Given 0.55 g per 1% BSA twice daily application, it is estimated that 55 g of cream or ointment are required for a total body treatment twice daily. Practically, this means that the dermatologist must write a prescription for a 60-g tube of medicine per day. Although most patients will not be covering themselves from head to toe in medication, a patient with psoriasis of both the elbows and knees has approximately 4% BSA involved. The patient will require 66 g of cream or ointment per month for twice daily application. Although a single tube of medicine will be sufficient for a patient with this severity of disease, those patients with more extensive involvement will require more than 1 tube of medicine. A detailed summary of the amount of medicine required monthly (Table 4) and the amount required to treat each body part (Table 5) are provided.

Selecting a Treatment Regimen

Topical therapies play an important role in the treatment of all patients with psoriasis, regardless of disease severity. Selecting the appropriate treatment regimen for patients is an art that is learned, the panel concluded. Clinicians must weigh factors such as the extent of disease, patient preferences, QOL issues, time available for application of topical agents, and patient finances. Most dermatologists make decisions on treatment options based on personal experiences, published clinical trials, pharmaceutical company promotional materials, and peer recommendations. While most published studies evaluate topical treatments for only 12 weeks, psoriasis in the real world requires lifelong treatment. The goal of treatment is to obtain an initial clearance, maintain an extended remission, and treat flares as necessary.

Psoriasis may be difficult to treat using monotherapy.²⁷ According to a 2003 consensus statement from the American Academy of Dermatology, the goal of psoriasis treatment is to produce a durable improvement while minimizing adverse events (AEs).²⁸ Multiple treatment modalities may be used together, and combination, sequential, and rotational regimens have been developed. The goal of these treatment strategies is to maximize efficacy while minimizing the risk for side effects.²⁸ Recently, the updated consensus statement from the American Academy of Dermatology noted that approximately 80% of patients affected with psoriasis have mild to moderate disease and most of these patients can be treated with topical agents.²⁶ However, the use of topical agents alone or in combination can be challenging in patients with extensive disease. In these cases, combination

Table 4.

Amount of Medicine Required Monthly^a

BSA Involved	Amount of Medicine
5% BSA	82.5 g/mo (twice daily)
10% BSA	165.0 g/mo (twice daily)
15% BSA	247.5 g/mo (twice daily)
25% BSA	412.5 g/mo (twice daily)

Abbreviation: BSA, body surface area.

^a0.55 g • % BSA • 30 days=gram prescribed per month.

therapy with topical and systemic agents may be beneficial.²⁶

Combination therapy is the concomitant use of 2 or more agents with synergistic or complementary mechanisms of action. By combining more than one agent, each may be used at a lower dose, thereby reducing the potential for toxicity. With sequential therapy, a strong but potentially more toxic agent is used to induce clearance, and then it is replaced with a less toxic agent for maintenance.²⁶ An example of a sequential regimen that has been evaluated is the initial use of potent topical steroids with topical vitamin D₃ treatment followed by topical vitamin D₃ treatment as monotherapy.²⁹ Sequential therapy maximizes efficacy while minimizing AEs and provides both rapid clearance and long-term remission.³⁰ With rotational therapy, an agent is used for a specified period and then is switched to an alternative. By rotating medicines, dermatologists can both limit the long-term toxicities of the medications and prevent resistance to individual medications.²⁶

Maintenance Therapy

Given the chronic nature of psoriasis, long-term management options are important. Long-term use of topical corticosteroids is limited by risks for cutaneous atrophy and hypothalamic-pituitary-adrenal (HPA) axis effects.³¹ Vitamin D topical treatments, such as calcitriol ointment, permit safe, effective, long-term management of psoriasis.³²

A long-term study evaluated the safety, tolerability, and efficacy of calcitriol ointment 3 μ g/g twice daily in patients with chronic plaque psoriasis.³²

Table 5. Amount of Medicine Needed Per Area^a

Body Part	BSA, %	No. Fingertip Units Needed Per Application	Amount of Medicine Needed Per Day (Twice Daily)	Amount of Medicine Needed Per Week (7 Days; Twice Daily)	Amount of Medicine Needed Per Month (30 Days; Twice Daily)
Scalp	6	3.0	3.3 g	23.1 g	99.0 g
Both elbows	2	1.0	1.1 g	7.7 g	33.0 g
Both knees	2	1.0	1.1 g	7.7 g	33.0 g
Both palms	2	1.0	1.1 g	7.7 g	33.0 g
Both soles	3	1.5	1.65 g	11.6 g	49.5 g
Face and neck	5	2.5	2.75 g	19.3 g	82.5 g
Trunk (anterior)	16	8.0	8.8 g	61.6 g	264.0 g
Trunk (posterior)	16	8.0	8.8 g	61.6 g	264.0 g
Entire leg (including foot)	16	8.0	8.8 g	61.6 g	264.0 g
Genitals	1	0.5	0.55 g	3.9 g	16.5 g
Buttocks	8	4.0	4.4 g	30.8 g	132.0 g

Abbreviation: BSA, body surface area.

^aCalculations based on 0.55 g per 1% BSA twice daily.

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The evaluation included 253 patients over a treatment period that extended up to 78 weeks. At end point, 40.1% of the participants showed definite or considerable improvement. There were no serious AEs or deaths, or any clinically relevant effects on calcium and phosphorous homeostasis or renal function. Fifteen percent of participants experienced a transient skin irritation, 2.8% withdrew because of local intolerance, and 0.4% withdrew because of hypercalcemia.³²

In a 52-week, open-label, multicenter study, 324 participants with mild to moderate chronic plaque psoriasis were treated with calcitriol ointment 3 μ g/g twice daily.³³ Adverse events (including abnormal laboratory test results) were reported in 40.1% of participants; however, only 13.9% of the AEs were considered study related. Eight participants (2.5%) withdrew because of AEs; AEs for 4 of these participants (1.2%) were considered treatment related, including irritant dermatitis, pruritus, kidney pain, and urine abnormality (1 participant each).³³

In this study, the psoriasis global severity score (0=clear; 1=minimal; 2=mild; 3=moderate; 4=severe; 5=very severe) was assessed at each visit.³³ At any given point during the study, 42.6% of participants received a rating of

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0 or 1 (clear or minimal psoriasis); the percentage rose to 47.1% during the last treatment period. When participants were asked to rate their improvement on a 7-point scale (5=clear to -1=worse), 52.6% of participants reported marked improvement at week 26. By week 52, the percentage had risen to 63.8%.³³

Another 52-week study evaluated the longterm safety and efficacy of a vitamin D topical treatment in participants with scalp psoriasis.³⁴ In this randomized study, combination therapy with calcipotriol 50 µg/g plus betamethasone dipropionate 0.5 mg/g (n=429) was compared with calcipotriol 50 μ g/g monotherapy (n=440) in 869 participants with moderate to severe scalp psoriasis. Overall, 92.3% of combination therapy participants were well-controlled compared with 80.0% of monotherapy participants (P < .001). Regarding safety and tolerability, 17.2% of participants in the combination group experienced adverse drug reactions compared with 29.5% of participants in the monotherapy group (P < .001). The main AEs were pruritus and erythema. Although the withdrawal rate was 21.4% in the combination group over the 52-week period, treatment generally was well-tolerated.34

A 52-week, randomized, double-blind study compared the efficacy of 3 different calcipotriolcontaining maintenance regimens in 634 participants: group 1 (the 2-compound group)(n=212), participants treated daily with calcipotriol 50 μ g/g and betamethasone dipropionate 0.5 mg/g; group 2 (n=213), participants treated over a 52-week period with an alternating regimen that included the 2-compound product for 4 weeks, followed by calcipotriol monotherapy for 4 weeks; group 3 (n=209), participants treated for 4 weeks with the 2-compound product, followed by calcipotriol monotherapy for 48 weeks.³⁵ Based on investigator assessments, 35.8% of participants in group 1 had a 100% satisfactory response compared with 27.7% of participants in group 2 and 24.4% of participants in group 3. The median values for the percentage of satisfactory responses in groups 1, 2, and 3 were 84%, 75%, and 70%, respectively. There did not appear to be a significant difference in the outcomes between the 3 treatment groups. Based on available evidence, it appears that various vitamin D topical treatment-based regimens are safe and effective as maintenance therapy in patients with psoriasis. In current clinical practice, combination regimens that include topical vitamin D have an important therapeutic role in maintaining longterm safe control while addressing the chronic nature of psoriasis.³⁵

Panel Tips: Use of Multiple Agents

Keep the regimen simple

- Limit the number of topical agents prescribed. Choose appropriate vehicles and medications that can be used on multiple body parts
- Consider combination treatments, especially in resistant areas such as the palms and soles
- Know which topical agents should not be combined (eg, vitamin D topical therapy is inactivated by the acid pH in topical agents such as ammonium lactate or salicylic acid). If you are unsure about combining medications, separate their applications in the morning and evening

Known Compatible Drugs

Calcipotriene ointment and topical halobetasol³⁶ Calcitriol ointment and clobetasol

propionate 0.05% (spray and lotion)^{29,37} Calcipotriene ointment and tazarotene gel³⁸ Topical halobetasol and ammonium lactate lotion 12%

Calcipotriene ointment and topical steroids in foam vehicles³⁸

Tazarotene gel and topical steroids³⁹

Maintaining Patient Adherence

Topical therapies are both safe and effective for psoriasis in clinical trials. However, patients in clinical trials are in a structured environment with frequent evaluations and medication logs to maintain adherence to the designated regimen. Psoriasis patients in clinical practice commonly report that applying messy topical medications is one of the most negative aspects of the disease.⁴⁰ A notable proportion of psoriasis patients do not use topical medications as directed. Lack of adherence may lead to poor outcomes and treatment failures. One potential outcome is decreasing response to treatment over time, so-called tachyphylaxis. Tachyphylaxis may be caused by poor adherence rather than loss of steroid receptor function.⁴¹

In line with other treating dermatologists, panel members expressed frustration over

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adherence challenges. One panel member suggested that it becomes clear that a patient is nonadherent if a biologic agent is having no effect on his/her psoriasis or if a very potent topical agent such as clobetasol is not working at all. Another member of the panel suggested having a patient come back within 3 days if he/she clearly demonstrated the need to be convinced of the importance of adherence.

Improving patient adherence to topical regimens is a challenge faced by all dermatologists. Several factors contribute to lack of patient adherence to treatment regimens, including patient perceptions that medications are not efficacious or are unsafe. In addition, patients may find prescribed regimens too complex to follow. Medication costs and personal preferences for specific medication vehicles also play a role.²⁵

Treatment of Scalp Psoriasis

Scalp psoriasis affects an estimated 50% to 80% of psoriasis patients and is a challenge to treat.⁴² It may manifest as localized areas of superficial scales or as thick warty plaques covering the entire scalp. In some cases, it may be visible and extend beyond the hairline to the face, neck, and ears. Additionally, patients frequently complain of marked pruritus.⁵ Scalp psoriasis has a negative impact on QOL and interferes with psychosocial functioning.^{6,43} There may be concern that the presence of hair on the scalp along with the thick scale of psoriatic plaques reduces the absorption of topical medications; however, a healthy scalp has penetration characteristics similar to the axilla, and diseased skin is expected to have even less barrier function. Nevertheless, the hair-bearing scalp often responds poorly to topical treatment, most likely because of poor adherence due to the difficulty of applying medications to the scalp. In addition, many topical medications interfere with daily hair grooming and are not cosmetically acceptable to patients.⁵ Thus patients frequently are dissatisfied with current treatments due to inconvenience of usage and perceived ineffectiveness.⁴

A recent consensus statement from the National Psoriasis Foundation gave recommendations for the treatment of scalp psoriasis.⁵ First-line therapy is the use of short-term topical corticosteroids followed by intermittent maintenance therapy. Alternatively, topical retinoids, vitamin D topical therapy, and salicylic acid preparations may be tried. Combination therapy also is recommended.⁵ Although topical agents are the most frequently used therapies for scalp psoriasis, selection of the appropriate

Panel Tips: Ways to Maintain Patient Adherence

Interact with patients

Provide written instructions

Make a deal with the patient (eg, "If you use this strong topical medication to start your regimen, we can use another less intense medication to maintain your good results once your symptoms improve")

Set realistic expectations

- On follow-up visits, before assuming a medicine did not work, ask questions about its usage (eg, "Did you have the chance to fill your prescription?" or "Did you have the chance to use your medicine?")
- Limit the number of refills on a medication to ensure that the patient does not use it for too long
- Confirm adherence and results at follow-up office visits. You may give different patients varying numbers of refills, taking into account economic considerations as well as the body part being treated
- For severe psoriasis (>10% BSA), it may not be feasible to treat the entire body. In these cases, first focus on areas of high importance to the patient, which likely will be areas most commonly exposed

Panel Tips: Medication-Related Advice to Improve Adherence

- Prescribe once daily medication application whenever possible
- Make sure the patient can afford a medicine before prescribing it
- Tailor the treatment to the patient's preference
- Avoid a treatment the patient did not like in the past
- Select a vehicle that matches the patient's preferences and is appropriate for the anatomic location

Provide appropriate handouts

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Panel Tips: Treatment of Scalp Psoriasis

General Advice

- Educate the patient: the medication is for the scalp, not the hair, and shampoos must lather for variable periods before being rinsed
- Choose the vehicle the patient is most willing to use
- Give written instructions. Set realistic expectations. Keep the regimen simple (eg, once daily therapy), if possible
- Tell the patient not to scratch, pick, or harshly shampoo the scalp
- Explain that medications must be used every day until the psoriasis is adequately controlled
- Reduce the burden of treatment by having the patient use the medication twice daily for only 3 days
- Have the patient's friend or relative apply the medication to ensure it gets applied and gets on the scalp
- Tell the patient that if the medication causes symptoms of burning, "it is a sign the medication is working" (ie, the medication has been applied to the scalp)

Panel Tips: Medication-Related Advice for Psoriasis

Treat scalp pruritus with antihistamines Ask the patient for his/her preference of vehicles; remember to offer spray, solution, or foam vehicle options

- Topical corticosteroid sprays with nozzles are especially appropriate for coifed hairstyles requiring a lot of hair spray
- Consider an oil-based medication for patients who have a cultural preference for using oils in the scalp for hair maintenance
- Avoid polypharmacy. Use same medicines for the scalp as for other areas of the body

Panel Tips: Treating Patients Who Failed Prior Therapies

(Note: Panel tips represent divergent viewpoints from different individuals.)

- Three days of potent topical agents can work, even when treatment has failed in the past. Try the same medicine in a different vehicle
- If all else fails, apply liquor carbonis detergens 10%–20% in a lotion or other ointment and a keratolytic such as ammonium lactate or lactic acid 10% to the scalp in the morning. Cover with a shower cap. At the end of the day, wash off gently without scrubbing the scalp. Repeat the process 3–4 times for a week
- Have the patient come to the office for 3 days and apply the medication in the office
- Heat olive oil and apply it to the scalp under shower cap occlusion
- Apply a steroid ointment to the scalp overnight under shower cap occlusion. Wash the ointment out gently with dishwashing detergent
- Before bed, apply baking soda to the scalp, then wet the area. Wash out the mix in the morning with a coal tar shampoo

vehicle is of utmost importance. For example, cream and ointment vehicles are messy and difficult to apply through the hair to reach the scalp.^{4,44,45} Newer vehicles such as shampoos, sprays, and foams are more appropriate for use on the scalp. The best vehicle is generally the one the patient prefers to use.

If patients fail topical therapies, systemic agents may need to be added, though one panel member suggested that measures to improve adherence should be used instead. Dermatologists must then evaluate what is considered scalp psoriasis refractory to treatment. The consensus of the panel defines scalp psoriasis refractory to topical treatment as failure of clearance after 4 weeks of adherence to an adequate topical regimen along with a negative impact on QOL. An example of an

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adequate topical regimen is the use of fluocinolone acetonide topical oil 0.01% at night with occlusion and clobetasol propionate 0.05% shampoo or spray in conjunction with a salicylic acid or coal tar shampoo in the morning. Alternatively, using a combination product of vitamin D_3 and a steroid frequently is helpful. Pending response and adherence to this regimen, a short course of systemic therapy may need to be considered.

Treatment of Palmoplantar Psoriasis

While the palms and soles collectively represent less than 5% BSA, palmoplantar psoriasis substantially affects QOL. Patients often experience physical difficulty and discomfort from daily activities. Therefore, patients with palmoplantar disease may be considered to have severe disease despite the small percentage of BSA involved. Moreover, palmoplantar psoriasis often is resistant to potent topical treatments. Recalcitrant palmar and plantar disease may require systemic therapies (eg, acitretin, methotrexate, cyclosporine), phototherapy, or biologic agents.⁶

The choice of vehicle is critical. Encourage patients to use an ointment of their choice. After applying the ointment, they must cover the treated area with wet cotton gloves for the hands or wet cotton socks for the feet and then occlude with plastic for 2 hours. This regimen needs to be repeated 2 to 3 times weekly. Also, encourage the patient not to debride but to use a skin-softening agent (emollient) of their choice, such as salicylic acid, urea cream, or a steroid ointment; the vehicle is vital in palmoplantar psoriasis treatment. Also, instruct the patient to regularly use a barrier hand cream during the day.

Treatment of Nail Psoriasis

Up to 80% of psoriasis patients may have nail involvement, which commonly is overlooked by healthcare providers.^{46,47} Nail psoriasis may manifest as either changes in the nail plate or the nail bed. Nail pitting commonly is observed in the nail plate, and discoloration or splinter hemorrhages may be seen in the nail bed.⁴⁶ Options for the treatment of nail psoriasis are limited. Various topical regimens have been used, but no therapy has emerged as the clear first-line treatment, as notable improvement seldom is obtained. Topical, intralesional, and systemic therapies have been used individually and in combination for nail disease.

Topical steroids often are used as first-line treatment of nail psoriasis, but their efficacy is limited by their inability to penetrate deeply into the nail matrix. Nonetheless, topical steroids, especially

Panel Tips: Treatment of Palmoplantar Psoriasis

- Soak hyperkeratotic fissured hands and feet without debriding. Apply the ointment of choice, then cover the area with wet cotton gloves or socks and occlude airtight with plastic for 2 hours. Remove and apply the emollient of choice (eg, salicylic acid, urea cream). Repeat this procedure 3–4 times the first week, then twice per week for the following weeks. On the off days, use emollients only
- Soak the palms and soles in crude coal tar, then apply salicylic acid lotion followed by clobetasol ointment (with or without occlusion)

Use a topical steroid cream during the day and an ointment at night

- Use tazarotene at night in combination with topical steroids by day. Be cautious to avoid contact with the dorsal aspects of the hands and feet
- Try a 3-step approach: (1) use a combination of topical agents, including vitamin D, tazarotene, and a class 1 topical steroid; (2) if this fails, add phototherapy or psoralen plus UVA (PUVA); (3) if this fails, add cyclosporine to decrease inflammation
- Consider compounding salicylic acid with a topical steroid. Salicylic acid enhances efficacy; however, it also may increase side effects of steroids

ointments, can be effective in reducing psoriatic changes in the periungual region, resulting in reduced secondary matrix inflammation and ridging. In patients with onycholysis, one approach that improves access to the diseased area is trimming the nail to the cleavage by making asymmetric snips on both sides of the nail until they meet in the middle, allowing for direct application of the steroid preparation.⁴⁸

In addition, treatment with tazarotene gel 0.1% is moderately effective in markedly reducing

onycholysis in nonoccluded nails and in reducing pitting in occluded nails with overall good tolerability.49

Triamcinolone acetonide 2.5 to 10 mg/mL can be injected directly into the psoriatic digit using a

Panel Tips: Treatment of Nail Psoriasis

General Advice

Nail psoriasis is frequently a marker for psoriatic arthritis

Medication-Related Advice

- Do not be afraid to give cortisone injections for severe nail psoriasis. Nail plate disease (eg, pitting) requires delivery of corticosteroids to the nail matrix, as injection to the nail fold does not work. Nail bed disease (eg, subungual hyperkeratosis) requires injections all the way around the nail through the lateral nail folds
- Try a potent topical corticosteroid, a vitamin D analogue, or a fixed-dose combination of calcipotriene 0.005%betamethasone dipropionate 0.064% ointment twice daily for 12 weeks
- Check a fungal culture to ensure there is no concurrent fungal infection. If the culture is positive, treat the fungal infection with an agent such as oral terbinafine because tinea unguium may induce psoriasis by a Köbner phenomenon
- Reduce pain with the use of topical anesthetics or ethyl chloride spray prior to injections. Also consider diluting triamcinolone in lidocaine for injection
- Change needles frequently to avoid dulling of the needle, which causes excess pain
- The experts suggest using either a 5-mg/mL dilution of triamcinolone with injections of 0.1 mL per nail, or a 10-mg/mL dilution of triamcinolone with injections of 0.05 mL per nail

fine gauge needle. However, injections directly into the nail bed or deep nail fold are painful and usually require anesthesia. Pain management options include a ring block or injection of lidocaine at the injection site. Injecting too frequently can lead to digital atrophy; however, at weaker concentrations, injections can be administered over approximately 3 months. Higher concentrations of triamcinolone acetonide (10 mg/mL) are more effective for the treatment of nail ridging and subungual hyperkeratosis rather than pitting or onycholysis.⁴⁸

One member of the panel reported not administering injections for nail psoriasis at all because of the pain to the patients. However, other panel members suggested that the pain is manageable.

Certain systemic therapies are effective, including acitretin, methotrexate, and cyclosporine.⁵⁰ Tumor necrosis factor α inhibitory agents (eg, adalimumab, etanercept, infliximab) are effective at improving nail psoriasis when used in patients with moderate to severe psoriasis.

Treatment of Intertriginous Psoriasis

Intertriginous psoriasis affects the body's skin folds, including the axillary, inguinal, inframammary, intergluteal, and abdominal folds, as well as the genital areas. "We can't just talk of intertriginous psoriasis as one disease," one of the panel members noted.

According to estimates, 4% to 6% of patients with psoriasis have intertriginous involvement.⁵¹ However, it is likely to be an underestimation, especially in the obese psoriatic population. Patients commonly complain of irritation, which is exacerbated by friction and perspiration in these areas. These areas have thin skin and relative occlusion. which limit the use of many medicines. Topical steroids, for example, should be applied cautiously because of a higher risk for cutaneous AEs (eg, atrophy, striae, telangiectasia) compared to other parts of the body.8 According to consensus statements of the National Psoriasis Foundation and American Academy of Dermatology, the recommended treatment is low-potency to midpotency topical steroids for no longer than 2 to 4 weeks. In addition, topical vitamin D (especially calcitriol) and calcineurin inhibitors are efficacious and can be safely used for longer periods of time.⁸

Treatment of Psoriasis in Pediatric Patients

Psoriasis in childhood is common. It is estimated that psoriasis represents 4% of skin conditions in North American children younger than 16 years.⁵² The same topical medications used in adults with psoriasis have been tried in pediatric

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Panel Tips: Treatment of Intertriginous Psoriasis

Lifestyle and General Advice

If the genitals are affected, patients should apply lubricants during sexual activity

Medication-Related Advice

- If areas are lichenified, patients may need to use higher-potency steroids for a short time (ie, 7–10 days), despite the intertriginous location
- If there is suspicion for a superimposed fungal infection, add a topical antifungal product. Fungal infections, especially candidiasis, frequently exacerbate intertriginous psoriasis

Panel Tips: Tolerability Issues for Medicines in Intertriginous Areas

- If calcipotriene causes irritation, try calcitriol
- Prescribe a high-potency steroid for a short period (eg, <1 week), then switch to a less potent steroid or another agent
- If there is concern about prescribing a high-potency steroid for an intertriginous area, remember it is not how strong but how long the medicine is used
- Try a regimen with a steroid for 1–2 weeks, then switch to weekends only, using calcitriol on weekdays
- Topical calcineurin inhibitors may cause self-limited irritation. If tacrolimus ointment cannot be tolerated, try pimecrolimus cream
- Make sure patients understand the black box warning associated with topical calcineurin inhibitors and document the discussion in their medical record
- Avoid tazarotene use in the genital area and other intertriginous areas

Panel Tips: Treatment of Psoriasis in Pediatric Patients

General Advice

Avoid potent topical steroids in neonates When treating pediatric patients with psoriasis, consider the way pediatric atopic dermatitis patients are treated Use appropriate emollients daily for 1–2 weeks

Panel Tips: Medication-Related Advice for Pediatric Patients

- Some panel members believe that mometasone furoate ointment 0.1% has a high benefit-risk ratio with virtually no systemic absorption
- Try a vitamin D topical treatment in combination with a topical steroid with an improved benefit-risk ratio (eg, mometasone, fluticasone)
- In extreme circumstances, superpotent topical steroids may be used for short periods (1–2 weeks, maximum)
- Consider the use of coal tar with or without light therapy
- If treating a pediatric patient with phototherapy, have the guardian (who should be well-protected from the UV light) go into the treatment room with the child
- If treating with a topical steroid, intermittently step-down the strength to avoid a rebound effect
- Try maintenance therapy with vitamin D topical therapy and phototherapy
- Reduce the topical steroid dose proportionately to body size
- Systemic (eg, methotrexate, cyclosporine) or biologic agents may be required for recalcitrant widespread psoriasis causing major QOL issues⁵³

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patients. However, there is greater concern for HPA axis suppression in infants and children because of a higher ratio of total skin surface area to body mass compared to adults.⁷ There are few evidence-based guidelines for the treatment of psoriasis in pediatric patients. A recent systematic review of the literature recommends first-line treatment with a vitamin D therapy with or without a topical steroid and second-line treatment with anthralin.⁵⁴

In reviewing topical steroid use in pediatric patients with psoriasis among the experts on the panel, many were concerned with the potential side effects of long-term use. Thus it may be prudent to reduce topical steroids to applications in accordance with the reduced size of the child. As one member of the panel commented:

When clobetasol propionate came out in 1973 in the United Kingdom, within a year there was HPA axis suppression in children because clobetasol was never studied in this population. All of us who use potent or superpotent topical steroids for a week or 10 days or 2 weeks to clear intractable psoriasis in the pediatric population need to be careful. We need to give specific instructions regarding how much, how long, and what to use.

One panel member stated that he would not use clobetasol in children younger than 6 years. Even then, he would focus on the arms, legs, hands, or feet rather than the face or trunk.

Treatment of Psoriasis in Older Patients

Many older patients have already used a substantial number of prior therapies, including topical agents, phototherapy, and systemic and biologic agents. Older patients have thin atrophic skin compared to their younger counterparts. Although all topical medications may be used for older patients, they may not be able to apply them as regularly because of potential concurrent health problems. A headto-toe skin examination also is important in older patients, and one of the panel members noted, "Many of these patients have treated their psoriasis for many years with phototherapy or PUVA therapy and lots of sun exposure, and they have an increased risk for skin cancer or even melanoma. I don't simply focus on the psoriasis. I also do a complete skin examination looking for skin cancers and melanoma in these patients."

Panel Tips: Treatment of Psoriasis in Older Patients

General Advice

Give older patients regular total body skin checks. These patients may be at an increased risk for developing skin cancers or melanoma because of a long history of phototherapy and/or PUVA therapy

Panel Tips: Medication-Related Advice for Older Patients

Use topical steroids with caution in older patients with thin skin, as it may increase the risk for atrophy and purpura

- Use vehicles that patients find easy to use. Some patients may prefer easy-to-spread vehicles including foams, sprays, and lotions
- It may be appropriate to use a cream-based vehicle to lubricate the scalp, which may be drier compared to younger patients
- Use ammonium lactate lotion as part of the regimen because it may prevent further thinning of the skin
- Consider using topical tazarotene in patients with thin skin to help reverse atrophy

Use nonsteroidal medications when possible

Treatment of Psoriasis in Patients With Skin of Color

Patients with dark skin (Fitzpatrick skin types IV–VI) tend to heal with marked postinflammatory hyperpigmentation. These skin changes may cause substantial psychosocial distress and must be addressed as much as their preceding psoriatic plaques. Postinflammatory hyperpigmentation may last for months to years, so measures must be taken to prevent psoriasis flares that will exacerbate existing pigmentation.

Treatment of Psoriasis in Pregnant Patients

Psoriasis runs a variable course during pregnancy. While approximately 60% of patients improve, others may experience worsening of their disease. Although topical steroids are the mainstay of topical treatment of psoriasis, there is

Panel Tips: Treatment of Psoriasis in Patients With Skin of Color

Consider using an ointment vehicle, as many patients prefer it and use ointments as part of their cultural practices Careful use of tazarotene may help improve postinflammatory hyperpigmentation. However, tazarotene can be irritating. If any irritation occurs, tazarotene must be discontinued to avoid further darkening of the skin from postinflammatory hyperpigmentation

limited information available on their efficacy and safety during pregnancy. However, a report of a potential association between first-trimester topical steroid use and orofacial clefts in neonates has been reported.⁵⁵ The experts on the panel agreed that pregnant patients should be treated with as much nonmedicine as possible. For severe disease, UVB phototherapy would be first-line treatment. However, the panel felt that topical steroids, vitamin D topical treatments, and coal tar likely

Panel Tips: Treatment of Psoriasis in Pregnant Patients

Treat patients with as few agents as possible Phototherapy and emollients should be

- used as first-line treatment in pregnancy First-trimester spontaneous abortion in the United States is 15%–20%
- For more information on treating pregnancy during psoriasis, refer to the Organization of Teratology Information Specialists registry at www.otispregnancy.org
- If it is necessary to treat a patient with an agent with any theoretical risk to the fetus, share the decision making with the patient
- In the postpartum period, topical agents may be used, except around the nipple if the patient is breastfeeding

Table 6.

Pregnancy Safety Categories of Medications^a

Medication	Safety Category
Topical steroids (most)	С
Vitamin D topical therapies	С
Coal tar	С
Anthralin	С
Biologic agents	В
Topical calcineurin inhibitors	С
Salicylic acid	С
Tazarotene	Х
Ammonium lactate	В

^aRisks to the fetus are categorized from A (safest) to

X (known danger).

pose little risk; most experts would use them in pregnant patients, if necessary, in individual circumstances. Table 6 outlines the pregnancy safety categories of various treatments.

Use of Topical Steroids

Topical steroids are the most commonly prescribed medicines for psoriasis. They range in strength across 7 classes based on their ability to induce vasoconstriction. Additionally, they are divided into 4 different groups according to their chemical composition. Corticosteroids bind to cell receptors whose downstream effects include an alteration of cytokine expression as well as inhibition of T cell proliferation and down-regulation of antimicrobial peptides.⁵⁶ Long-term use of topical steroids is limited by cutaneous side effects, including skin atrophy, telangiectasia, striae, and acne. Additionally, HPA axis suppression may occur with the overuse of potent topical corticosteroids.⁵⁶ The potential side effects have led to the development of combination, sequential, and rotational regimens using more than one medication.²⁸ Many questions still remain unanswered and the experts on the panel had differing opinions.

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Panel Tips: Using Topical Steroids

Primary Treatment Considerations

- Don't give up on using a topical steroid. If one preparation or vehicle does not work, try another
- Patients can occasionally develop sensitivity to topical steroids; perform a patch test if you suspect sensitivity
- Initiate treatment with a superpotent steroid such as clobetasol propionate or halobetasol propionate. The induction period should include twice daily application for 2 weeks. If the condition does not clear, continue twice daily for 4 weeks. Thereafter, reduce usage to 1–2 times weekly while introducing a nonsteroidal (eg, vitamin D_3) preparation
- Cutaneous atrophy may reverse but striae do not. Anecdotally, most striae develop in patients aged 8–30 years, especially when topical steroids are used in intertriginous areas. Avoid the use of corticosteroids on the abdomen in younger patients, particularly women prior to pregnancy

The maximum dosage of most potent steroids is 50 g/wk; check package insert

Table 7.

Maximum Doses of Vitamin D– Containing Treatments

Medicine	Allowed Total Dose Per Week
Calcitriol ointment 3 µg/g	200 g
Calciotriene cream 0.005%	100 g
Calcipotriene 0.005%– betamethasone dipropio- nate 0.064% ointment	100 g

Panel Tips: Combination Topical Therapy

Concurrent use of salicylic acid with topical steroids enhances efficacy as well as toxicity Ammonium lactate and tazarotene may be used with topical steroids to decrease steroid atrophy

- Prescribe a vitamin D topical therapy in combination with a topical steroid.⁵⁷ Either use the vitamin D topical therapy from the beginning with the topical steroid or start the vitamin D therapy after the 2–4-week induction period, making sure it is compatible with the prescribed topical steroid (eg, halobetasol in combination with calcipotriene). Otherwise, apply one topical agent in the morning and the other in the evening Consider a fixed-dose combination product.
- It has advantages over monotherapy with a similar application regimen Make sure the topical steroids are compatible with any second agent being used

Maintenance Therapy Strategies

After an initial induction phase of 2–4 weeks, use topical steroids less frequently (ie, 1–2 days per week) Prescribe topical steroids to areas that have cleared (histologically, there may be evidence of inflammation despite clinical clearance, which is a justification for continued therapy)

- Prescribe topical steroids only as needed In the event of a psoriasis flare, go back to an initial induction regimen
- Use steroid-sparing agents (especially vitamin D topical therapy) topically alone, and in combination with tazarotene, coal tar, anthralin, and emollients

Use of Vitamin D Topical Treatments

Vitamin D topical agents have emerged as first-line therapy for psoriasis. Vitamin D topical treatments bind to vitamin D receptors in the skin, leading to differential expression of genes relating to

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Panel Tips: Using Vitamin D Topical Treatments

General Advice

- Some panel members agree that patients can take up to 50,000 IU/mo of vitamin D orally when using a vitamin D topical therapy
- Start a vitamin D topical therapy concurrently with topical steroids, otherwise improvement will be slow
- Calcitriol is less irritating than calcipotriene58
- Vitamin D topical therapy can be used as monotherapy for the face and intertriginous areas
- Vitamin D topical therapies have demonstrated long-term safety and efficacy up to 52 weeks without a clinically significant effect on calcium homeostasis³³

Combination Therapy With Vitamin D Topical Treatments and Other Agents

- Know which agents are compatible with vitamin D topical therapies. They are inactivated by many agents that have acidic pH, including hydrocortisone valerate, ammonium lactate, salicylic acid, and phototherapy. A medication vehicle may matter for compatibility. If compatibility is uncertain, separate the applications by time of day
- The combination of a vitamin D topical therapy with a topical steroid is superior to monotherapy with a steroid alone
- There is no information yet to determine if mixing a vitamin D topical therapy with another topical agent will dilute the agents or enhance their absorption
- According to panel members, the vehicle makes a difference in efficacy for calcipotriene; ointment is more effective than cream. The combination of a single agent containing calcipotriene and betamethasone dipropionate once daily is safe and effective in patients with mild, moderate, or severe psoriasis³⁵

cellular differentiation, which ultimately results in decreased inflammation, inhibition of keratinocyte proliferation, and improved cellular differentiation.⁵⁹ The main side effect of vitamin D topical treatments is local skin irritation and pruritus.^{58,60} Vitamin D topical therapies have been used effectively as monotherapy or in conjunction with other agents. Maximum doses of vitamin D–containing treatments are highlighted in Table 7.

Use of Topical Retinoids

Topical retinoids have effects on epidermal differentiation. Tazarotene is a third-generation topical retinoid that is approved for the treatment of plaque psoriasis. After binding to cellular retinoid receptors, tazarotene has been shown to decrease keratinocyte proliferation, inhibit inflammatory mediators, and normalize cellular differentiation.⁵⁶ The use of tazarotene is limited by substantial local irritation, especially perilesional irritation. It may help reduce the incidence of steroid-induced cutaneous atrophy. Tazarotene currently is available in cream and gel formulations, both in 0.05% and 0.1% concentrations. Currently, there is no limit on the maximum dose used on the skin, and the drug is pregnancy category X.⁶¹

Panel Tips: Use of Tazarotene

- Consider combination use of tazarotene and mometasone furoate cream 0.1%, which has greater efficacy than tazarotene gel 0.1% alone.³⁹ The combination also has resulted in longer remissions than using mometasone alone⁶²
- Tazarotene has been used in combination with vitamin D topical therapy with efficacy almost equal to clobetasol propionate ointment³⁸
- Tazarotene helps prevent steroid atrophy⁶³ Tazarotene cream is more efficacious and
- less irritating than the gel formulation⁵⁴ Consider using cream on the trunk but gel on the scalp
- Do not use tazarotene in body folds because of irritation
- Some success has been shown with the use of short-contact tazarotene gel 0.1%

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Panel Tips: Use of Coal Tar

General Advice

While exonerated by the US Food and Drug Administration, the state of California warns that coal tar is a carcinogen Avoid coal tar in patients with blonde or colored hair because of staining

Administration and Application-Related Considerations

- Coal tar is commercially available in new formulations, such as a foam, which have little staining of the skin and lack the odor of prior formulations
- Coal tar can be used effectively in combination with phototherapy.⁶⁴ Remove coal tar before initializing the light treatment, otherwise patients can develop "tar smarts" (delayed erythema and skin pain)
- Coal tar has been especially helpful in shampoos
- Consider compounding liquor carbonis detergens with betamethasone in hydrophilic ointment to use at night
- Coal tar may work well in combination with salicylic acid

Panel Tips: Use of Anthralin

- Commercially available as Zithranol-RR[®], Psoriatec[®], or Drithro-cream[®]
- Consider use in a short-contact regimen to avoid staining of household items
- Use of triethanolamine prevents irritation
- Anthralin powder can be compounded in 3%, 5%, or 10% formulations
- Do not use with white towels because of the risk for staining
- Acidic soaps, such as SAStid[®] (containing salicylic acid) and Salises, can help remove anthralin stains
- Basic soaps, such as Ivory[®] and Dove[®], can make stains worse

Panel Tips: Use of Topical Calcineurin Inhibitors

- May be used as monotherapy for psoriasis on the face or intertriginous areas
- Discuss with patients the black box warning that these medications carry
- Discuss with patients the risk for self-limited skin burning associated with these agents Tacrolimus ointment may be more effective but may cause slightly more irritation than pimecrolimus cream

Panel Tips: Use of Keratolytics and Emollients

Be aware of potential incompatibility issues with other medicines (eg, acidic pH may inactivate a vitamin D topical therapy) Emollients such as ammonium lactate may prevent steroid atrophy

Consider seasonal use of emollients only as maintenance treatment

Use of Other Topical Agents

In addition to topical steroids, vitamin D topical therapy, and retinoids, several other topical therapies are available to treat psoriasis, such as coal tar, anthralin, calcineurin inhibitors, keratolytics, and emollients. These medicines have been used as monotherapy but are more commonly combined with other treatments. These steroid-sparing agents should not be forgotten in determining a regimen for patients. However, they must be carefully prescribed, as some may inactivate other medications if used together.

Combination Use of Topical Agents and Phototherapy

Despite new and emerging drugs for psoriasis, UV light (ie, narrowband UVB, broadband UVB, PUVA) is still an essential part of psoriasis treatment. Patients undergoing phototherapy traditionally have marked BSA involvement (eg, >5%). Phototherapy also may be useful in patients with more localized disease, particularly with use of focused narrowband laser or nonlaser UVB phototherapy. Phototherapy is both

Panel Tips: Phototherapy

General Advice

- A topical medication should not be used within 2 hours prior to phototherapy unless there is certainty it will not be inactivated by light. Otherwise, apply the medicine after phototherapy
- Topical PUVA therapy is useful for psoriasis affecting the palms and soles
- Apply emollients before phototherapy but only those agents that do not block light (eg, petrolatum, mineral oil, Theraplex[®]). Mineral oil enhances penetration of light through psoriatic plaques
- To avoid phototoxicity, use photosensitizing medicines (including antibiotics) subsequent to phototherapy sessions
- Failure of topical PUVA therapy does not mean that oral PUVA therapy also will fail (and vice versa)
- For treatment with topical PUVA therapy, dissolve 1 tablet (10 mg) of methoxsalen in 2 L of water
- For treatment with bath PUVA therapy, dissolve 5 tablets (50 mg) of methoxsalen in a bathtub half filled with water, which will make patients extremely photosensitive and should be used with appropriate caution
- Have patients use wristbands after soaking in oxsoralen to prevent burns on the wrists in areas that may not consistently soak
- PUVA therapy penetrates deeper into the skin and may be especially helpful for thick psoriasis plaques

efficacious and safe without the potential side effects of systemic immunosuppressive therapies; it has been used effectively as monotherapy or in combination with systemic and topical agents (Table 8).²⁶

A member of the panel suggested that the safety profile of phototherapy may be appropriate for certain pregnant women. He noted, "We prefer not to treat pregnant patients, but if we have

Combination Therapy (Phototherapy)

Apply a topical steroid to an area that is resistant to treatment with phototherapy

- Consider using tazarotene in combination with UVB therapy to enhance the efficacy of phototherapy⁶⁵
- Vitamin D topical therapies can help reduce the frequency of phototherapy needed to treat psoriasis⁶⁶
- For patients receiving tazarotene, decrease the phototherapy dose by one-third or one-half. It takes approximately one week for tazarotene to thin the stratum corneum and make the skin more photosensitive
- For resistant cases, use an induction therapy with a vitamin D topical therapy (with or without a topical steroid) in combination with phototherapy
- For patients with erythrodermic psoriasis, first cool down the skin with dilute topical steroids and wet compresses; then treat carefully with phototherapy
- Consider priming patients with topical agents for 2 weeks prior to phototherapy, which may help decrease the number of phototherapy sessions needed

Table 8.

What to Avoid Before Phototherapy

- Avoid calcipotriene before UVA
- Avoid calcitriol for at least 3–6 hours before UVA and UVB
- Avoid applying too much of an emollient, as it physically blocks light; a thin application of petrolatum or mineral oil would be best prior to phototherapy

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to, narrowband and broadband phototherapy are safe options."

The Use of Topical Agents With Systemic Agents

Traditional systemic medications and biologic agents are effective at treating moderate to severe psoriasis, but patients may not be totally clear all of the time. Systemic agents often have a slow onset of action. Topical agents easily can be used as adjunctive therapy until the systemic agent starts to show efficacy. Moreover, some patients will have resistant plaques that do not resolve with a systemic or biologic medication, and topical agents can complement a systemic medication on these areas. When psoriasis flares occur, it is not necessary to abandon the systemic agent. Regardless of the cause of the flare, patients can be maintained on a systemic agent while the flare is treated by addition of a topical medicine. Adjunctive therapy with a clobetasol propionate spray 0.05% was evaluated as add-on therapy in patients receiving other medications (including topical or systemic agents), resulting in improvement of disease severity.⁶⁷ There are many questions about combining topical and systemic medications that may be answered through personal experience and future clinical trials.

Conclusion

Although the experience of having psoriasis is subjective and differs from patient to patient, there are guidelines for determining the level of severity. Mild psoriasis generally is defined as BSA involvement of 3% or less. Moderate disease involves 5% to 10% BSA. Severe psoriasis is disease that affects greater than 10% BSA. Dermatologists must take into consideration the percentage of BSA involved; location, severity, and number of individual lesions; response to topical therapies; associated physical disability, including psoriatic arthritis; and psychosocial and QOL issues.

Existing guidelines provide a framework for categorizing patients as well as the severity and type of psoriasis. Nonetheless, psoriasis manifests in various ways. Psoriasis is a systemic inflammatory condition that gives rise to increased risk for comorbidities, including the metabolic syndrome X, depression, hypertension, and dyslipidemia.

In psoriasis therapy, the goal of treatment is durable improvement with minimal AEs. There are numerous therapies available for patients with psoriasis, including topical steroids, vitamin D_3 treatments, retinoids, and other topical agents, as well as phototherapy and systemic and biologic agents. The topical agents can be delivered in many different vehicles. Although the choices are broad, problems of adherence can undermine treatment success. The use of vehicle is important in bolstering adherence rates and, when possible, vehicles should be chosen based on the preference of the patient. In addition, it generally helps to have the first follow-up appointment soon after the baseline visit.

Guidelines differ based on the population involved. Special care is warranted in children, older patients, and pregnant women. Overall, therapeutic options allow dermatologists to use a variety of well-researched approaches to treat

Panel Tips: Using Topical Agents With Systemic Agents

- Use a topical agent with a systemic agent when beginning therapy to give patients a quicker response
- Add topical agents to recalcitrant areas and help improve response
- Add topical agents to treat flares of psoriasis while continuing the systemic or biologic agent
- Topical agents may be particularly useful for psoriasis plaques on the lower extremities and scalp that may be less responsive to systemic and biologic agents than other body parts
- Continue using a topical agent while tapering a systemic agent and switching to another systemic agent
- Use topical agents while waiting for insurance coverage approval for a systemic agent
- Consider using a vitamin D topical therapy in combination with an oral retinoid,⁶⁸ cyclosporine,⁶⁹ or methotrexate⁷⁰

Fixed-dose calcipotriene 0.005%– betamethasone dipropionate 0.064% ointment plus etanercept may be more beneficial than etanercept alone for some patients

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their patients with the goal of improving overall health and QOL. Topical therapy is important in the treatment of mild to severe psoriasis and can be used safely and effectively as maintenance therapy.

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