Health Monitor®

Clinician Update

Plaque Psoriasis

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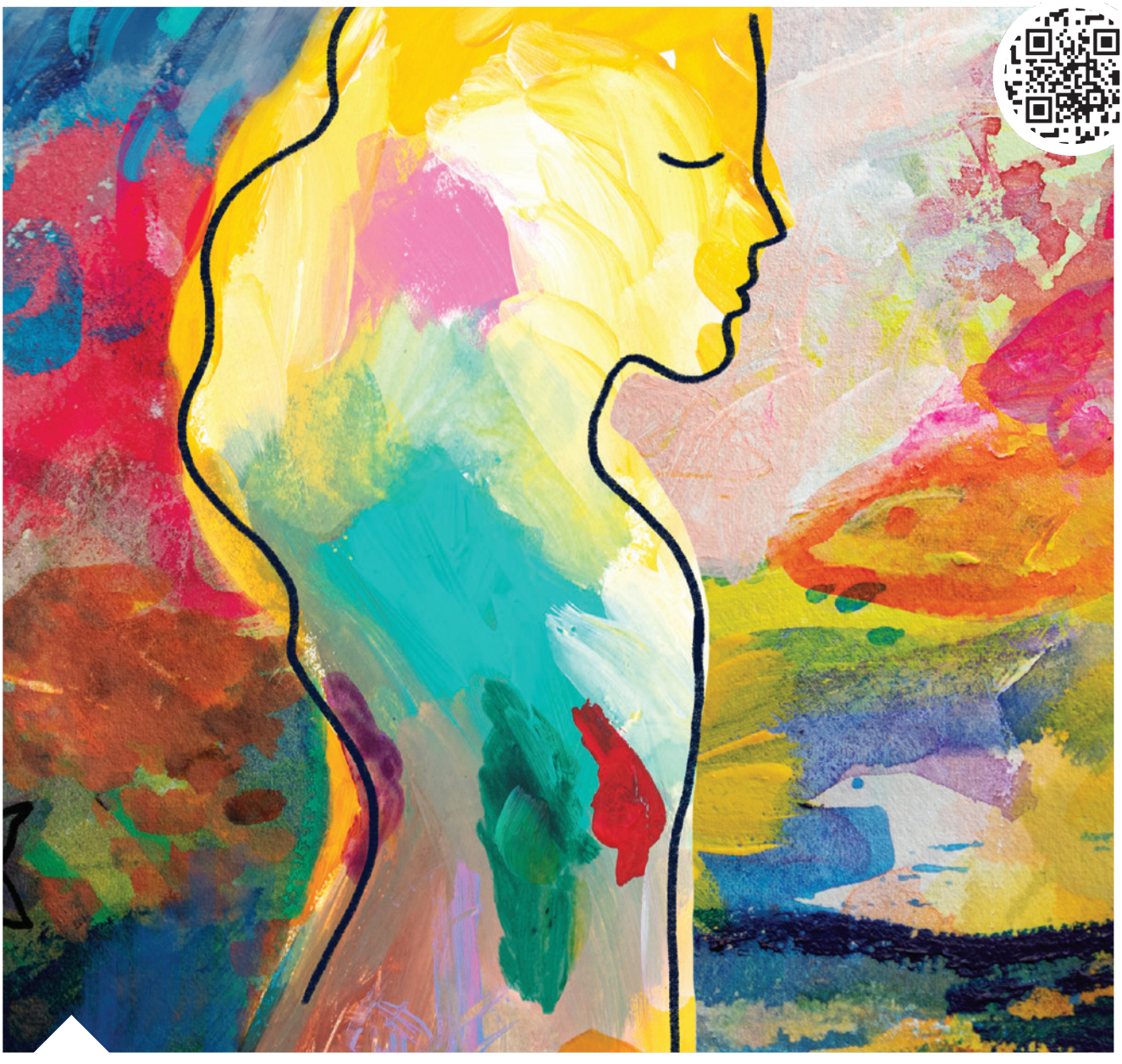

Strategies for optimizing BIOLOGIC THERAPY

Experts discuss key factors to consider when initiating—or switching—biologic agents.

It's difficult to imagine a more significant development in the treatment of plaque psoriasis than the introduction of biologic medications. "They have totally revolutionized psoriasis therapy. Biologics have been life-changing for many, many patients," says Craig Elmets, MD, Professor and Immediate Past Chair, Department of Dermatology, University of Alabama, Birmingham and cochair of the 2019 American Academy of Dermatology (AAD)/National Psoriasis Foundation (NPF) guidelines for the management and treatment of psoriasis with biologics.[1] "They have been a wonderful addition to our therapeutic armamentarium." The main reason: Unlike systemic drugs such as methotrexate, which act on the entire immune system, biologics target only specific immune proteins known to be involved in the inflammatory process.

While the AAD/NPF guidelines offer evidence-based recommendations for biologic therapy, there is a caveat to keep in mind: Since the guidelines were released in 2019, newer data have been published confirming the efficacy, safety and durability of certain biologics, including in Black patients and other undertreated populations.

Therefore, it's essential to become familiar with the latest data on various agents and what to consider before prescribing them. Here are some of the key considerations, along with expert strategies for making sure your patients get the most from biologic therapy.

Continued on p. 4 ►

Illustration by Donna Grethen / Ikon Images

"Now we have great treatments that are much safer and much more effective."
—Mark G. Lebwohl, MD

Individualize treatment based on history and patient preferences.

The good news: There are a number of options for a wide range of patients. "Anyone with moderate to severe psoriasis or psoriatic arthritis is a candidate for biologic therapy," notes Mark G. Lebwohl, MD, Professor and Chairman Emeritus, Kimberly and Eric J. Waldman Department of Dermatology, Icahn School of Medicine at Mount Sinai. However, there are several factors to consider when choosing a biologic, including patient characteristics, disease history and treatment-related considerations (see box, *opposite*).[2-4] In addition, it's essential that your patients understand the different classes' benefits and risks to facilitate shared decision-making. Dr. Lebwohl notes a few key points to discuss before prescribing a biologic: "Some of the older biologic therapies, such as TNF blockers, include black box warnings about infection and malignancy, and all patients receiving biologics are asked to undergo annual TB tests," notes Dr. Lebwohl. "Counseling about the infection and malignancy warnings is prudent, as it's better that patients hear the facts from their physicians than read about them and imagine worse risks than truly exist."

Regarding other classes, says Dr. Lebwohl: "The newer biologics that block IL-17 and IL-23 don't carry black box warnings regarding infection and malignancy. However, one agent has a unique mandated warning to counsel patients about depression and suicide, as there were four suicides among approximately 4,000 psoriasis patients treated in clinical trials with the drug," he says. (For factors to consider when choosing a biologic, see box, *opposite*.)

Don't delay changing agents in nonresponders.

If a patient fails to respond to an initial biologic within 12 weeks, either try a different agent within the same class or switch to a biologic with a different mechanism of action. The first biologic many psoriasis patients receive is often a TNF inhibitor. The AAD/NPF guidelines note that a patient who fails to respond to one TNF inhibitor may get symptom relief from another, though primary failure with a TNF inhibitor often suggests that switching to another class is more likely to produce a satisfactory response.

In partial responders, make a decision: Add, escalate or switch?

Patients who achieve partial response to a biologic present a clinical quandary: Do you add, escalate or switch therapies? "Combination therapy is highly effective," says Dr. Lebwohl. "Occasionally, when we have a patient who responds to a therapy, but not enough, we'll add a medication." Possible additions include topical corticosteroids, vitamin D analogues, methotrexate or ultraviolet B light.

The alternative, of course, is to escalate the patient's dose. If that doesn't produce an adequate response, prescribe a different biologic. The AAD/NPF guidelines state that, when clinically necessary, any biologic may be switched to another for the purpose of improving efficacy, safety and/or tolerability. Since there's little data on which biologic to use following primary or secondary failure of another, patient preference plays an even greater role. "I have a discussion with the patient about the pros and cons of each class of biologic agents, and I prefer to have them decide among those options," says Dr. Elmets.

Consider real-world efficacy and durability.

While Dr. Elmets always offers patients a choice among biologic agents, he notes that a significant number of patients are indecisive, in which case he considers the severity of the patient's disease and comorbidities, among other factors, then recommends the biologic he believes offers the best balance of efficacy and safety.

Another consideration: durability of response. Recent data provided evidence of not only efficacy but also durability of response for certain biologic classes. For example, separate analyses of real-world data released in 2023 showed greater treatment persistence for certain IL-23 inhibitors vs. IL-17 inhibitors in patients with psoriasis, including difficult-to-treat areas such as the scalp, while other data confirmed durable efficacy in both biologic-naïve and biologic-experienced patients.[5-7]

Don't be discouraged by prior authorization or reimbursement issues.

Prior authorization is usually necessary when prescribing biologic drugs, and denials are common, says Dr. Lebwohl, as when insurers refuse to cover one of the drugs until a patient has tried a less expensive therapy and failed to achieve a response. However, one recent study showed that most patients were able to obtain the prescribed biologic, and while wait times varied, the majority were approved in about a month.[8] In addition, biologic medications were obtained through a wide range of insurance plans, including federally funded plans such as Medicaid, where people often assume getting approval is more challenging. The AAD website (*aad.org*) offers a prior authorization letter generator and other tools that members can use to expedite patient access to biologics and other medications.

Ultimately, no matter what biologic you choose, one thing's for sure: The latest medications are helping patients achieve clearer skin—and lead fuller lives. In fact, many dermatologists recall the pre-biologics era with little fondness. "I started practicing when all we had was ultraviolet light treatment and methotrexate," says Dr. Lebwohl. But ultraviolet light required multiple office visits per week, and many patients found methotrexate intolerable and not very effective. "Patients used to be angry with doctors. They thought we weren't doing enough for them," recalls Dr. Lebwohl. But thanks in large part to the arrival of biologics, he says, "Now we have great treatments that are much safer and much more effective."

—by Tim Gower

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Key factors to consider when choosing a biologic therapy[2-4]

Patient characteristics

- Patient age, sex, body weight
- Patient expectations
- Comorbidities that may contraindicate or raise a caution on the use of selected biologics (e.g., latent tuberculosis, severe heart failure, personal history or strong family history of demyelinating disease or alopecia areata for TNF inhibitors, Crohn's disease for IL-17 inhibitors)
- Presence of concomitant diseases that may benefit from the same treatment (e.g., psoriatic arthritis, Crohn's disease, ulcerative colitis)

Disease characteristics

- Disease severity, activity and stability
- Skin areas involved
- Severity of symptoms (e.g., pruritus)
- Disease and treatment history, rapid relapse after treatment withdrawal, intermittent or continuous disease activity

Treatment-related considerations

- Drug availability
- Overall efficacy (short- and long-term) and the need for a rapid response
- Tolerability and safety (including patient concerns about side effects)
- Need for flexible treatment (e.g., need for easy interruption or restart)
- Administration modality (subcutaneous, intravenous; frequency of injections)

MANAGING COMORBIDITIES OF PLAQUE PSORIASIS

These strategies can help ensure prompt diagnosis and treatment of conditions that often go hand-in-hand with this systemic disease.

With growing recognition that psoriasis is a "whole body" disease, the American Academy of Dermatology (AAD) and National Psoriasis Foundation (NPF) collaborated for the first time to produce the joint AAD/NPF 2019 guidelines for managing plaque psoriasis, which included a section on comorbidities.[1] The AAD last issued recommendations for managing related conditions in 2008 as a subtopic in guidelines for treating patients with biologic therapy. "But when the earlier guidelines were published, little was known about comorbidities of psoriasis," says dermatologist Craig A. Elmets, MD, cochair for the AAD/NPF guidelines and a Professor of Dermatology at the University of Alabama at Birmingham. "Now, it's quite clear that psoriasis is a systemic disease, and that skin disease is only one manifestation."

Fortunately, the extensive research summarized in the guidelines sheds light on which conditions are associated with psoriasis. Here, experts discuss four major comorbidities often seen in patients with psoriasis as well as recommendations for identifying and managing each one.

1. Psoriatic arthritis

Roughly one third of patients diagnosed with psoriasis eventually develop psoriatic arthritis (PsA), typically about a decade after skin symptoms manifest. However, a minority of patients have joint symptoms (such as stiffness and swelling) at the time psoriasis is diagnosed. Psoriasis patients with a high degree of affected body surface area have the greatest risk for developing PsA.[1]

Untreated PsA can result in significant joint damage and diminished quality of life, making early detection critical, so the AAD/NPF guidelines recommend routine screening for PsA. "It can't be something you do just at the first visit with a patient—screening for PsA has to happen on an ongoing basis," says Dr. Elmets. Formal screening tools are available, though the AAD/NPF guidelines note that their reliability and validity are moderate. For that reason, Mark G. Lebwohl, MD, Professor and Chairman Emeritus, Department of Dermatology, Icahn School of Medicine at Mount Sinai in New York and a coauthor of the AAD/NPF guidelines,

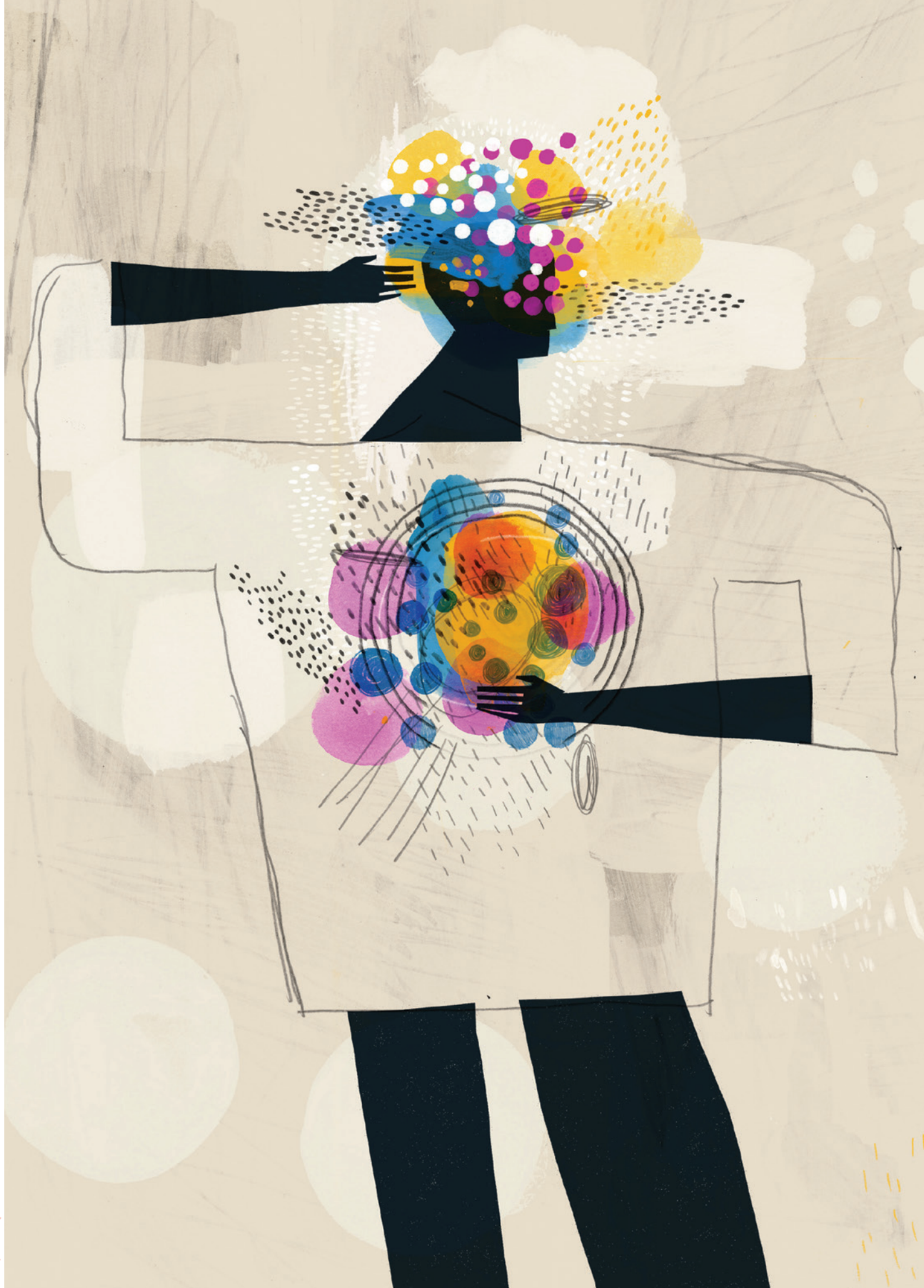

Illustration by Keith Negley

emphasizes the importance of careful assessment to identify PsA, including the following:

- **Ask about joint pain, but be discriminate.** "If the patient complains of a sore knee after playing tennis, and they have had that for 20 years, then I'm more likely to think that's osteoarthritis," says Dr. Lebwohl. On the other hand, if the patient has stiffness and swelling, especially in the fingers and toes, upon rising in the morning that resolves with activity, consider PsA as a possible cause.
- **Look for asymmetry.** Dr. Elmets notes that PsA often has asymmetrical presentation—for example, symptoms occurring in one knee but not the other.
- **Check for lower back pain.** This can be another red flag, says Dr. Elmets, since it may be brought on by sacroiliitis, which can occur in PsA.
- **Be aware of other key signs,** including enthesitis, or inflammation at the juncture where tendons and ligaments insert into bones. PsA patients often develop enthesitis in the Achilles tendon, though the hips, knees and other joints may be affected. Another problem: dactylitis, or inflammation of the small joints of the hands and feet, which produces "sausage-like" digits.

If you suspect PsA, consult the American College of Rheumatology (ACR)/NPF guidelines for PsA and refer to a rheumatologist. "I take care of a lot of psoriatic arthritis patients but seek the help of a rheumatologist when I'm not sure of the diagnosis," says Dr. Lebwohl, who notes that there are many drugs and drug combinations in the dermatologist's armamentarium that can relieve symptoms of both psoriasis and PsA. A few things to consider: Methotrexate may reduce inflammation related to PsA but does not stop radiographic progression of the disease; other older agents are rarely adequate as monotherapy. Apremilast is approved for PsA but has not been shown to prevent the radiographic progression of joint disease. However, several biologics are also approved for PsA and prevent X-ray changes, including certain TNF inhibitors and IL-17 blockers. An IL-12/23 inhibitor is approved for PsA, although appears to be more effective for treating skin manifestations than joint symptoms. In addition, certain IL-23 inhibitors are approved for PsA as well as a T-cell inhibitor.[2] A TYK2 inhibitor is also under investigation to treat PsA.

2. Cardiovascular disease

People with psoriasis have an increased risk for cardiovascular disease (CVD); the more severe the psoriasis, the greater the threat. In a meta-analysis of nine studies, researchers assessed the CVD risk of 201,239 patients with mild psoriasis and 17,415 patients with severe psoriasis. Mild psoriasis conferred a 29% increased risk for myocardial infarction (MI), while severe disease increased the likelihood of developing CVD by 70%. Other research suggests that severe psoriasis increases the risk for stroke by up to 43%.[1,3] One reason for the high incidence is the inflammatory nature of the disease. The American College of Cardiology has identified psoriasis and other chronic inflammatory diseases as risk factors for atherosclerosis. In addition, research suggests that people with psoriasis are more likely than those without the disease to have certain CVD risk factors. Notably, a study in *JAMA Dermatology* found a five-fold increased risk for coronary calcification in people with psoriasis.[4] To help protect patients:

- **Monitor risk factors.** Blood tests performed for all psoriasis patients should include lipid panels, "so if a patient's cholesterol is high, we direct him or her to see a clinician who can treat it," says Dr. Lebwohl. Be sure patients have routine lipid screening, whether by you or another doctor (see Table 1, *opposite*).
- **Consider possible beneficial effects** of some biologics, especially in patients with moderate-to-severe psoriasis and increased risk factors for CVD. Although clinical trials for biologics were not powered to detect cardiovascular benefits, later research suggests that the ability of these agents to suppress inflammatory pathways in the immune system may help lower CVD risks. For example, a study of 8,845 psoriasis patients found that those treated with TNF inhibitors had half the risk for MI compared with others given topical therapies. A follow-up study by the same group found that patients on a TNF inhibitor had a lower risk for major adverse cardiovascular events than others given methotrexate.[1,5]

3. Metabolic syndrome

People with psoriasis have an increased risk for developing the cluster of risk factors known as metabolic syndrome, which includes abdominal obesity, hypertension, high triglycerides, low HDL cholesterol and high fasting blood glucose. For a diagnosis of metabolic syndrome, a patient must have at least three of the following:

- Increased waist circumference (male, >40 inches; female, >35 inches)
- Blood pressure >130/85 mmHg
- Fasting triglycerides ≥150 mg/dL
- Fasting HDL cholesterol levels <40 mg/dL for men and <50 mg/dL for women
- Fasting glucose ≥100 mg/mL

One analysis found that roughly a third of psoriasis patients met the criteria for metabolic syndrome compared with about one quarter of controls, with the likelihood rising among patients with greater affected body surface area (≥10%).[1] Metabolic syndrome increases the risk for CVD, type 2 diabetes, fatty liver disease, some cancers and premature death. It's not clear why metabolic syndrome is more common among psoriasis patients, though a genetic link is being explored, says Dr. Lebwohl. Work closely with the patient's primary care provider to control risk factors, and keep in mind the following:

- **Be aware of psoriasis therapies that may contribute to CVD risk.** For example, cyclosporine may cause or worsen hypertension, though the effects may be reversed by the calcium channel blocker amlodipine. Likewise, acitretin and cyclosporine can negatively affect lipids.
- **Use a team approach to control hyperglycemia.** Consider referring patients with prediabetes or newly diagnosed diabetes to an endocrinologist and/or diabetes educator, as these specialists can help patients get hyperglycemia under control quickly. ►

Table 1.

Recommended CVD risk factor screening in patients with plaque psoriasis

CONDITION	CRITERIA	SCREENING FREQUENCY
Hypertension	Age 18-39, no risk factors, BP <130/85	Every 3-5 years
	Age ≥40 and those who are at increased risk (BP 130-139/85-89, overweight/obesity, African American)	Yearly
Diabetes	Age 40-70 with BMI ≥25; in those without risk factors, testing should begin at age 45	Every 3 years
Cardiovascular risk assessment*	Age 20-79 with standard risks; for adults age 40-79, estimate 10-year risk	Every 4-6 years

Source: Evidenced-based guidelines as noted in the AAD/NPF guidelines on psoriasis comorbidities.[1]

*Traditional CVD risk factors include age, sex, total cholesterol, LDL cholesterol, systolic BP, hypertension (treated or untreated), diabetes and current smoker. To assess 10-year risk, go to *cvriskcalculator.com*.

4. Obesity

Overall, people with psoriasis are 66% more likely than others to have obesity, which is defined as a body mass index (BMI) ≥30 kg/m², according to a review of 16 studies that included more than 2 million patients.[6] The link between the two conditions is unclear, but studies suggest that losing weight can modestly improve management of the skin disorder. In a small trial, 60 patients with obesity and psoriasis (median Psoriasis Area Severity Index [PASI] score of 5) were randomly assigned to a low-calorie diet plan (800 to 1,000 calories/day for 2 months, followed by 1,200 calories/day for 2 months) or were instructed to eat healthy foods.[4] Patients in the low-calorie group lost 34 more pounds than nondieters, on average, and reduced their PASI scores by an additional 2 points.[7] "Reducing body weight makes psoriasis medications work better," says Dr. Lebwohl, noting that it's a matter of math: If two patients get the same dose of a drug, and one weighs 125 lbs. and the other 250 lbs., the latter is getting half as much drug per unit of weight. To help patients maintain a healthy weight, try these strategies:

"It's quite clear that psoriasis is a systemic disease, and that skin disease is only one manifestation."
—Craig A. Elmets, MD

- **Do a weight screening at least once a year.** Calculate BMI and instruct patients who fall into the category of overweight (BMI 25 to 29.9) or obesity (BMI ≥30) to discuss weight-loss strategies with their primary care physician and/or refer them to an endocrinologist or other specialist in obesity medicine.
- **Review their medications.** Some therapies for various conditions are associated with weight gain, including antidepressants and beta blockers. In addition, studies suggest that two psoriasis medications, etanercept and infliximab, appear to promote modest weight gain, so keep in mind this potential downside when using these drugs.
- **Consider bariatric surgery.** For patients with a BMI ≥40 who fail conventional weight-loss strategies, consider referral to a specialist in bariatric surgery. One study found that gastric bypass cut the risk for psoriasis progression from mild to severe by more than half. Note, though, that gastric banding (an alternative bariatric procedure) did not prevent worsening of skin manifestations.[8]

–by Tim Gower

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PATIENT: MARIEL, 55, HAD A 10-YEAR HISTORY OF PLAQUE PSORIASIS, COMPLICATED OF LATE BY LIFE STRESSORS.

"Her topical meds were no longer working"

History:
Mariel, a native of the Philippines, was diagnosed with plaque psoriasis about 10 years ago. She started off with minimal disease, covering about 3% of her body. We were able to control it well with topicals, including clobetasol and triamcinolone, but about a year ago, her plaque psoriasis flared, and the redness and inflammation spread to about 30% of her body. When I asked Mariel what was going on in her life, she said that she had recently lost her job as a receptionist and that her husband was dealing with a serious health problem. Her comorbidities included hypertension, fatty liver disease and hypercholesterolemia, all of which were being managed by her PCP.

The psoriasis that was once limited to Mariel's elbows and knees had now spread to her scalp and trunk, and the itching and scaling were interfering with her sleep. And the visible signs of moderate-to-severe plaque psoriasis were making it difficult for Mariel to find a new job, since who, she thought, would want to hire a front-desk person with such an obvious, disfiguring condition? She confided that the shame and embarrassment were becoming overwhelming.

Initiating treatment:
Because Mariel's plaque psoriasis was now too advanced to control with topical medications, we had to turn to a systemic drug. I considered several biologics and decided on an IL-23 inhibitor because of its excellent record of safety and efficacy. Mariel was a little hesitant to self-inject the medication, but her experience of working in a medical office made her more open to the idea.

Before starting Mariel on medication, I had her tested for tuberculosis and hepatitis, the effects of which are increased in patients taking a medicine that lowers the ability to fight infections. There's some debate regarding whether this is necessary when starting IL-23 biologics, but I believe it's a worthwhile step to take, especially when treating patients from other countries where infections like tuberculosis may be endemic. As I had expected given her age and length of time in the U.S., Mariel's results came back negative.

Mariel received her first injection in our office, then gave herself the next one at 4 weeks. Two weeks later—6 weeks prior to her next injection—she came in for a follow-up. She admitted that she was a little disappointed in the results, until I told her that the effects of an IL-23 inhibitor are not immediate. I call this my "cheerleading" appointment, during which I tell patients like Mariel that they're doing a good job and that within a few months their skin will be vastly improved.

Like most of my patients who start an IL-23 inhibitor, Mariel's skin was 80% to 90% clearer after about 4 months. Except for some reversible post-inflammatory hyperpigmentation that can occur in patients with darker skin, she hasn't had any side effects. More important, because her psoriasis is well controlled and she doesn't have to hide her skin, Mariel has regained her self-confidence and is thriving in a new job.

Considerations:
The future of biologics for moderate-to-severe psoriasis is bright for patients like Mariel, but we're only now focusing on assessing these agents in people of color, who have traditionally been underrepresented in clinical studies. However, there's already positive data from an ongoing study for an IL-23 biologic that included patients across all skin tones, which is very exciting. By conducting new studies and educating clinicians on the results, ethnically diverse patients with psoriasis will be much better served in the years to come. ►

PHYSICIAN:
Tina Bhutani, MD
Co-director of the UCSF Psoriasis and Skin Treatment Center in San Francisco

Illustrations by Juhee Kim

NEW!
KOL ON DEMAND VIDEO
Scan here for more insight on Mariel's case.

PATIENT: RICHARD, 35, HAD HYPERTENSION AND A 15-YEAR HISTORY OF PLAQUE PSORIASIS.

"Frequent dosing made it difficult to stay on his therapy"

PHYSICIAN:
Tina Bhutani, MD

Co-director of the UCSF Psoriasis and Skin Treatment Center in San Francisco

History:
When he came to see me, Richard was an executive for a major corporation whose plaque psoriasis was first diagnosed when he was in college. He started on topical therapy, then progressed to methotrexate and, finally, to a biologic—in this case, a TNF inhibitor. He did well on this for several years, but as his career took off, he began to find it increasingly difficult to keep up with the dosing schedule of every 2 weeks due to the amount of travel that was required in his position. Moreover, Richard's plaque psoriasis was worsening, and he developed joint pain due to psoriatic arthritis. The symptoms, he told me, were interfering with the frequency and intensity of his gym workouts, which, in addition to daily hydrochlorothiazide, were helping to manage his high blood pressure.

Initiating treatment:
Richard's affected body surface area was roughly 20% to 25% on his first visit, mostly on the arms and legs, but on his genitals as well. His joint paint was increasing, too, prompting him to tell me that his TNF inhibitor "wasn't cutting it anymore." Once I began to ask Richard about his work and lifestyle, I knew that his best treatment option would be an IL-23 inhibitor, which would improve his moderate-to-severe plaque psoriasis symptoms while at the same time drastically reducing the number of annual doses he'd have to inject, from 26 a year to just 6 a year (after two starter doses in month 1). This biologic also had the added benefit of being the first IL-23 inhibitor to be FDA-approved for both plaque psoriasis and psoriatic arthritis.

"It's important to educate patients about the advantages of taking an injectable medication for their moderate-to-severe psoriasis."

That was all Richard had to hear. We stopped his TNF inhibitor and waited 2 weeks before starting the IL-23 inhibitor. Once on the new medication, Richard showed steady improvement, and after the second injection, his skin was mostly clear. He reported less joint pain, too. That allowed him to increase his number of weekly workouts, which made him very happy. Perhaps just as important, Richard doesn't have to pack medications or rework his travel schedule to comply with his psoriasis treatment regimen.

Considerations:
In my experience, the IL-23 drugs are a really effective and safe option for patients with moderate-to-severe plaque psoriasis—I've been hard pressed to find someone they're not suitable for. They have many advantages over some of the older biologics, including a broader dosing schedule, which appeals to busy younger patients like Richard. The IL-23 biologic therapies also work well with medications used to treat other conditions.

Finally, it's important to take a little time to educate patients about the advantages of taking an injectable medication for their moderate-to-severe plaque psoriasis. Even the most upbeat television ads, which are now common for several biologics, include an intimidating list of potential side effects that patients may find frightening. However, by explaining to them that IL-23 medications have been effective in patients who have failed previous psoriasis therapies, including other biologics, you can help secure the "buy in" you need to help them effectively treat this stress-inducing and very visible autoimmune disease.

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215 k patients treated[2]¶

*Psoriatic disease is defined as moderate to severe plaque PsO and active PsA.
†Represents completed and ongoing PsA clinical trials.
‡First large-scale, prospective PsO biologic study in patients with skin of color across the entire spectrum of the Fitzpatrick scale (I-VI).
§Based on a phase 1 clinical trial of TREMFYA® initiated in 2009.
‖Represents completed and ongoing PsO and PsA clinical trials.
¶More than 215,000 patients treated with TREMFYA® in the United States from July 2017 to September 2023. Estimations are based on calculations using product-utilization data collected in the United States for TREMFYA® to determine patient type, average dose per administration, total number of administrations, and patient persistency rates.

Study Designs

VOYAGE 1 (n=837) and **VOYAGE 2** (n=992) were phase 3, multicenter, double-blind, placebo-controlled trials in adult patients with moderate to severe plaque PsO. Patients were randomized to TREMFYA® 100 mg SC injection at Weeks 0, 4, and 12, then every 8 weeks (q8w); placebo at Weeks 0, 4, and 12, followed by crossover to TREMFYA® at Week 16, Week 20, and q8w; or active comparator through Week 47 (VOYAGE 1) or Week 23 (VOYAGE 2). In VOYAGE 1, patients initially randomized to active comparator entered a washout period after their final dose at Week 47 and entered open-label TREMFYA® from Week 52-252. VOYAGE 2 incorporated a randomized withdrawal and re-treatment from Week 28-72, followed by open-label TREMFYA® from Week 76-252. Safety was assessed through Week 264.[1,4,5]

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Indications

TREMFYA® is indicated for the treatment of adults with moderate to severe plaque psoriasis (PsO) who are candidates for systemic therapy or phototherapy and adults with active psoriatic arthritis (PsA).

Important Safety Information

CONTRAINDICATIONS

TREMFYA® is contraindicated in patients with a history of serious hypersensitivity reaction to guselkumab or to any of the excipients.

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions

Serious hypersensitivity reactions, including anaphylaxis, have been reported with postmarket use of TREMFYA®. Some cases required hospitalization. If a serious hypersensitivity reaction occurs, discontinue TREMFYA® and initiate appropriate therapy.

Infections

TREMFYA® may increase the risk of infection. Treatment with TREMFYA® should not be initiated in patients with a clinically important active infection until the infection resolves or is adequately treated.

Consider the risks and benefits of treatment prior to prescribing TREMFYA® in patients with a chronic infection or a history of recurrent infection. Instruct patients receiving TREMFYA® to seek medical help if signs or symptoms of clinically important chronic or acute infection occur. If a patient develops a clinically important or serious infection, or is not responding to standard therapy, closely monitor and discontinue TREMFYA® until the infection resolves.

Pre-Treatment Evaluation for Tuberculosis (TB)

Evaluate patients for TB infection prior to initiating treatment with TREMFYA®. Initiate treatment of latent TB prior to administering TREMFYA®. Monitor patients for signs and symptoms of active TB during and after TREMFYA® treatment. Do not administer TREMFYA® to patients with active TB infection.

Immunizations

Prior to initiating TREMFYA®, consider completion of all age-appropriate immunizations according to current immunization guidelines. Avoid use of live vaccines in patients treated with TREMFYA®.

ADVERSE REACTIONS

Most common (≥1%) adverse reactions associated with TREMFYA® include upper respiratory infections, headache, injection site reactions, arthralgia, bronchitis, diarrhea, gastroenteritis, tinea infections, and herpes simplex infections.

The overall safety profile observed in patients with psoriatic arthritis is generally consistent with the safety profile in patients with plaque psoriasis, with the addition of bronchitis and neutrophil count decreased.

Please read the Brief Summary of the full Prescribing Information for TREMFYA® within this ad.

cp-82625v3

Tremfya® (guselkumab)

Johnson&Johnson

Brief Summary of Prescribing Information for TREMFYA® (guselkumab)
TREMFYA® (guselkumab) injection, for subcutaneous use
See package insert for full Prescribing Information.

INDICATIONS AND USAGE Plaque Psoriasis: TREMFYA is indicated for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy. **Psoriatic Arthritis:** TREMFYA is indicated for the treatment of adult patients with active psoriatic arthritis. **CONTRAINDICATIONS** TREMFYA is contraindicated in patients with a history of serious hypersensitivity reaction to guselkumab or to any of the excipients *[see Warnings and Precautions]*. **WARNINGS AND PRECAUTIONS Hypersensitivity Reactions:** Serious hypersensitivity reactions, including anaphylaxis, have been reported with postmarket use of TREMFYA. Some cases required hospitalization. If a serious hypersensitivity reaction occurs, discontinue TREMFYA and initiate appropriate therapy. **Infections:** TREMFYA may increase the risk of infection. In clinical trials in subjects with plaque psoriasis, infections occurred in 23% of subjects in the TREMFYA group versus 21% of subjects in the placebo group through 16 weeks of treatment. Upper respiratory tract infections, gastroenteritis, tinea infections, and herpes simplex infections occurred more frequently in the TREMFYA group than in the placebo group *[see Adverse Reactions]*. The rate of serious infections for the TREMFYA group and the placebo group was ≤ 0.2%. A similar risk of infection was seen in placebo-controlled trials in subjects with psoriatic arthritis. Treatment with TREMFYA should not be initiated in patients with any clinically important active infection until the infection resolves or is adequately treated. In patients with a chronic infection or a history of recurrent infection, consider the risks and benefits prior to prescribing TREMFYA. Instruct patients to seek medical help if signs or symptoms of clinically important chronic or acute infection occur. If a patient develops a clinically important or serious infection or is not responding to standard therapy, monitor the patient closely and discontinue TREMFYA until the infection resolves. **Pre-treatment Evaluation for Tuberculosis:** Evaluate patients for tuberculosis (TB) infection prior to initiating treatment with TREMFYA. Initiate treatment of latent TB prior to administering TREMFYA. In clinical trials, 105 subjects with plaque psoriasis and 71 subjects with psoriatic arthritis with latent TB who were concurrently treated with TREMFYA and appropriate TB prophylaxis did not develop active TB. Monitor patients for signs and symptoms of active TB during and after TREMFYA treatment. Consider anti-TB therapy prior to initiating TREMFYA in patients with a past history of latent or active TB in whom an adequate course of treatment cannot be confirmed. Do not administer TREMFYA to patients with active TB infection. **Immunizations:** Prior to initiating therapy with TREMFYA, consider completion of all age appropriate immunizations according to current immunization guidelines. Avoid use of live vaccines in patients treated with TREMFYA. No data are available on the response to live or inactive vaccines. **ADVERSE REACTIONS** The following adverse reactions are discussed in greater detail in other sections of labeling: • Infections *[see Warnings and Precautions]* • Hypersensitivity Reactions *[see Contraindications and Warnings and Precautions]* **Clinical Trials Experience:** Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. Plaque Psoriasis: In clinical trials, a total of 1823 subjects with moderate-to-severe plaque psoriasis received TREMFYA. Of these, 1393 subjects were exposed to TREMFYA for at least 6 months and 728 subjects were exposed for at least 1 year. Data from two placebo- and active-controlled trials (PsO1 and PsO2) in 1441 subjects (mean age 44 years; 70% males; 82% white) were pooled to evaluate the safety of TREMFYA (100 mg administered subcutaneously at Weeks 0 and 4, followed by every 8 weeks). *Weeks 0 to 16:* In the 16-week placebo-controlled period of the pooled clinical trials (PsO1 and PsO2), adverse events occurred in 49% of subjects in the TREMFYA group compared to 47% of subjects in the placebo group and 49% of subjects in the U.S. licensed adalimumab group. Serious adverse events occurred in 1.9% of subjects in the TREMFYA group (6.3 events per 100 subject-years of follow-up) compared to 1.4% of subjects in the placebo group (4.7 events per 100 subject-years of follow-up), and in 2.6% of subjects in U.S. licensed adalimumab group (9.9 events per 100 subject-years of follow-up). Table 1 summarizes the adverse reactions that occurred at a rate of at least 1% and at a higher rate in the TREMFYA group than in the placebo group during the 16-week placebo-controlled period.

Table 1: Adverse Reactions Occurring in ≥1% of Subjects through Week 16 in PsO1 and PsO2

	TREMFYA[a] 100 mg N=823 n (%)	Adalimumab[b] N=196 n (%)	Placebo N=422 n (%)
Upper respiratory infections[c]	118 (14.3)	21 (10.7)	54 (12.8)
Headache[d]	38 (4.6)	2 (1.0)	14 (3.3)
Injection site reactions[e]	37 (4.5)	15 (7.7)	12 (2.8)
Arthralgia	22 (2.7)	4 (2.0)	9 (2.1)
Diarrhea	13 (1.6)	3 (1.5)	4 (0.9)
Gastroenteritis[f]	11 (1.3)	4 (2.0)	4 (0.9)
Tinea infections[g]	9 (1.1)	0	0
Herpes simplex infections[h]	9 (1.1)	0	2 (0.5)

[a] Subjects receiving 100 mg of TREMFYA at Week 0, Week 4, and every 8 weeks thereafter
[b] U.S. licensed adalimumab
[c] Upper respiratory infections include nasopharyngitis, upper respiratory tract infection (URTI), pharyngitis, and viral URTI.
[d] Headache includes headache and tension headache.
[e] Injection site reactions include injection site erythema, bruising, hematoma, hemorrhage, swelling, edema, pruritus, pain, discoloration, induration, inflammation, and urticaria.
[f] Gastroenteritis includes gastroenteritis and viral gastroenteritis.
[g] Tinea infections include tinea pedis, tinea cruris, tinea infection, and tinea manuum infections.
[h] Herpes simplex infections include oral herpes, herpes simplex, genital herpes, genital herpes simplex, and nasal herpes simplex.

Adverse reactions that occurred in < 1% but > 0.1% of subjects in the TREMFYA group and at a higher rate than in the placebo group through Week 16 in PsO1 and PsO2 were migraine, candida infections, and urticaria. Specific Adverse Reactions: *Infections:* Infections occurred in 23% of subjects in the TREMFYA group compared to 21% of subjects in the placebo group. The most common (≥ 1%) infections were upper respiratory infections, gastroenteritis, tinea infections, and herpes simplex infections; all cases were mild to moderate in severity and did not lead to discontinuation of TREMFYA. *Elevated Liver Enzymes:* Elevated liver enzymes were reported more frequently in the TREMFYA group (2.6%) than in the placebo group (1.9%). Of the 21 subjects who were reported to have elevated liver enzymes in the TREMFYA group, all events except one were mild to moderate in severity and none of the events led to discontinuation of TREMFYA. *Safety through Week 48:* Through Week 48, no new adverse reactions were identified with TREMFYA use and the frequency of the adverse reactions was similar to the safety profile observed during the first 16 weeks of treatment. Psoriatic Arthritis: TREMFYA was studied in two placebo-controlled trials in subjects with psoriatic arthritis (748 subjects on TREMFYA and 372 subjects on placebo). Of the 748 subjects who received TREMFYA, 375 subjects received TREMFYA 100 mg at Week 0, Week 4, and every 8 weeks thereafter and 373 subjects received TREMFYA 100 mg every 4 weeks. The overall safety profile observed in subjects with psoriatic arthritis treated with TREMFYA is generally consistent with the safety profile in subjects with plaque psoriasis with the addition of bronchitis and neutrophil count decreased. In the 24-week placebo-controlled period, combined across the two studies, bronchitis occurred in 1.6% of subjects in the TREMFYA q8w group and 2.9% of subjects in the TREMFYA q4w group compared to 1.1% of subjects in the placebo group. Neutrophil count decreased occurred in 0.3% of subjects in the TREMFYA q8w and 1.6% of subjects in the TREMFYA q4w group compared to 0% of subjects in the placebo group. The majority of events of neutrophil count decreased were mild, transient, not associated with infection and did not lead to discontinuation. **Immunogenicity:** As with all therapeutic proteins, there is the potential for immunogenicity with TREMFYA. The detection of antibody formation is highly dependent on the sensitivity and specificity of the assay. Additionally, the observed incidence of antibody (including neutralizing antibody) positivity in an assay may be influenced by several factors including assay methodology, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, comparison of incidence of antibodies to guselkumab across indications or with the incidences of antibodies to other products may be misleading. Plaque Psoriasis: Up to Week 52, approximately 6% of subjects treated with TREMFYA developed antidrug antibodies. Of the subjects who developed antidrug antibodies, approximately 7% had antibodies that were classified as neutralizing antibodies. Among the 46 subjects who developed antibodies to guselkumab and had evaluable data, 21 subjects exhibited lower trough levels of guselkumab, including one subject who experienced loss of efficacy after developing high antibody titers. Up to Week 156, approximately 9% of subjects treated with TREMFYA developed antidrug antibodies and of these subjects approximately 6% were classified as neutralizing antibodies. However, antibodies to guselkumab were generally not associated with changes in clinical response or development of injection-site reactions. Psoriatic Arthritis: Up to Week 24, 2% (n=15) of subjects treated with TREMFYA developed antidrug antibodies. Of these subjects, 1 had antibodies that were classified as neutralizing antibodies. Overall, the small number of subjects who were positive for antibodies to guselkumab limits definitive conclusion of the effect of immunogenicity on the pharmacokinetics, efficacy and safety of guselkumab. **Postmarketing Experience:** The following adverse reactions have been reported during post-approval of TREMFYA. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to TREMFYA exposure. *Immune system disorders:* Hypersensitivity, including anaphylaxis *[see Warnings and Precautions] Skin and subcutaneous tissue disorders:* Rash *[see Warnings and Precautions]* **DRUG INTERACTIONS CYP450 Substrates:** The formation of CYP450 enzymes can be altered by increased levels of certain cytokines (e.g., IL-1, IL-6, IL-10, TNFα, interferon) during chronic inflammation. Results from an exploratory drug-drug interaction study in subjects with moderate-to-severe plaque psoriasis suggested a low potential for clinically relevant drug interactions for drugs metabolized by CYP3A4, CYP2C9, CYP2C19 and CYP1A2 but the

TREMFYA® (guselkumab) injection

interaction potential cannot be ruled out for drugs metabolized by CYP2D6. However, the results were highly variable because of the limited number of subjects in the study. Upon initiation of TREMFYA in patients who are receiving concomitant CYP450 substrates, particularly those with a narrow therapeutic index, consider monitoring for therapeutic effect or drug concentration and consider dosage adjustment as needed *[see Clinical Pharmacology (12.3) in Full Prescribing Information]*. **USE IN SPECIFIC POPULATIONS Pregnancy:** Pregnancy Exposure Registry: There is a pregnancy registry that monitors pregnancy outcomes in women exposed to TREMFYA during pregnancy. Patients should be encouraged to enroll in the registry by visiting www.mothertobaby.org/ongoing-study/tremfya-guselkumab, by calling 1-877-311-8972, or emailing MotherToBaby@health.ucsd.edu. Risk Summary: There are no available data on TREMFYA use in pregnant women to inform a drug associated risk of adverse developmental outcomes. Human IgG antibodies are known to cross the placental barrier; therefore, TREMFYA may be transmitted from the mother to the developing fetus. In a combined embryofetal development and pre- and post-natal development study, no adverse developmental effects were observed in infants born to pregnant monkeys after subcutaneous administration of guselkumab during organogenesis through parturition at doses up to 30 times the maximum recommended human dose (MRHD). Neonatal deaths were observed at 6- to 30-times the MRHD *(see Data)*. The clinical significance of these nonclinical findings is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively. Data: *Animal Data:* In a combined embryofetal development and pre- and post-natal development study, pregnant cynomolgus monkeys were administered weekly subcutaneous doses of guselkumab up to 50 mg/kg (30 times the MRHD based on a mg/kg comparison) from the beginning of organogenesis to parturition. Neonatal deaths occurred in the offspring of one control monkey, three monkeys administered guselkumab at 10 mg/kg/week (6 times the MRHD based on a mg/kg comparison) and three monkeys administered guselkumab at 50 mg/kg/week (30 times the MRHD based on a mg/kg comparison). The clinical significance of these findings is unknown. No guselkumab-related effects on functional or immunological development were observed in the infants from birth through 6 months of age. **Lactation:** Risk Summary: There are no data on the presence of guselkumab in human milk, the effects on the breastfed infant, or the effects on milk production. Guselkumab was not detected in the milk of lactating cynomolgus monkeys. Maternal IgG is known to be present in human milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for TREMFYA and any potential adverse effects on the breastfed infant from TREMFYA or from the underlying maternal condition. **Pediatric Use:** The safety and efficacy of TREMFYA in pediatric patients (less than 18 years of age) have not been established. **Geriatric Use:** Of the 3406 subjects with plaque psoriasis or psoriatic arthritis exposed to TREMFYA, a total of 185 subjects were 65 years or older, and 13 subjects were 75 years or older. No overall differences in safety or effectiveness were observed between older and younger subjects who received TREMFYA. However, the number of subjects aged 65 years and older was not sufficient to determine whether they respond differently from younger subjects *[see Clinical Pharmacology (12.3) in Full Prescribing Information]*. **OVERDOSAGE** In the event of overdosage, monitor the patient for any signs or symptoms of adverse reactions and administer appropriate symptomatic treatment immediately. **PATIENT COUNSELING INFORMATION** Advise the patient and/or caregiver to read the FDA-approved patient labeling *(Medication Guide and Instructions for Use)* before starting TREMFYA therapy, and each time the prescription is renewed, as there may be new information they need to know. Hypersensitivity Reactions: Advise patients to discontinue TREMFYA and seek immediate medical attention if they experience any symptoms of serious hypersensitivity reactions *[see Warnings and Precautions]*. Infections: Instruct patients of the importance of communicating any history of infections to the healthcare provider and contacting their healthcare provider if they develop any symptoms of an infection *[see Warnings and Precautions]*. Instruction on Injection Technique: Instruct patients or caregivers to perform the first self-injection under the supervision and guidance of a qualified healthcare professional for proper training in subcutaneous injection technique. Instruct patients who are self-administering to inject the full dose of TREMFYA *[see Medication Guide and Instructions for Use]*. Instruct patients or caregivers in the technique of proper needle and syringe disposal. Needles and syringes should be disposed of in a puncture-resistant container. Advise patients and caregivers not to reuse needles or syringes. Remind patients if they forget to take their dose of TREMFYA to inject their dose as soon as they remember. They should then take their next dose at the appropriate scheduled time.

Manufactured by: Janssen Biotech, Inc., Horsham, PA 19044, USA
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For patent information: www.janssenpatents.com

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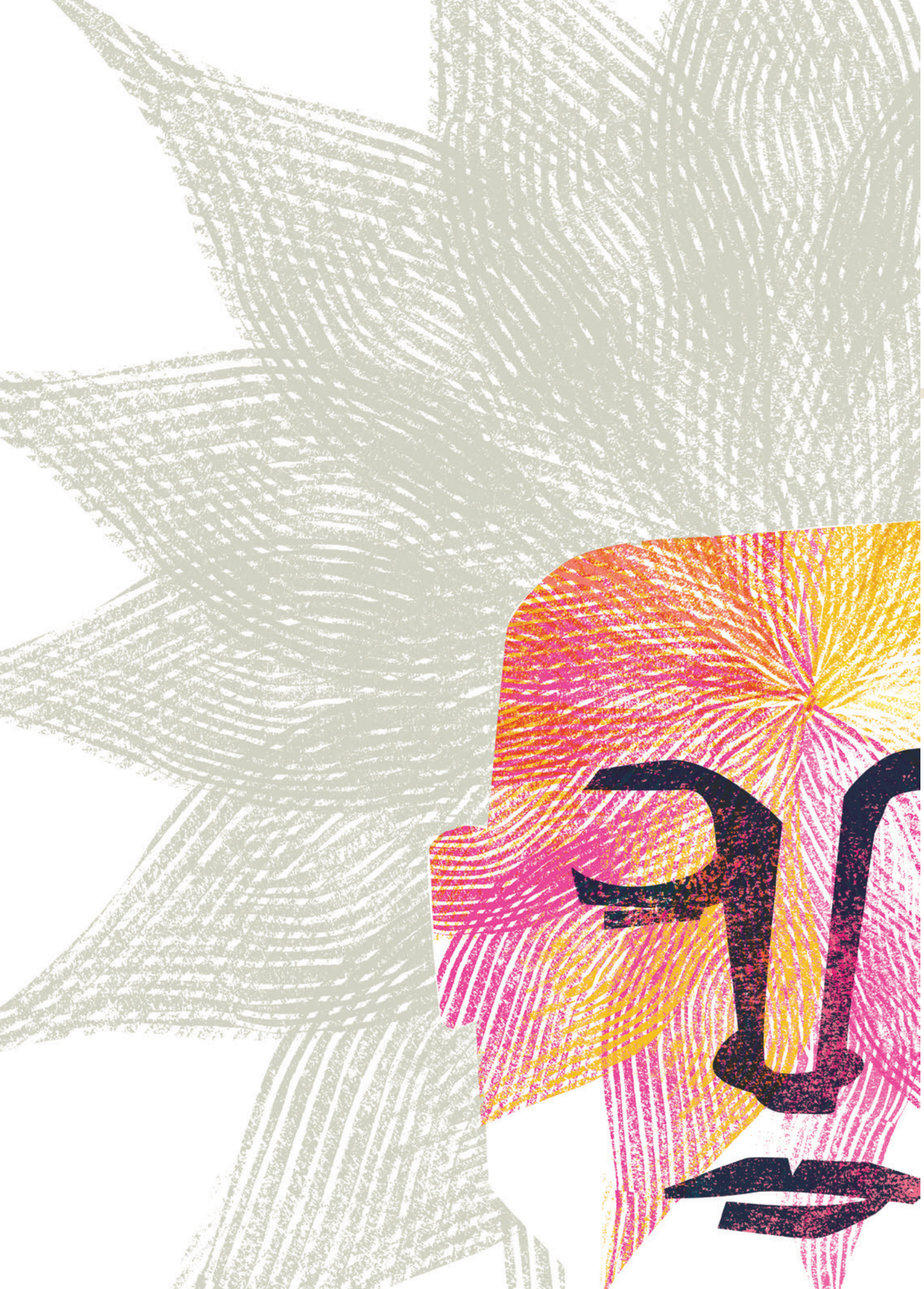

Illustration by Jing Jing Tsong

PATIENT ENGAGEMENT

Helping patients cope with PSYCHOSOCIAL CHALLENGES

Social anxiety is common in patients with psoriasis, often causing them to self-isolate, avoid social activities, feel hopeless about their condition and, ultimately, impact their ability to adhere to treatment.[1] Unfortunately, while patients may ask for help with controlling symptoms, it is less likely they will ask for help managing their mental health and social struggles. In fact, in one report by a London-based health organization, 98% of psoriasis patients in the United Kingdom said their skin disease had affected their emotional or psychological well-being, but only 18% had sought help.[2] One reason: They may not feel the severity of their situation warrants reaching out, as patients with non-life-threatening skin conditions often trivialize the impact it has on their lives, feeling they should not need psychological support for dealing with psoriasis.[1]

However, the need is obvious, with nearly half of patients with psoriasis reporting they suffer from depression and/or anxiety.[3] Patients may then turn to unhealthy ways to cope—which could help explain why people with psoriasis have a higher rate of smoking and alcohol use, as well as a greater risk of dying from alcohol-related causes, than people without psoriasis.[4]

Even mild cases can be impacted. Research suggests that prevalent drawbacks, including social stigmatization, high stress levels and employment problems, do not always correlate with disease severity.[5] That means every patient with psoriasis presents an opportunity for a clinician to have an impact on their psychosocial health, paving the way for better outcomes.

Mohammad Jafferany, MD, a psychiatrist and clinical professor of psychodermatology at Central Michigan University College of Medicine, has seen this dynamic in his own patients, explaining that patients with visible plaques often suffer. "They get embarrassed, anxious and present with very low self-esteem. They start to avoid social gatherings or going out in public places." What's more, he adds, "I have seen significant marital difficulties and even a divorce in one couple due to psoriatic lesions all over the body."

Carmen Castilla, MD, a dermatologist and clinical instructor at Mount Sinai in New York City, agrees, explaining, "I have had patients who do not want to go on job interviews or go out with their friends due to their psoriasis." And it can impact things big and small. She adds, "It can even limit a person's willingness to shake hands, since people may perceive the hand psoriasis as something contagious." And every negative interaction adds up, as she explains, "The desire or perceived need to avoid social situations can exacerbate feelings of shame and depression." To help patients overcome their psychosocial hurdles, Drs. Jafferany and Castilla offer these suggestions.

Help them connect.

Ensuring a patient has a strong support system that includes other psoriasis patients is key. Dr. Jafferany explains, "Supportive therapy, group therapy and patient support groups have substantially improved outcomes for stigmatized psoriasis patients. When a patient with psoriasis sees another patient suffering from the same ailment and psychosocial challenges, they feel that they are not alone, and many other people share the same feelings."

Dr. Castilla echoes this idea, explaining, "Having similar experiences can help someone feel understood." That understanding can help alleviate some of the burden patients feel when meeting new people. "There is often a significant amount of explaining people have to do about their psoriasis. It can be a relief to not have to explain anything when other people have the same condition," she says. Where she sends patients to connect: The National Psoriasis Foundation (*psoriasis.org*) and the Psoriasis and Psoriatic Arthritis Alliance (*papaa.org*).

Arm them with knowledge.

Coming with facts about psoriasis can make any conversation go a little more smoothly for patients. Explains Dr. Jafferany, "Basic

understanding of their disease, its lack of contagiousness, the role of stress in aggravating the lesions and the benefits of modern treatment approaches can make patients more comfortable in discussing their psoriasis with others."

This can be especially helpful in tricky situations like dating. Dr. Castilla explains, "When becoming intimate with a new partner, inverse psoriasis, which affects the genitals, can be especially anxiety provoking. Explaining psoriasis as a chronic noncontagious autoimmune condition helps answer any questions and alleviates anxiety around the situation." The key? To have the conversation before the intimate moments so new partners can get information that they feel they need without interrupting the moment–minimizing the chances of a negative experience for the patient.

Whether or not a patient wants to disclose their condition at their workplace is a personal choice, says Dr. Castilla, "However, a conversation with an employer about having a chronic autoimmune condition can help provide a supportive working environment." Her advice? "There is no need to overshare, but providing facts relevant to your workplace can help alleviate stress around flare-ups and allow for you to receive the accommodations you may need," she says, such as helping to ensure a patient has a humidifier at their desk. Additionally, if a patient is comfortable telling colleagues about their condition, it may eliminate the concern that people around them will jump to conclusions about the contagiousness of their plaques.

Screen for mood disorders and urge counseling.

With instances of depression in psoriasis so high and so much stigma surrounding it, the Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA) treatment guidelines state that, "Screening for mood disorders should be part of the standard clinic review and patients should be referred for diagnosis and for psychological support as appropriate."[6] Dr. Jafferany says that he's seen that advising a patient to seek counseling is worth it. "Depression and anxiety are easily treatable and significantly improve the self-esteem and their depression and anxiety symptoms."

Therapy may also help their treatment plan. One meta-analysis found that 64% of patients treated with cognitive behavioral therapy along with medication achieved 75% improvement in their psoriasis vs. 23% of patients treated with medication alone.[7] All the more reason to refer them to a mental health professional–and let them know their condition is worthy of seeking help.

Head off feelings of helplessness.

Patients who feel like they've tried everything and retreat because they feel like no one understands the reality of living with their condition can benefit from empathy and reassurance. One place Dr. Castilla starts is by reminding patients that "there has been a significant amount of media coverage about psoriasis in the past few years, which has improved the general population's awareness and understanding of the condition." This can help reduce the stigma in the general public–and also help in reducing the patient's shame and embarrassment.

Dr. Castilla also finds keeping a positive attitude about treatment is helpful. "I remind patients that over the past 5 years, there have been an incredible number of new psoriasis treatments coming to market." So patients have every reason to be hopeful that if the first few therapies they try don't work, they have other options. The attitude she brings to her patients: "Finding the right treatment can be frustrating. However, with the variety of treatment options now available or on the verge of becoming available, there is something that will work." ●

–by Beth Shapouri

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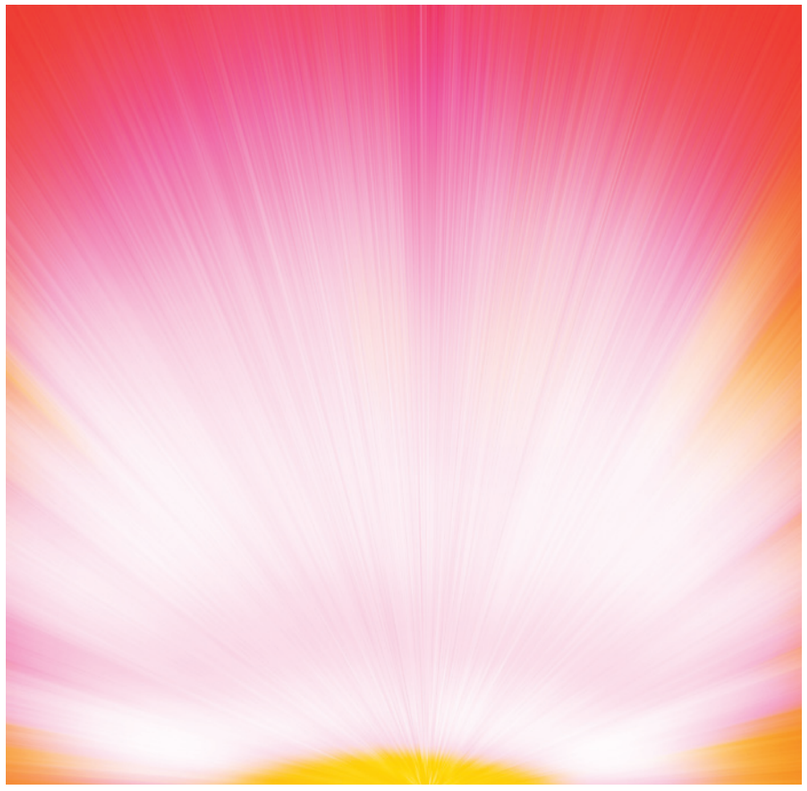
Q A

Insight on managing plaque psoriasis



Candidates for phototherapy

Q: Which patients could benefit from phototherapy and why?

A: I think phototherapy is great option for the right patient. Good candidates include those who have a large body surface area of involvement. These patients are excellent candidates for light box therapy because it is much less cumbersome than taking topicals and trying to apply them over the whole body. Phototherapy is also an excellent technique when there's involvement in the hands and feet because we have special boxes designed just for those extremities. In addition, patients who have already used a lot of topical steroids may benefit, as overuse of steroids increases the risk of skin thinning or discoloration. Patients of advanced age who are not candidates for biologics may also be candidates for phototherapy. Finally, it is a good choice for patients who have flexible schedules, since it does involve going to an office, generally two to three times a week for several months. One important caution: Phototherapy is not a great option for patients with a history of multiple skin cancers, as some forms of UV light can increase the risk of recurrence.

*–**Sonya Kenkare, MD,** Director of Dermatology, Rush University Medical Group; Assistant Professor, Rush University Medical Center, Chicago*

Partnering with patients

Q: How do you establish a strong partnership after a patient is diagnosed?

A: The importance of creating a strong therapeutic relationship cannot be overstated. You want to convince them that you're there to help them for the long haul and will help them in their journey through this disease. I tell my patients that it may seem overwhelming, but over time it will get easier and their lives will get better." One technique I used to inspire trust in the treatment plan is to ask, "What is your psoriasis keeping you from doing?" After patients answer, I tell them that by next year at this time, they'll be able to do what they wished for. This gives them something to look forward to and the confidence that you're taking care of them as a person, not just a disease, and that you're invested in them.

*–**Lakshi M. Aldredge, MSN, ANP-BC,** nurse practitioner in the Dermatology Service, VA Portland Healthcare System, Oregon*

Avoiding flares

Q: What are common psoriasis triggers? How can patients manage them?

A: There are certain medications known to trigger psoriasis, including the withdrawal of systemic steroids and treatment with antimalarials, interferon, beta blockers, angiotensin converting enzyme inhibitors and lithium, among others. Some of these are well established triggers while others have only minimal negative impact on psoriasis and, of course, the impact varies from patient to patient. It is best to avoid those medications when possible, but occasionally we have to treat patients with psoriasis therapies to prevent those medications from causing flares. Perhaps the most common trigger is the reduction of sunlight that occurs in northern latitudes, particularly in the wintertime. While some patients rely on trips to sunny places, we have many treatments, including phototherapy and systemic therapies, to control psoriasis and maintain remission during long winters.

*–**Mark Lebwohl, MD,** Professor and Chairman Emeritus, Kimberly and Eric J. Waldman Department of Dermatology, Icahn School of Medicine at Mount Sinai*

Strategies for itching

Q: How do you help patients manage itching?

A: Itch is a tough one. Textbooks often say psoriasis is not associated with itch, but the Greek root of the word psoriasis, *psora*, actually means itch. Topical treatments—steroids, vitamin D analogs and newer treatments like tapinarof cream or roflumilast cream—can help with itching. Occasionally, we may also prescribe oral antihistamines to help improve sleep quality if itch is interfering with that. In addition, topical therapies such as shampoos, lotions and creams that include coal tar can be beneficial for reducing inflammation, which subsequently lowers itch, especially for psoriasis on the scalp.

I also encourage gentle skin care, with a focus on hydrating the skin by using a humidifier, moisturizing a couple times a day and taking lukewarm showers. Very hot or very cold showers can feel good, but they strip the skin of its natural oils, often leaving it more dry or itchy after bathing, and we want to avoid that. In general, we find that when psoriasis is under good control, the itch subsides, too. Itch is usually directly related to how poorly psoriasis is controlled.

*–**Sonya Kenkare, MD***

Illustration by Jose A. Bernat Bacete / Getty Images

Special thanks to our medical reviewer:
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Professor and Chairman Emeritus, Kimberly and Eric J. Waldman Department of Dermatology, and Dean for Clinical Theraputics, Icahn School of Medicine at Mount Sinai

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Clinician Update

EXAM TOOL

PLAQUE PSORIASIS ASSESSMENT

Moderate-to-severe plaque psoriasis not only causes debilitating skin symptoms, it also impacts every area of a patient's life, from their ability to work to the quality of their personal relationships. To assess how well a patient's treatment plan is working, consider the following criteria to gauge symptom severity and patient satisfaction.

ASSESS DISEASE ACTIVITY:

1. How much of body surface area (BSA) is affected (palm of hand=1% BSA)?

	CLEAR OR MINIMAL	SOME CLEAR SKIN	WIDESPREAD
Scalp/hairline	☐	☐	☐
Face/neck/ears	☐	☐	☐
Arms	☐	☐	☐
Hands/fingers/fingernails	☐	☐	☐
Chest/abdomen	☐	☐	☐
Back/shoulders	☐	☐	☐
Genital area	☐	☐	☐
Buttocks/thighs	☐	☐	☐
Knees/lower legs	☐	☐	☐
Feet/toes/toenails	☐	☐	☐

2. Rate the severity of lesions:

	SLIGHT/MILD	MODERATE	SEVERE OR MARKED	VERY SEVERE OR VERY MARKED
Erythema	☐	☐	☐	☐
Induration	☐	☐	☐	☐
Scaling	☐	☐	☐	☐

ASK THE PATIENT:

1. Since your last visit, how often have you experienced the following:

	RARELY	SOMETIMES	OFTEN	ALWAYS
Flaky patches	☐	☐	☐	☐
Itching	☐	☐	☐	☐
Cracked or bleeding skin	☐	☐	☐	☐
Scalp flaking	☐	☐	☐	☐
Depression/anxiety	☐	☐	☐	☐

2. Are you satisfied with:

	YES	NO	SOMEWHAT
How your skin looks	☐	☐	☐
Your ability to work	☐	☐	☐
Your social life	☐	☐	☐
Your sex life	☐	☐	☐
Your ability to travel/pursue hobbies	☐	☐	☐