Health Monitor®

Clinician Update

Psoriatic Arthritis

Scan here for a behind-the-scenes look at the case study on p. 20

When first-line therapy fails:

INSIGHT ON IL-23 INHIBITORS AS A SECOND-LINE BIOLOGIC

Many patients do not respond to initial treatment, yet early control of PsA is crucial—making the second-line choice key for achieving minimal disease activity.

The stakes are high when treating patients with psoriatic arthritis (PsA). The disease progresses from skin lesions to joint pain within 10 years for many patients,[1] and structural joint damage can manifest within 2 years of onset of initial symptoms for some.[2] Aggressive PsA activity can lead to increased healthcare costs, diminished quality of life, disability and mortality.[3,4]

Slowing disease activity early is critical to preserving patients' independence and improving long-term outcomes.[2] But achieving control in PsA can be challenging, given the disease's aggressive nature and its assault on multiple domains. As many as 40% of patients with PsA do not respond to first-line treatment,[5] and between 30% and 40% do not achieve minimal PsA disease activity despite long-term treatment.[6]

This makes the choice of second-line therapy crucial. "It really comes down to what your treatment goals are for any given patient," says Philip Seo, MD, MHS, Associate Professor in the Division of Rheumatology at Johns Hopkins University School of Medicine. "Remember that psoriatic arthritis consists of six domains: peripheral arthritis, axial arthritis, dactylitis, enthesitis, psoriasis and nail involvement. When selecting a treatment, you have to consider which of these domains is most important to the patient. It can be particularly challenging to find a treatment that works for both the cutaneous and the joint manifestations of psoriatic arthritis."

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Illustration by Matt Chinworth

2018 ACR/NPF guidelines: still valuable but not up to date

The American College of Rheumatology (ACR) and National Psoriasis Foundation (NPF) recommend TNF inhibitors, which halt inflammation by blocking TNF activity and suppressing the immune system, as first-line treatment for PsA and as second-line for patients who have failed an oral medication such as methotrexate, sulfasalazine, apremilast, hydroxychloroquine and azathioprine, known collectively as oral small molecules (OSMs).[3]

However, the guidelines note that other biologics may be considered first line over a TNF inhibitor. For example. IL-17 inhibitors can be considered in some situations in patients who have severe psoriasis or desire less frequent dosing.

In addition, IL-12/23 inhibitors may be considered instead of a TNF inhibitor or IL-17 inhibitor for either first- or second-line therapy for patients who have severe psoriatic disease activity, want less frequent dosing or have a comorbidity for which the agent is indicated (e.g., Crohn's disease or ulcerative colitis).

For second-line therapy, the ADA/NPF guidelines recommend an IL-17 inhibitor or IL-12/23 inhibtor for patients who have not responded to either a TNF inhibitor or OSM. However, since thepublication of the 2018 ADA/NPF guidelines, agents in another biologic class, IL-23 inhibitors, have been FDA approved for treating active PsA.

"Remember that psoriatic arthritis consists of six domains... when selecting a treatment, you have to consider which of these domains is most important to the patient."
—Philip Seo, MD, MHS

2021 GRAPPA guidelines: more comprehensive

IL-23 inhibitors are included in the recommendations for treating active PsA in the 2021 guideline updates from the Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA), an international organization of clinical PsA and psoriasis thought leaders. GRAPPA supports the use of all biologics approved for PsA (Il-17, IL-12/23 and IL-23 inhibitors) in early-line therapy.[7] But whereas the 2018 ADA/NPF recommendations are based on disease activity and tolerability or effectiveness of previous or alternative therapies, GRAPPA offers treatment guidelines by disease domain, recommending that clinicians assess disease activity in each domain and take into account comorbidities, previous therapies and patient preference when planning treatment.[7] "This is probably the resource most people should be using at this point," Dr. Seo says.

However, Dr. Seo adds, "The overall framework of the 2018 guidelines is still valuable. The guidelines discuss the importance of nonpharmacologic therapies and definitions for severe psoriasis and psoriatic arthritis, which can be used to frame discussions with patients."

IL-23 inhibitors: safe and effective in multiple domains

The 2021 GRAPPA treatment recommendations for PsA include "strong recommendations for IL-23 inhibitors for all domains in PsA, with the exception of dominant axial disease."[7] This is based on robust clinical trial data that led to the FDA approval of certain IL-23 inhibitors for treating PsA.[2] Some key highlights from the trials:

- ***Improvement in signs and symptoms of active PsA.*** In double-blind, randomised, placebo-controlled phase 3 trials, Il-23 inhibitors were safe and effective for treating PsA in adults, with significant proportions of patients achieving at least an ACR20 response (overall 20% improvement in joint disease) after 24 weeks.[7-10]
- ***Improvement in skin, enthesitis and dactylitis.*** Clinical trial data also showed that IL-23 inhibitors work in multiple domains, a key consideration in the GRAPPA guidelines. In addition to joint disease, IL-23 inhibitors were effective for improving skin manifestations of psoriasis as well as enthesitis and dactylitis after 24 weeks.[7-10]
- ***Effective after TNF failure.*** Double-blind, randomized placebo-controlled phase 3 trials have also confirmed that IL-23 inhibitors are safe and effective for improving active PsA in patients who were biologic-naïve as well as patients in whom TNF inhibitor therapy failed.[7,11]

Considerations when starting IL-23 therapy

As with any disease-modifying therapy for PsA, before initiating treatment with an IL-23 inhibitor, assess patients for contraindications, test for tuberculosis infection and make sure they are up to date on all CDC-recommended immunizations.

IL-23 inhibitors carry no black box warning in contrast to TNF inhibitors, which have a warning to use cautiously in patients with a history of malignancy. Although data on the link between TNF blockers and cancer occurrence or re-occurrence are mixed,[12,13] Dr. Seo notes that no association with recurrent malignancy has been found with the interleukin-targeting biologics.

However, Dr. Seo points out that data on the safety of IL-23 inhibitors during pregnancy and lactation are limited. "For women who may be contemplating pregnancy, discuss this uncertainty upfront with the patient prior to starting these agents," Dr. Seo says. In addition, patients who are needle-averse, are naïve to parenteral agents or have responded poorly to self-administered parenteral drugs might not respond well to taking either a TNF inhibitor or an IL-23 inhibitor.

That said, in patients who are good candidates for an IL-23 inhibitor, Dr. Seo suggests keeping in mind the following:

- ***Re-assess the patient's symptoms.*** Confirm that you're treating psoriatic arthritis and not some other form of musculoskeletal pain or fibromyalgia. "Long-standing pain may lead to central sensitization, which can be challenging to treat," Dr. Seo notes.
- ***Discuss dosing frequency.*** IL-23 inhibitors are administered every 8 to 12 weeks, rather than every 1 to 2 weeks for many other biologic agents. "This frequency can make IL-23 inhibitors very attractive for some patients," Dr. Seo says. ►

Illustration by Matt Chinworth

- ***Ease administration concerns.*** Patients who are needle-averse or have never taken parenteral agents may be anxious about starting an injectable biologic. For patients who are reluctant, Dr. Seo suggests bringing them into the office for their first injection so you can walk them through the process. "Patients may be surprised by how autoinjectors truly do automate the process, so they never actually see the needle," he notes.
- ***Remind them to be patient,*** as some people do not respond within 4 weeks of starting an IL-23, and patients may continue to respond over time. "It may take the skin longer to respond to an IL-23 inhibitor than to other biologic agents, so alert patients that they may need at least a few months of therapy before they see the desired response," Dr. Seo says.

"This [dosing] frequency can make IL-23 inhibitors very attractive for some patients." —*Philip Seo, MD, MHS*

Illustration by Matt Chinworth

- ***Screen for mood disorders,*** as depression may also aggravate pain symptoms and hinder treatment adherence. Roughly one-third of patients with PsA grapple with depression and anxiety, and both mental disorders have a bidirectional association with pain.[14] Refer them to a mental health specialist if necessary.
- ***Assess their weight.*** "Obesity can make treatments less effective than they would be otherwise, while weight loss alone may make some treatments more effective," says Dr. Seo, as studies indicate patients with PsA and obesity may have higher disease activity and poorer response to biologic treatment.[15] Dr. Seo adds that such patients may benefit from referral to a weight-loss specialist or nutritionist.
- ***Thoroughly document prior treatment failures,*** Dr. Seo advises, to facilitate insurer prior authorizations. Once the patient begins an IL-23, it is equally important to document ongoing treatment response. "When a patient is doing well, we may forget to include this documentation in our notes, but some insurers will look for a statement confirming continued response to a current therapy before deciding to keep approving it," Dr. Seo says. And for patients who have a substantial copay, he adds, "in many cases, the manufacturers have patient assistance programs that can help cover part of these costs." ●

–by Pete Kelly

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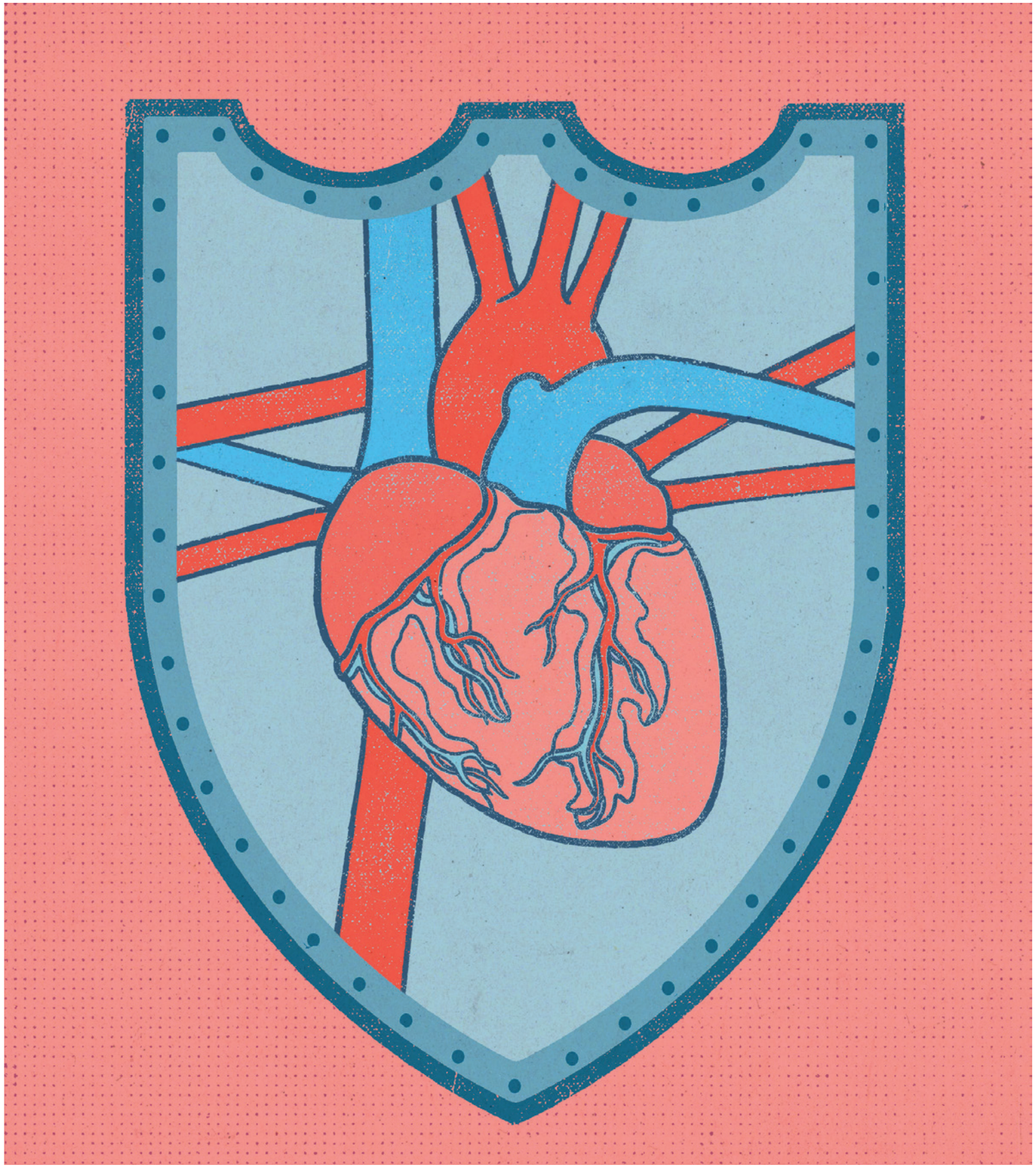

Illustration by Dan Page

PRACTICE PEARLS

REDUCING CVD RISK IN PATIENTS WITH PsA

Having psoriatic arthritis (PsA) puts patients at risk for more than inflamed joints and itchy skin: Research shows they are also up to 50% more likely to develop cardiovascular disease (CVD) vs. those without the disease. In fact, several major guidelines recommend that a patient's PsA treatment plan include CVD risk prediction and prevention strategies.[1]

Such recommendations are especially crucial in light of a 2022 population-based study of people with at least one autoimmune disease vs. matched controls. Results showed that the incidence of CVD was 1.5 to 3.5 times higher in people with autoimmune disease, and they had a twofold higher risk of developing CVD before the age of 65, suggesting that the burden of inflammation accumulates with time.[2]

In addition, patients with PsA are more likely to have metabolic disorders that increase their cardiovascular risk, notes Michael S. Garshick, MD, a cardiologist at NYU Langone Health who has training in and a research focus on inflammatory conditions, particularly psoriatic disease. Dr. Garshick notes that studies have shown that CVD, metabolic syndrome, diabetes, psoriatic disease, obesity and overweight all run together, and they are all related to inflammation.

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Likewise, a patient's CVD risk increases as the severity of their skin disease increases. "A tiny plaque on the scalp is different than severe PsA," says Dr. Garshick. "We are still trying to figure out the specific mechanism. The same inflammatory process in skin and joints may be happening in blood vessels," he says, as research shows the immune response that causes psoriatic disease is associated with vascular inflammation and atherosclerosis development.[1]

Whatever the causal connection, Dr. Garshick stresses the importance of not only controlling PsA but also the accompanying risk for CVD. Here, he offers a three-pronged approach for helping to ensure maximum cardioprotection for patients with PsA.

1. Education

Studies shown there is a significant lack of awareness of the relationship between psoriatic disease and CVD.[3] "More education needs to be made available on the patient side," Dr. Garshick says, adding that dermatologists, rheumatologists and cardiologists are aware of the link and the many major guidelines that highlight this connection. But physicians may be pressed to include this in the long list of issues patients need to consider. "There is so much to talk about with PsA that some doctors may not want to add, 'Oh, by the way, you are also at risk for cardiovascular disease.' " explains Dr. Garshick. Along with simply alerting patients to their increased risk for CVD, here are other points of discussion:

Explain that controlling PsA and CV risk require separate strategies. Despite the clear link between psoriatic disease and CVD, it is less clear if treating PsA decreases CV risk. A study led by Dr. Garshick found that while data suggest treatment for psoriasis reduces vascular inflammation and coronary plaque burden and may reduce CV risk, placebo-controlled trials are inconclusive to date. He notes that further studies are needed to define CV risk factor goals, the optimal role of lipid-lowering and antiplatelet therapy in inflammatory disease and whether targeted PsA therapies can lower CV risk.[1] Adds Dr. Garshick: "That makes it more important to control the things you can control."

> "The same inflammatory process in skin and joints may be happening in blood vessels. We are still trying to figure out the specific mechanism."
> *–Michael S. Garshick, MD*

Urge them to have regular primary care visits. "Patients should prioritize seeing their primary care provider for basic health screenings," says Dr. Garshick. "Many don't even know if they have high blood pressure, high blood sugar, high cholesterol and other risks for cardiovascular disease. Their PCP can diagnose those things, and thankfully all are very treatable."

2. Lifestyle counseling

Dr. Garshick acknowledges that rheumatologists are not necessarily experts in nutrition, exercise and weight loss. But there are steps you can take to encourage patients to adopt a heart-healthy lifestyle. For example:

Take a brief history. "We do lifestyle counseling," Dr. Garshick says. "I take a diet and exercise history at the first visit, similar to a medical or family history. "We talk about heart health goals and what activities are beneficial."

Offer simple dietary tips. Dr. Garshick gives patients simple ways to adopt a healthy eating plan:

- "Look at your plate; make it half veggies, at least one-quarter protein and the rest carbohydrates," he says. "That helps get you a lower overall calorie content, with more nutritional density and fiber."
- When snacking, "reach for fruits and veggies, not processed food. Not only are these snacks healthier, their high-fiber, nutrient-dense calories are also more satisfying."
- Avoid alcohol, which contains empty calories.

Discuss increasing physical activity. "Just walking more is good," Dr. Garshick says, adding that walking 30 minutes a day, three or more times a week, can have a significant impact on cardiac health. Other tips he offers patients: When at work or shopping, park farther away from the door to increase steps, and take the stairs instead of the escalator or elevator. For patients with active joint disease in whom weight-bearing activity is painful, water aerobics and other pool exercises may be more tolerable. Referral to a physical therapist may also be warranted

Advise consultation with a specialist. "I also suggest nutrition and weight-loss counseling," says Dr. Garshick, who advises patients talk with their primary care providers, as they address these topics more often and can connect patients with resources and experts, such as a dietitian, behavioral therapist or endocrinologist.

3. Pharmacotherapy

The treatments are well established: statins to lower cholesterol, medications to control blood pressure and blood sugar and, if indicated, newer drugs that can help with weight loss. However, making sure patients are prescribed, and adhere to, these medications can be a challenge. A few suggestions from Dr. Garshick:

Remind them to seek treatment. Dr. Garshick reiterates that the first step to being prescribed the proper medication is identifying a patient's risk factors. "A lot of PsA patients have unrecognized CVD. Their blood pressure may be 140 or 150 [systolic], but that may not be recognized as needing treatment because they are more concerned with their skin disease," he says. "They may not be getting lipids or AlC checked. They think seeing a dermatologist is enough."

Probe for reluctance to take medication. Of course, patients should follow their regimens carefully. Some, however, may be especially resistant to taking a statin due to fear of side effects such as muscle pain. Dr. Garshick tries to allay those concerns by stressing that side effects are rare and trying a different statin may be the answer if they occur.

He also points out a recent study that showed no difference in symptoms between taking a statin and a placebo.[4] The upshot: Clinicians and patients should not interpret symptom intensity or timing of symptom onset as indicating pharmacologic causation, because the pattern is identical for placebo. And if taking a statin is the cause: "I tell them that statins are very safe to retry if they had issues," Dr. Garshick says. "We can get you on something."

Suggest they see a cardiologist. A personalized approach to treatment helps, says Dr. Garshick, and assessment by a specialist can be more convincing than a visit with their PCP. For example, he says, "We can start adding in medications slowly. We can also do calcium scores or angiograms to try to give patients good reasons to be on these medications." ●

–by David Levine

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INDICATIONS

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

FOR ADULTS WITH ACTIVE PsA

Know the Tremfya® (guselkumab) difference

Explore the data across multiple domains of active PsA

Scan to view the data

Primary Endpoint: At Week 24, adult patients with active PsA receiving TREMFYA® demonstrated a greater clinical response in ACR20 compared to placebo, in both the **DISCOVER 1** (52% vs 22%) and **DISCOVER 2** (64% vs 33%) trials, respectively (*P*<0.0001).[1-3]

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 see the Brief Summary of full Prescribing Information and Study Designs within this ad.

cp-82625v3

References **1.** TREMFYA® (guselkumab) [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. **2.** Mease PJ, Rahman P, Gottlieb AB, et al. Guselkumab in biologic-naïve patients with active psoriatic arthritis (DISCOVER 2): a double-blind, randomized, placebo-controlled phase 3 trial. *Lancet*. 2020;395(10230):1126-1136. **3.** Deodhar A, Helliwell PS, Boehncke W-H, et al. Guselkumab in patients with active psoriatic arthritis who were biologic-naïve or had previously received TNFα inhibitor treatment (DISCOVER 1): a double-blind, randomised, placebo-controlled phase 3 trial. *Lancet*. 2020;395(10230):1115-1125.

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 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.

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Study Designs

DISCOVER 1 and DISCOVER 2 were phase 3, multicenter, randomized, double-blind, placebo-controlled studies evaluating the efficacy and safety of TREMFYA® administered q8w subcutaneously after starter doses at Week 0 and Week 4 (n=127 and n=248, respectively) or placebo (n=126 and n=246, respectively), with starter doses at Week 0, and then every 4 weeks in patients with active PsA (fulfilling ClASsification criteria for Psoriatic ARthritis [CASPAR]) despite standard therapies (nonbiologic disease-modifying antirheumatic drugs [DMARDs], apremilast, and nonsteroidal anti-inflammatory drugs [NSAIDs]). A stable dose of 1 selected nonbiologic DMARD, corticosteroids, and NSAIDs was permitted but not required. In DISCOVER 1, eligible patients (≥18 years of age) had active PsA (swollen/tender joints ≥3, C-reactive protein [CRP] ≥0.3 mg/dL) for at least 6 months and included patients with prior biologic experience of ≤2 anti-tumor necrosis factor alpha (TNFα) treatments. Patients with other inflammatory diseases and those who had previously received Janus kinase (JAK) inhibitors or biologics other than TNFα inhibitors were excluded. In DISCOVER 2, eligible patients (≥18 years of age) had active PsA (swollen/tender joints ≥5, CRP ≥0.6 mg/dL) for at least 6 months and no prior JAK inhibitor or biologic experience. At Week 16, patients in all treatment groups who had <5% improvement from baseline in both swollen and tender joint counts were considered as meeting early escape criteria and were allowed to initiate or increase the dose of one of the permitted concomitant medications up to the maximum dose allowed. The primary endpoint in DISCOVER 1 and DISCOVER 2 was ACR20 response at Week 24.[1-3]

Illustration by Matt Chinworth

PATIENT ENGAGEMENT

OVERCOMING BARRIERS TO TREATMENT ADHERENCE

Experts discuss the most common obstacles and how you can help patients stay on track with their treatment plan—and in turn build a more effective partnership.

CONTINUED ON NEXT PAGE

Managing psoriatic arthritis (PsA) comes with unique challenges for both patients and healthcare professionals. Although there are more options than ever for controlling skin and joint symptoms, research shows a range of factors can thwart treatment goals. For patients, a major impediment is lack of clarity about what the disease entails. "There are so many myths and so much misinformation," says Lakshi M. Aldredge, MSN, ANP-BC, a nurse practitioner in the VA Portland Healthcare System in Oregon. "It's a relatively common condition, but so much of the public and even some providers still don't understand the disease and the implications for it."

This lack of understanding can make it more difficult for patients to adhere to their treatment plan and adopt the lifestyle changes and coping strategies that can help improve their symptoms. What's more, uncontrolled PsA can result in permanent joint damage as well as comorbidities such as depression, cardiovascular disease and cardiometabolic disorders.[1]

The good news? A study coauthored by Aldredge found that relationship building—which includes identifying and breaking down roadblocks patients may be experiencing—is the key to success.[2] "The more healthcare providers can help patients overcome these barriers, the better their treatment outcomes will be," confirms Megan Rogge, MD, Assistant Professor at McGovern Medical School at UTHealth in Houston. Here are some of the most common obstacles and how you can help patients overcome them—and in turn build a more effective partnership.

PATIENT BARRIER:

Inaccurate perception of the disease

"Really, truly understanding the whole picture can be overwhelming," says Dr. Rogge. "It can be hard to grasp the disease burden and how much of an impact it can have," she says.

Another issue: Many patients focus more on their skin symptoms than joint symptoms, notes Erin Arnold, MD, FACR, of Arnold Arthritis & Rheumatology of the North Shore of Chicago. "People really get distracted by their skin," she says. "It is hard for them to think about taking a biologic medicine for the skin and easy to minimize the potential severity of the illness as a result."

How to overcome it: To correct this perception, says Dr. Arnold, "I tell them the skin is the window to what is happening in the rest of their body, so I emphasize how destructive inflammation can be on other parts of their body." Dr. Rogge takes a similar approach, explaining that it's a chronic autoimmune condition that raises the risk for other health problems. "It's important for patients to realize that cardiovascular events, depression and other conditions tend to occur more commonly in patients with any psoriatic disease," Dr. Rogge says. "I talk about it to make sure patients are aware of these associations and will have proper follow-up."

PATIENT BARRIER:

Lack of connection with their healthcare provider

Research suggests that healthcare providers may underestimate the impact that PsA has on a person's life versus patients' self-reported feelings of a diminished quality of life.[3] And if patients feel overwhelmed by their disease or feel their provider lacks empathy, they can "check out" and not follow their treatment plan, notes Aldredge.

How to overcome it: To prevent this, Aldredge stresses the importance of creating a strong therapeutic relationship. "You want to convince them that you're there to help them for the long haul. You will help them in their journey through this disease," she says. "I tell my patients that it may seem overwhelming, but over time it will get easier and their lives will get better."

One technique she uses to get patients on board with treatment: Ask them, "What is your disease keeping you from doing?" After they answer, she tells them that by next year at this time, they'll likely 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."

PATIENT BARRIER:

Unrealistic expectations

Dr. Rogge says that some patients may come to an appointment thinking there's a quick fix—and become impatient or even give up when the first medication they try doesn't work.

How to overcome it: Dr. Rogge clearly explains that it will take time to find the right treatment and that some insurance plans do not make it easy. There are many different options to try, she tells them, and it may take a combination of treatments to keep the disease well-controlled. "To get approval for the newer biologic drugs, insurance companies want you to try and fail everything else first," notes Dr. Rogge. "I tell my patients, 'Just be patient with us. It may take months to get approvals, but then it's great because these medications work really well.' I set those expectations early on that it's not a prescription we can simply send to a neighborhood pharmacy right away."

PATIENT BARRIER:

Insurance coverage

Concerns about the expense of biologic drugs keep many patients from seeking treatment, Dr. Rogge says. "These newer biologic agents work incredibly well, but you have to jump through hoops with insurance companies to get them covered," says Aldredge. "It can be difficult for a patient to afford even the co-pay."

How to overcome it: In her office, Aldredge says, they help patients by connecting them with assistance programs set up by the pharmaceutical companies. "Every one of the newer biologic manufacturers has these programs," she says. "It's a free service that assesses the patient's insurance status and gets them into the right channels to be able to get the drug."

PATIENT BARRIER:

Isolation

It's very easy for patients with psoriatic plaques to become cut off from other people, even within their own families. But the disease affects the whole family, not just the patient, says Aldredge.

How to overcome it: Encourage patients to bring a family member to each visit. "It's important to get someone else as a partner in treating the disease," Aldredge says. A loved one can also provide information that the patient may withhold. "A patient may say his skin symptoms don't bother him, but his wife will tell me he's wearing long sleeves and pants even on the hottest days. Or he'll say he doesn't have joint pain, but she sees that he's stiff when he wakes up," notes Aldredge. "She may tell me that he never plays with the kids anymore because it's too painful or he's too embarrassed."

All this information is important to understanding the full impact PsA has on the patient's life and developing an effective treatment plan—which the family member can help the patient adhere to. "You want to get that second set of ears and also get their commitment and support," notes Aldredge.

PATIENT BARRIER:

Depression

An extensive body of research has shown a significant link between depression and psoriatic disease.[1] "In a patient with another autoimmune condition, such as type 1 diabetes, you can't see the disease. But patients with psoriasis and psoriatic arthritis wear their disease on their skin for the world to see, which is very emotionally taxing," Aldredge says.

How to overcome it: "From the second I walk in the room, I'm looking for signs that a patient may be depressed. Do they make eye contact? What is their mood? How are they dressed?" Aldredge says. On the other hand, many of her patients self-report signs of depression. "They will say, 'I'm miserable. I don't want to be around people. I don't want to participate in life,'" she says. She refers them to a mental health provider and may also provide a prescription for an antidepressant. Therapy and medication can make a positive impact, as can improving PsA symptoms. "Once we get their symptoms controlled, they'll say, 'I didn't realize how emotionally drained I was,'" she notes. "If we get patients on the right treatment, it can really transform their lives. It's so rewarding to see that."

–by Tim Gower

"People really get distracted by their skin. It is hard for them to think about taking a biologic medicine for the skin and easy to minimize the severity of the illness."
–Erin Arnold, MD, FACR

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PATIENT: SARAH, 28, HAD A HISTORY OF PSORIATIC ARTHRITIS CHARACTERIZED BY PSORIASIS, ARTHRITIS, ENTHESITIS AND FATIGUE. AFTER INITIALLY RESPONDING TO TOPICAL THERAPIES, HER SYMPTOMS RETURNED A DECADE LATER.

"Sarah's symptoms made it difficult to perform routine daily tasks"

PHYSICIAN:
Monica Schwartzman, MD, MS
Assistant Attending Physician, Hospital for Special Surgery, Clinical Instructor in Medicine, Weill Cornell Medical College/New York Presbyterian Hospital, New York

Treatment history:
At age 14, Sarah was diagnosed with psoriasis on her scalp and elbows. Her symptoms responded at the time to topical therapies. At age 21, however, she developed wrist pain, swelling and fatigue. Sarah was treated with methotrexate, which helped her arthritis but not her psoriasis or fatigue. She stopped methotrexate after developing gastrointestinal side effects. Five years later, her joint symptoms returned. Her psoriasis remained active, and her fatigue worsened. She had no back pain, dactylitis, nail changes, uveitis or inflammatory bowel disease. Family histories included a grandmother who had ulcerative colitis and a sister who was diagnosed with breast cancer at age 28. Sarah tested positive for the BRCA1 and BRCA2 gene.

She worked as a teacher, and her constant exposure to young children increased her risk of infection. She was started on a TNF inhibitor by another provider, and I first saw her 3 months after she initiated therapy. She had some improvement in her arthritis, but her enthesitis and skin symptoms remained active, and her fatigue was particularly bothersome. Her articular symptoms were making it difficult to perform routine daily tasks, and she was embarrassed by her scalp psoriasis.

Initiating treatment:
On physical examination, Sarah had a swollen and tender left wrist, right knee and right ankle. She had bilateral lateral epicondylitis, Achilles tendinitis and psoriasis on her scalp and elbows. Given her ongoing skin and joint symptoms, I recommended switching biologics to an IL-23 inhibitor. Though Sarah did not have dactylitis, this biologic has demonstrated efficacy in treating this often recalcitrant component of psoriatic arthritis. Given Sarah's personal, genetic and family history, the safety profile of this medication was reassuring. Despite the side effects, which include hypersensitivity reactions, lab abnormalities and infections, the rate of serious infection is extremely low (less than 1% in the placebo-controlled period of the randomized clinical trials). There is no risk of inflammatory bowel disease, and there is no boxed warning for malignancy. Sarah also appreciated the convenience of every 8 weeks dosing. After 1 month, her musculoskeletal symptoms, skin symptoms and fatigue started to improve. By 3 months her symptoms had largely resolved. I followed her progress for approximately a year and a half—her skin and musculoskeletal symptoms remained well controlled.

Considerations:
This case demonstrates how psoriatic arthritis is a heterogenous disease, which can make it challenging to treat. In clinical trials, however, IL-23 inhibitors have demonstrated efficacy in treating multiple domains of this disease, including in patients who have failed prior biologic therapy. It has been shown to be effective in treating not only psoriasis and arthritis but also enthesitis and fatigue—all important aspects of Sarah's disease. For that reason, it is essential to choose a therapy that addresses as many components of a patient's disease as possible. Just as important as efficacy is safety, and IL-23 inhibitors are medications that patients can feel comfortable taking to effectively control their disease.

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

Illustration by Juhee Kim

Q

A

Insight on managing psoriatic arthritis

Illustration by Matt Chinworth

Treatment plan

Q: When deciding on a treatment option for a patient, what factors do you consider?

A: While of course there are multiple factors to weigh, initially the most relevant is how will the cost be covered as these drugs can be expensive. With that resolved, we then consider the major domain affecting the patient. Is it predominantly the skin or the joints, or specifically the spine, or really a combination of these? We also must consider the patient's sex as current data demonstrate that women and men respond differently to different subsets of medications. For example, it's been shown that women have a significantly lower efficacy and response rate with TNF inhibitors compared with men.

Another factor is pain. Medications that help with inflammation don't always alleviate pain. This is where we can get aggressive about the complementary therapies these patients should pursue and behavioral modifications they should make. I recommend physical therapy and following an anti-inflammatory diet.

*–**Erin Arnold, MD, FACR,** Arnold Arthritis & Rheumatology, North Shore of Chicago*

Addressing comorbidities

Q: What are common comorbidities in patients with PsA, and how do you manage them?

A: The systemic chronic inflammation underlying PsA means that patients with the disease are at increased risk of cardiovascular disease, inflammatory bowel disease, diabetes mellitus, obesity, metabolic syndrome, osteoporosis and ophthalmologic disease.

The primary goal of treatment is to eliminate the inflammation and work toward remission while also preventing such comorbidities. To that end, I stress the importance of adhering to the CDC-recommended annual vaccinations, shingles and COVID vaccinations; CDC-recommended cancer screenings (colonoscopy, mammography, PSA screenings); and annual eye examinations at each visit. Likewise, I routinely perform a lymphatic, pulmonary, cardiovascular, joint, and skin evaluation and ask about the patient's psychosocial status.

Surveilling for symptoms associated with CVD, depression, malignancy, lung disorders and infections is paramount in ensuring the best outcomes in patients with PsA, so at every visit, they complete an HAQ survey, and I monitor CDAI scores. I also monitor CBC, CMP, ESR or CRP every 2 months if they are on methotrexate) and every 4 months if on other therapies. Additionally, I get a TB QuantiFERON at baseline and every year thereafter.

Because infection risks are huge in the biologic-treated population, my practice uses routine monitoring as well as collaborative management with primary care providers. Patients with CV risk are referred to cardiology for baseline evaluation. And because medication adverse effects include the potential for interstitial lung disease, we perform a lung auscultation exam at each visit and order a yearly chest radiograph. Appropriate and early referrals to specialty clinics are initiated for any suspected comorbidity outside the rheumatology specialty. Often dermatology and gastroenterology are common referral sources.

*–**Susan Quisenberry, DNP, APRN, CNP, FNP-C,** Advanced Practice Specialty in Rheumatology and Clinical Professor, Texas Woman's University College of Nursing, Dallas*

Countering misconceptions

Q: What are common patient misconceptions about PsA, and how do you address them?

A: The most common misconception–which is a major barrier to treatment adherence–is that PsA only affects the skin and joints. Often, patients are referred to my office from other rheumatologists who have not taken the time to educate patients about the body-wide implications of PsA and the risks inherent in not treating it effectively. I fill the gap by explaining that in addition to leading to permanent joint damage and subsequent disability, PsA is also linked with an increased risk of heart disease and cancer. When patients are fully informed, they can better weigh the risks and benefits of taking medication.

*–**Erin Arnold, MD, FACR***

Lifestyle changes

Q: How do you counsel patients on diet and exercise?

A: I have found that discussing self-efficacy training in the first three visits is worthwhile as it promotes compliance and provides patients with a sense of partial ownership in their treatment plan. It also helps patients understand that successful outcomes include both pharmaceutical and nonpharmaceutical strategies, including lifestyle modifications.

First and foremost, if they smoke, they need to stop. Smoking alone contributes to the inflammatory cascade and diminishes pharmacologic treatment efficacy. Smoking cessation is discussed at every visit (and, yes, they still come back to see us!).

For patients with a BMI >30, I discuss the benefits of achieving and maintaining a healthy BMI and recommend they start tracking their caloric intake using the free calorie-tracking app MyFitnessPal. I also recommend they follow the Mediterranean diet, which includes fish, vegetables and fruits, and substitutes olive oil for butter, and advise taking turmeric twice daily if there are no contraindications. To keep expectations reasonable, we talk about short-term goals only, such as weight loss of 1 to 2 lbs. per week.

Regarding physical activity, the patient and I collaboratively develop a plan tailored to their likes, starting with just 5 to 10 minutes per day and working up to 150 minuntes/week or 30 minutes per day of aerobic activity. For patients with joint deformities or severe mobility issues, I recommend a structured exercise program like the YMCA yoga class, Silver Sneakers or water exercise programs.

To promote compliance, I revisit these topics at every visit. Reviewing self-efficacy strategies–and including the patient as a main stakeholder on the healthcare team–is key because we each play a major role in achieving disease remission and reduced comorbidities.

*–**Susan Quisenberry, DNP, APRN, CNP, FNP-C***

SPECIAL THANKS TO OUR MEDICAL REVIEWER:
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Cover illustration by Matt Chinworth

RPA24

Health Monitor

Clinician Update

EXAM TOOL

Psoriatic arthritis assessment

Psoriatic arthritis not only causes debilitating skin and joint 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 IS AFFECTED?

	Clear or minimal	Some clear skin	Widespread
Scalp/hairline	☐	☐	☐
Face/neck/ears	☐	☐	☐
Arms/hands/fingernails	☐	☐	☐
Chest/back	☐	☐	☐
Genital area	☐	☐	☐
Buttocks/thighs	☐	☐	☐
Knees/lower legs	☐	☐	☐
Feet/toenails	☐	☐	☐

2. RATE THE SEVERITY OF JOINT SYMPTOMS:

	Slight/mild	Moderate	Severe	Very severe
Pain	☐	☐	☐	☐
Tenderness	☐	☐	☐	☐
Redness/swelling	☐	☐	☐	☐
Stiffness	☐	☐	☐	☐

ASK THE PATIENT

1. SINCE YOUR LAST VISIT, HOW OFTEN HAVE YOU EXPERIENCED THE FOLLOWING:

	Rarely	Sometimes	Often	Always
Flaky patches	☐	☐	☐	☐
Itching	☐	☐	☐	☐
Trouble sleeping	☐	☐	☐	☐
Fatigue	☐	☐	☐	☐
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	☐	☐	☐