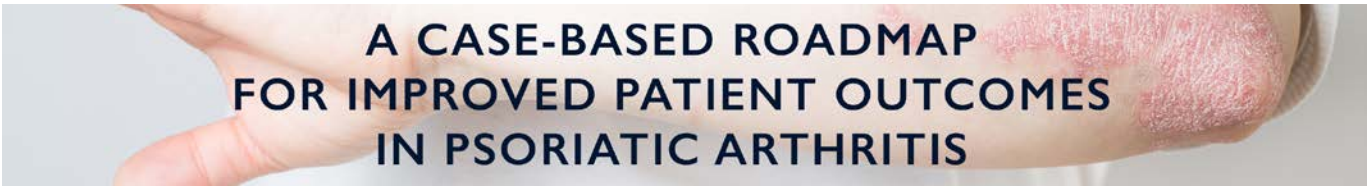

OVERVIEW

Patients with psoriatic arthritis (PsA) experience significant disease burden due to incomplete diagnostic evaluation and suboptimal use of effective therapies. In this case-based activity, Dr. Leonard Calabrese of the Cleveland Clinic addressing these practice gaps by sharing his recommendations for patient management at critical decision points in the diagnosis and treatment of patients with PsA. Dr. Calabrese also discusses the important role of shared decision-making over the course of the disease as a key strategy to individualize treatment and improve patient adherence. For each of the 3 cases, Dr. Calabrese provides a concise summary of key concepts to facilitate integration into clinical practice.

TARGET AUDIENCE

This activity was developed for Rheumatologists, dermatologists, primary care physicians, nurse practitioners, physician assistants and other healthcare providers who manage patients with psoriatic arthritis.

LEARNING OBJECTIVES

At the conclusion of this activity, participants should be better able to:

- Utilize validated tools to assess Psoriatic Arthritis (PsA) disease burden and response to treatment
- Summarize the clinical pharmacology, including mechanism of action, as well as safety and efficacy, of evidence-based medications for PsA
- Utilize a treat-to-target approach with individualized evidence-based therapy to achieve disease remission/low disease activity and reduce symptom burden
- Individualize treatment of PsA based on treatment history and comorbidities

FACULTY

Leonard Calabrese, DO
Professor of Medicine
Cleveland Clinic Lerner College of Medicine
Director, RJ Fasenmyer Center for Clinical Immunology
Cleveland Clinic
Cleveland, Ohio

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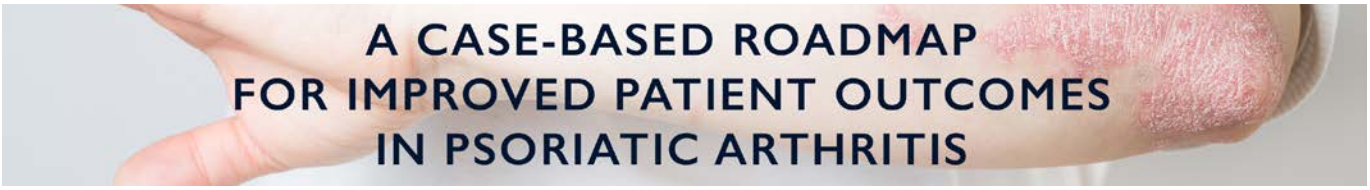

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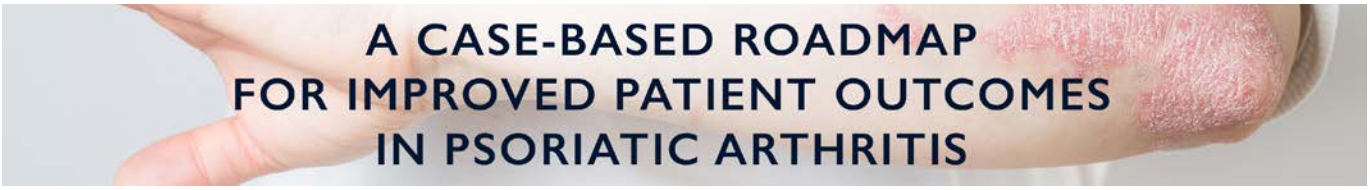


CASE SCENARIO #1

A 63-year-old woman is referred to a specialist by her primary care clinician for worsening psoriasis. A retired postal worker, her disease had been well controlled until a year or so ago, with minimal pruritus, using a topical corticosteroid. At that time, she began to experience morning stiffness that is relieved after a few minutes of routine physical activity. As needed use of a nonsteroidal anti-inflammatory drug (NSAID) provides minimal relief.

1. Based upon her history, what would you do next?
    a. Conduct a more detailed history and physical examination
    b. Order an X-ray of her spine
    c. Start an oral small-molecule drug such as methotrexate
    d. Start a tumor necrosis factor inhibitor

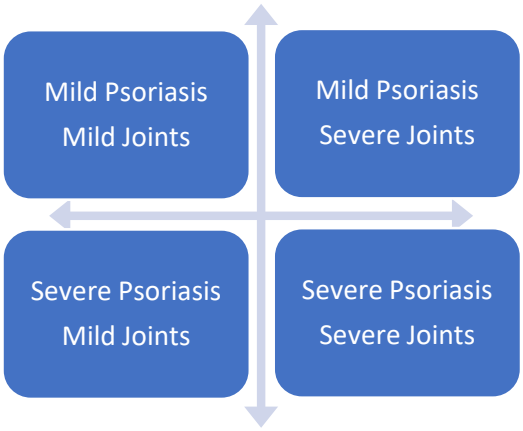
Answer: a/Conduct a more detailed history and physical examination

The limited history of this patient with psoriasis suggests that she is among the 10% to 30% of patients with psoriasis who develop psoriatic arthritis (PsA). To guide treatment, it is essential to fully characterize the nature and severity of her PsA, including both her skin disease and musculoskeletal or joint disease (**Figure** 1).[1] This is accomplished by undertaking a more detailed history and physical examination, followed by laboratory and radiologic testing as appropriate.

Figure 1. Spectrum of psoriatic arthritis.

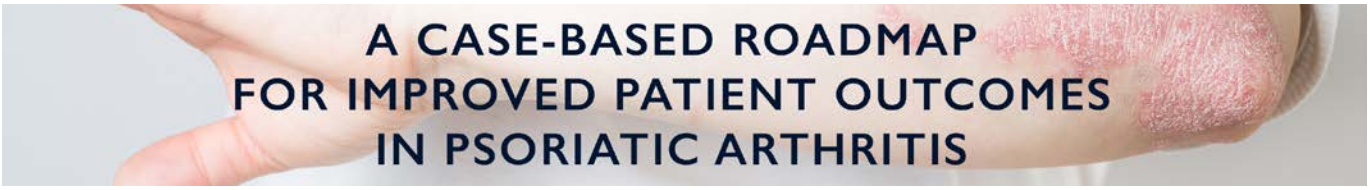
The history and physical examination should assess the following:

- Are her musculoskeletal complaints due to arthritis alone or are they due to enthesitis, spondylitis, and/or dactylitis?
- Does she have axial disease involving the spine?



    - If so, are they worse in the morning? Are they relieved by exercise (as in this patient)? Are they relieved with over-the-counter analgesics such as NSAIDs? Was the onset of symptoms gradual?

- Is her musculoskeletal disease severe?
    - Among the laboratory tests to obtain are the erythrocyte sedimentation rate and C-reactive protein level, although neither is diagnostic for PsA
    - X-ray findings showing joint erosion indicate more extensive disease
    - Severe musculoskeletal disease is generally associated with substantial limitations in activities of daily living and impaired quality of life
- What is the extent and location of skin involvement?
    - Skin involvement >3% to 5% of body surface area is considered severe disease, often requiring more aggressive therapy to achieve clear skin
    - The location of skin disease is generally very important to patients since visible disease is usually more distressing.



2. Which is the best approach to assess the disease burden?

a. Ask the patient
b. Utilize the Psoriatic Arthritis Impact of Disease questionnaire
c. Utilize the Patient-Reported Outcomes Measurement Information System
d. Utilize the Multidimensional Health Assessment Questionnaire
e. Utilize the Routine Assessment of Patient Index Data 3

Answer: a/Ask the patient

Asking the patient is a reasonable approach to be sure that the treatment goals are shared by patient and clinician. In addition, talking to the patients is important as hearing their concerns is central to developing and modifying the treatment plan. If talking to the patient does not provide sufficient insight as to the burden they experience due to PsA, using the Psoriatic Arthritis Impact of Disease (PsAID) questionnaire recently developed by the European League Against Rheumatism is helpful.[2] The PsAID is specific to PsA, provides a relatively complete picture of the PsA disease burden as it assesses 12 domains of physical and psychological functioning, and is quick and simple to perform. Each domain is assessed by a single question with patient response on a numeric rating scale 0-10, with a higher rating indicating a more severe condition. Among the 12 domains, pain carries the greatest weight.

The Patient-Reported Outcomes Measurement Information System (PROMIS) is a set of person-centered measures that evaluates and monitors physical, mental, and social health in adults and children with chronic conditions.[3] PROMIS provides patient-reported information about the effect of therapy, and when used with traditional clinical measures of health, allows clinicians to better understand how various treatments might affect what patients are able to do and the symptoms they experience.

The Multidimensional Health Assessment Questionnaire (MDHAQ) is a 2-page questionnaire intended for patients with rheumatic diseases.[4-6] It is completed by the patient and assesses 10 activities of daily living related to physical and psychological functioning. The MDHAQ can be reviewed quickly to provide a global assessment or scored formally in 20 seconds using the scoring template.

The Routine Assessment of Patient Index Data 3 (RAPID3) is a patient-reported, composite index, initially designed for rheumatoid arthritis, but found to be clinically useful in many rheumatic diseases. It appears to be comparably informative to some other measures for PsA, with greater flexibility for routine clinical care.[7]

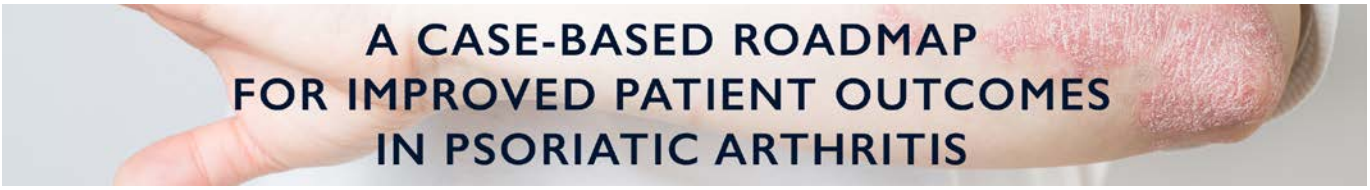
3. The presence of which 1 of the following is the most important to assess to guide treatment selection?

a. Detailed evaluation for comorbidities including cardiovascular disease
b. Computed tomographic scan of affected joints
c. HLA-B*27
d. Rheumatoid factor level
e. All are equally important

Answer: a/Cardiovascular disease

Identifying comorbidities is critical to the optimal management and treatment of patients with PsA.[8] Comorbidities may play a role in terms of impact on disease activity, as well as on the patient's functioning and quality of life.[9] Common comorbidities include cardiovascular disease, metabolic syndrome, inflammatory disease, and psychiatric disorders (Table 1).

With regard to imaging, radiographs of affected joints and the spine (if involved) should be obtained to identify the extent of joint disease. If enthesitis is suspected, ultrasonography or magnetic resonance imaging, but not computed tomographic imaging, may be useful. While radiographs provide useful information and are important for evaluation, they do not influence early treatment decisions.



HLA-B*27 testing is not diagnostic and is not recommended in patients with suspected PsA, although it may be helpful to inform prognosis, but not treatment decisions. Rheumatoid factor is generally absent in patients with PsA.

Table 1. Key comorbidities in psoriatic arthritis

- Cardiovascular disease
- Hypertension
- Obesity
- Metabolic syndrome
- Diabetes
- Ulcerative colitis
- Crohn's disease
- Uveitis
- Osteoporosis
- Malignancy
- Fatty liver disease
- Chronic kidney disease
- Depression
- Anxiety

Case scenario #1 (continued)

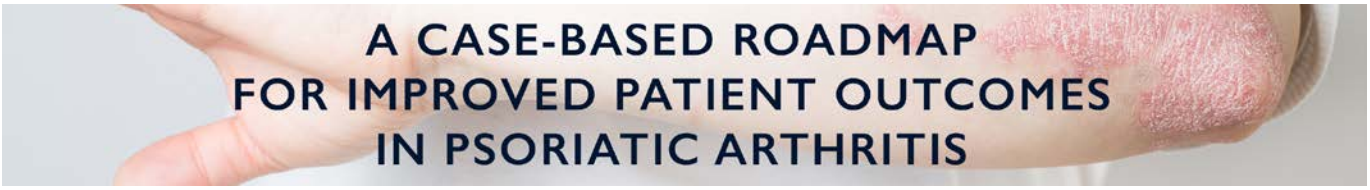
Diagnostic evaluation shows that the patient's metatarsophalangeal and metacarpophalangeal joints are tender but without swelling. There is no evidence of dactylitis, enthesitis, or spondylitis. Laboratory results show no elevated markers and imaging shows no evidence of joint bone erosion. Psoriatic lesions are confined to the elbows and trunk, involving <2% of the patient's body surface area. It is concluded that the patient has mild psoriasis and mild joint disease.

4. Which pharmacologic treatment is recommended for this patient?

a. IL-12/23 inhibitor biologic
b. IL-17 inhibitor biologic
c. Oral small molecule
d. Tumor necrosis factor inhibitor
e. Any of the above

Answer: d/Tumor necrosis factor inhibitor

According to the 2018 American College of Rheumatology/National Psoriasis Foundation (ACR/NPF) PsA guidelines, preferred pharmacologic treatment for a patient with treatment-naïve active PsA is a tumor necrosis factor inhibitor (TNFi) (ie, etanercept, infliximab, adalimumab, golimumab, or certolizumab pegol). A TNFi is preferred over an oral small molecule drug, IL-17 inhibitor biologic, or IL-12/23 inhibitor biologic.[10] An oral small molecule drug (ie, methotrexate, sulfasalazine, leflunomide, cyclosporine, or apremilast) might be preferred over a TNFi if the patient does not have severe PsA or severe psoriasis, prefers oral therapy, has concerns over starting a biologic as first-line therapy, or has a contraindication to TNFi therapy, eg, congestive heart failure, previous serious infections, recurrent infections, or demyelinating disease.[8,10] Similar recommendations have been recently developed by the European League Against Rheumatism.[11]



CASE SCENARIO #2

A 39-year-old man was diagnosed with PsA involving both hands 1½ years ago. Careful history and physical examination revealed tender wrists and swelling of 2 metacarpophalangeal joints, as well as prominent bilateral Achilles tenderness and a tender infrapatellar tendon on the right side. No axial symptoms or dactylitis were noted. Approximately 5% of the body surface area was involved, affecting the scalp, abdomen, back, and groin.

Laboratory results showed an elevated C-reactive protein (1.1 mg%).
Radiographic imaging showed no evidence of erosive disease.

Results of the Psoriatic Arthritis Impact of Disease questionnaire confirmed that the patient had severely diminished physical functioning, quality of life, and socialization.

Methotrexate was initiated and titrated to 17.5 mg/week. However, the patient's response to methotrexate was limited. Consequently, methotrexate was discontinued and the tumor necrosis factor inhibitor (TNFi) adalimumab initiated. Initial response to adalimumab was modest, so the dose was increased to 80 mg every other week. The patient achieved no additional benefit at the higher dose of adalimumab.

1. What is the goal of therapy?
    a. Achieve lowest possible level of disease activity in all domains
    b. Optimize functional status
    c. Prevent structural damage to the greatest extent possible
    d. Avoid or minimize complications from untreated active disease as well as treatment
    e. All of the above

Answer: e/All of the above

The ultimate goals of therapy for all patients with PsA are to: 1) achieve the lowest possible level of disease activity in all domains of disease; 2) optimize functional status; 3) improve quality of life and well-being; 4) prevent structural damage to the greatest extent possible; and 5) avoid or minimize complications, both from untreated active disease and from therapy.[8]

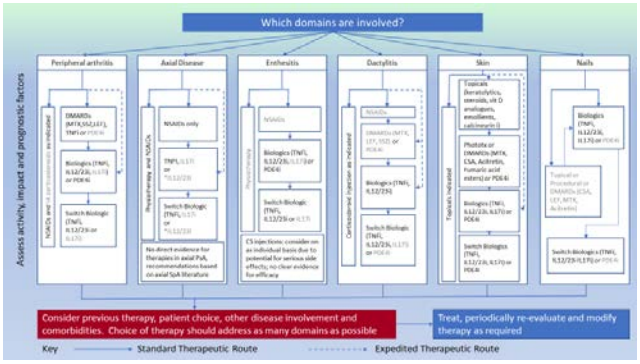
While achieving disease remission is the ideal goal, this is seldom possible in patients with PsA. Instead, a treat-to-target approach to achieve low disease activity (LDA) or minimal disease activity (MDA) is recommended.[1] Evidence supports the MDA as a valid measure of disease activity in PsA that can detect between-group and within-subject change.[12] Criteria for achieving MDA were developed by Coates et al in 2010 (**Table 2**). Formal use of MDA is uncommon in clinical practice, however. Instead, a shared decision-making approach is often utilized to engage the patient in establishing treatment goals and to select therapy to address as many of the 6 domains of PsA as possible (**Figure 2**).[8] For this patient, this would include relieving pain involving his feet, as well as addressing skin concerns and quality of life issues.

Table 2. Criteria for minimal disease activity

Must exhibit 5 of the following 7 criteria:

- Tender joint count ≤1
- Swollen joint count ≤1
- Psoriasis Activity and Severity Index ≤1 or body surface area ≤3
- Patient pain visual analog score ≤15
- Patient global disease activity visual analog score ≤20
- Health assessment questionnaire ≤0.5
- Tender entheseal points ≤1

Figure 2. GRAPPA treatment schema for active psoriatic arthritis.



Light text identifies conditional recommendations for drugs that do not currently have regulatory approvals or for which recommendations are based on abstract data only.

CS, corticosteroid; CSA, cyclosporin A; DMARDs, disease-modifying anti-rheumatic drugs; IA, intraarticular; IL-12/23i, interleukin-12/23 inhibitor; LEF, leflunomide; MTX, methotrexate; NSAIDs, nonsteroidal anti-inflammatory drugs; PDE4i, phosphodiesterase-4 inhibitor (apremilast); phototx, phototherapy; SpA, spondyloarthritis; SSZ, sulfasalazine; TNFi, tumor necrosis factor inhibitor; vit, vitamin

2. How would you modify his therapy?
   a. Initiate an oral small molecule other than methotrexate
   b. Switch to a different tumor necrosis factor inhibitor
   c. Switch to an IL-17 inhibitor
   d. Switch to an IL-12/23 inhibitor
   e. Switch to an IL-23 inhibitor

Answer: c/Switch to an IL-17 inhibitor

This patient has moderate skin disease, but severe musculoskeletal symptoms. Given the limited response to methotrexate and adalimumab, initiating another oral small molecule such as apremilast is unlikely to yield the desired goals. While a TNF inhibitor is generally effective for musculoskeletal symptoms, and the current ACR/NPF guidelines recommend switching to another TNFi[10], this patient's modest response to high-dose adalimumab suggests that switching to another TNFi may not be a good option. Moreover, medications that act via a mechanism of action different from a TNFi and are effective in reducing musculoskeletal symptoms are available.

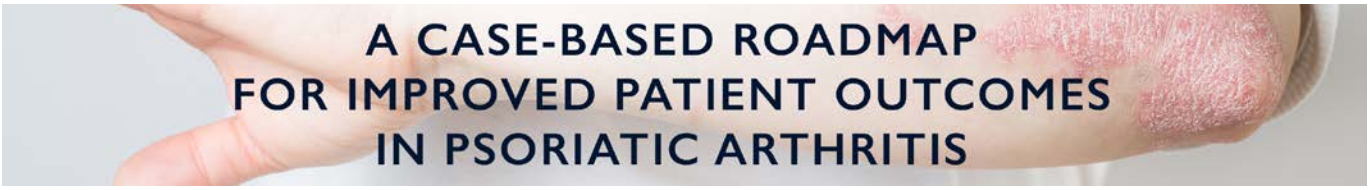
The 2018 ACR/NPF guidelines recommend switching to an IL-17 inhibitor (ixekizumab, secukinumab) over the IL-12/23 inhibitor ustekinumab, the cytotoxic T-lymphocyte-associated protein 4 (CTLA4) immunoglobulin abatacept, or the Janus kinase (JAK) inhibitor tofacitinib. The IL-17 inhibitors are highly active for psoriatic skin disease and are effective for arthritis, enthesitis, dactylitis, and axial symptoms, with a good safety profile. Tofacitinib is effective across several PsA domains in patients with an inadequate response to a TNF inhibitor[13,14] and may be considered if the patient prefers an oral therapy or in a patient with concomitant inflammatory bowel disease or a history of recurrent *Candida* infections.[10]

Limited evidence indicates the IL-12/23 inhibitor ustekinumab may be superior to a TNFi in treating enthesitis, with high activity for psoriatic skin disease and a good safety profile.[15] Ustekinumab also would be appropriate for a patient with inflammatory bowel disease.[10] The IL-23i guselkumab has shown good activity for psoriatic skin disease with less experience for the musculoskeletal symptoms observed in PsA.[16]

3. How would you modify his therapy if he had recurrent or serious infections?
   a. Switch to an IL-17 inhibitor
   b. Switch to an IL-12/23 inhibitor
   c. Switch to an IL-23 inhibitor
   d. Switch to the CTLA-4 immunoglobulin
   e. Switch to a JAK inhibitor

Answer: d/Switch to the CTLA-4 immunoglobulin

Recurrent and serious infections are a concern with most immunomodulatory therapies as reflected in the prescribing information. The CTLA-4 immunoglobulin abatacept might be preferred, but close monitoring is advised.[10]



CASE SCENARIO #3

A 47-year-old otherwise healthy woman was diagnosed with PsA 5 years ago. She had mild skin disease but more severe musculoskeletal symptoms. She was treated with MTX then etanercept for the first 3 years, at which point she was switched to an IL-17 inhibitor at a standard dose because of persistent musculoskeletal pain. Her mild skin disease responded to etanercept and IL-17 inhibitor therapy. Shortly after, she was lost to follow-up. She now returns nearly 2 years later complaining of increasing axial pain; ibuprofen provides little relief.

1. How would you proceed?
    a. Perform a thorough diagnostic evaluation
    b. Restart the same IL-17 inhibitor
    c. Begin a different IL-17 inhibitor
    d. Begin an IL-12/23 inhibitor

Answer: a/Perform a thorough diagnostic evaluation

Since it has been nearly 2 years since she was last seen and she has experienced progressive disease, before developing the treatment plan, it is necessary to perform a thorough diagnostic evaluation to identify the symptoms and disease burden she has experienced over the past nearly 2 years.

2. Which 1 of the following would be the most important to investigate in the patient's history?
    a. Assess comorbidities
    b. Tolerability to methotrexate and etanercept
    c. The reason that she stopped seeking medical care
    d. Use of complementary and alternative medicines
    e. All of the above

Answer: c/The reason that she stopped seeking medical care

The key issue to investigate is the reason(s) why she stopped seeking medical care, including no longer taking the IL-17 inhibitor. Common reasons include intolerability due to an adverse event, fear of an adverse event, discomfort with the injection, psychosocial reasons, and limitations or changes in insurance coverage. Once identified, it may be possible to resolve her concerns related to IL-17 inhibitor therapy, which is important since IL-17 inhibitor therapy is recommended for nonradiographic axial SpA.

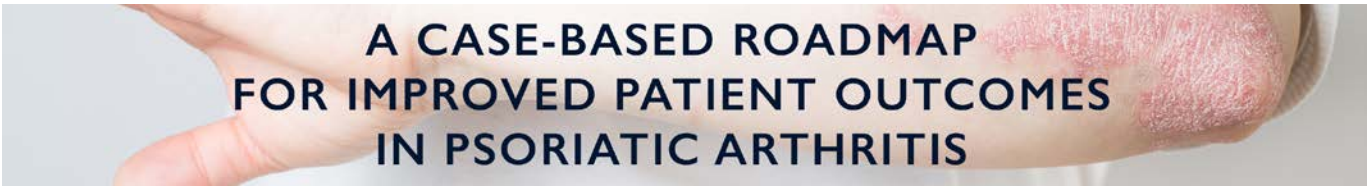
Since the patient had minimal response to methotrexate and etanercept, investigating her tolerability to these medications would serve no useful purpose. Learning about her use of complementary and alternative medicines would be of value, especially to avoid potential safety issues. Although the patient had no identified comorbidities at the time of PsA diagnosis, it would be important to assess any change in this regard.

Case scenario #3 (continued)

In addition to confirming her history prior to being lost to follow-up, the detailed history strongly suggests the presence of axial disease. She experiences morning back pain that is relieved by moving around. Over-the-counter analgesics provide little relief. She reports poor sleep, with occasional awakening during the night due to neck and back pain, and generally feeling tired when she gets up in the morning. She attributes this, and her daytime fatigue, to her neck and back pain.

Further questioning reveals that she stopped seeking medical care as a result of a change in her insurance carrier. Her new insurance carrier no longer covered the IL-17 inhibitor, which she says was effective in reducing her musculoskeletal symptoms. Consequently, she thought it a waste of time to continue with medical care.

The physical examination confirms that she has pain in her neck and thorax. She reports that her primary care clinician told her this pain was due to fibromyalgia. Her Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score is 5.5, indicating suboptimal disease control.



To determine the extent of her axial pain, a plain radiograph of the pelvis is ordered. The findings are unremarkable. She shows no evidence of synovitis or enthesitis, but has decreased lumbar flexion which is painful. She is unable to touch her toes, which she was able to do in the past. Peripheral manifestations of PsA are minimal.

The CRP is 1.3 mg%.

Based on her pain scores, presence of inflammatory back pain, physical examination, and elevated CRP level, it is concluded that she likely has nonradiographic axial spondyloarthritis (nrAxSpA). Nonradiographic axial SpA is often confused as fibromyalgia in women.

3. What would be the best way to improve patient acceptance of the treatment plan?

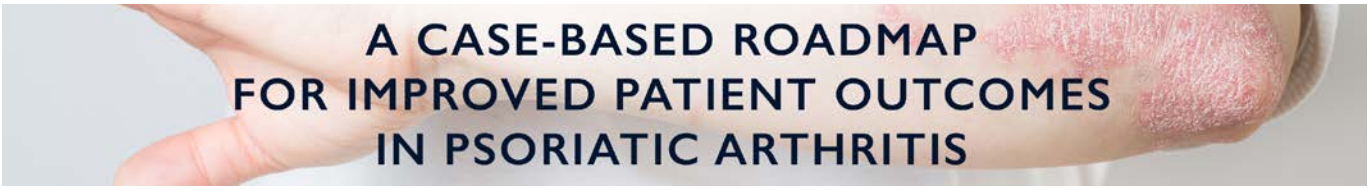
a. Agree on the composite outcome measure to assess treatment response
b. Develop the treatment plan using shared decision-making
c. Confirm insurance coverage
d. Provide a written action plan

Answer: b/Develop the treatment plan using shared decision-making

Patient willingness and ability to adhere to the treatment plan is of critical importance due to its impact on health-related outcomes and costs.[17] Treatment adherence over 12 months is, however, poor to several classes of medications utilized for PsA.[18] A validated strategy to improve treatment adherence is to utilize shared decision-making. Shared decision-making is a process wherein the clinician and patient work together to make a healthcare decision that is best for the patient. One model of shared decision-making was developed by the Agency for Healthcare Research and Quality, consisting of 5 key steps[19]:

S	eek your patient's participation
H	elp your patient explore and compare treatment options
A	ssess your patient's values and preferences
R	each a decision with your patient
E	valuate your patient's decision

Confirming insurance coverage and patient affordability, as well as providing a written action plan, are important factors that also can impact treatment adherence and should be included in the shared decision-making process. While it is important for the clinician and patient to agree on treatment goals, agreeing on the composite outcome measure to assess treatment response is not necessary. However, once a measure to assess treatment response is selected, it is best to utilize the same measure over the course of treatment.[20]



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