Project ECHO®

Individualizing Treatment Approaches in SpA Conditions:

Best Practices for Selection, Intensification, and Shared Decision-Making

MED LEARNING GROUP

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This activity is supported by an educational grant from Lilly.

PROGRAM AGENDA

I. Didactic Content Shared by Faculty Using Slides and Infographic Data

- **Overview of Evidence Supporting the Benefit and Risk Profiles of Available and Emerging Targeted Treatments for PsA and axSpA**
  - Biologics: TNFis, JAKis, and IL-17 or -12/23 inhibitors
  - DMARDs including csDMARDs and bDMARDs
  - Efficacy (e.g., ASAS40, ACR, PASI responses and MDA) and safety (e.g., most common AEs) data from clinical trials and real-world analyses
- **Best Practices for Individualizing Treatment for Patients With SpA Conditions**
  - Factors to consider for personalized selection (e.g., QoL, treatment adherence barriers, and comorbidities)
  - SDM Framework: Understanding patient preferences, perception of disease severity, improving patient-HCP communication

II. Case Study Discussion

III. Conclusions, Q&A, & Post-Test

Individualizing Treatment Approaches in SpA Conditions: Best Practices for Selection, Intensification, and Shared Decision-Making

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PROGRAM OVERVIEW

This TeleECHO series provides a comprehensive overview of current and emerging therapies for spondyloarthritis (SpA) conditions, translating the latest clinical data and guideline recommendations into practical, real-world applications for healthcare providers. Through case-based discussions led by experts in the field, attendees will learn to critically evaluate the benefit-risk profiles of different agents across diverse patient populations. The program is designed to enhance clinical decision-making skills, empowering participants to effectively implement strategies for treatment selection, modification, and intensification in accordance with established guidelines, ultimately resulting in improved patient outcomes. Additionally, shared decision-making will be discussed as an important component of designing treatment plans for patients with SpA conditions.

TARGET AUDIENCE

This activity is intended for advanced practice professionals (APPs), including physician assistants (PAs) and nurse practitioners (NPs), who care for patients with psoriatic arthritis (PsA) and radiographic or nonradiographic axial spondyloarthritis (axSpA).

LEARNING OBJECTIVES

Upon the completion of this program, attendees should be able to:

- Evaluate clinical data for current and emerging therapies for SpA conditions, including real-world and comparative data, to differentiate the benefit-risk profiles of agents across domains and sub-populations
- Describe guideline recommendations for treating patients with SpA conditions including strategies for treatment selection, modification, and intensification
- Utilize SDM and clinical considerations to individualize treatment for patients with SpA conditions

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Katherine Runyan, PA-C	Has nothing to disclose.

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Treatment Approaches in SpA Conditions: Best Practices for Selection, Intensification, and Shared Decision-Making

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Faculty Disclosures

- **Robert Laugherty** reports the following

Relationships	Manufacturer
Speakers Bureau	Amgen, BI, Lilly, UCB

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Learning Objectives

- Evaluate clinical data for current and emerging therapies for spondyloarthritis (SpA) conditions, including real-world and comparative data, to differentiate the benefit-risk profiles of agents across domains and subpopulations
- Describe guideline recommendations for treating patients with SpA conditions including strategies for treatment selection, modification, and intensification
- Utilize shared decision-making and clinical considerations to individualize treatment for patients with SpA conditions

Case 1

Case 1: John – History

- 50-year-old Hispanic male comes in with a 10-year history of worsening joint pain. Complains of pain in his neck and mid and lower back with at least 90 minutes of morning stiffness each day, sometimes up to 3-4 hours depending on the weather. Cold and wet weather make his symptoms worse. In addition to his back pain, he has pain in his hips and knees, as well as occasionally a shoulder.
- John owns a business installing and cleaning gutters and participates in the work himself, although “not as much as I used to” due to his pain. When he is active all his joint pain seems to get worse, he says. There is some mild relief with rest at the day of the day.
- He also has seen dermatology for an initial visit for a recurrent rash but has not been given a definitive diagnosis. The rash is present on his anterior thighs and legs and is very itchy, he says. It also “comes and goes” and OTC meds have had only modest effects at controlling the symptoms. He is awaiting the results of a biopsy.

Case 1: John – Examination

Vitals at initial visit:

- Weight: 202 lbs
- BP 150/80
- Pulse 86
- ESR 25 mm/hr (Normal <20)
- CRP 12 mg/L (Normal <10)
- Right hand dominant

Physical exam findings:

- Para spina tenderness in the lower cervical and upper lumbar spine without spasms. Intervertebral tenderness at C6-7 and at T12-L1, L1-2, L2-3
- Extreme tenderness to palpation of the right SI joint
- Bouchard's nodes present on the 2nd and 3rd PIPs of both hands as well as a Heberden's node on the right 2nd DIP
- He has used OTC and Rx NSAIDs, muscle relaxers, and intermittent steroids in the past with varying levels of relief. He has had a very robust response to steroids saying he feels "super good" when taking them

DIP = distal interphalangeal joint; PIP = proximal interphalangeal; SI = sacroiliac.

Case 1: John – Question 1

What additional tests will you order to help make a diagnosis? (Choose all that apply)

a) X-rays to detect joint changes
b) Dual-Energy X-ray Absorptiometry (DEXA) scan to detect osteoporosis
c) MRI to detect inflammation in spine and feet
d) Ultrasound to detect inflammation in tendons and joints

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Case 1: John – Examination

X-ray findings:

- Lateral osteophytes noted at the inferior aspect of T12 superior and inferior aspects of L1 and L2. Also, facet OA and multilevel DDD in the C and L spine and lower T spine
- Joint space narrowing of the medial knees bilaterally and patellar-femoral narrowing on the right. Also noted was peaked tibial spines at the insertion of the ACL/PCL in both knees[1]
- AC joint on the right shows inferior spurring and joint space narrowing indicative of OA
- Evidence of sacroiliitis in the right SI joint including joint space narrowing and subchondral sclerosis

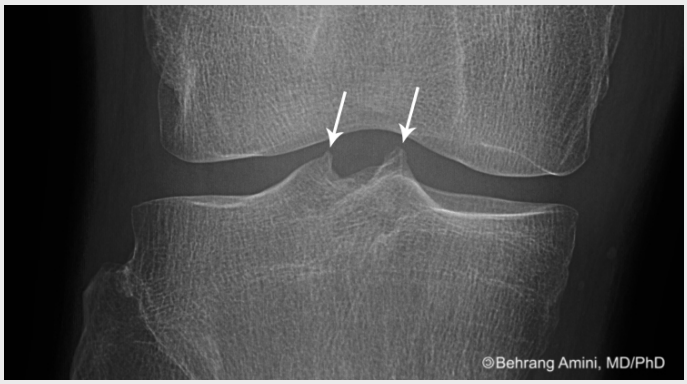
MRI findings:

- MRI of the SI joints confirmed right sacroiliitis with evident bone marrow edema

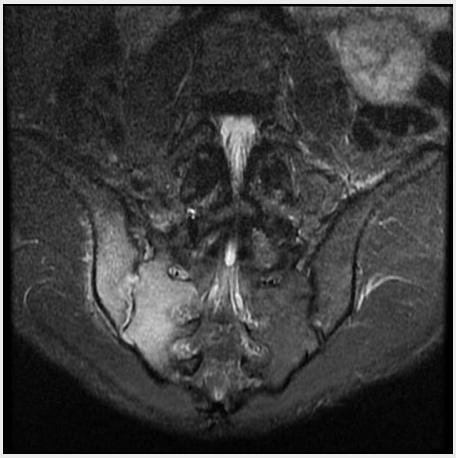
AC = acromioclavicular; ACL = anterior cruciate ligament; DDD = degenerative disc disease; OA = osteoarthritis; PCL = posterior cruciate ligament.

1. Alvarez A, Tiu TK. Enthesopathies. [Updated 2023 Jun 5]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK559030/

Case 1: John – Imaging



Peaked tibial spines on X-ray



Sacroiliitis on MRI

Photos courtesy of Dr. Laugherty.

Case 1: John – Diagnostic Considerations

- Many features of AS including meeting the ASAS criteria for AS
- Differential diagnosis includes axial PsA and differentiated inflammatory back pain
- Supported by evidence of possible early bridging osteophytes on his X-rays
- Evidence of chronic enthesitis
- He also has a history of rash (currently there is no definitive psoriatic spondylitis diagnosis)
- Evidence of primary osteoarthritis of multiple joints by his symptoms and X-ray findings
- Past robust response to steroids could indicate a predominantly inflammatory rather than mechanical process

Case 1: John – Question 2

How would you treat this patient?

a) NSAIDs (eg, naproxen)
b) TNF-alpha inhibitor (eg, adalimumab)
c) JAK inhibitor (eg, tofacitinib)
d) IL-17 inhibitor (eg, ixekizumab)

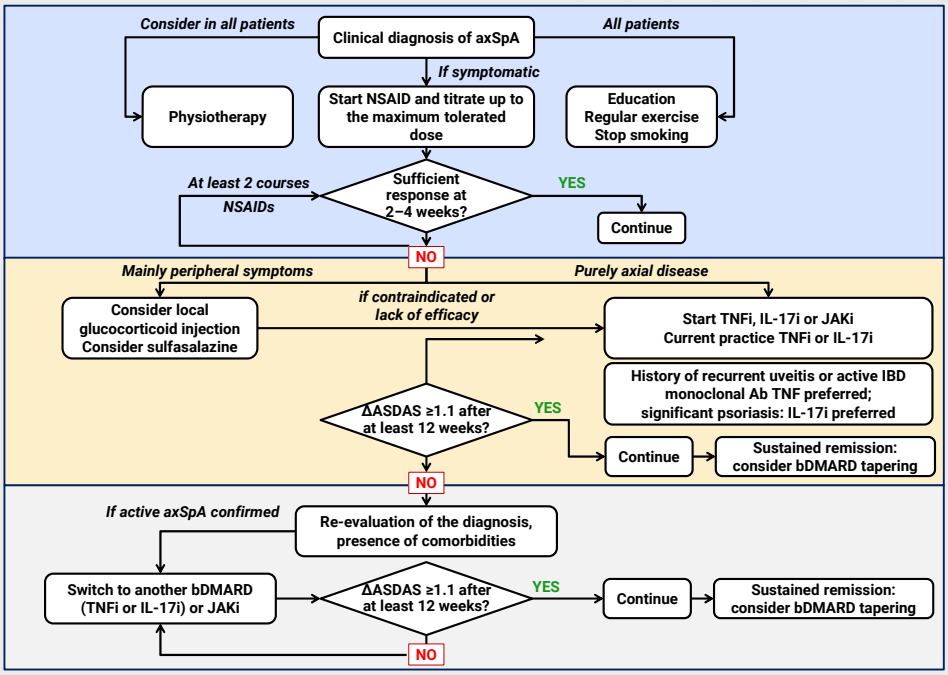
Case 3: John – Question 2

How would you treat this patient?

a) NSAIDs (eg, naproxen)
b) TNF-alpha inhibitor (eg, adalimumab)
c) JAK inhibitor (eg, tofacitinib)
d) IL-17 inhibitor (eg, ixekizumab)

Supported by ASAS Guidelines especially in light of the "rash" that could possibly be PsO.

ASAS/EULAR Guidelines



bDMARD = biologic disease-modifying anti-rheumatic drug; EULAR = European Alliance of Associations for Rheumatology;
Ramiro S, et al. *Ann Rheum Dis.* 2023;82:19-34.

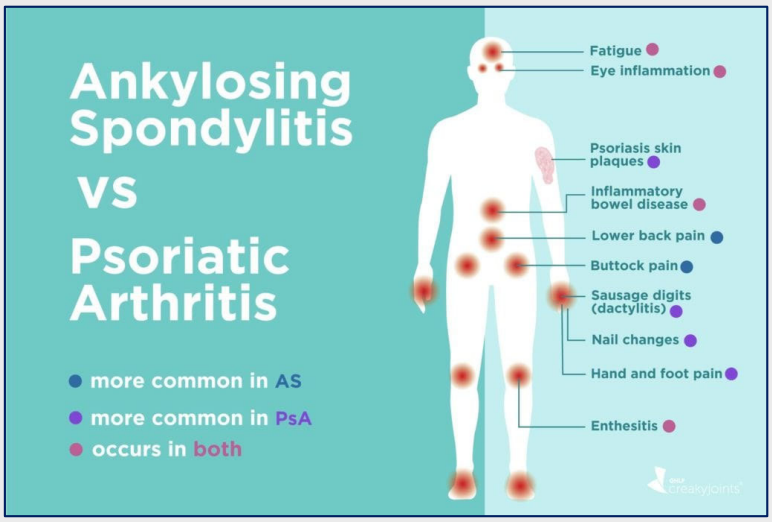
Case 1: John – Treatment

- Diagnosis is AS and started treatment with ixekizumab 80 mg SC Q4W. Was also given 4 mg of tizanidine at bedtime as needed for spasms. He improved greatly over the course of the next 6 weeks, and treatment was continued
- At 3 months, ESR and CRP came back within normal, and his morning stiffness was reduced to 20 minutes. Of note: his rash was also resolved. The previous biopsy was “inconclusive” per patient report, and discussion with dermatology did not reveal a definitive diagnosis, but derm stated that PsO was definitely in the differential
- This case shows the blurred lines between ankylosing spondylitis and axial psoriatic arthritis

CRP = C-reactive protein; ESR = erythrocyte sedimentation rate; PsO = psoriatic arthritis; Q4W = every 4 weeks; SC = subcutaneous.

Ankylosing Spondylitis vs Psoriatic Arthritis

Ankylosing spondylitis and psoriatic arthritis can present very differently in some patients and very similarly in others



Sturt K. Ankylosing spondylitis vs. psoriatic arthritis: what's the difference? https://creakyjoints.org/living-with-arthritis/symptoms/ankylosing-spondylitis-vs-psoriatic-arthritis/. Accessed 10/15/24.

ASAS Classification Criteria for AxSpA

In Patients With Chronic (≥ 3 Months) Back Pain, Age at Onset < 45 Years

Sacroiliitis plus**
≥ 1 clinical parameter*

****Sacroiliitis (X-rays or MRI):**

- Definite radiographic sacroiliitis according to modified NY criteria

or

- Active inflammation of SI joints on MRI

HLA-B27 plus
≥ 2 other clinical parameters*

***Clinical parameters:**

- Inflammatory back pain
- Arthritis
- Enthesitis
- Uveitis
- Dactylitis
- Psoriasis
- Crohn's disease/ulcerative colitis
- Good response to NSAIDs
- Family history for SpA
- Elevated CRP

ASAS = Assessment of SpondyloArthritis international Society; CRP = C-reactive protein; HLA-B27 = human leukocyte antigen B27; SI = sacroiliac; SpA = spondyloarthritis.

Dubreuil M, Deodhar A. *Curr Opin Rheumatol*. 2017;29(4):317-322.

2017 Updated Recommendations for Treat-to-Target for Axial and Peripheral Spondyloarthritis

Overarching principles	
A.	The treatment target must be based on a shared decision between patient and rheumatologist
B.	Treatment to target by measuring disease activity, and adjusting therapy accordingly, improves outcomes
C.	SpA and PsA are multifaceted systemic diseases; the management of musculoskeletal and extra-articular manifestations should be coordinated, as needed, between the rheumatologist and other specialists (such as dermatologist, gastroenterologist, ophthalmologist)
D.	The goals of treating the patient with SpA or PsA are to optimize long-term health-related quality of life and social participation through control of signs and symptoms, prevention of structural damage, normalization or preservation of function, avoidance of toxicities, and minimization of comorbidities
E.	Abrogation of inflammation is important to achieve these goals

PsA = psoriatic arthritis; SpA = spondyloarthritis.

Smolen JS, et al. *Ann Rheum Dis*. 2018;77:3-17.

Treating SpA Conditions

Conventional DMARDs

- Methotrexate
- Leflunomide
- Sulfasalazine
- Hydroxychloroquine (use with caution in psoriasis)

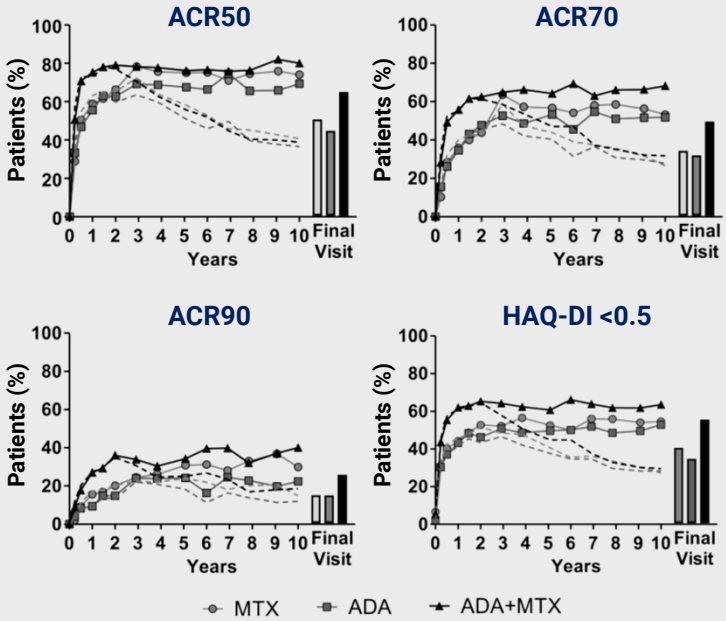
Nimmana BK, Patel P. StatPearls [Internet]. Treasure Island (FL); 2025 Jan.

Biologic and Targeted Synthetic DMARDs

- TNF-inhibitor: infliximab, etanercept, adalimumab, golimumab, certolizumab pegol
- Phosphodiesterase 4 (PDE-4) inhibitor: apremilast
- IL-12/23 inhibitor: ustekinumab
- IL-17A inhibitors: secukinumab, ixekizumab
- IL 17 A/F inhibitor: bimekizumab
- T-cell co-stimulation modulator: abatacept
- Janus kinase inhibitor: tofacitinib, upadacitinib
- IL-23 inhibitor: guselkumab, risankizumab

Nimmana BK, Patel P. StatPearls [Internet]. Treasure Island (FL); 2025 Jan.

Adalimumab in PsA (PREMIER Trial Long-term Extension)



ACR = American College of Rheumatology; ACR50/70/90 = ≥50%/70%/90% improvement in ACR response criteria; ADA = adalimumab; HAQ-DI = Health Assessment Questionnaire-Disability Index; MTX = methotrexate.

Keystone EC, et al. *J Rheumatology*. 2014;41:5-14.

Long-term Adalimumab Safety Data Across Multiple Indications

Incidence Rates of Serious Adverse Events of Interest

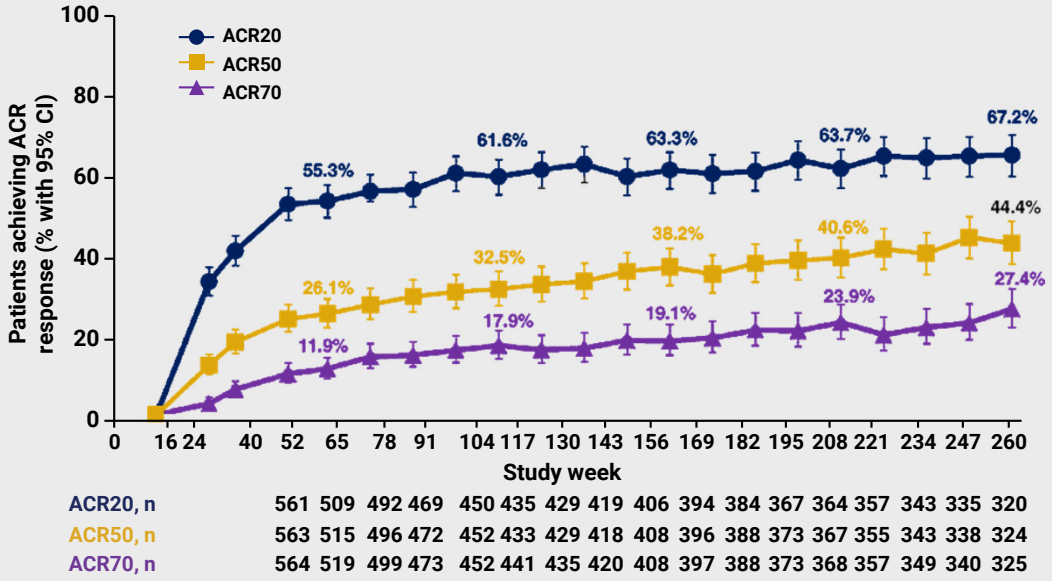
Characteristics	RA	AS	Br-axSpA	pSpA	PsA	Ps	HS	CD	UC	UV	Total†
n	15,512	2026	863	165	837	3732	733	3896	1739	464	29,987
Exposure, PYs	24,922	2120	709	391	998	5479	1198	4359	3407	1151	56,951
Serious infection	4.6	1.8	2.5	1.0	2.8	1.8	2.8	6.9	3.5	4.1	3.7
Tuberculosis	0.3	0.1	0.1	0.3	0.2	0.2	0	0.2	<0.1	0.4	0.2
Active	0.3	0.1	0.1	0	0.2	0.2	0	0.1	<0.1	0.2	0.2
Latent	<0.1	0	0	0.3	0	0	0	<0.1	0	0.3	<0.1
Opportunistic infection*	<0.1	0	0.1	0	0	0	0	<0.1	<0.1	0.4	<0.1
Demyelinating disorder	<0.1	<0.1	0	0	0	0	0	0.1	<0.1	0.3	<0.1
Lupus-like syndrome	<0.1	<0.1	0.1	0	0	0	0	<0.1	<0.1	<0.1	<0.1
CHF	0.2	<0.1	0	0	0	0.1	0.2	0	<0.1	<0.1	0.2
Ps new onset/worsening	<0.1	<0.1	0	0	0.1	<0.1	<0.1	<0.1	<0.1	0	<0.1
Malignancy§	0.7	0.2	0.1	0.3	0.2	0.5	0.5	0.4	0.6	0.7	0.6
Lymphoma	0.1	<0.1	0	0	0.2	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1
NMSC	0.2	0.2	0	0	0.1	0.1	<0.1	<0.1	<0.1	0.2	0.1
Melanoma	<0.1	<0.1	0	0	0	0.2	0	0	<0.1	0	<0.1
Sarcoidosis	<0.1	<0.1	0	0	0	0	0	0	0	<0.1	<0.1
Any AE leading to death	0.7	<0.1	0.3	1.0	0.3	0.2	0.5	0.1	0.1	0.6	0.5

AE = adverse event; AS = ankylosing spondylitis; CD = Crohn's disease; CHF = congestive heart failure; HS = hidradenitis suppurativa; NMSC = nonmelanoma skin cancer; ar-axSpA = non-radiographic axial SpA; Ps = plaque psoriasis; PsA = psoriatic arthritis; pSpA = peripheral SpA; PY = patient-year; RA = rheumatoid arthritis; SpA = spondyloarthritis; UC = ulcerative colitis; UV = uveitis.

*Rates in events/100 PYs. †Total includes the 10 populations shown plus 20 patients with Behcet's disease (35.5 PY). ‡Excludes oral candidiasis and tuberculosis. §Excludes lymphoma, hepatoplenic T-cell lymphoma, leukemia, NMSC, and melanoma.

Burmester G, et al. *Adv Ther.* 2019;37(1):364-380.

Apremilast Efficacy in PsA (Pooled Data From PALACE 1-3 Trials)



Kavanaugh A, et al. *Arthritis Res Ther.* 2019;21:118.

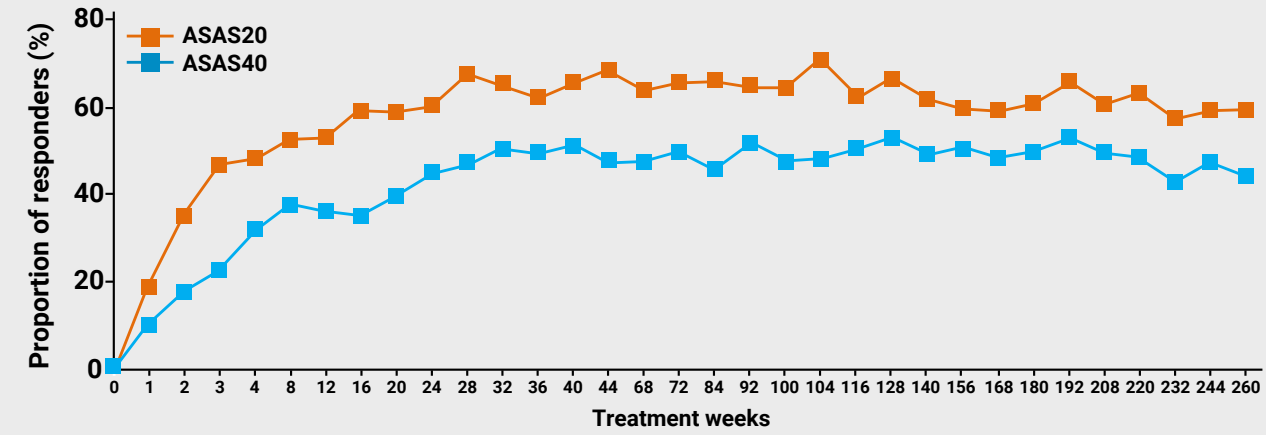
Apremilast Safety in PsA (Pooled Data From PALACE 1-3)

	APR-Exposure Period*			
	Weeks 0 to ≤52	Weeks >52 to ≤104	Weeks >104 to ≤156	Weeks >156 to ≤208
	APR30 (n = 721)	APR30 (n = 520)	APR30 (n = 443)	APR30 (n = 401)
Subjects, n (%)				
≥1 adverse event	524 (72.7)	316 (60.8)	284 (64.1)	234 (58.4)
≥1 serious adverse event	47 (6.5)	35 (6.7)	40 (9.0)	28 (7.0)
Adverse event leading to drug withdrawal	56 (7.8)	13 (2.5)	7 (1.6)	7 (1.7)
Death	0 (0.0)	1‡ (0.2)	0 (0.0)	2‡§ (0.5)
Adverse events in ≥5% of subjects, n (%)				
Diarrhea	112 (15.5)	20 (3.8)	12 (2.7)	4(1.0)
Nausea	108 (15.0)	11 (2.1)	10 (2.3)	3 (0.7)
Headache	75 (10.4)	17 (3.3)	42 (2.7)	7 (1.7)
Upper respiratory tract infection	60 (8.3)	27 (5.2)	24 (5.4)	21 (6.2)
Nasopharyngitis	41 (5.7)	31 (6.0)	20 (4.5)	26 (6.5)
Select marked abnormalities in clinical laboratory parameters, n/m (%)				
Alanine aminotransferase >3x ULN	9/713 (1.3)	2/518 (0.4)	2/442 (0.5)	1/401 (0.2)
Creatinine >1.7x ULN	1/713 (0.1)	0/518 (0.0)	0/442 (0.0)	1/401 (0.2)
Leukocytes <1.5, $10^9$7L	0/713 (0.0)	0/517 (0.0)	0/442 (0.0)	0/401 (0.0)
Neutrophils <1, 10^9/L	2/713 (0.3)	3/517 (0.6)	2/442 (0.5)	2/401 (0.5)
Platelets <75, 10^9/L	0/713 (0.0)	0/517 (0.0)	1/441 (0.2)	0/399 (0.0)
Hemoglobin, male <10.5 g/dL, female <8.5 g/dL	5/713 (0.7)	4/517 (0.8)	5/442 (1.1)	5/401 (1.2)

*Includes all subjects who received apremilast during the time interval relative to start of APR treatment. †Motor vehicle accident on Day 489. ‡Cerebrovascular accident on Day 1, 330 in a 69-year-old man, considered unrelated to study drug; subject had history of myocardial infarction, atrial fibrillation, and cerebrovascular accident. §Stroke on Day 1,224 in a 58-year-old woman, considered unrelated to study drug; subject had a history of chronic ischemic heart disease, hypertension, alcoholism, and atrial fibrillation. APR30= apremilast 30 mg BID; ULN = upper limit of normal.

Mease PJ, et al. *Arthritis Rheumatol.* 2017; 69 (suppl 10). https://acrabstracts.org/abstract/consistent-safety-profile-with-up-to-4-years-of-apremilast-treatment-analysis-of-data-from-1493-subjects-with-psoriatic-arthritis-in-3-large-phase-iii-long-term-studies/. Accessed January 29, 2026.

MEASURE 2: Secukinumab in AS: 5-Year Efficacy



	Week 1	Week 24	Year 1	Year 2	Year 3	Year 4	Year 5
No. of patients:	70	65	61	59	58	57	54

ASAS20 and ASAS40 response rates up to 5 years in the secukinumab 150 mg group (N = 72)*

*Includes patients originally randomized to secukinumab 150 mg (ie, without placebo switchers or patients whose dose was escalated). Results are reported as observed data.
AS = ankylosing spondylitis; ASAS = Assessment of SpondyloArthritis international Society; ASAS20 = ASAS 20% response; ASAS40 = ASAS 40% response.

Marzo-Ortega H, et al. *Lancet Rheumatol*. 2020;2:e339-e346.

MEASURE 2 and 3: Long-term Safety

Summary of Secukinumab Safety Up to 5 Years (Week 260)

	Any secukinumab (n = 211)
Exposure to study treatment, days	1459.1 (597.8)
Deaths	3 (1%)
Discontinuation due to adverse events	22 (10%)
Any adverse events	130.8 (113.0–150.7)
Any serious adverse events	7.3 (5.5–5.9)
Common adverse events*	
Nasopharyngitis	9.3 (7.1–11.9)
Upper respiratory tract infection	3.9 (2.6–5.6)
Bronchitis	3.7 (2.4–5.3)
Influenza	3.5 (2.3–5.0)
Diarrhea	3.4 (2.2–4.9)
Headache	3.1 (2.0–4.7)
Hypertension	3.1 (2.0–4.6)
Gastroenteritis	2.3 (1.3–3.6)

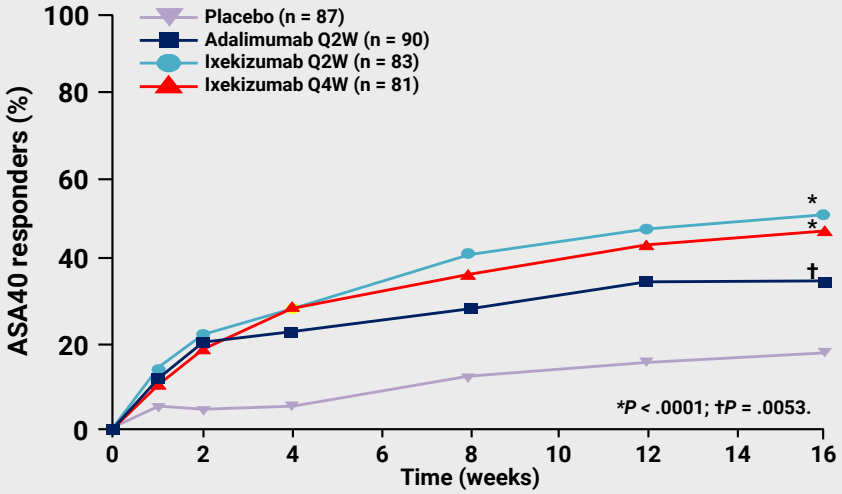
	Any secukinumab (n = 211)
Adverse events of special interest	
Candida infection†	1.0 (0.4–1.9)
Crohn's disease	0.5 (0.1–1.2)
Ulcerative colitis	0.4 (0.1–1.1)
Uveitis	0.5 (0.1–1.2)
Major adverse cardiovascular events	0.6 (0.2–1.4)
Malignancy‡	0.6 (0.2–1.4)

Data are mean (SD), n (%), or EAIR per 100 patient-years (95% CI).
*AEs with an EAIR of ≥ 2 per 100 patient-years during the entire study period. †High-level term category. ‡Standardized Medical Dictionary for Regulatory Activities query category.
AE = adverse event; CI = confidence interval; EAIR = exposure-adjusted incidence rate per 100 patient-years; SD = standard deviation.

Marzo-Ortega H, et al. *Lancet Rheumatol*. 2020;2:e339-e346.

COAST-V: Ixekizumab in AS or r-AxSpA vs Adalimumab or Placebo

Proportion of patients achieving ASAS40 response through Week 16



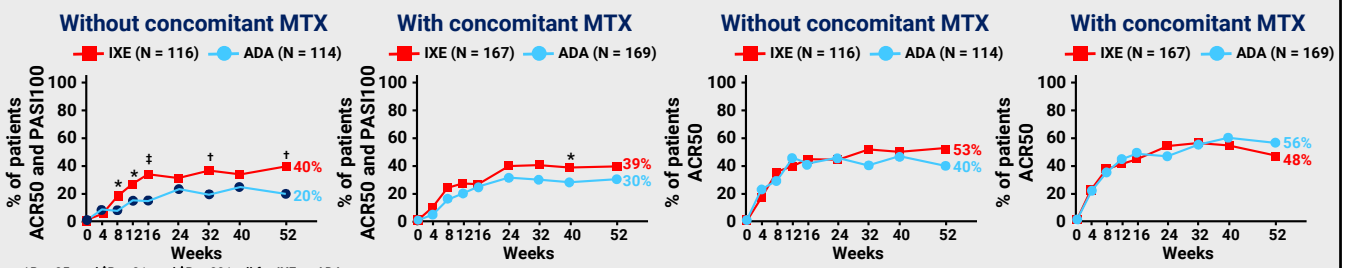
AS = ankylosing spondylitis; ASAS40 = ASAS 40% response; r-axSpA = radiographic axial spondyloarthritis; Q2W = every 2 weeks; Q4W = every 4 weeks.

van der Heijde D, et al. *Lancet*. 2018;392:2441-2451.

Ixekizumab vs Adalimumab in PsA: SPIRIT-H2H

- 483/566 patients completed 52-week study[1]
- IXE superior for PASI100 + ACR50 at primary endpoint at Week 24[2]
- MTX showed treatment interaction effects, with better ACR 20/50/70 at Week 52 seen with IXE vs ADA as monotherapy, but slightly better outcome with ADA vs IXE with MTX combination[1]
- Response with ADA for other endpoints were higher when used with MTX[1]
- ADA efficacy appears to increase with the concomitant use of MTX[1]

	ACR50 + PASI100	ACR50	PASI100
IXE	36%	51%	60%
ADA	28%	47%	47%
	Percent achieving response at Week 24	Percent achieving response at Week 24	Percent achieving response at Week 24



*P < .05, and †P ≤ .01; and ‡P ≤ .001, all for IXE vs ADA.

ADA = adalimumab; ACR = American College of Rheumatology; ACR20/50/70 = ACR criteria 20%/50%/70% improvement; IXE = ixekizumab; MTX = methotrexate; LDI-B = Leeds Dactylitis Index–Basic; LEI = Leeds Enthesitis Index; PASI100 = Psoriasis Area and Severity Index improvement of 100%.

1. Smolen JS, et al. *Rheumatol Ther*. 2020;7:1021-1035. 2. Mease PJ, et al. *Ann Rheum Dis*. 2020;79:123-131.

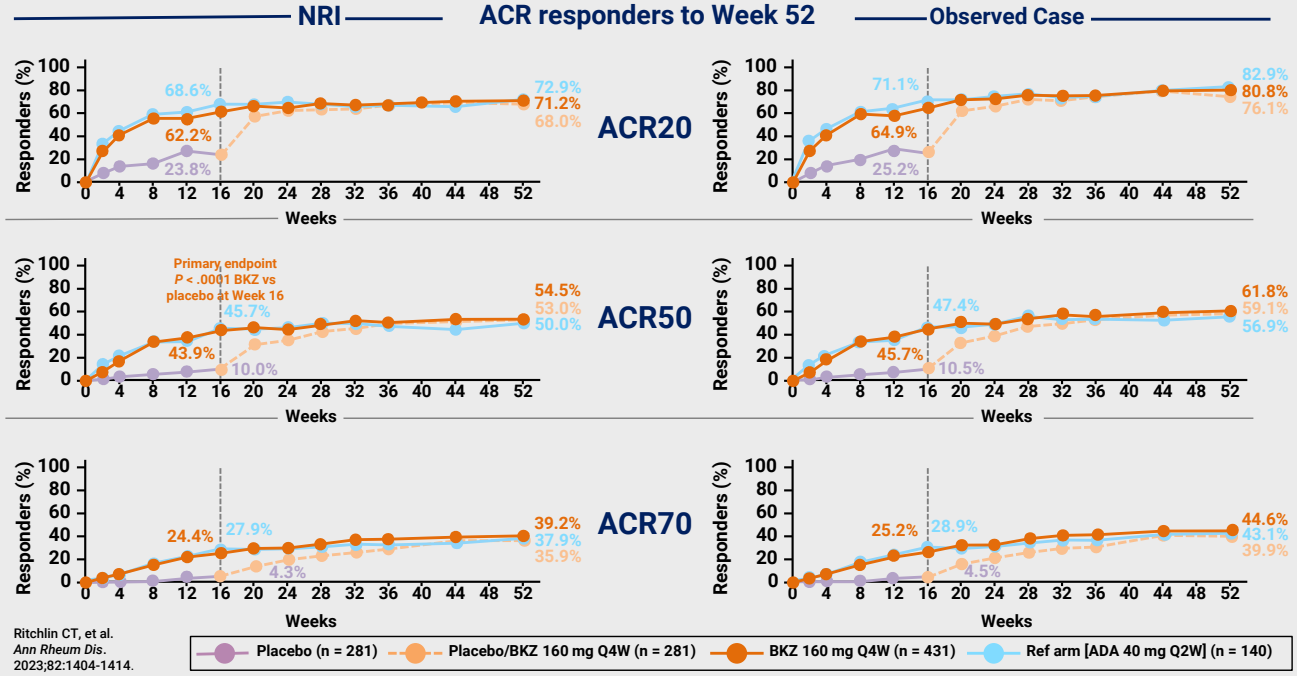
SPIRIT-H2H: Safety

	IXE (N = 283)	ADA (N = 283)
Extent of exposure, mean days (total patient-years)	236.8 (183.5)	228.9 (117.3)
Treatment-emergent adverse events	197 (69.6)	173 (61.1)
Mild	97 (34.3)	87 (30.7)
Moderate	91 (32.2)	71 (25.1)
Severe	9 (3.2)	15 (5.3)
Serious adverse events	10 (3.5)	24 (8.5)
Deaths	0	0
Discontinuations due to adverse events	7 (2.5)	13 (4.6)
Adverse events of special interest		
Infections	102 (36.0)	87 (30.7)
Serious infections	4 (1.4)	8 (2.8)
***Candida* infections**	7 (2.5)	2 (0.7)
Injection-site reactions	27 (9.5)	9 (3.2)
Allergic/hypersensitivity reactions	7 (2.5)	11 (3.9)
Potential anaphylaxis	0	0
Cytopenias	5 (1.8)	11 (3.9)
Cerebrocardiovascular events	3 (1.1)	5 (1.8)
Malignancies	0	3 (1.1)
Depression	3 (1.1)	7 (2.5)
Inflammatory bowel disease	2 (0.7)	0
Ulcerative colitis	1 (0.4)	0
Crohn's disease	1 (0.4)	0

ADA = adalimumab; H2H = head-to-head; IXE = ixekizumab.

Mease PJ, et al. *Ann Rheum Dis*. 2020;79:123-131.

BE OPTIMAL: Bimekizumab 52-Week Efficacy



Ritchlin CT, et al. *Ann Rheum Dis*. 2023;82:1404-1414.

Bimekizumab: BE OPTIMAL Safety

Most common AEs to Week 52:

- Patients receiving BKZ: nasopharyngitis, upper respiratory tract infection, urinary tract infection, oral thrush
- Patients receiving ADA: nasopharyngitis, ALT elevation, hypertension

	BKZ 160 mg Q4W (n = 702)* (PYAR: 603.4)	Reference arm [ADA 40 mg Q2W] (n = 140) (PYAR: 136.8)
Severe treatment-emergent adverse events (TEAEs)	23 (3.3)	9 (6.4)
Study discontinuation due to TEAEs	21 (3.0) (3.5)	7 (5.0) (5.2)
Drug-related TEAEs	224 (31.9)	54 (38.6)
Serious TEAEs	46 (6.6) (7.9)	10 (7.1) (7.5)

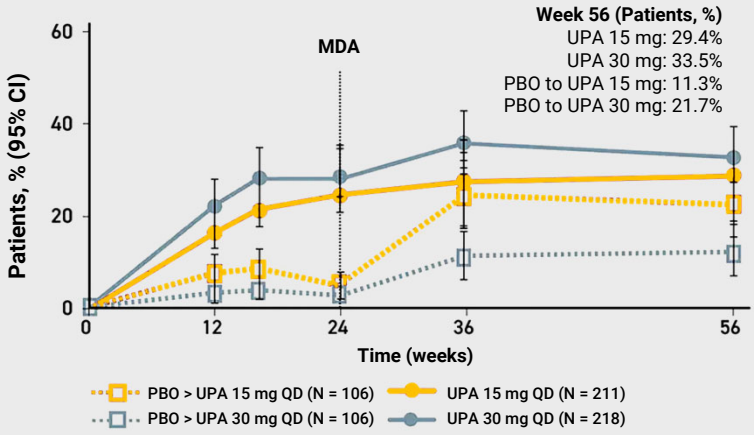
*Note that BKZ sample size is 5 times larger than ADA

ADA = adalimumab; AE = adverse event; ALT = alanine aminotransferase; BKZ = bimekizumab; PYAR = patient-years at risk; Q2W = every 2 weeks; Q4W = every 4 weeks.

Ritchlin CT, et al. *Ann Rheum Dis*. 2023;82:1404-1414.

Upadacitinib Trial Data (SELECT-PSA2)

SELECT-PsA 2: clinical improvements based on minimal disease activity were maintained from Week 24 to Week 56



PBO = placebo; QD = once daily; UPA = upadacitinib.

Adapted from Mease P, et al. Presented during EULAR 2021, POSOI96. https://themedicalxchange.com/fr/2021/06/14/2426_la-prolongation-des-essais-select-psa-1-et-select-psa-2-met-au-jour-une-efficacite-persistante-contre-larthrite-psoriasique/#.

Upadacitinib Safety Data (SELECT-PsA1 and 2 Pooled Data)

SELECT-PsA 1 and SELECT-PsA 2 Safety Over 24 Weeks (PBO-controlled)

TEAEs of special interest	Integrated SELECT-PsA 1 and SELECT-PsA 2		SELECT-PsA 2	
	PBO (N = 635) n/PYs (n/100 PYs)	UPA 15 mg QD (N = 640) n/PYs (n/100 PYs)	PBO (N = 212) n/PYs (n/100 PYs)	UPA 15 mg QD (N = 211) n/PYs (n/100 PYs)
Serious infections	5/268.0 (1.9)	6/281.2 (2.1)	1/85.1 (1.2)	1/91.9 (1.1)
Active tuberculosis	0	0	0	0
Opportunistic Infection	0	1/281.7 (0.4)	0	0
Herpes zoster	5/267.9 (1.9)	7/280.5 (2.5)	2/84.8 (2.4)	3/91.1 (3.3)
Malignancy	0	3/281.8 (1.1)	0	2/91.8 (2.2)
Lymphoma	0	1/281.5 (0.4)	0	1/91.5 (1.1)
Nonmelanoma skin cancer	1/268.4 (0.4)	1/281.8 (0.4)	0	1/91.8 (1.1)
Adjudicated VTE	1/268.6 (0.4)	1/281.9 (0.4)	0	1/91.9 (1.1)
Adjudicated MACE	1/268.6 (0.4)	1/281.5 (0.4)	0	1/91.5 (1.1)
Adjudicated GI perforations	0	0	0	0

GI = gastrointestinal; MACE = major adverse cardiovascular event; PBO = placebo; PY = patient year; TEAE = treatment emergent adverse event; UPA = upadacitinib; VTE = venous thromboembolic event.

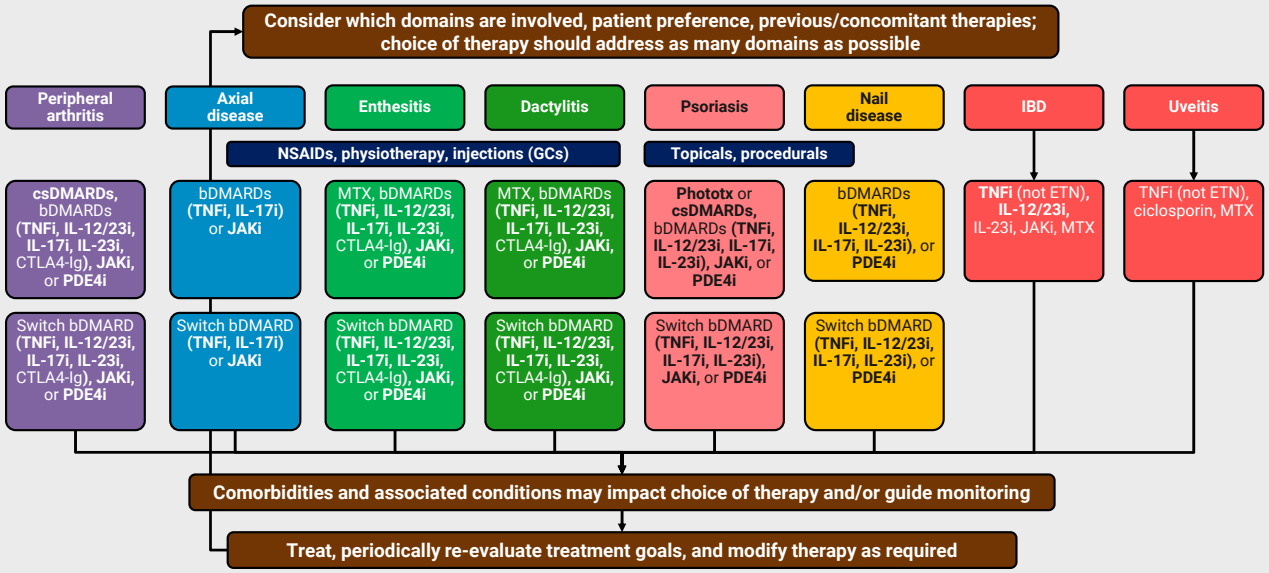
https://www.consultant360.com/partner-spotlight/abbvie/The-Science-of-a-JAK-Inhibitor-in-Psoriatic-Arthritis. May 4, 2022.

Individualizing Treatment for Patients With SpA Conditions

- **Multidisciplinary care:**
  Management usually requires a team approach coordinated by a rheumatologist, potentially involving physical therapists, gastroenterologists, ophthalmologists, and dermatologists, depending on the patient's specific manifestations
- **Shared decision-making:**
  The patient and physician collaborate to define the treatment target and select therapies, ensuring the patient's values and preferences are considered in decision-making process

Agency for Healthcare Research and Quality: ahrq.gov. Smolen JS, et al. *Ann Rheum Dis*. 2018;77:3-17.

GRAPPA: Updated Treatment Recommendations for Psoriatic Arthritis 2021



bDMARD = biologic DMARD; csDMARD = conventional synthetic DMARD; CTLA4-Ig = CTLA4–immunoglobulin fusion protein; DMARD = disease-modifying antirheumatic drug; ETN = etanercept; GC = glucocorticoid; GRAPPA = Group for Research and Assessment of Psoriasis and Psoriatic Arthritis; IBD = inflammatory bowel disease; IL-12/23i = interleukin-12/23 inhibitor; IL-17i = interleukin-17 inhibitor; IL-23i = interleukin-23 inhibitor; JAKi = Janus kinase inhibitor; MTX = methotrexate; PDE4i = phosphodiesterase 4 inhibitor; phototx = phototherapy; TNFi = TNF inhibitor.

Coates LC, et al. *Nat Rev Rheumatol*. 2022;18:465-479.

Case 2

Case 2: Jason – History

- 32-year-old white male who presents with peripheral joint pain and swelling for 18 months that began suddenly. It affects the hands, shoulders, ankles, and feet. He states that he has had severe psoriasis covering a large portion of his body, including genital involvement.
- His skin disease has been ongoing for the last 5 years, and he has tried topical and light therapy with suboptimal results.
- Recent history of bilateral plantar fasciitis.
- Pain 8/10. AM stiffness up to 4 hours daily.
- No GI complaints but has a first-degree family member (father) with a diagnosis of Crohn's disease. Complains of severe fatigue to the point of having to call out of work as a grocery store manager.
- He drinks alcohol at least three times a week.

Case 2: Jason – Examination

Vitals at initial visit:

- Weight 320 lbs
- BP 135/90
- Pulse 90
- Pain level 8/10

Labs:

- CRP 23 (<10)
- ESR 35
- HLA-B27 positive
- No significant abnormalities in the CBC, CMP

Case 2: Jason – Examination (continued)

- Synovitis and tenderness in the wrists and ankles bilaterally as well as dactylitis of the right 3rd toe
- Entheseal tenderness over the right elbow lateral epicondyle and bilateral plantar insertion points

X-rays

- Early OA changes in both knees, ankles, and feet
- Hands normal and no joint erosions present
- Soft tissue swelling in the right 3rd toe and effusions in both ankles
- Peaked tibial spines in both knees and calcifications at the Achilles insertion bilaterally

OA = osteoarthritis.

Case 2: Jason

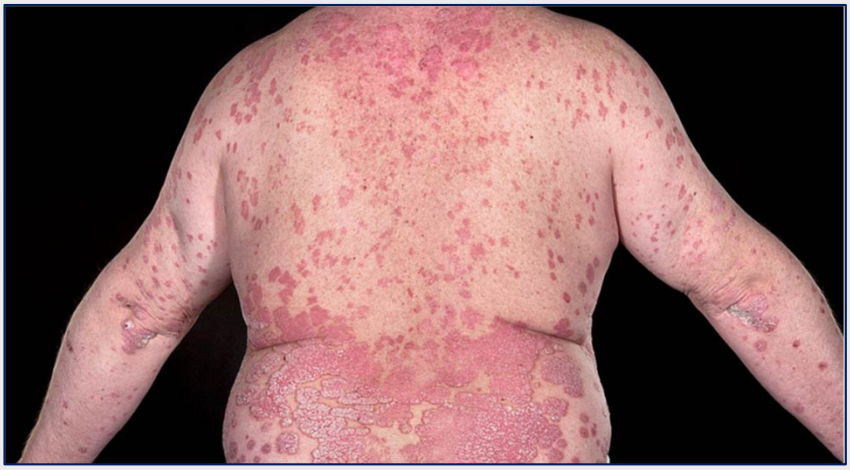


Photo courtesy of Dr. Laugherty.

Case 2: Jason – X-ray

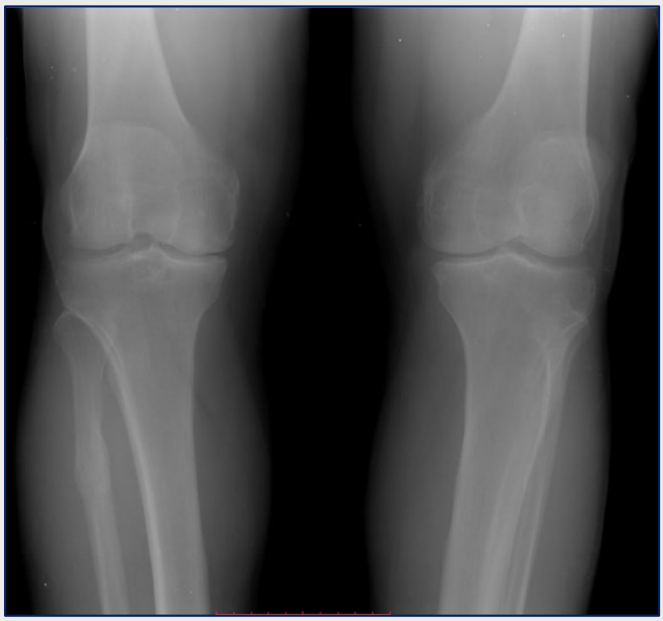


Photo courtesy of Dr. Laugherty.

Case 2: Jason – Question 1

To satisfy the ASAS classification criteria for axial spondyloarthritis (axSpA), which of the following combinations must be present?

a) Age at onset < 45 years AND HLA-B27 positivity alone
b) Chronic back pain ≥ 3 months, age at onset < 45 years, AND sacroiliitis on imaging plus ≥ 1 other SpA feature
c) Age at onset < 50 years AND positive response to NSAIDs within 48 hours
d) Chronic back pain ≥ 1 month AND limited lumbar spinal motion in all three planes

Case 2: Jason – Question 1

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c) Age at onset < 50 years AND positive response to NSAIDs within 48 hours
d) Chronic back pain ≥ 1 month AND limited lumbar spinal motion in all three planes

Discussion

- Discussion: What features/dimensions of Jason's presentation are consistent with PsA? (Multidimensional findings)
- Are there any features or history that influence your medical decision-making in his case?

Case 2: Jason – Question 2

Are there certain drug classes you would think about first for someone like Jason? (Choose all that apply)

a) Conventional DMARDs (eg, methotrexate)
b) JAK inhibitors (eg, tofacitinib)
c) NSAIDs (eg, naproxen)
d) TNF-alpha inhibitors (eg, adalimumab)

Case 2: Jason – Question 2

Are there certain drug classes you should NOT consider for someone like Jason?

a) Conventional DMARDs (eg, methotrexate)
b) JAK inhibitors (eg, tofacitinib)
c) NSAIDs (eg, Naproxen)
d) TNF-alpha inhibitors (eg, adalimumab)

Methotrexate due to Jason's alcohol use and JAK inhibitors due to his obesity and CV risk.

Case 2: Jason – Treatment

- Because of the severity of Jason's skin disease and his ongoing alcohol use (which he is unwilling to change), methotrexate was skipped over.
- Treatment was initiated with an IL-17 A and IL-17F inhibitor bimekizumab. Dosing for moderate to severe psoriasis was used:
  - A loading dose of 320 mg SQ Q4W x 5 doses
  - Followed by a maintenance dose of 320 mg SQ Q8W thereafter
- His skin was essentially clear by week 8 with just mild flat erythema at sites of some previous large plaques.
- He had improvement in his joint pain and stiffness over the first 3 months, but this plateaued, and he complained of inter dose worsening of the stiffness and pain and occasional PIP joint swelling and tenderness.
- Because of his weight (320 lbs) it was elected to increase the dose frequency to Q4W per the package insert. After 3 months at this dose his symptoms were improved and stable without the cycling between doses.
- Adverse events: an episode of oral thrush at week 6 was treated with nystatin suspension with no recurrence.

Case 3

Case 3: Mary – History

- Mary is a 55-year-old black female who presents with sudden onset of bilateral hand pain including MCP pain and swelling that started about a year prior to presentation at Rheumatology. Evaluated by her PCP and treated with Tylenol, OTC NSAIDs (both oral and topical), and occasional tramadol.
- Initial labs showed a negative ANA, negative rheumatoid factor, and normal ESR.
- X-rays of the hands were significant for only soft tissue swelling at the MCPs bilaterally.
- Mary had little improvement in her condition and was referred to Rheumatology for further evaluation.
- It took about 4 months to get an appointment.

MCP = metacarpophalangeal.

Case 3: Mary – Examination

- Condition at first rheumatology visit was unchanged from her initial presentation

Vitals:

- Weight 135 lbs
- BP 125/80
- Pulse 82
- Pain level 6/10

Labs:

- Anti CCP: negative
- HLA B-27: negative
- CRP: 27 (<10 ULN)

Exam findings:

- Synovitis and tenderness of the MCPs 2-4 of both hands

Case 3: Mary – History

- Mary used straightening products in her hair and complained of past intermittent scalp itching during the interview.
- Exam revealed a psoriasiform rash on the posterior scalp that was difficult to evaluate due to hair texture and skin color.
- Referral to Dermatology was initiated, which confirmed a Dx of psoriasis

Case 3: Mary

Scalp psoriasis on Black skin to emphasize how subtle the findings are and different from White skin

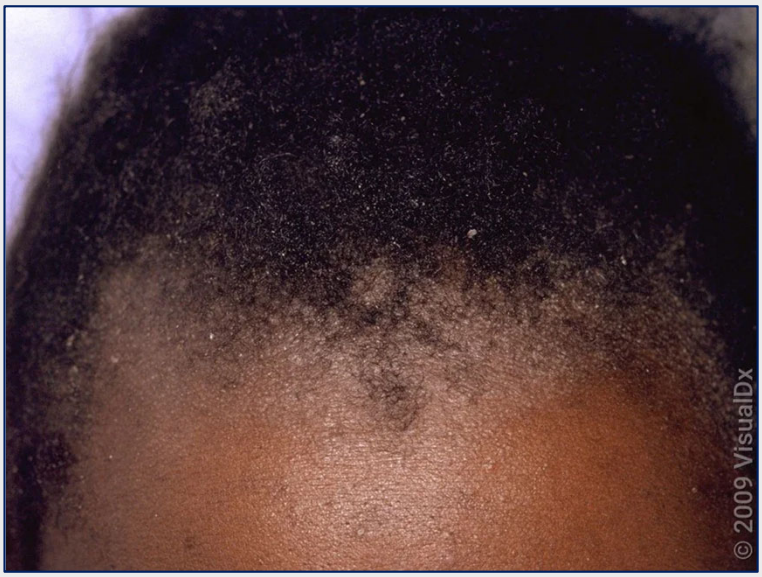

Photo courtesy of Dr. Laugherty.

Case 3: Mary – Diagnosis

- Symmetric, polyarticular presentation consistent with DDx of rheumatoid arthritis, PsA, and possible CPPD or hemochromatosis
- One question about skin rashes… changed EVERYTHING!
- Multidisciplinary approach continues to be of utmost importance

CPPD = calcium pyrophosphate deposition disease; PsA = psoriatic arthritis.

Case 3: Mary – Question

What are some treatments that you would consider for treating this patient? (Choose all that apply)

a) IL-17 inhibitor (eg, ixekizumab)
b) Conventional DMARD (eg, methotrexate)
c) JAK inhibitor (eg, upadacitinib)
d) TNF-alpha inhibitor (eg, adalimumab)

Case 3: Mary – Question

What are some treatments that you would consider for treating this patient?

a) IL-17 inhibitor (eg, Ixekizumab)
b) Conventional DMARD (eg, methotrexate)
c) JAK inhibitor (eg, upadacitinib)
d) TNF-alpha inhibitor (eg, adalimumab)

Any of these would be appropriate based on GRAPPA guidelines.

Case 3: Mary – Treatment

- Treatment initiated with MTX 10 mg PO weekly and folic acid 1 mg daily. Patient returned in 8 weeks for re-evaluation. Derm initiated topical clobetasol solution for scalp to be used up to BID for up to 2 weeks PRN then hold for 2 weeks.
- At the 8 weeks visit her scalp rash and itching were resolved per patient report.
- Pain level reported at 2/10.
- Exam revealed no synovitis in her MCPs and only tenderness in the right 2nd MCP.

Case 3: Mary – Shared Decision-Making

- Mary was not tolerating the MTX well due to severe GI upset, with nausea and occasional vomiting and moderate fatigue for the 2 days after her weekly dose.
- Declined to continue MTX. Multiple treatment options were discussed including the risks and benefits of each, and with Mary's input it was decided to start guselkumab.
- At her follow-up visit 3 months later, her scalp continued to be clear, and she had only one tender joint and no swollen joints and reported no adverse effects with her medication. She was very happy with treatment and had resumed all her regular daily activities without interruption.

Shared Decision-Making Framework

- **Patient-Centered Goals:** Defining shared objectives such as reducing pain, improving function, preventing damage, or achieving low disease activity
- **Addressing Knowledge Gaps:** Patients often lack awareness of treatment effectiveness or potential harms, leading to undertreatment; SDM helps bridge this gap
- **Managing Complex Choices:** The array of treatments (NSAIDs, biologics, nonpharmacological) and their complexities (side effects, administration, cost) necessitates patient involvement
- **Incorporating Values:** Patients have unique priorities (efficacy, side effects, convenience, cost, fertility impact) that sociodemographics or disease severity don't always predict, requiring tools like conjoint analysis to understand these preferences
- **Overcoming Barriers:** Some patients feel unable to speak up due to feeling overwhelmed, while some doctors might lean paternalistic, highlighting the need to invite participation

SHARE Approach (Agency for Healthcare Research and Quality)

- **Invite Participation:** Actively ask the patient to join the decision-making process
- **Explore Options:** Help the patient understand different treatments, including non-drug therapies like physical activity, which are vital
- **Assess Values:** Discuss what matters most to the patient (eg, avoiding injection, long-term joint health)
- **Reach Decision:** Jointly decide on a treatment plan, acknowledging it may need future adjustments

Agency for Healthcare Research and Quality: ahrq.gov.

SDM: Why it Matters for SpA

- **Individualized Care:** SpA treatment is highly individual; SDM ensures choices fit personal situations, unlike relying solely on demographics or disease markers
- **Improved Outcomes:** Aligns treatment with patient values, leading to better adherence and potentially better management of the chronic, progressive disease
- **Guideline Endorsement:** Major organizations like the American College of Rheumatology (ACR) and the European Alliance of Associations for Rheumatology (EULAR) endorse SDM for SpA management

Agency for Healthcare Research and Quality: ahrq.gov.

Conclusions

Patient goals are important

- Improve quality of life, function, and social participation
- Control symptoms and inflammation (enthesitis, dactylitis, joints, other domains)
- Prevent irreversible structural joint damage

Start treatment early

Multidisciplinary care: *Communication is key!*

Therapy is monitored and adjusted—sometimes every 8 to 12 weeks to T2T goal

- Traditional oral medications—DMARDs (methotrexate, leflunomide, hydroxychloroquine, sulfasalazine)
- TNF inhibitors
- Multiple new targets (IL-12/23, IL-17, IL-17A & IL-17F, JAK, T-cell co-stimulation, PDE4)
- Combination therapy

Minimize comorbidities

DMARD = disease-modifying antirheumatic drug; IL = interleukin; JAK = Janus kinase; PDE4 = phosphodiesterase 4; T2T = treat to target; TNF = tumor necrosis factor.

Thank You!