PARTICIPANTS

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**ECRI Institute Staff**
Karen Schoelles, MD
ORGANIZATIONAL LEADERSHIP AND SUPPORT

This collaborative project of the American College of Rheumatology (ACR) and the National Psoriasis Foundation has the broad objective of developing an evidence-based clinical practice guideline for the management of psoriatic arthritis (PsA), not covering skin manifestations of psoriasis.

BACKGROUND

Psoriatic arthritis (PsA) is a chronic inflammatory arthritis associated with psoriasis. Patients have joint pain, stiffness, and swelling, along with psoriasis (patches of thick, inflamed red skin that are usually covered with silvery scales). PsA is a highly heterogeneous disorder affecting multiple different tissues, including the peripheral joints, skin (psoriasis), axial joints (spondylitis), enthesitis (inflammation where tendons or ligaments insert onto the bone), and dactylitis (swelling of a whole toe or finger, like a sausage). Additionally, the distribution of the peripheral arthritis can be variable – patients can have symmetric polyarthritis, asymmetric oligoarthritis, arthritis affecting the distal joints only, spondyloarthitis, and arthritis mutilans. Finally, nail abnormalities, such as pitted, discolored, or crumbly nails, can also occur in ~80-90% of people. There are no biomarkers or single tests for the diagnosis of PsA. Diagnosis is made via history and physical examination, as well as imaging of the joints in some circumstances. The Classification of Psoriatic Arthritis (CASPAR) criteria may help in establishing the correct diagnosis.

PsA affects both men and women equally. In the majority of patients, the skin symptoms of psoriasis develop first followed by the arthritis; however, in 15% of cases, the arthritis is noticed first. Approximately 40% of patients with PsA have family members with psoriasis or PsA. The incidence of PsA is ~6 per 100,000 per year, with a prevalence of ~1-2 per 1,000 in the general population. The annual incidence estimated from a prospective study of patients with psoriasis is 2.7%.

Both non-pharmacologic and pharmacologic treatment can help treat the symptoms and lead to disease remission. Weight loss (~40-50% of patients are obese) can improve the responsiveness of pharmacologic treatments and exercise/physical therapy can help treat symptoms. A wide variety of pharmacologic treatments are now available for PsA. Very mild arthritis may be treated with nonsteroidal anti-inflammatory drugs (NSAIDs) and sometimes intraarticular glucocorticoid injections are helpful. Most patients with PsA are treated with immunomodulatory therapies, which include:

- Oral small molecule agents: methotrexate; leflunomide; sulfasalazine; cyclosporine; apremilast
- Tumor necrosis factor inhibitors (TNFi): infliximab; adalimumab; entercept; golimumab; certolizumab
OBJECTIVES

Specifically, we aim to:
1. Develop pharmacologic treatment recommendations for adult patients with active PsA.
2. Develop guidelines for non-pharmacologic therapies for active PsA.

METHODS

Identification of Studies

Literature search strategies, based on PICO questions (Population/patients, Intervention, Comparator, and Outcomes; see Appendix A) will be developed by the principal investigator, systematic literature review leader, and a research librarian, with input from the Core Team. The search strategies will be peer reviewed by another medical librarian using Peer Review of Electronic Search Strategies (PRESS) (1). Searches will be performed in OVID Medline (1946 +), Embase (1974 +), the Cochrane Library, and PubMed (mid-1960s +).

The search strategies will be developed using the controlled vocabulary or thesauri language for each database: Medical Subject Headings (MeSH) for OVID Medline, PubMed and Cochrane Library; and Emtree terms for Embase. Text words will also be used in OVID Medline, PubMed, and Embase, and keyword/title/abstract words in the Cochrane Library.

Search Limits

Only English language articles will be retrieved.

Grey Literature

The websites of appropriate agencies, such as the Agency for Healthcare Research and Quality (AHRQ), will be searched for peer-reviewed reports not indexed by electronic databases.

Literature Search Update

Literature searches will be updated just before and again at some point after the voting panel meeting but prior to publication of the guideline, to ensure completeness.
Inclusion/Exclusion Criteria

See PICO questions (Appendix A), which outline the defined patient population, interventions, comparators and outcomes.

Management of Studies and Data

References and abstracts will be imported into bibliographic management software (Reference Manager) (2), duplicates removed, and exported to Distiller SR, a web-based systematic review manager (3). Screening and data abstraction forms will be created in Distiller SR. Search results will be divided among reviewers, and two reviewers will screen each title/abstract, with disagreements at the title/abstract screening stage defaulting to inclusion for full manuscript review. Following the same dual review process, disagreements at the full manuscript screening stage will be discussed and adjudicated by the literature review leadership, if necessary.

Phases

1. A search for randomized controlled trials and observational studies about interventions aimed at treatment of PsA and prevention of PsA flares and complications, as well as treatment of psoriatic arthritis will be performed to determine existing studies covering outcomes of interest. Subsequently, identified studies will be assessed using the RevMan (4) and GRADE Pro tools (5).

2. Chosen studies will be quality-assessed using the Cochrane Risk of Bias Tool (6) or the Newcastle-Ottawa Scale (3).

3. Additionally, recently published systematic reviews covering outcomes of interest will also be sought and used for reference cross-checking.

GRADE Methodology

GRADE methodology will be used in this project to grade available evidence and facilitate development of recommendations. The quality of evidence will be graded as high, moderate, low or very low. The strength of recommendations will be graded as strong or conditional. The strength of recommendations will not depend solely on quality of evidence, but also on patient preferences and values, and the weight between benefits and harms. A series of articles that describe the GRADE methodology can be found on the GRADE working group’s website: www.gradeworkinggroup.org.
Analysis and Synthesis

The literature review team will analyze and synthesize data from included studies that address the PICO questions. An evidence profile, including a GRADE Summary of Findings table, will be prepared for each PICO question using Review Manager (RevMan) (2) and GRADEprofiler (GRADEpro) software (5). The Summary of Findings table contains the benefits and harms for each outcome across studies, the assumed and corresponding risk for comparators and interventions (95% CI), the absolute risk and relative effect (95% CI), the number of participants/number of studies and number needed to treat, and the quality of evidence for each critical and important outcome (i.e., high, moderate, low or very low).

The evidence profile documents the quality of the evidence across studies for each critical and important outcome and summarizes the quality factors for randomized controlled trials (risk of bias, inconsistency, indirectness, imprecision and publication bias), and also for observational studies (large magnitude of effect, dose-response gradient, and all plausible confounding that would reduce a demonstrated effect).

Development of Recommendation Statements

PICO questions will be reversed into drafted recommendation statements. Using the GRADE Evidence Profiles and Summaries of Findings tables, the voting panel, consisting of eight rheumatologists, one rheumatology physician assistant, one dermatologist, and two patient representatives, will consider the drafted recommendation statements in two stages. The first assessment will be done individually, and the results will be anonymous; this vote will only be used to determine where consensus might or might not already exist and develop the voting panel meeting agenda. At the face-to-face voting panel meeting, chaired by the PI, the panel will discuss the evidence in the context of their clinical experience and expertise to arrive at consensus on the final recommendations. The voting panel meeting discussions will be supported by the literature review leader, the GRADE expert, and selected members of the literature review team, who will attend the meeting to provide details about the evidence, as requested. Voting panel discussions and decisions will be informed by a separately convened patient panel, which will meet the day before the voting panel, to provide unique patient perspectives on the drafted recommendations based on their experiences and the available literature.

PLANNED APPENDICES (AT MINIMUM)

A. Final literature search strategies
B. GRADE evidence profiles and summary of findings tables for each PICO question
AUTHORSHIP

Authorship of the guidelines will include: principal investigator and voting panel leader, Dr. Jasvinder Singh, as the lead author; Dr. James Reston, literature review leader; Drs. Dafna Gladman and Alexis Ogdie, content experts; and Dr. Gordon Guyatt, GRADE expert. Members of the literature review team and voting panel will also be authors. The PI will determine final authorship, dependent on the efforts made by individuals throughout the guideline development process, using international authorship standards as guidance.

DISCLOSURES/CONFLICTS OF INTEREST

The ACR’s disclosure and COI policies for guideline development will be followed for this project. These can be found in the ACR Guideline Manual on this page of the ACR web site, under Policies & Procedures. See Appendix B for participant disclosures.

REFERENCES

This ACR-NPF guideline will focus on treatment of patients with “active PsA:”

- Psoriatic arthritis is an inflammatory musculoskeletal disease associated with psoriasis.
- We define active PsA as disease causing symptoms at an unacceptably bothersome level as reported by the patient, and judged by the examining clinician to be due to PsA based on \( \geq 1 \) of the following:
  - Swollen joints
  - Tender joints
  - Dactylitis
  - Enthesitis
  - Axial disease
  - Active skin and/or nail involvement
  - Extra-articular inflammatory manifestations such as uveitis, IBD

- The examining clinician may take into account:
  - Inflammatory markers (CRP, ESR)
  - Imaging
  - Patient reported outcomes

To standardize the terms below, we used the terminology derived by the pharmacological therapy consolidation team. All groups present at the psoriatic arthritis guideline project face-to-face meeting in Atlanta in September 2016 agreed to the definition above and the definitions of medication groups specified below.
Pharmacological Treatment Groups:
1. Oral Small Molecules (OSM) = methotrexate (MTX), sulfasalazine (SSZ), leflunomide (LEF), apremilast (APR), cyclosporine (CsA)
2. TNFi biologics
3. IL12/23 biologic/s
4. IL17 biologic/s

Outcomes: The critical outcomes were defined as follows:
1. MSK disease activity, as determined by measures such as ACR20, ACR50 and ACR70.
   a. If all three indices are provided, ACR20 will be presented in the summary of findings (SoF) tables, since it’s most universally reported.
   b. Hierarchy for choice of measures to be abstracted for SoF tables, if more than one measure are presented in study results:
      i. American College of Rheumatology 20% Response Criteria (ACR20)
      ii. Psoriatic Arthritis Response Criteria (PsARC)
      iii. ACR50
      iv. ACR70
      v. Minimal Disease Activity (MDA)
      vi. Enthesitis: Leeds Enthesitis Index
      vii. Enthesitis: Spondyloarthritis Research Consortium Canada (SPARCC)
      viii. Enthesitis: PsA-modified Maastricht Ankylosing Spondylitis Enthesitis Score (MASES)
      ix. Enthesitis: count
      x. Dactylitis: count
      xi. Dactylitis: Leeds Dactylitis Index
      xii. Joint count: 66/68 (swollen/tender)
      xiii. Joint count: 76/78 (swollen/tender)
      xiv. Joint count: 28 (excluding lower extremity joints)
   2. Physical function, as determined by measures such as HAQ-DI and others.
a. If several indices are provided, the following hierarchy will be used to pick one measure for SoF tables based on relevance for patient care and the most universally reported and used scales:
   i. Proportion with HAQ-DI with clinically meaningful improvement (MCID >0.35)
   ii. Continuous HAQ-DI score
   iii. SF-36 Physical Functioning (PF) scale
   iv. PROMIS-PF scale
   v. Another validated function scale

3. Psoriasis skin scores/indices, as determined by measures such as PASI75, PASI90, PGA, BSA.
   a. If several indices are provided, the following hierarchy will be used to pick one measure for SoF tables based on relevance for patient care and the most universally reported and used scales:
      i. Psoriasis Activity and Severity Index (PASI)-75
      ii. PASI90
      iii. Physician Global Assessment (PGA)
      iv. Body Surface Area (BSA)

4. Adverse events, which are different by comparison and specifically noted below for each category:
   • Harms for OSM include:
      o Liver toxicity (liver function tests >1.5X and >2X upper limit) or liver failure/cirrhosis (if both presented we will choose the latter due to greater patient relevance)
      o GI intolerance (nausea, vomiting, diarrhea)
      o Depression
   • Harms for TNFi, IL17 or IL12/23 include:
      o Serious infection
      o Herpes zoster
      o Overall malignancy (or cancer)
      o Depression
American College of Rheumatology (ACR) and National Psoriasis Foundation (NPF)
Psoriatic Arthritis Guideline

Project Plan – November 2016

- Major adverse cardiovascular events as a composite
  - Harms for non-pharmacologic include:
    - Flare of disease activity
    - Injury
    - Tendon rupture

NON-PHARMACOLOGIC

1. In adult patients with active PsA, what are the benefits and harms of exercise compared to no exercise?
2. In adult patients with active PsA, what are the benefits and harms of low impact exercise (e.g., tai chi, yoga, swimming) compared to high impact exercise (e.g., running)?
3. In adult patients with active PsA with active peripheral arthritis and/or enthesitis, what are the benefits and harms of physical therapy (PT) compared with no PT?
4. In adult patients with active PsA with active peripheral arthritis and/or enthesitis, what are the benefits and harms of occupational therapy (OT) compared with no OT?
5. In adult patients with active PsA who are overweight (e.g., BMI 25 and over), what are the benefits and harms of weight loss compared with no weight loss?
6. In adult patients with active PsA who smoke, what are the benefits and harms of smoking cessation compared with no smoking cessation?
7. In adult patients with active PsA, what are the benefits and harms of massage therapy compared with no massage therapy?
8. In adult patients with active PsA, what are the benefits and harms of acupuncture compared with no acupuncture?

PHARMACOLOGIC INTERVENTIONS

Treatment-naïve (defined as naïve to OSM, TNFi, IL17 and IL12/23; patients may have experienced NSAIDs, glucocorticoids, and/or other pharmacological and/or non-pharmacological interventions)
9. In adult patients with active PsA who are treatment-naïve, what are the benefits and harms of an OSM vs. TNFi?

10. In adult patients with active PsA who are treatment-naïve, what are the benefits and harms of an OSM vs. IL12/23?

11. In adult patients with active PsA who are treatment-naïve, what are the benefits and harms of an OSM vs. IL17i?

12. In adult patients with active PsA who are treatment-naïve, what are the benefits and harms of a TNFi vs. IL12/23i?

13. In adult patients with active PsA who are treatment-naïve, what are the benefits and harms of TNFi vs. IL17i?

14. In adult patients with active PsA who are treatment-naïve, what are the benefits and harms of IL12/23i vs. IL17i?

15. In adult patients with active PsA despite treatment with OSM, what are the benefits and harms of switching to TNFi compared to switching to IL12/23i?

16. In adult patients with active PsA despite treatment with OSM, what are the benefits and harms of switching to TNFi compared to switching to IL17i?

17. In adult patients with active PsA despite treatment with OSM, what are the benefits and harms of switching to IL12/23i compared to switching to IL17i?

18. In adult patients with active PsA despite treatment with an OSM, what are the benefits and harms of switching to MTX and TNFi combination therapy compared to switching to TNFi monotherapy?

19. In adult patients with active PsA despite treatment with an OSM, what are the benefits and harms of switching to MTX and IL12/23i combination therapy compared to switching to IL12/23i monotherapy?

20. In adult patients with active PsA despite treatment with an OSM, what are the benefits and harms of switching to MTX and IL17i combination therapy compared to switching to IL17i monotherapy?

21. In adult patients with active PsA despite treatment with an OSM, what are the benefits and harms of switching to another OSM monotherapy compared to adding another OSM?

22. In adult patients with active PsA despite treatment with an OSM, what are the benefits and harms of switching to a different OSM monotherapy compared to switching to a TNFi?
23. In adult patients with active PsA despite treatment with an OSM, what are the benefits and harms of switching to a different OSM monotherapy compared to switching to an IL12/23i?

24. In adult patients with active PsA despite treatment with an OSM, what are the benefits and harms of switching to a different OSM monotherapy compared to switching to an IL17i?

TNFi Failure

25. In adult patients with active PsA despite treatment with a TNFi monotherapy, what are the benefits and harms of switching to a second TNFi + MTX compared to adding MTX to the same TNFi monotherapy?

26. In adult patients with active PsA despite treatment with a TNFi monotherapy, what are the benefits and harms of switching to a second TNFi compared to switching to IL12/23i?

27. In adult patients with active PsA despite treatment with a TNFi monotherapy, what are the benefits and harms of switching to a second TNFi compared to switching to IL17i?

28. In adult patients with active PsA despite treatment with a TNFi monotherapy, what are the benefits and harms of switching to an IL12/23i compared to switching to IL17i?

29. In adult patients with active PsA despite treatment with a TNFi monotherapy, what are the benefits and harms of switching to a second TNFi and MTX combination therapy compared to a second TNFi monotherapy?

30. In adult patients with active PsA despite treatment with a TNFi monotherapy, what are the benefits and harms of switching to MTX and IL12/23i combination therapy compared to switching to IL12/23i monotherapy?

31. In adult patients with active PsA despite treatment with a TNFi monotherapy what are the benefits and harms of switching to MTX and IL17i combination therapy compared to switching to IL17i monotherapy?

32. In adult patients with active PsA despite treatment with a TNFi and MTX combination therapy, what are the benefits and harms of switching to a second TNFi and MTX combination therapy compared to switching to a second TNFi monotherapy?

33. In adult patients with active PsA despite treatment with a TNFi and MTX combination therapy, what are the benefits and harms of switching to MTX and IL12/23i combination therapy compared to switching to IL12/23i monotherapy?
34. In adult patients with active PsA despite treatment with a TNFi and MTX combination therapy, what are the benefits and harms of switching to MTX and IL17i combination therapy compared to switching to IL17i monotherapy?

35. In adult patients with active PsA despite treatment with an IL23/23i, what are the benefits and harms of adding MTX to the IL12/23i compared to switching to TNFi?

36. In adult patients with active PsA despite treatment with an IL23/23i, what are the benefits and harms of adding MTX to the IL12/23i compared to switching to IL17i?

37. In adult patients with active PsA despite treatment with an IL23/23i, what are the benefits and harms of switching to a TNFi compared to switching to IL17i?

38. In adult patients with active PsA despite treatment with an IL17i, what are the benefits and harms of adding MTX to the IL17i compared to switching to IL12/23i?

39. In adult patients with active PsA despite treatment with an IL17i, what are the benefits and harms of adding MTX to the IL17i compared to switching to TNFi?

40. In adult patients with active PsA despite treatment with an IL17i, what are the benefits and harms of switching to a TNFi compared to switching to IL12/23i?

41. In adult patients with active PsA despite treatment with an IL17i, what are the benefits and harms of switching to a different IL17i compared to switching to TNFi?

42. In adult patients with active PsA despite treatment with an IL17i, what are the benefits and harms of switching to a different IL17i compared to switching to IL12/23i?
Treatment Strategy
43. Among adults with active PsA, what are the benefits and harms of treat to target (or intensive therapy) compared to a not treat to target strategy (include liver toxicity, zoster, malignancy, infection, cardiovascular, IBD, uveitis)?

PSORIATIC SPONDYLITIS/AXIAL
In the opinion of our group, psoriatic spondyloarthritis is not sufficiently different from axial spondyloarthritis. ACR-SAA-SPARTAN treatment guidelines have been published in February 2016 and the reader is referred to that manuscript for treatment recommendations for axial PsA. However, inhibitors of IL12/IL-23 or IL-17 were not studied in the ACR-SAA-SPARTAN axial SpA treatment guidelines. Thus, this group has few additional PICO questions to adequately cover these clinical situations:

44. In adult patients with active axial PsA despite treatment with NSAIDs, what are the benefits and harms of switching to IL12/23i compared to switching to TNFi?
45. In adult patients with active axial PsA despite treatment with NSAIDs, what are the benefits and harms of switching to IL17i compared to switching to TNFi?
46. In adult patients with active axial PsA despite treatment with NSAIDs, what are the benefits and harms of switching to IL17i compared to switching to IL12/23i?

ENTHESITIS (enthesitis score/grade will be an additional critical outcome for these PICO questions)
47. In adult patients with active PsA and predominant enthesitis who are both OSM and biologic treatment-naïve, what are the benefits and harms of starting OSM compared to starting NSAIDs?
48. In adult patients with active PsA and predominant enthesitis despite treatment with OSM, what are the benefits and harms of switching to TNFi compared to switching to IL12/23i?
49. In adult patients with active PsA and predominant enthesitis despite treatment with OSM, what are the benefits and harms of switching to TNFi compared to switching to IL17i?
50. In adult patients with active PsA and predominant enthesitis despite treatment with OSM, what are the benefits and harms of switching to IL12/23i compared to switching to IL17i?

51. In adult patients with active PsA and predominant enthesitis despite treatment with NSAIDs, what are the benefits and harms of switching to tofacitinib compared to switching to OSM?

SPECIAL POPULATIONS

52. In patients with active PsA, what are the benefits and harms of vaccination with killed vaccines prior to starting biologic compared to vaccination while using a biologic?

53. In patients with active PsA, what are the benefits and harms of vaccination with live attenuated vaccines prior to starting biologic compared to vaccination while using a biologic?

COMORBIDITIES

54. In adult patients with active PsA and IBD despite treatment with an OSM, what are the benefits and harms of switching to TNFi (monoclonal antibodies [MABs]) vs. switching to TNFi soluble receptor biologic (i.e. etanercept)?

55. In adult patients with active PsA and IBD despite treatment with an OSM, what are the benefits and harms of switching to TNFi (MABs) vs. switching to IL17i?

56. In adult patients with active PsA and IBD despite treatment with an OSM, what are the benefits and harms of switching to IL12/23i vs. switching to IL17i?

57. In adult patients with active PsA and IBD despite treatment with an OSM, what are the benefits and harms of switching to TNFi (MABs) vs. switching to IL12/23i?

58. In adult patients with active PsA and IBD who are both OSM and biologic treatment-naïve, what are the benefits and harms of starting OSMs vs. starting TNFi (MABs)?
59. In adult patients with active PsA and diabetes who are both OSM and biologic treatment-naïve, what are the benefits and harms of starting OSM vs. starting TNFi?

60. In adult patients with active PsA and frequent serious infections who are both OSM and biologic treatment-naïve, what are the benefits and harms of starting OSMs vs. starting TNFi?

61. In adult patients with active PsA and frequent serious infections despite treatment with an OSM, what are the benefits and harms of switching to TNFi vs. switching to IL12/23i?
APPENDIX B - Participant Disclosures

In order for the College to most effectively further its mission and to otherwise maintain its excellent reputation in the medical community and with the public, it is important that confidence in the College’s integrity be maintained. The cornerstone of the ACR’s Disclosure Policy is disclosure of actual and potential conflicts so that they can be evaluated by the College in order to avoid undue influence of potential conflicts. The purpose of the ACR’s Disclosure Policy is identification of relationships which may pose actual or potential conflicts. These actual or potential conflicts can then be evaluated by the College so that adjustments can be made that will avoid any undue influence. This policy is based on the principle that, in many cases, full disclosure of the actual or potentially conflicting relationship will of itself suffice to protect the integrity of the College and its interests.

<table>
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<tr>
<th>Participants</th>
<th>Role</th>
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<th>Sources of personal income (salary information from primary employer is not required):</th>
<th>Research Grants/Contracts</th>
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<th>Organizational Benefit</th>
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