



**American College of Rheumatology (ACR) and National Psoriasis Foundation (NPF)
Psoriatic Arthritis Guideline**

Project Plan – November 2016

PARTICIPANTS

Core Oversight Team

Jasvinder Singh, MD, MPH (*Principal Investigator, Voting Panel Leader*)
James Reston, MD (*Literature Review Leader*)
Dafna Gladman, MD (*Content Expert*)
Alexis Ogdie, MD, MSCE (*Content Expert*)
Gordon Guyatt, MD (*GRADE Expert*)

Literature Review Team

Helena Jonsson, MD
Amit Aakash Shah, MD, MPH
Nancy Sullivan, BA
Marat Turgunbaev, MD, MPH

Voting Panel

Chad Deal, MD
Atul Deodhar, MD
Deborah Desir, MD
Maureen Dubreuil, MD
Jonathan Dunham, MD
Elaine Husni, MD, MPH
Sarah Kenny
Paula Marchetta, MD, MBA
Phil Mease, MD
Julie Miner, PT
Christopher Ritchlin, MD, MPH
Ben Smith, PA-C
Abby Van Voorhees, MD

Expert Panel

Laura Coates, MD
Marina Magrey, MD
Joseph Merola, MD, MMSC
Ben Nowell, PhD
Ana-Maria Orbai, MD
Soumya Reddy, MD

Veronica Richardson, NP
Jose Scher, MD
Evan Siegel, MD
Michael Siegel, PhD
Ingrid Steinkoenig
Jessica Walsh, MD

Patient Panel

Eddie Applegate
Gail C. Richardson
Hilary Wilson

ACR Staff

Robin Lane
Amy S. Miller
Regina Parker

NPF Staff

Emily Boyd

ECRI Institute Staff

Karen Schoelles, MD



**American College of Rheumatology (ACR) and National Psoriasis Foundation (NPF)
Psoriatic Arthritis Guideline**

Project Plan – November 2016

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38

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, spondyloarthritis, 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



**American College of Rheumatology (ACR) and National Psoriasis Foundation (NPF)
Psoriatic Arthritis Guideline**

Project Plan – November 2016

- 39 • Interleukin-12/23 (IL12/232): ustekinumab
40 • Interleukin 17 (IL17): secukinumab; ixekizumab

41

42 **OBJECTIVES**

43

44 Specifically, we aim to:

- 45 1. Develop pharmacologic treatment recommendations for adult patients with active PsA.
46 2. Develop guidelines for non-pharmacologic therapies for active PsA.

47

48 **METHODS**

49

50 *Identification of Studies*

51

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

58

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

63

64 *Search Limits*

65

66 Only English language articles will be retrieved.

67

68 *Grey Literature*

69

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

72

73 *Literature Search Update*

74

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



**American College of Rheumatology (ACR) and National Psoriasis Foundation (NPF)
Psoriatic Arthritis Guideline**

Project Plan – November 2016

77

78 *Inclusion/Exclusion Criteria*

79

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

82

83 *Management of Studies and Data*

84

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

92

93 *Phases*

94

- 95 1. A search for randomized controlled trials and observational studies about interventions aimed
96 at treatment of PsA and prevention of PsA flares and complications, as well as treatment of
97 psoriatic arthritis will be performed to determine existing studies covering outcomes of interest.
98 Subsequently, identified studies will be assessed using the RevMan (4) and GRADE Pro tools (5).
- 99 2. Chosen studies will be quality-assessed using the Cochrane Risk of Bias Tool (6) or the
100 Newcastle-Ottawa Scale (3).
- 101 3. Additionally, recently published systematic reviews covering outcomes of interest will also be
102 sought and used for reference cross-checking.

103

104 *GRADE Methodology*

105

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

112

113

114



**American College of Rheumatology (ACR) and National Psoriasis Foundation (NPF)
Psoriatic Arthritis Guideline**

Project Plan – November 2016

115 *Analysis and Synthesis*

116
117 The literature review team will analyze and synthesize data from included studies that address the PICO
118 questions. An evidence profile, including a GRADE Summary of Findings table, will be prepared for each
119 PICO question using Review Manager (RevMan) (2) and GRADEprofiler (GRADEpro) software (5). The
120 Summary of Findings table contains the benefits and harms for each outcome across studies, the
121 assumed and corresponding risk for comparators and interventions (95% CI), the absolute risk and
122 relative effect (95% CI), the number of participants/number of studies and number needed to treat, and
123 the quality of evidence for each critical and important outcome (i.e., high, moderate, low or very low).
124

125 The evidence profile documents the quality of the evidence across studies for each critical and
126 important outcome and summarizes the quality factors for randomized controlled trials (risk of bias,
127 inconsistency, indirectness, imprecision and publication bias), and also for observational studies (large
128 magnitude of effect, dose-response gradient, and all plausible confounding that would reduce a
129 demonstrated effect).
130

131 *Development of Recommendation Statements*

132
133 PICO questions will be reversed into drafted recommendation statements. Using the GRADE Evidence
134 Profiles and Summaries of Findings tables, the voting panel, consisting of eight rheumatologists, one
135 rheumatology physician assistant, one dermatologist, and two patient representatives, will consider the
136 drafted recommendation statements in two stages. The first assessment will be done individually, and
137 the results will be anonymous; this vote will only be used to determine where consensus might or might
138 not already exist and develop the voting panel meeting agenda. At the face-to-face voting panel
139 meeting, chaired by the PI, the panel will discuss the evidence in the context of their clinical experience
140 and expertise to arrive at consensus on the final recommendations. The voting panel meeting
141 discussions will be supported by the literature review leader, the GRADE expert, and selected members
142 of the literature review team, who will attend the meeting to provide details about the evidence, as
143 requested. Voting panel discussions and decisions will be informed by a separately convened patient
144 panel, which will meet the day before the voting panel, to provide unique patient perspectives on the
145 drafted recommendations based on their experiences and the available literature.
146

147 **PLANNED APPENDICES (AT MINIMUM)**

- 148
149 A. Final literature search strategies
150 B. GRADE evidence profiles and summary of findings tables for each PICO question
151
152



**American College of Rheumatology (ACR) and National Psoriasis Foundation (NPF)
Psoriatic Arthritis Guideline**

Project Plan – November 2016

153 **AUTHORSHIP**

154

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

161

162 **DISCLOSURES/CONFLICTS OF INTEREST**

163

164 The ACR's disclosure and COI policies for guideline development will be followed for this project. These
165 can be found in the ACR Guideline Manual on [this page of the ACR web site](#), under Policies &
166 Procedures. *See Appendix B for participant disclosures.*

167

168 **REFERENCES**

169

- 170 1. Sampson M, McGowan J, Lefebvre C, Moher D, Grimshaw J. PRESS: Peer Review of Electronic
171 Search Strategies. Ottawa: Canadian Agency for Drugs and Technologies in Health; 2008.
- 172 2. Review Manager [software]. Oxford (UK): Cochrane Collaboration; 2013.
173 <http://ims.cochrane.org/revman>
- 174 3. DistillerSR. Ottawa, Canada: Evidence Partners; 2013. <http://systematic-review.net/>
- 175 4. Reference Manager [software]. Thomson Reuters; 2013. <http://www.refman.com/>
- 176 5. GRADEprofiler [software]. Oxford (UK): Cochrane Collaboration; 2013.
177 <http://ims.cochrane.org/revman/gradepr>
- 178 6. Wells GA, Shea B, O'Connell D, Welch V, Losos M, Tugwell P. The Newcastle-Ottawa Scale (NOS)
179 for assessing the quality of nonrandomised studies in meta-analyses. 2010. Available:
180 http://www.ohri.ca/programs/clinical_epidemiology/oxford.asp



**American College of Rheumatology (ACR) and National Psoriasis Foundation (NPF)
Psoriatic Arthritis Guideline**

Project Plan – November 2016

181 APPENDIX A

182 **PICO Questions**

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

- 184
- 185 • Psoriatic arthritis is an inflammatory musculoskeletal disease associated with psoriasis.
 - 186 • We define **active PsA** as disease causing symptoms at an unacceptably bothersome level as reported by the patient, and judged by
187 the examining clinician to be due to PsA based on ≥ 1 of the following:
 - 188 ○ Swollen joints
 - 189 ○ Tender joints
 - 190 ○ Dactylitis
 - 191 ○ Enthesitis
 - 192 ○ Axial disease
 - 193 ○ Active skin and/or nail involvement
 - 194 ○ Extra-articular inflammatory manifestations such as uveitis, IBD
 - 195 • The examining clinician may take into account:
 - 196 ○ Inflammatory markers (CRP, ESR)
 - 197 ○ Imaging
 - 198 ○ Patient reported outcomes

199 **To standardize the terms below, we used the terminology derived by the pharmacological therapy consolidation team. All groups present at**
200 **the psoriatic arthritis guideline project face-to-face meeting in Atlanta in September 2016 agreed to the definition above and the definitions**
201 **of medication groups specified below.**

202

203



**American College of Rheumatology (ACR) and National Psoriasis Foundation (NPF)
Psoriatic Arthritis Guideline**

Project Plan – November 2016

204 **Pharmacological Treatment Groups:**

- 205 1. Oral Small Molecules (OSM) = methotrexate (MTX), sulfasalazine (SSZ), leflunomide (LEF), apremilast (APR), cyclosporine (CsA)
206 2. TNFi biologics
207 3. IL12/23 biologic/s
208 4. IL17 biologic/s

209 **Outcomes:** The critical outcomes were defined as follows:

- 210 1. MSK disease activity, as determined by measures such as ACR20, ACR50 and ACR70.
211 a. If all three indices are provided, ACR20 will be presented in the summary of findings (SoF) tables, since it's most universally
212 reported.
213 b. Hierarchy for choice of measures to be abstracted for SoF tables, if more than one measure are presented in study results:
214 i. American College of Rheumatology 20% Response Criteria (ACR20)
215 ii. Psoriatic Arthritis Response Criteria (PsARC)
216 iii. ACR50
217 iv. ACR70
218 v. Minimal Disease Activity (MDA)
219 vi. Enthesitis: Leeds Enthesitis Index
220 vii. Enthesitis: Spondyloarthritis Research Consortium Canada (SPARCC)
221 viii. Enthesitis: PsA-modified Maastricht Ankylosing Spondylitis Enthesitis Score (MASES)
222 ix. Enthesitis: count
223 x. Dactylitis: count
224 xi. Dactylitis: Leeds Dactylitis Index
225 xii. Joint count: 66/68 (swollen/tender)
226 xiii. Joint count: 76/78 (swollen/tender)
227 xiv. Joint count: 28 (excluding lower extremity joints)
228 2. Physical function, as determined by measures such as HAQ-DI and others.



**American College of Rheumatology (ACR) and National Psoriasis Foundation (NPF)
Psoriatic Arthritis Guideline**

Project Plan – November 2016

- 229 a. If several indices are provided, the following hierarchy will be used to pick one measure for SoF tables based on relevance for
230 patient care and the most universally reported and used scales:
- 231 i. Proportion with HAQ-DI with clinically meaningful improvement (MCID >0.35)
 - 232 ii. Continuous HAQ-DI score
 - 233 iii. SF-36 Physical Functioning (PF) scale
 - 234 iv. PROMIS-PF scale
 - 235 v. Another validated function scale
- 236 3. Psoriasis skin scores/indices, as determined by measures such as PASI75, PASI90, PGA, BSA.
- 237 a. If several indices are provided, the following hierarchy will be used to pick one measure for SoF tables based on relevance for
238 patient care and the most universally reported and used scales:
- 239 i. Psoriasis Activity and Severity Index (PASI)-75
 - 240 ii. PASI90
 - 241 iii. Physician Global Assessment (PGA)
 - 242 iv. Body Surface Area (BSA)
- 243 4. Adverse events, which are different by comparison and specifically noted below for each category:
- 244 • Harms for **OSM** include:
 - 245 ○ Liver toxicity (liver function tests >1.5X and >2X upper limit) or liver failure/cirrhosis (if both presented we will choose the
246 latter due to greater patient relevance)
 - 247 ○ GI intolerance (nausea, vomiting, diarrhea)
 - 248 ○ Depression
 - 249 • Harms for **TNFi, IL17 or IL12/23** include:
 - 250 ○ Serious infection
 - 251 ○ Herpes zoster
 - 252 ○ Overall malignancy (or cancer)
 - 253 ○ Depression



**American College of Rheumatology (ACR) and National Psoriasis Foundation (NPF)
Psoriatic Arthritis Guideline**

Project Plan – November 2016

- 254 ○ Major adverse cardiovascular events as a composite
- 255 ● Harms for non-pharmacologic include:
- 256 ○ Flare of disease activity
- 257 ○ Injury
- 258 ○ Tendon rupture

259

260 **NON-PHARMACOLOGIC**

- 261 1. In adult patients with active PsA, what are the benefits and harms of **exercise** compared to **no exercise**?
- 262 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
- 263 **high impact exercise** (e.g., running)?
- 264 3. In adult patients with active PsA with active peripheral arthritis and/or enthesitis, what are the benefits and harms of physical therapy
- 265 **(PT)** compared with **no PT**?
- 266 4. In adult patients with active PsA with active peripheral arthritis and/or enthesitis, what are the benefits and harms of occupational
- 267 therapy **(OT)** compared with **no OT**?
- 268 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
- 269 with **no weight loss**?
- 270 6. In adult patients with active PsA who smoke, what are the benefits and harms of **smoking cessation** compared with **no smoking**
- 271 **cessation**?
- 272 7. In adult patients with active PsA, what are the benefits and harms of **massage therapy** compared with **no massage therapy**?
- 273 8. In adult patients with active PsA, what are the benefits and harms of **acupuncture** compared with **no acupuncture**?

274

275 **PHARMACOLOGIC INTERVENTIONS**

276

277 **Treatment-naïve** (defined as naïve to OSM, TNFi, IL17 and IL12/23; patients may have experienced NSAIDs, glucocorticoids, and/or other
278 pharmacological and/or non-pharmacological interventions)



American College of Rheumatology (ACR) and National Psoriasis Foundation (NPF)
Psoriatic Arthritis Guideline

Project Plan – November 2016

- 279 9. In adult patients with active PsA who are treatment-naïve, what are the benefits and harms of an **OSM** vs. **TNFi**?
- 280 10. In adult patients with active PsA who are treatment-naïve, what are the benefits and harms of an **OSM** vs. **IL12/23**?
- 281 11. In adult patients with active PsA who are treatment-naïve, what are the benefits and harms of an **OSM** vs. **IL17i**?
- 282 12. In adult patients with active PsA who are treatment-naïve, what are the benefits and harms of a **TNFi** vs. **IL12/23i**?
- 283 13. In adult patients with active PsA who are treatment-naïve, what are the benefits and harms of **TNFi** vs. **IL17i**?
- 284 14. In adult patients with active PsA who are treatment-naïve, what are the benefits and harms of **IL12/23i** vs. **IL17i**?

285

Failed OSM Only

- 286
- 287 15. In adult patients with active PsA despite treatment with OSM, what are the benefits and harms of switching to **TNFi** compared to
- 288 switching to **IL12/23i**?
- 289 16. In adult patients with active PsA despite treatment with OSM, what are the benefits and harms of switching to **TNFi** compared to
- 290 switching to **IL17i**?
- 291 17. In adult patients with active PsA despite treatment with OSM, what are the benefits and harms of switching to **IL12/23i** compared to
- 292 switching to **IL17i**?
- 293 18. In adult patients with active PsA despite treatment with an OSM, what are the benefits and harms of switching to **MTX and TNFi**
- 294 **combination therapy** compared to switching to **TNFi monotherapy**?
- 295 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**
- 296 **combination therapy** compared to switching to **IL12/23i monotherapy**?
- 297 20. In adult patients with active PsA despite treatment with an OSM, what are the benefits and harms of switching to **MTX and IL17i**
- 298 **combination therapy** compared to switching to **IL17i monotherapy**?
- 299 21. In adult patients with active PsA despite treatment with an OSM, what are the benefits and harms of switching to **another OSM**
- 300 **monotherapy** compared to **adding another OSM**?
- 301 22. In adult patients with active PsA despite treatment with an OSM, what are the benefits and harms of switching to **a different OSM**
- 302 **monotherapy** compared to switching to a **TNFi**?



American College of Rheumatology (ACR) and National Psoriasis Foundation (NPF)
Psoriatic Arthritis Guideline

Project Plan – November 2016

- 303 23. In adult patients with active PsA despite treatment with an OSM, what are the benefits and harms of switching to a **different OSM**
304 **monotherapy** compared to switching to an **IL12/23i**?
305 24. In adult patients with active PsA despite treatment with an OSM, what are the benefits and harms of switching to a **different OSM**
306 **monotherapy** compared to switching to an **IL17ii**?

307

308 **TNFi Failure**

- 309 25. In adult patients with active PsA despite treatment with a TNFi monotherapy, what are the benefits and harms of switching to a **second**
310 **TNFi + MTX** compared to **adding MTX to the same TNFi monotherapy**?
311 26. In adult patients with active PsA despite treatment with a TNFi monotherapy, what are the benefits and harms of switching to a **second**
312 **TNFi** compared to switching to **IL12/23i**?
313 27. In adult patients with active PsA despite treatment with a TNFi monotherapy, what are the benefits and harms of switching to a **second**
314 **TNFi** compared to switching to **IL17i**?
315 28. In adult patients with active PsA despite treatment with a TNFi monotherapy, what are the benefits and harms of switching to an
316 **IL12/23i** compared to switching to **IL17i**?
317 29. In adult patients with active PsA despite treatment with a TNFi monotherapy, what are the benefits and harms of switching to a **second**
318 **TNFi and MTX combination therapy** compared to a **second TNFi monotherapy**?
319 30. In adult patients with active PsA despite treatment with a TNFi monotherapy, what are the benefits and harms of switching to **MTX and**
320 **IL12/23i combination therapy** compared to switching to **IL12/23i monotherapy**?
321 31. In adult patients with active PsA despite treatment with a TNFi monotherapy what are the benefits and harms of switching to **MTX and**
322 **IL17i combination therapy** compared to switching to **IL17i monotherapy**?
323 32. In adult patients with active PsA despite treatment with a TNFi and MTX combination therapy, what are the benefits and harms of
324 switching to a **second TNFi and MTX combination therapy** compared to switching to a **second TNFi monotherapy**?
325 33. In adult patients with active PsA despite treatment with a TNFi and MTX combination therapy, what are the benefits and harms of
326 switching to **MTX and IL12/23i combination therapy** compared to switching to **IL12/23i monotherapy**?



**American College of Rheumatology (ACR) and National Psoriasis Foundation (NPF)
Psoriatic Arthritis Guideline**

Project Plan – November 2016

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

329

330 **IL12/23i Failure**

331 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
332 compared to switching to **TNFi**?

333 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
334 compared to switching to **IL17i**?

335 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
336 switching to **IL17i**?

337

338 **IL17i Failure**

339 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
340 to switching to **IL12/23i**?

341 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
342 to switching to **TNFi**?

343 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
344 switching to **IL12/23i**?

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

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

349

350

351



**American College of Rheumatology (ACR) and National Psoriasis Foundation (NPF)
Psoriatic Arthritis Guideline**

Project Plan – November 2016

352

353 **Treatment Strategy**

354 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**
355 **target strategy** (include liver toxicity, zoster, malignancy, infection, cardiovascular, IBD, uveitis)?

356

357 **PSORIATIC SPONDYLITIS/AXIAL**

358 In the opinion of our group, psoriatic spondyloarthritis is not sufficiently different from axial spondyloarthritis. ACR-SAA-SPARTAN treatment
359 guidelines have been published in February 2016 and the reader is referred to that manuscript for treatment recommendations for axial PsA.
360 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
361 additional PICO questions to adequately cover these clinical situations:

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

364 45. In adult patients with active axial PsA despite treatment with NSAIDs, what are the benefits and harms of switching to **IL17i** compared to
365 switching to **TNFi**?

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

368

369 **ENTHESITIS (enthesitis score/grade will be an additional critical outcome for these PICO questions)**

370 47. In adult patients with active PsA and predominant enthesitis who are both OSM and biologic treatment-naïve, what are the benefits and
371 harms of starting **OSM** compared to starting **NSAIDs**?

372 48. In adult patients with active PsA and predominant enthesitis despite treatment with OSM, what are the benefits and harms of switching
373 to **TNFi** compared to switching to **IL12/23i**?

374 49. In adult patients with active PsA and predominant enthesitis despite treatment with OSM, what are the benefits and harms of switching
375 to **TNFi** compared to switching to **IL17i**?



**American College of Rheumatology (ACR) and National Psoriasis Foundation (NPF)
Psoriatic Arthritis Guideline**

Project Plan – November 2016

- 376 50. In adult patients with active PsA and predominant enthesitis despite treatment with OSM, what are the benefits and harms of switching
377 to **IL12/23i** compared to switching to **IL17i**?
- 378 51. In adult patients with active PsA and predominant enthesitis despite treatment with NSAIDs, what are the benefits and harms of
379 switching to **tofacitinib** compared to switching to **OSM**?

380

381 **SPECIAL POPULATIONS**

- 382 52. In patients with active PsA, what are the benefits and harms of **vaccination with killed vaccines prior to starting biologic** compared to
383 **vaccination while using a biologic**?
- 384 53. In patients with active PsA, what are the benefits and harms of **vaccination with live attenuated vaccines prior to starting biologic**
385 compared to **vaccination while using a biologic**?

386

387 **COMORBIDITIES**

388 *IBD*

- 389 54. In adult patients with active PsA and IBD despite treatment with an OSM, what are the benefits and harms of switching to **TNFi**
390 **(monoclonal antibodies [MABs])** vs. switching to **TNFi soluble receptor biologic (i.e. etanercept)**?
- 391 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)**
392 vs. switching to **IL17i**?
- 393 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.
394 switching to **IL17i**?
- 395 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)**
396 vs. switching to **IL12/23i**?
- 397 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
398 **OSMs** vs. starting **TNFi (MABs)**?

399



American College of Rheumatology (ACR) and National Psoriasis Foundation (NPF)
Psoriatic Arthritis Guideline

Project Plan – November 2016

400

401 *Diabetes*

402 59. In adult patients with active PsA and diabetes who are both OSM and biologic treatment-naïve, what are the benefits and harms of
403 starting **OSM** vs. starting **TNFi**?

404

405 *Serious Infection*

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

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

410

411

412

413

414

415

416

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.

Participants	Role	Primary employer	Sources of personal income (salary information from primary employer is not required):	Research Grants/Contracts	Investments to include medical industry and nonmedical industry	Organizational Benefit	Activities with other organizations	Family or other relations
Jasvinder Singh	PI/Core Team	Birmingham VA Med Ctr; University of Alabama at Birmingham	Bioiberica; Horizon Pharmaceuticals/DINORA; Takeda Pharmaceuticals; WebMD; UBM LLC; Crealta/DINORA; American College of Rheumatology	PCORI; NIAMS; AHRQ; VA	NA	NA	OMERACT; Editorial Board, JCR; Editorial Board, BMC MSD; VA Field Advisory committee	NA
Alexis Odgie	Content Expert/Core Team	University of Pennsylvania	Novartis; GRAPPA-SPARTAN; New York University; National Psoriasis Foundation; MedNet; Academy for Continued Health Care Learning	Pfizer; NIH/NIAMS; McCabe Foundation	NA	Celgene; AbbVie; Pfizer	Pharmacoepidemiology & Drug Safety; GRAPPA, ACR; Rheumatology News	NA
Dafna Gladman	Content Expert/Core Team	Self Employed	Amgen; Abbvie; BMS; Celgene; Novartis; Pfizer; UCB; Eli Lilly; Janssen	Krembil Foundatio; The Arthritis Society; Abbvie Canada; Janssen	NA	NA	NA	NA
James Reston	Lit Review Leader/Core Team	ECRI Institute	NA	NA	NA	NA	NA	NA
Gordon Guyatt	GRADE Expert/Core Team	McMaster University	CIHR	NA	NA	NA	NA	NA
Deborah Desir	BOD Liaison	Self-employed	NA	NA	NA	NA	NA	NA
Laura Coates	Expert Panel	University of Leeds, Leeds, UK	UCB; Pfizer; MSD; Novartis; Abbvie; Lilly; Sun Pharma; BMS	Janssen; Abbvie; National Institute for Health Research UK; Academy of Medical Sciences	NA	NA	NA	NA

Alice Gottlieb	Expert Panel	Metropolitan Hospital	Janssen; Abbvie; Lilly; Novartis; Valeart; Pfizer; Merck	Dysimmune Disease; Abbott/Abbvie; Abbvie; Amgen; Baxalta; Biogen; Coronado Biosciences, Inc.; Centocor Inc., Corrona; Demira; Novarits; Janssen; Lerner Medical Devices, Inc.; Lilly; Merck; Pfizer; Sandoz; Xenoport	NA	NA	GRAPPA; NPF; International Psoriasis Council; Massachusetts Academy of Dermatology; Massachusetts Medical Society; National Psoriasis Foundation; IDEOM; Journal of Psoriasis and Psoriatic Arthritis; Editorial Board of the American Journal of Clinical Dermatology; Clinical Imm. Reviews; Advances in Psoriasis & Inflamm Skin Dis.; Skin and Allergy News; Current Dermatology Reports; Dermatologic Therapy, etc.	NA
Marina N Magrey	Expert Panel	MetroHealth Medical Center	UCB Pharma	National Institute of Arthritis and Musculoskeletal Disease; Celgene Corporation; Abbvie; Amgen	NA	NA	NA	NA
William Benjamin ("Ben") Nowell	Expert Panel	Global Healthy Living Foundation	NA	PCORI	NA	NA	NA	NA
Ana-Maria Orbai	Expert Panel	Johns Hopkins University	Janssen	Rheumatology Research Foundation; Celgene; Janssen; Eli Lilly	NA	NA	NA	NA
Soumya M. Reddy	Expert Panel	New York University School of Medicine	Novartis AG; Abbvie	Amgen; Celgene; Pfizer	NA	NA	Hospital for Joint Disease Bulletin	NA
Veronica Richardson	Expert Panel	University of Pennsylvania Health System	NA	NA	NA	NA	NA	NA
Jose U. Scher	Expert Panel	New York University School of Medicine	Abbvie; Novartis; Janssen	NIAMS/NIH; Arthritis Foundation; Pfizer	NA	NA	Current Opinion Rheumatology	NA

Evan Siegel	Expert Panel	Arthritis and Rheumatism Associates, PC	Abbvie; Amgen; BMS; Janssen; Novartis	Abbvie; Allergan BOTOX; Amgen; AMPEL BioSolutions; BMS; Boehringer Ingelheim; Celgene; Coherus; CRBR-IIR Elastography; Daiichi-Sankyo; HGS; Janssen; Nodality; Novartis; PeriRx; Pfizer; Roche; Sanofi-aventis; Savient; SKK; STARA; Takeda; UCB	NA	NA	NA	NA
Michael Siegel	Expert Panel	National Psoriasis Foundation	NA	PCORI	NA	Amgen	NA	Spouse
Ingrid Steinkoenig	Expert Panel	Self-employed	NA	NA	NA	NA	NA	NA
Jessica Walsh	Expert Panel	University of Utah; George E Wahlen VA	Novartis	Pfizer; Abbvie; UCB; Celgene; Amgen	NA	NA	NA	NA
Joseph Merola	Expert Panel	Brigham and Women's Hospital	Biogen IDEC; AbbVie; Amgen; Eli Lilly; Novartis; Pfizer; Janssen; Momenta; Mallinckrodt	Biogen IDEC; Amgen; Prizer; Boehringer Ingelheim	NA	NA	IDEOM; National Psoriasis Foundation	NA
Anna Helena Jonsson	Lit Review Team	Brigham and Women's Hospital	NA	NA	NA	NA	NA	NA
Nancy Sullivan	Lit Review Team	ECRI Institute	NA	NA	NA	NA	NA	NA
Julie Miner	Voting Panel	CTC; Therapy Steps, Inc.	NA	NA	NA	NA	NA	NA
Chad Deal	Voting Panel	Cleveland Clinic	Amgen; Lilly	NA	NA	NA	NA	NA
Atul Deodhar	Voting Panel	Self-employed	Janssen; Eli Lilly; Novartis; Pfizer; UCB; Sun Pharma	Amgen; Eli Lilly; Novartis; Pfizer; Janssen		AbbVie; Amgen; Eli Lilly; Novartis; UCB	SPARTAN	
Jonathan Dunham	Voting Panel	Clinical Practices of the University of Pennsylvania	NA	NA	NA	NA	NA	NA
M. Elaine Husni	Voting Panel	Cleveland Clinic	Abbvie; Janssen; BMS; Genentech; Lilly; Novartis, ACR	Genzyme/Sanofi; PRECISION Trial	NA	NA	National Psoriasis Foundation; ACR; PRECISION trial; GRAPPA; Arthritis Foundation	NA
Paula Marchetta	Voting Panel	Self-Employed	University Physicians Network, LLC, NYU IPA	NA	NA	NA	NA	NA
Philip Mease	Voting Panel	Self-employed	Abbvie; Amgen; BMS; Celgene; Crescendo Bioscience; Lilly; Novartis; UCB; Pfizer	NA	NA	NA	National Psoriasis Foundation; GRAPPA	NA

Christopher Ritchlin	Voting Panel	University of Rochester Medical Center	Abbvie; Amgen; Janssen; Novartis; Lilly; Sanofi; Boehringer Ingelheim; UCB	NIH; Rheumatology Research Fdn.; Amgen; Abbvie and UCB	NA	NA	NA	NA
Abby S. Van Voorhees	Voting Panel	Eastern Virginia Medical School	Pfizer; Celgene; Dermira; AstraZeneca; Novartis; Corrona; Mt. Sinai Grand Rounds; Winter Clinical Derm Course	NIAMS; Abbvie	NA	DUSA	National Psoriasis Foundation; American Acad. Derm; Corrona	NA
Maureen Dubreuil	Voting Panel	Boston University Sch of Medicine; VA Boston Healthcare System	NA	NIH; Arthritis Foundation; Boston University	NA	NA	NA	NA
Benjamin J. Smith	Voting Panel	McIntosh Clinic, P.C.	American Academy of PA's	NA	NA	NA	ABIM; AAPA; ARHP	NA
Sarah Kenny	Voting Panel (Patient Rep)	Disney Theatrical Group	NA	NA	NA	NA	Arthritis Foundation	NA