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**American College Of Rheumatology**
**Updated Guideline for the Management of Gout**

***Project Plan – October 2018***

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## ORGANIZATIONAL LEADERSHIP AND SUPPORT

This updated clinical practice guideline is being developed by the American College of Rheumatology (ACR) with funding by the ACR.

## BACKGROUND

Gout is the most common inflammatory arthritis, affecting 4% of adults in the United States. While the pathophysiology is well-understood and effective treatments are available, the management of gout remains poor, with 70% experiencing recurrent flares, and a substantial proportion burdened by tophi, joint damage, and functional limitations.

## OBJECTIVES

The objective of this project is to develop recommendations for the management of patients with gout. Specifically, we aim to develop recommendations for:

1. Indications for urate-lowering therapy.
2. Approaches to initiating urate-lowering therapy.
3. Ongoing management of urate-lowering therapy.
4. Management of gout flares.
5. Lifestyle factors in patients with gout.
6. Asymptomatic hyperuricemia.

Additionally, we will develop recommendations for each of the categories above for specific subgroups of patients as appropriate.

## 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 research librarian, systematic literature review leader, and principal investigators, 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).

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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 one month prior to the voting panel meeting 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 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.

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*Phases*

1. A search for randomized controlled trials and observational studies about interventions aimed at the management of gout will be performed to determine existing studies covering outcomes of interest.
2. Additionally, recently published systematic reviews covering outcomes of interest will also be sought and used for reference cross-checking.
3. Data will be abstracted and evidence will be synthesized using RevMan (4) and GRADE Pro software (5), respectively.
4. Chosen studies will be assessed for risk of bias using modified versions of the Cochrane Risk of Bias tool (6) and the ROBINS-I (7).
5. The evidence will be synthesized and assessed at the outcome level within each question using the GRADE approach.

*GRADE Methodology*

GRADE methodology (8) will be used in this project to rate the certainty of evidence and facilitate development of recommendations. The certainty in the evidence (also known as "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 the certainty in the evidence, but also on patient preferences and values, the balance between benefits and harms, and other important considerations when necessary (e.g., resources, feasibility, acceptability). 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 appraise and synthesize data from included studies that address the PICO questions. Meta-analysis will be conducted to pool results across studies whenever possible. When not possible, a narrative synthesis of the results will be presented. An evidence summary, which includes the estimates of effects comparing the options and details regarding the assessment of the certainty of the evidence, will be prepared for each PICO question using GRADEprofiler (GRADEpro) software (5). The evidence summary will contain all of the outcomes (benefits and harms) considered important for formulating recommendations summarized across studies. For each outcome, the summary will present the relative effects comparing the options under consideration, the assumed and corresponding risk for comparators and interventions (95% CI), the risk difference, the number of

participants/number of studies providing evidence for that outcome, and the certainty of the evidence (i.e., high, moderate, low or very low).

The evidence summary will also document the overall certainty in the evidence for each critical and important outcome across studies and summarize the rationale of the GRADE criteria for rating down (risk of bias, inconsistency, indirectness, imprecision and publication bias), or rating up the certainty in a body of evidence (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 revised to formulate recommendation statements. Using the evidence summaries, the voting panel, consisting of nine rheumatologists, one nephrologist, one physician assistant, one health services researcher, and two patient representatives (one still to be determined), will consider the drafted recommendation statements in two stages. The voting panel will first individually evaluate and vote on each drafted recommendation statement using the evidence summary. The initial votes are anonymous and used to determine where consensus (70% or greater agreement) exists on the drafted recommendation statements. The results of round 1 voting will determine the in person voting panel meeting agenda. At the face-to-face voting panel meeting, chaired by the co-principal investigators, the panelists will review results of all PICO round 1 votes, discuss the evidence in the context of their clinical experience and expertise to reach 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 in the days before the voting panel meeting, to provide unique patient perspectives on the drafted recommendations based on their experiences and the available literature; the two patients on the voting panel will participate in the separate patient panel meeting.

**PLANNED APPENDICES (AT MINIMUM)**

A. Final literature search strategies
B. Evidence summaries, including GRADE evidence profiles, for each PICO question

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## AUTHORSHIP

Authorship of the guideline will include: co-principal investigators, Drs. John FitzGerald and Tuhina Neogi, as the lead authors and voting panel leaders; Dr. Romina Brignardello-Petersen, literature review leader; Drs. Ted Mikuls and Nicola Dalbeth, content experts; and Dr. Gordon Guyatt, GRADE expert. Members of the literature review team and voting panel will also be authors. The co-PIs will determine final authorship and order of authors, 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

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## APPENDIX A – PICO Questions

***Best Practice Statements***

- Unless otherwise stated, prescribers should adhere to regulatory and labelling guidance.
- Patients starting any therapy for gout should be educated on the role of each therapy (e.g. anti-inflammatory for symptoms relief, urate lowering with purpose of reducing risk of gout attack or tophus burden), and for those starting ULT, the need for continuous use.
- Pertinent comorbidities (e.g., cardiovascular disease, hypertension, diabetes, renal insufficiency, nephrolithiasis) should be assessed in all patients with gout with appropriate management of the condition(s).

***Definitions***

- ACTH: adrenocorticotropic hormone
- Anti-IL1 therapy: anakinra, canakinumab, rilonacept
- Anti-inflammatory treatments for flare or prophylaxis: colchicine, NSAIDs, glucocorticoids (oral, parenteral or intra-articular), anti-IL-1 therapy
- Asymptomatic Hyperuricemia: individual with serum urate >=6.8mg/dL with no prior gout flares or subcutaneous tophi or imaging
- Chronic Kidney Disease Stage 3, Glomerular Filtration Rate < 60 ml/min/1.73m2
- Clinical remission: no gout flares in the last 12 months AND no subcutaneous tophi
- Flare Frequency:
    - Infrequent gout flares (< 2 per year) vs.
    - Frequent gout flares (≥ 2 per year)
- Medications that impact serum urate levels:
    - Increase serum urate: hydrochlorothiazide, furosemide, low-dose ASA (<=325mg/d)
    - Decrease serum urate: losartan, fenofibrate
- Suboptimal Flare Treatment Response: Failure to achieve low pain score (e.g. ≤ 2 using a VAS scale of 0 to 10) OR failure to return to baseline pain score
- ULT (urate-lowering therapy): allopurinol, febuxostat, probenecid, lesinurad, pegloticase
    - Low dose ULT: Allopurinol ≤150 mg/day, Febuxostat ≤ 40 mg/day, Probenecid ≤250 mg twice daily
    - Intensive ULT: pegloticase **OR** serum urate target < 3 mg/dL
- Subcutaneous tophus – A tophus that is detectable by physical examination.
- Imaging evidence of MSU crystal deposition - Findings that are highly suggestive of monosodium urate crystals on an imaging test (regardless if clinically palpable)
- Durability of ULT: Duration of ULT adherence. Lack of ULT abandonment.

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**Indications for urate-lowering therapy**

1. For patients with one or more subcutaneous tophi (with any number of gout flares), what is the impact of starting ULT compared with no ULT on gout flares, pain scores, tophus, patient global assessment, health related quality of life, activity limitation, joint damage, serum urate, changes in gout flares or tophus as inferred by changes in serum urate, cost, adverse events (mild-moderate and serious)?
    - Does the relative impact differ across different ULT medications (allopurinol, febuxostat, probenecid, lesinurad, pegloticase)?
    - Does this differ in patients with radiographic damage vs. those without radiographic damage?
    - Do the effects differ in patients with tophi on advanced imaging (ultrasound, MRI, CT, or dual energy CT) but no subcutaneous tophi vs those with subcutaneous tophi?
    - People with CKD 3 or worse versus normal or mild CKD stages (1 or 2)?
2. For patients with radiographic damage (any modality) due to gout, but no subcutaneous tophi on exam (with any number of gout flares), what is the impact of starting ULT compared with no ULT on gout flares, pain scores, tophus, patient global assessment, health related quality of life, activity limitation, joint damage, serum urate, changes in gout flares or tophus as inferred by changes in serum urate, cost, adverse events (mild-moderate and serious)?
    - Does the relative impact differ across different ULT medications (allopurinol, febuxostat, probenecid, lesinurad, pegloticase)?
    - People with CKD 3 or worse versus normal or mild CKD stages (1 or 2)?
3. For patients without subcutaneous tophi and with frequent gout flares (two or more gout flares/year), what is the impact of starting ULT compared with no ULT on gout flares, pain scores, tophus, patient global assessment, health related quality of life, activity limitation, joint damage, serum urate, changes in gout flares or tophus as inferred by changes in serum urate, cost, adverse events (mild-moderate and serious)?
    - Does the relative impact differ across different ULT medications (allopurinol, febuxostat, probenecid, lesinurad, pegloticase)?
    - People with CKD 3 or worse versus normal or mild CKD stages (1 or 2)?
4. For patients without tophi who have previously experienced more than one flare but have had a low frequency < 2/year of flares, what is the impact of starting ULT compared with no ULT on gout flares, pain scores, tophus, patient global assessment, health related quality of life, activity limitation, joint damage, serum urate, changes in gout flares or tophus as inferred by changes in serum urate, cost, adverse events (mild-moderate and serious)?

- Does the relative impact differ across different ULT medications (allopurinol, febuxostat, probenecid, lesinurad, pegloticase)?
- Do these effects differ in the following subgroups?
  - People with CKD 3 or worse versus normal or mild CKD stages (1 or 2)?
  - People with urolithiasis versus no urolithiasis?
  - People with cardiovascular disease versus no cardiovascular disease?
  - People with hypertension versus no hypertension?
  - People with marked hyperuricemia (SU > 9 mg/dl), versus SU ≤9mg/dL?
  - People with early onset disease (<30 in men, premenopausal women) versus those with later onset?
  - People with renal transplantation versus no renal transplantation?

5. For patients without tophi and who have experienced a single gout flare, what is the impact of starting ULT compared with no ULT on gout flares, pain scores, tophus, patient global assessment, health related quality of life, activity limitation, joint damage, serum urate, changes in gout flares or tophus as inferred by changes in serum urate, cost, adverse events (mild-moderate and serious)?
   - Does the relative impact differ across different ULT medications (allopurinol, febuxostat, probenecid, lesinurad, pegloticase)?
   - Do these effects differ in the following subgroups?
     - People with CKD 3 or worse versus normal or mild CKD stages (1 or 2)?
     - People with urolithiasis versus no urolithiasis?
     - People with cardiovascular disease versus no cardiovascular disease?
     - People with hypertension versus no hypertension?
     - People with marked hyperuricemia (SU > 9 mg/dl), versus SU ≤9mg/dL?
     - People with early onset disease (<30 in men, premenopausal women) versus those with later onset?
     - People with renal transplantation versus no renal transplantation?

**Approaches to Initiating urate lowering therapy (ULT)**

6. For patients diagnosed with gout starting any ULT, what is the impact of starting ULT during a gout flare compared with starting ULT after the gout flare has resolved on: current gout flare severity, current gout flare duration, subsequent gout flares, pain scores, tophus, patient global assessment, serum urate, changes in gout flares or tophus as inferred by changes in serum urate, cost, adverse events (mild-moderate and serious)?
   - Does the relative impact differ across different ULT medications (allopurinol, febuxostat, probenecid, lesinurad, pegloticase)?

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7. For patients diagnosed with gout starting any ULT, what is the impact of starting a low dose of the ULT agent (e.g., allopurinol ≤150mg, febuxostat ≤40mg, probenecid 250mg bid) with gradual dose escalation compared with starting the ULT at a higher dose (e.g., allopurinol 300mg, febuxostat 80mg, probenecid 1g bid) on: gout flares, pain scores, tophus, patient global assessment, health related quality of life, activity limitation, joint damage, serum urate, changes in gout flares or tophus as inferred by changes in serum urate, cost, adverse events (mild-moderate and serious), patient adherence, durability of ULT?
    - Does the relative impact differ across different ULT medications (allopurinol, febuxostat, probenecid, lesinurad, pegloticase)?
8. For patients diagnosed with gout prescribed any ULT (allopurinol, febuxostat, probenecid, lesinurad, pegloticase), what is the impact of an non-physician health care professional-augmented (e.g. nursing or pharmacy) package of care compared with usual care on: gout flares, pain scores, tophus, patient global assessment, health related quality of life, activity limitation, joint damage, serum urate, changes in gout flares or tophus as inferred by changes in serum urate, cost, adverse events (mild-moderate and serious) patient adherence, durability of ULT?
    - Does the relative impact differ across different ULT medications (allopurinol, febuxostat, probenecid, lesinurad, pegloticase)?
9. For patients diagnosed with gout starting any ULT (allopurinol, febuxostat, probenecid, lesinurad, pegloticase), what is the relative impact of concomitant anti-inflammatory prophylaxis therapy (colchicine, NSAIDs, prednisone/prednisolone, canakinumab, rilonacept, anakinra) compared with no anti-inflammatory prophylaxis on: gout flares, pain scores, tophus, patient global assessment, health related quality of life, activity limitation, joint damage, serum urate, changes in gout flares or tophus as inferred by changes in serum urate, cost, adverse events (mild-moderate and serious) patient adherence, durability of ULT?
    - Does the impact differ if the anti-inflammatory prophylaxis is continued for only three months, if continued for six months, or if continued until complete resolution of tophi and gout flares?
    - Does the relative impact differ across different ULT medications (allopurinol, febuxostat, probenecid, lesinurad, pegloticase)?
    - Does the relative impact of prophylaxis differ across different starting dosage levels of ULT (e.g., allopurinol ≤150mg, febuxostat ≤40mg, probenecid 250mg bid) with gradual dose escalation compared with starting the ULT at a higher dose (e.g., allopurinol 300mg, febuxostat 80mg, probenecid 1g bid?
10. For patients diagnosed with gout starting ULT, what is the relative impact of starting allopurinol, febuxostat, probenecid, allopurinol/lesinurad 200mg combination, febuxostat/lesinurad 200mg combination, or pegloticase on: gout flares, pain scores, tophus, patient global assessment, health

related quality of life, activity limitation, joint damage, serum urate, changes in gout flares or tophus as inferred by changes in serum urate, cost, adverse events (mild-moderate and serious)?

- Do the effects differ in people in people with or without established cardiovascular disease, or in people in people with CKD 3 or worse versus normal or mild CKD stages (1 or 2)?

11. For patients diagnosed with gout receiving haemodialysis who are starting ULT, what is the impact of starting allopurinol compared with febuxostat on: gout flares, pain scores, tophus, patient global assessment, health related quality of life, activity limitation, joint damage, serum urate, changes in gout flares or tophus as inferred by changes in serum urate, cost, adverse events (mild-moderate and serious)?
12. For patients diagnosed with gout starting allopurinol, what is the impact of testing HLA-B*5801 and avoiding allopurinol if positive result compared with not testing HLA-B*5801 and starting allopurinol in all patients on: cost, adverse events (mild-moderate and serious)?
    - Do the effects differ in people of African American ancestry versus people with Chinese, Thai, or Korean ancestry versus those with all other ancestries?
    - Do the effects differ in people with CKD 3 or worse versus normal or mild CKD stages (1 or 2)?
    - Do the effects differ in people starting a low allopurinol dose (e.g. ≤100mg) with gradual dose escalation vs. starting allopurinol at a higher dose (eg, 300mg)?

**Ongoing Management of Urate-Lowering Therapy in patients with gout**

**Definitions: Conceptual detail for ULT dosing for PICO 13**

ULT dosing is either a

- *Pre-specified ULT fixed dose* based on drug, dose and renal function: E.g. allopurinol 300 mg, febuxostat 40 mg, probenecid 500 mg twice daily or allopurinol 200 mg (or lower), febuxostat 40 mg in patients with CKD > 3 **OR**
- *Serum urate target specified ULT dose* where ULT dosing is guided by serial serum urate values measured after each change in dose

13. For patients with gout on ULT, what is the relative impact of ULT dose titration and subsequent management guided by serial serum urate values compared with fixed, standard doses of ULT on: gout flares, pain scores, tophus, patient global assessment, health related quality of life, activity limitation, joint damage, serum urate, changes in gout flares or tophus as inferred by changes in serum urate, cost, adverse events (mild-moderate and serious), patient adherence, durability of ULT?

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- Does the impact of dosing strategy differ by presence vs absence of comorbid disease (e.g. CKD 3 or worse or cardiovascular disease), frequency of gout flares, presence of subcutaneous tophi?
- Specifically, could serum urate target dosing exceeding Hande dosing recommendations?
- Does the impact differ by frequency of monitoring?

14. For patients with gout on ULT who are not in *clinical remission*, what is the relative impact of prescribing ULT to achieve a serum urate target of [INSERT VALUE] on: gout flares, pain scores, tophus, patient global assessment, health related quality of life, activity limitation, joint damage, serum urate, changes in gout flares or tophus as inferred by changes in serum urate, cost, adverse events (mild-moderate and serious), patient adherence, durability of ULT?
    < 6 mg/dL vs. ≥ 6mg/dL, OR
    < 5 mg/dL vs. ≥5mg/dL OR
    < 4 mg/dL vs. ≥4mg/dL OR
    < 3 mg/dL vs. ≥3mg/dL?

    - Does the impact differ by flare frequency, presence of subcutaneous tophi? (See below for patients in *clinical remission*.)
    - Does the impact differ by frequency of monitoring?

15. For patients with gout on ULT who are in *clinical remission*, what is the relative impact of prescribing ULT to achieve a serum urate target of [INSERT VALUE] on: gout flares, pain scores, tophus, patient global assessment, health related quality of life, activity limitation, joint damage, serum urate, changes in gout flares or tophus as inferred by changes in serum urate, cost, adverse events (mild-moderate and serious), patient adherence, durability of ULT?
    < 8 mg/dL vs. ≥ 8mg/dL, OR
    < 7 mg/dL vs. ≥ 7mg/dL, OR
    < 6.8 mg/dL vs. ≥ 6.8mg/dL, OR
    < 6 mg/dL vs. ≥ 6mg/dL?

    - Does the impact differ by duration of clinical remission (e.g., 1-year vs. 5-years)?
    - Does the impact differ by frequency of monitoring?

16. For patients with gout on *ULT > 2 years*, what is the impact of checking serum urate on a regular schedule and making adjustments in ULT guided by serum urate concentration compared with not checking serum urate to guide future ULT use / dosing on: gout flares, pain scores, tophus, patient global assessment, health related quality of life, activity limitation, joint damage, serum urate, changes in gout flares or tophus as inferred by changes in serum urate, cost, adverse events (mild-moderate and serious), patient adherence, and durability of ULT?

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- Does the impact of checking vs. not checking differ by:
  - Frequency of monitoring (e.g., every 6 months vs. every 12 months)
  - Disease severity: presence or duration of clinical remission, flare frequency, presence of subcutaneous tophi

17. For patients with gout on ULT who have achieved serum urate target but still have sufficient inflammatory symptoms to warrant ULT re-evaluation (e.g., ≥ 2 flares in the last 12-months), what is the impact of lowering serum urate target by an additional 1 mg/dL and dose escalating ULT to this target compared with not changing the serum urate target and making no change to ULT on: gout flares, pain scores, tophus, patient global assessment, health related quality of life, activity limitation, joint damage, serum urate, changes in gout flares or tophus as inferred by changes in serum urate, cost, adverse events (mild-moderate and serious)?
18. For patients with gout adherent to ULT who have not achieved serum urate target, but have *infrequent symptoms* (gout flares well controlled (≤ 1 flare in last 6 months)) and no subcutaneous tophi, what is the impact of increasing ULT dose to achieve serum urate target compared with continuing current ULT dose on gout flares, pain scores, tophus, patient global assessment, health related quality of life, activity limitation, joint damage, serum urate, changes in gout flares or tophus as inferred by changes in serum urate, cost, adverse events (mild-moderate and serious)?
    - Does this impact differ if patient is in 1-year or 5-year *clinical remission*?
19. For patients with gout on ULT in *clinical remission*, what is the impact of stopping or reducing ULT compared with continuing ULT on gout flares, pain scores, tophus, patient global assessment, health related quality of life, activity limitation, joint damage, serum urate, changes in gout flares or tophus as inferred by changes in serum urate, cost, adverse events (mild-moderate and serious)?
    - Do these effects differ based on the sustainable serum urate level following ULT reduction or cessation off ULT or the duration of clinical remission (e.g. 1-year vs. 5-years)?
20. For patients with gout on ULT in clinical remission, what is the impact of relaxing the serum urate target compared with continuing current serum urate target on gout flares, pain scores, tophus, patient global assessment, health related quality of life, activity limitation, joint damage, serum urate, changes in gout flares or tophus as inferred by changes in serum urate, cost, adverse events (mild-moderate and serious)?
    - Do these effects differ based on the duration of clinical remission (e.g. 1-year vs. 5-years)?
21. For patients with gout on *intensive ULT* management (e.g. ULT to achieve sUA < 3 mg/dL), what is the impact of the duration of intensive ULT therapy for [INSERT VALUE] on gout flares, tophus burden, neurotoxicity and cancer risk, mortality rates?

    < 1 year vs. ≥ 1 year OR
    < 2 years vs. ≥ 2 years

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22. For patients with gout on febuxostat with a history of CVD or a new CV event, what is the impact of stopping and switching to an alternative ULT agent compared with continuing febuxostat after reviewing the risks and benefits of febuxostat with the patient on: gout flares, pain scores, tophus, patient global assessment, health related quality of life, activity limitation, joint damage, serum urate, changes in gout flares or tophus as inferred by changes in serum urate, cost, adverse events (mild-moderate and serious)?
23. In patients with gout who have experienced an allergic response to allopurinol and who cannot be treated with other oral ULT, what is the impact of allopurinol desensitization on tolerability of allopurinol, adverse events, cost, and patient acceptability.

*For patients not at serum urate target and the inflammatory symptoms of gout or tophi are poorly controlled:*

24. For patients with gout on their first XOI monotherapy at maximum tolerated or FDA indicated dose who are not at serum urate target and/or have continued frequent gout flares or non-resolving subcutaneous tophi, what is the impact of switching the first XOI to an alternate XOI agent compared with adding a uricosuric agent on: gout flares, pain scores, tophus, patient global assessment, health related quality of life, activity limitation, joint damage, serum urate, changes in gout flares or tophus as inferred by changes in serum urate, cost, adverse events (mild-moderate and serious)?
    - Do these effects differ based on the presence of chronic kidney disease or the magnitude of hyperuricemia?
25. For patients with gout on second (maximum tolerated or FDA indicated dose) XOI agent who are not at serum urate target and/or have continued frequent gout flares or non-resolving subcutaneous tophi, what is the impact of adding a uricosuric compared with switching to uricosuric monotherapy on: gout flares, pain scores, tophus, patient global assessment, health related quality of life, activity limitation, joint damage, serum urate, changes in gout flares or tophus as inferred by changes in serum urate, cost, adverse events (mild-moderate and serious)?
    - Do these effects differ based on the presence of chronic kidney disease or the magnitude of hyperuricemia or 24 hour urate excretion?
26. For patients with gout on (max) probenecid monotherapy (e.g. XOI failure) who are not at serum urate target and/or have continued frequent flares or non-resolving subcutaneous tophi, what is the impact of adding XOI compared with switching to lesinurad/XOI on gout flares, pain scores, tophus, patient global assessment, health related quality of life, activity limitation, joint damage, serum urate, changes in gout flares or tophus as inferred by changes in serum urate, cost, adverse events (mild-moderate and serious)?

- Do these effects differ based on the presence of chronic kidney disease or the magnitude of hyperuricemia?

27. For patients with gout where XOI, uricosurics and other interventions failed to achieve serum urate target and have frequent gout flares or non-resolving subcutaneous tophi what is the impact of changing to pegloticase compared with continuing current ULT on: gout flares, pain scores, tophus, patient global assessment, health related quality of life, activity limitation, joint damage, serum urate, changes in gout flares or tophus as inferred by changes in serum urate, cost, adverse events (mild-moderate and serious)?
    - Does the impact differ by frequency or severity of symptoms or presence or severity of tophi affect recommendation?

*For patients considered for or on uricosuric treatment:*

28. Prior to starting any uricosuric treatment, what is the impact of checking urinary uric acid compared with not checking urinary uric acid on: nephrolithiasis?
    - Does this recommendation differ for patients where uricosuric is to be added to XOI treatment compared with those who will receive uricosuric treatment alone?
29. For all patients on uricosuric treatment, what is the impact of alkalinizing urine compared with not doing so on: nephrolithiasis?
    - Does this recommendation differ for patients where uricosuric is to be added to XOI treatment compared with those who will receive uricosuric treatment alone?
30. For all patients on uricosuric treatment, what is the impact of monitoring urinary uric acid at regular intervals while on therapy compared with not doing so on: nephrolithiasis?
    - Does this recommendation differ for patients where uricosuric is to be added to XOI treatment compared with those who will receive uricosuric treatment alone?

## Gout Flares

### *General Management of a Gout Flare*

31. For patients experiencing a gout flare initiating anti-inflammatory treatment, what is the impact of using topical ice as an adjuvant treatment compared with no adjuvant treatment on: pain scores, patient global assessment, joint tenderness, activity limitation, adverse events (mild-moderate and serious)?
32. For patients experiencing a gout flare, what is the relative impact of colchicine, NSAIDs, systemic glucocorticoids (e.g. prednisone/prednisolone), intra-articular glucocorticoids, ACTH, or IL-1

inhibition on: pain scores, patient global assessment, joint tenderness, joint swelling, activity limitation, cost, or adverse events (mild-moderate and serious)?

- Does the relative impact of these agents differ based on any of the following?
  - The number of joints involved
  - Pain levels
  - Duration of the flare at presentation
  - Duration of anti-inflammatory therapy
  - Ability to tolerate or take oral agents (e.g. NPO status)
  - Dose of the agent given

33. For patients experiencing a gout flare for whom anti-inflammatory therapies are poorly tolerated or contraindicated, what is the impact of IL-1 inhibition compared with no therapy (beyond supportive / analgesic treatment) on: pain scores, patient global assessment, joint tenderness, joint swelling, activity limitation, cost, or adverse events (mild-moderate and serious)?

***Management in Patients with Suboptimal Treatment Responses after 36-48 hours***

34. For patients experiencing a gout flare and achieving a suboptimal treatment response after 36-48 hours, what is the impact of switching to an alternative anti-inflammatory monotherapy compared with continuing the same treatment on: pain scores, patient global assessment, joint tenderness, joint swelling, activity limitation, cost, or adverse events (mild-moderate and serious)?
35. For patients experiencing a gout flare and achieving a suboptimal treatment response after 36-48 hours, what is the impact of adding an additional anti-inflammatory agent (e.g. escalating to combination therapy) compared with continuing the same treatment on pain scores, patient global assessment, joint tenderness, joint swelling, activity limitation, cost, or adverse events (mild-moderate and serious)?
36. For patients experiencing a gout flare and achieving a suboptimal treatment response after 36-48 hours, what is the impact of switching to an alternative anti-inflammatory monotherapy compared with adding an additional anti-inflammatory agent (e.g. escalating to combination therapy) on: pain scores, patient global assessment, joint tenderness, joint swelling, activity limitation, cost, or adverse events (mild-moderate and serious)?
37. For patients experiencing a gout flare and achieving a suboptimal treatment response after 36-48 hours, what is the impact of switching to an alternative anti-inflammatory agent compared with switching to or adding IL-1 inhibition on: pain scores, patient global assessment, joint tenderness, joint swelling, activity limitation, cost, or adverse events (mild-moderate and serious)?
38. For patients experiencing a gout flare and achieving a suboptimal treatment response after 36-48 hours, what is the impact of adding an additional anti-inflammatory agent (e.g. escalating to combination therapy) compared with switching to or adding IL-1 inhibition on: pain scores, patient

global assessment, joint tenderness, joint swelling, activity limitation, cost, or adverse events (mild-moderate and serious)?

39. For patients experiencing a gout flare and achieving a suboptimal treatment response to an oral anti-inflammatory after 36-48 hours, what is the impact of switching to an alternative oral anti-inflammatory agent compared with the use of intra-articular glucocorticoids on: pain scores, patient global assessment, joint tenderness, joint swelling, activity limitation, cost, or adverse events (mild-moderate and serious)?
    - Does the relative impact of these strategies differ by the number of joints involved (e.g. mono- or oligoarticular involvement vs. polyarticular involvement)?
40. For patients experiencing a gout flare and achieving a suboptimal treatment response to an oral anti-inflammatory after 36-48 hours, what is the impact of adding an additional anti-inflammatory agent (e.g. escalating to combination therapy) compared with the use of intra-articular glucocorticoids on pain scores, patient global assessment, joint tenderness, joint swelling, activity limitation, cost, or adverse events (mild-moderate and serious)?
    - Does the relative impact of these strategies differ by the number of joints involved (e.g. mono- or oligoarticular involvement vs. polyarticular involvement)?

**Lifestyle factors in patients with gout**

*For patients with gout, regardless of disease activity:*

41. What is the impact of limiting or abstaining from alcohol intake compared with no limited intake of alcohol on: gout flares, pain scores, tophus, patient global assessment, health related quality of life, activity limitation, joint damage, serum urate, changes in gout flares or tophus as inferred by changes in serum urate, cost, adverse events (mild-moderate and serious), patient acceptability, QOL?
    - Does the impact differ by flare frequency (frequent vs. infrequent)?
    - Does the impact differ by the type of alcohol?
42. What is the impact of limiting purine intake compared with no limited intake of purines on: gout flares, pain scores, tophus, patient global assessment, health related quality of life, activity limitation, joint damage, serum urate, changes in gout flares or tophus as inferred by changes in serum urate, cost, adverse events (mild-moderate and serious), patient acceptability, QOL?
    - Does the impact differ by flare frequency (frequent vs. infrequent)?
43. What is the impact of limiting or abstaining from high-fructose corn syrup (HFCS) compared with no limited intake of HFCS on: gout flares, pain scores, tophus, patient global assessment, health related quality of life, activity limitation, joint damage, serum urate, changes in gout flares or tophus as

inferred by changes in serum urate, cost, adverse events (mild-moderate and serious), patient acceptability, QOL?

- Does the impact differ by flare frequency (frequent vs. infrequent)?

44. What is the impact of increasing dairy protein intake compared with no increase in dairy intake on: gout flares, pain scores, tophus, patient global assessment, health related quality of life, activity limitation, joint damage, serum urate, changes in gout flares or tophus as inferred by changes in serum urate, cost, adverse events (mild-moderate and serious), patient acceptability, QOL?
    - Does the impact differ by flare frequency (frequent vs. infrequent)?
45. What is the impact of following the DASH (Dietary Approaches to Stop Hypertension) diet compared with no specific diet or any other diet on: gout flares, pain scores, tophus, patient global assessment, health related quality of life, activity limitation, joint damage, serum urate, changes in gout flares or tophus as inferred by changes in serum urate, cost, adverse events (mild-moderate and serious), patient acceptability, QOL?
    - Does the impact differ by flare frequency (frequent vs. infrequent)?
46. What is the impact of weight loss compared with no weight loss on: gout flares, pain scores, tophus, patient global assessment, health related quality of life, activity limitation, joint damage, serum urate, changes in gout flares or tophus as inferred by changes in serum urate, cost, adverse events (mild-moderate and serious), patient acceptability, QOL?
    - Does the impact differ by flare frequency (frequent vs. infrequent)?
47. What is the impact of changing or adding medications that affect urate levels compared with no change in medication on: gout flares, pain scores, tophus, patient global assessment, health related quality of life, activity limitation, joint damage, serum urate, changes in gout flares or tophus as inferred by changes in serum urate, cost, adverse events (mild-moderate and serious)?
    - Does the impact differ by flare frequency (frequent vs. infrequent)?
    - Does the impact differ by type of medication change?
    - Does the impact differ by CKD?
48. What is the impact of vitamin C supplementation compared with no supplementation on: gout flares, pain scores, tophus, patient global assessment, health related quality of life, activity limitation, joint damage, serum urate, changes in gout flares or tophus as inferred by changes in serum urate, cost, adverse events (mild-moderate and serious), patient acceptability, QOL?
    - Does the impact differ by flare frequency (frequent vs. infrequent)?
49. What is the impact of cherry extract intake compared with no intake on: gout flares, pain scores, tophus, patient global assessment, health related quality of life, activity limitation, joint damage, serum urate, changes in gout flares or tophus as inferred by changes in serum urate, cost, adverse events (mild-moderate and serious), patient acceptability, QOL?
    - Does the impact differ by flare frequency (frequent vs. infrequent)?

**American College Of Rheumatology**
**Updated Guideline for the Management of Gout**

***Project Plan – October 2018***

**Asymptomatic Hyperuricemia**

*For individuals with asymptomatic hyperuricemia:*

50. What is the impact of limiting or abstaining from alcohol intake compared with no limited intake of alcohol on: development of gout (flare, subcutaneous tophi), adverse events (mild-moderate and serious), patient acceptability, QOL?
    Does the impact differ for:
    - People with marked hyperuricemia (SU > 9 mg/dl), versus SU 6.8-≤9mg/dL?
    - People with CKD 3 or worse versus stages 1 or 2 or no renal disease?
    - People with urolithiasis versus no urolithiasis?
    - People with cardiovascular disease versus no cardiovascular disease?
    - People with hypertension versus no hypertension?
    - People with renal transplantation versus no renal transplantation?
    - People with radiographic gouty bone erosion?
    - People with advanced imaging (US/DECT) evidence of MSU deposition?
    - People with early onset hyperuricemia (<30 in men, premenopausal women) versus those with later onset?
51. What is the impact of limiting purine intake compared with no limited intake of purines on: development of gout (flare, subcutaneous tophi), adverse events (mild-moderate and serious), patient acceptability, QOL?
    Does the impact differ for:
    - People with marked hyperuricemia (SU > 9 mg/dl), versus SU 6.8-≤9mg/dL?
    - People with CKD 3 or worse versus stages 1 or 2 or no renal disease?
    - People with urolithiasis versus no urolithiasis?
    - People with cardiovascular disease versus no cardiovascular disease?
    - People with hypertension versus no hypertension?
    - People with renal transplantation versus no renal transplantation?
    - People with radiographic gouty bone erosion?
    - People with advanced imaging (US/DECT) evidence of MSU deposition?
    - Does the impact differ by type of source purine (e.g. animal vs. vegetable)?
52. What is the impact of limiting or abstaining from high-fructose corn syrup (HFCS) compared with no limited intake of HFCS on: development of gout (flare, subcutaneous tophi), adverse events (mild-moderate and serious), patient acceptability, QOL?
    Does the impact differ for:
    - People with marked hyperuricemia (SU > 9 mg/dl), versus SU 6.8-≤9mg/dL?

- People with CKD 3 or worse versus stages 1 or 2 or no renal disease?
- People with urolithiasis versus no urolithiasis?
- People with cardiovascular disease versus no cardiovascular disease?
- People with hypertension versus no hypertension?
- People with renal transplantation versus no renal transplantation?
- People with radiographic gouty bone erosion?
- People with advanced imaging (US/DECT) evidence of MSU deposition?
- People with early onset hyperuricemia (<30 in men, premenopausal women) versus those with later onset?

53. What is the impact of increasing dairy protein intake compared with no increase in dairy intake on: development of gout (flare, subcutaneous tophi), adverse events (mild-moderate and serious), patient acceptability, QOL?
    Does the impact differ for:
    - People with marked hyperuricemia (SU > 9 mg/dl), versus SU 6.8-≤9mg/dL?
    - People with CKD 3 or worse versus stages 1 or 2 or no renal disease?
    - People with urolithiasis versus no urolithiasis?
    - People with cardiovascular disease versus no cardiovascular disease?
    - People with hypertension versus no hypertension?
    - People with renal transplantation versus no renal transplantation?
    - People with radiographic gouty bone erosion?
    - People with advanced imaging (US/DECT) evidence of MSU deposition?
    - People with early onset hyperuricemia (<30 in men, premenopausal women) versus those with later onset?
54. What is the impact of following the DASH (Dietary Approaches to Stop Hypertension) diet compared with no specific diet or any other diet on: development of gout (flare, subcutaneous tophi), adverse events (mild-moderate and serious), patient acceptability, QOL?
    Does the impact differ for:
    - People with marked hyperuricemia (SU > 9 mg/dl), versus SU 6.8-≤9mg/dL?
    - People with CKD 3 or worse versus stages 1 or 2 or no renal disease?
    - People with urolithiasis versus no urolithiasis?
    - People with cardiovascular disease versus no cardiovascular disease?
    - People with hypertension versus no hypertension?
    - People with renal transplantation versus no renal transplantation?
    - People with radiographic gouty bone erosion?
    - People with advanced imaging (US/DECT) evidence of MSU deposition?

- People with early onset hyperuricemia (<30 in men, premenopausal women) versus those with later onset?

55. What is the impact of weight loss compared with no weight loss on: development of gout (flare, subcutaneous tophi), adverse events (mild-moderate and serious), patient acceptability, QOL? Does the impact differ for:
    - People with marked hyperuricemia (SU > 9 mg/dl), versus SU 6.8-≤9mg/dL?
    - People with CKD 3 or worse versus stages 1 or 2 or no renal disease?
    - People with urolithiasis versus no urolithiasis?
    - People with cardiovascular disease versus no cardiovascular disease?
    - People with hypertension versus no hypertension?
    - People with renal transplantation versus no renal transplantation?
    - People with radiographic gouty bone erosion?
    - People with advanced imaging (US/DECT) evidence of MSU deposition?
    - People with early onset hyperuricemia (<30 in men, premenopausal women) versus those with later onset?
56. What is the impact of changing or adding medications that affect urate levels (such as losartan or fenofibrate) compared with no change in medication on: development of gout (flare, subcutaneous tophi), adverse events (mild-moderate and serious), patient acceptability, QOL? Does the impact differ for:
    - People with marked hyperuricemia (SU > 9 mg/dl), versus SU 6.8-≤9mg/dL?
    - People with CKD 3 or worse versus stages 1 or 2 or no renal disease?
    - People with urolithiasis versus no urolithiasis?
    - People with cardiovascular disease versus no cardiovascular disease?
    - People with hypertension versus no hypertension?
    - People with renal transplantation versus no renal transplantation?
    - People with radiographic gouty bone erosion?
    - People with advanced imaging (US/DECT) evidence of MSU deposition?
    - People with early onset hyperuricemia (<30 in men, premenopausal women) versus those with later onset?
57. What is the impact of initiating any pharmacologic urate-lowering therapy (allopurinol, febuxostat, probenecid) compared with no initiation of pharmacologic ULT on: development of gout (flare, subcutaneous tophi), adverse events (mild-moderate and serious), patient acceptability, QOL? Does the impact differ for:
    - People with marked hyperuricemia (SU > 9 mg/dl), versus SU 6.8-≤9mg/dL?
    - People with CKD 3 or worse versus stages 1 or 2 or no renal disease?
    - People with urolithiasis versus no urolithiasis?

- People with cardiovascular disease versus no cardiovascular disease?
- People with hypertension versus no hypertension?
- People with renal transplantation versus no renal transplantation?
- People with radiographic gouty bone erosion?
- People with advanced imaging (US/DECT) evidence of MSU deposition?
- People with early onset hyperuricemia (<30 in men, premenopausal women) versus those with later onset?

**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 Employment | Sources of Personal Income | Intellectual Property | Research Grants/Contracts | Investments to include medical industry and nonmedical industry | Organizational Benefit | Activities with Other Organizations | Family or Other Relations |
|---|---|---|---|---|---|---|---|---|---|
| John FitzGerald, MD, PhD | Core Team/Co-PI/Voting Panel Leader | UCLA | N/A | N/A | UCLA OAIC | N/A | N/A | N/A | N/A |
| Tuhina Neogi, MD, PhD, FRCPC | Core Team/Co-PI/Voting Panel Leader | Boston University | N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| Ted Mikuls, MD, MSPH | Core Team/Content Expert | University of Nebraska Medical Center, Omaha VA Medical Center | N/A | N/A | VA; NIH/NIGMS; NIH/NIAAA; NIH/NIAMS; BMS; Horizon; Ironwood; RRF; Pfizer | N/A | Pfizer (Steering Committee/Consultant for Phase 4 Study) | N/A | N/A |
| Nicola Dalbeth, MD, FRACP | Core Team/Content Expert | The University of Auckland | N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| Romina Brignardello-Petersen, DDS, MSc, PhD | Core Team/Lit Review Leader | McMaster University | N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| Gordon Guyatt, MD, MSc, FRCP, OC | Core Team/GRADE Expert | McMaster University | N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| Seoyoung Kim, MD, ScD, MSCE | Lit Review Team | Brigham and Women's Hospital | Arthritis Care & Research (Associate Editor) | N/A | NIH/NIAMS; Bristol Myers Squibb; Roche; Biologics & Biosimilars Collective Intelligence Consortium; Merck; BMS; AstraZeneca/Ironwood; Genentech | N/A | N/A | N/A | N/A |
| Puja P. Khanna, MD, MPH | Lit Review Team | University of Michigan, VA Ann Arbor Healthcare System | SOBI (Advisory Board) | N/A | AstraZeneca; NIH; Horizon; Ironwood | N/A | N/A | VA Consortium (Co-I CRYSTAL Research Registry) | N/A |
| Sharon Bae, MD | Lit Review Team | UCLA | N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| Mary Ann Zhang, MD | Lit Review Team | Brigham and Women's Hospital | N/A | N/A | N/A | N/A | N/A | N/A | N/A |
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| Aleksander Lenert, MD, FRCPC | Lit Review Team | University of Kentucky | N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| Samuel Poon, MD | Lit Review Team | Manchester VA Medical Center | N/A | N/A | N/A | N/A | N/A | N/A | N/A |
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| Michael Toprover, MD | Lit Review Team | NYU Langone Health Department of Medicine | N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| Marat Turgunbaev, MD, MPH | Lit Review Team | American College of Rheumatology | N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| Amit Aakash Shah, MD, MPH | Lit Review Team | American College of Rheumatology | N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| Anila Qasim, HBSc, MSc | Lit Review Team | Toronto Public Library and McMaster University | N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| Shiv T. Sehra, MD | Lit Review Team | Cambridge | N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| Linan Zeng | Lit Review Team | West China Second University Hospital, Sichuan University, McMaster University | N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| N. Lawrence Edwards, MD, MACP, MACR | Voting Panel | University of Florida | Takeda (Consultant); Horizon | N/A | N/A | N/A | N/A | Gout and Uric Acid Education Society (CEO and Chair) | N/A |
| Aryeh Abeles, MD | Voting Panel | University of Connecticut | Abbvie | N/A | N/A | N/A | N/A | N/A | N/A |
| Michael Pillinger, MD | Voting Panel | New York University School of Medicine | (Advisory Board); Ironwood | N/A | Takeda | N/A | N/A | Current Rheumatology Reports (Editorial Board) | N/A |
| Gerald Levy, MD, MBA | Voting Panel | Southern California Permanente Medical Group | N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| Dinesh Khanna, MD, MSc | Voting Panel | University of Michigan | N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| Charles King, MD | Voting Panel | North Mississippi Medical Center | N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| Benjamin J. Smith, PA-C, DFAAPA | Voting Panel | Florida State University College of Medicine | N/A | N/A | N/A | N/A | N/A | American Board of Internal Medicine; Member, Rheumatology Specialty Board; American Academy of Physician Assistants (Chair, Commission on Continuing Professional Development and Education); American Academy of Physician Assistants (Member, Audit Committee); American College of Rheumatology/Association of Rheumatology Health Professionals (Scientific Editor, Advanced Rheumatology Course) | N/A |
| Allan Gelber, MD, MPH, PhD | Voting Panel | Johns Hopkins University | Honoraria (gout CME presentation) | N/A | ACR RRF; Harvard/Hopkins | N/A | N/A | NIH/NIAMS (Study Safety Officer) | N/A |
| Leslie Harrold, MD | Voting Panel | UMass Medical School | Bristol Myers Squib (Advisory Board); Roche (presentation at EULAR) | N/A | Pfizer | N/A | N/A | N/A | N/A |
| David Mount, MD | Voting Panel | Harvard BWH | N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| Svetlana Krasnokutsky, MD | Voting Panel | NYU Langone Medical Center | N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| Ann Rosenthal, MD | Voting Panel | Medical College of Wisconsin | N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| Jasvinder Singh, MD, MPH | Voting Panel | University of Alabama at Birmingham | American College of Rheumatology; Horizon Pharmaceuticals/DINORA; Fidia Pharmaceuticals; WebMD (CME activity); UBM, LLC (CME activity); MMedscape (CME activity); South Carolina Society Rheumatology; Georgia Society of Rheumatology | N/A | PCORI; Individualized Patient Decision Making for Treatment Choices Among Minorities with Lupus; NIAMS; Gout and Hyperuricemia Center for Research and Translation (CORT); AHRQ; UAB Center for Education and Research on Therapeutics (CERTs); VA; Storytelling to Improve Disease outcomes in Gout: The STRIDE-GO2 study | N/A | N/A | OMERACT (Steering Committee, Editorial Board); JCR (Editorial Board); BMC MSD (Editorial Board); VA Field Advisory Committee (Member) | N/A |
| James Edward Sims (patient) | Voting Panel | Fulton County Georgia | N/A | N/A | N/A | N/A | N/A | N/A | Amy Turner (daughter/ACR employee) |
| Angelo Gaffo, MD, MSPH | Expert Panel | University of Alabama at Birmingham | N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| Kenneth G. Saag, MD, MSc | Expert Panel | University of Alabama at Birmingham | Ironwood/AstraZeneca (Consultant); Horizon (Consultant); SOBI (Consultant); Takeda (Consultant) | N/A | Ironwood/AstraZeneca; Horizon; SOBI; Takeda | N/A | N/A | National Osterporosis Foundation (Board President) | N/A |
| Ted Fields, MD, FACP | Expert Panel | HSS | N/A | N/A | N/A | N/A | N/A | N/A | N/A |