



Janus Kinase Inhibitors for Rheumatoid Arthritis: Effectiveness and Value

Draft Questions for Deliberation and Voting: December 9, 2019 Public Meeting

These questions are intended for the deliberation of the CTAF voting body at the public meeting.

Clinical Evidence

Patient population for questions 1-5: Adults ages 18 or older with moderately-to-severely active rheumatoid arthritis who are naïve to targeted immune modulators (TIMs).

1. In patients who are naïve to TIMs, is the evidence adequate to demonstrate that the net health benefit of upadacitinib plus a conventional disease-modifying antirheumatic drug (DMARD) is superior to that provided by a conventional DMARD alone?

Yes No

2. In patients who are naïve to TIMs, is the evidence adequate to demonstrate that the net health benefit of upadacitinib plus a conventional DMARD is superior to that provided by adalimumab plus a conventional DMARD?

Yes No

3. In patients who are naïve to TIMs, is the evidence adequate to demonstrate that the net health benefit of tofacitinib plus a conventional DMARD is superior to that provided by a conventional DMARD alone?

Yes No

4. In patients who are naïve to TIMs, is the evidence adequate to demonstrate that the net health benefit of tofacitinib plus a conventional DMARD is superior to that provided by adalimumab plus a conventional DMARD alone?

Yes No

5. In patients who are naïve to TIMs, is the evidence adequate to distinguish the net health benefit between upadacitinib and tofacitinib?

Yes No

5a. If the answer to Q5 is Yes: Based on the available evidence in patients who are naïve to TIMs, which therapy has greater net health benefit: (a) upadacitinib plus a conventional DMARD, or (b) tofacitinib plus a conventional DMARD?

a. Upadacitinib b. Tofacitinib

Patient population for questions 6-8: Adults ages 18 or older with moderately-to-severely active rheumatoid arthritis who are TIM-experienced.

6. In patients who are TIM-experienced, is the evidence adequate to demonstrate that the net health benefit of upadacitinib plus a conventional DMARD is superior to that provided by a conventional DMARD alone?

Yes No

7. In patients who are TIM-experienced, is the evidence adequate to demonstrate that the net health benefit of tofacitinib plus a conventional DMARD is superior to that provided by a conventional DMARD alone?

Yes No

8. In patients who are TIM-experienced, is the evidence adequate to demonstrate that the net health benefit of baricitinib plus a conventional DMARD is superior to that provided by a conventional DMARD alone?

Yes No

Potential Other Benefits and Contextual Considerations

Patient population for questions 9-10: Adults ages 18 or older with moderately-to-severely active rheumatoid arthritis who are TIM-naïve and TIM-experienced.

9. Does treating patients with JAK inhibitors plus a conventional DMARD offer one or more of the following potential “other benefits” in comparison to conventional DMARDs alone? (Select all that apply.)
- a. These interventions offer reduced complexity that will significantly improve patient outcomes.
 - b. These interventions will reduce important health disparities across racial, ethnic, gender, socioeconomic, or regional categories.
 - c. These interventions will significantly reduce caregiver or broader family burden.
 - d. These interventions offer a novel mechanism of action or approach that will allow successful treatment of many patients for whom other available treatments have failed.
 - e. These interventions will have a significant impact on improving patients’ ability to return to work and/or their overall productivity.
 - f. There are other important benefits or disadvantages that should have an important role in judgments of the value of these interventions: _____.
10. Are any of the following contextual considerations important in assessing the long-term value for money of JAK inhibitors? (Select all that apply.)
- a. These interventions are intended for the care of individuals with a condition of particularly high severity in terms of impact on length of life and/or quality of life.
 - b. These interventions are intended for the care of individuals with a condition that represents a particularly high lifetime burden of illness.
 - c. These interventions are the first to offer any improvement for patients with this condition.
 - d. There is significant uncertainty about the long-term risk of serious side effects of these interventions.
 - e. There is significant uncertainty about the magnitude or durability of the long-term benefits of these interventions.
 - f. There are additional contextual considerations that should have an important role in judgments of the value of these interventions: _____.

Long-Term Value for Money¹

Patient population for questions 11-13: Adults ages 18 or older with moderately-to-severely active rheumatoid arthritis who are naïve to TIMs.

11. Given the available evidence on comparative effectiveness and incremental cost-effectiveness, and considering other benefits, disadvantages, and contextual considerations, what is the long-term value for money of treatment at current pricing with upadacitinib plus a conventional DMARD versus conventional DMARDs alone?
 - a. Low long-term value for money
 - b. Intermediate long-term value for money
 - c. High long-term value for money

12. Given the available evidence on comparative effectiveness and incremental cost-effectiveness, and considering other benefits, disadvantages, and contextual considerations, what is the long-term value for money of treatment at current pricing with upadacitinib plus a conventional DMARD versus adalimumab plus a conventional DMARD?
 - a. Low long-term value for money
 - b. Intermediate long-term value for money
 - c. High long-term value for money

13. Given the available evidence on comparative effectiveness and incremental cost-effectiveness, and considering other benefits, disadvantages, and contextual considerations, what is the long-term value for money of treatment at current pricing with tofacitinib plus a conventional DMARD versus conventional DMARDs alone?
 - a. Low long-term value for money
 - b. Intermediate long-term value for money
 - c. High long-term value for money

¹As described in ICER's value assessment framework, questions on long-term value for money are subject to a value vote when incremental cost-effectiveness ratios for the interventions of interest are between \$50,000 and \$175,000 per QALY in the primary base-case analysis.

Patient population for questions 14-16: Adults ages 18 or older with moderately-to-severely active rheumatoid arthritis who are TIM-experienced.

14. Given the available evidence on comparative effectiveness and incremental cost-effectiveness, and considering other benefits, disadvantages, and contextual considerations, what is the long-term value for money of treatment at current pricing with upadacitinib plus a conventional DMARD versus conventional DMARDs alone?
 - a. Low long-term value for money
 - b. Intermediate long-term value for money
 - c. High long-term value for money

15. Given the available evidence on comparative effectiveness and incremental cost-effectiveness, and considering other benefits, disadvantages, and contextual considerations, what is the long-term value for money of treatment at current pricing with tofacitinib plus a conventional DMARD versus conventional DMARDs alone?
 - a. Low long-term value for money
 - b. Intermediate long-term value for money
 - c. High long-term value for money

16. Given the available evidence on comparative effectiveness and incremental cost-effectiveness, and considering other benefits, disadvantages, and contextual considerations, what is the long-term value for money of treatment at current pricing with baricitinib plus a conventional DMARD versus conventional DMARDs alone?
 - a. Low long-term value for money
 - b. Intermediate long-term value for money
 - c. High long-term value for money