Janus Kinase Inhibitors for Rheumatoid Arthritis: Effectiveness and Value

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 1-6: Adults ages 18 or older with moderately-to-severely active rheumatoid arthritis on conventional DMARD therapy 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?
   
   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

6. In patients who are naïve to TIMs, is the evidence adequate to demonstrate that the biosimilar infliximab-dyyb produces a net health benefit comparable to that of the originator biologic infliximab?

   Yes  No

Patient population for questions 7-9: Adults ages 18 or older with moderately-to-severely active rheumatoid arthritis who are TIM-experienced.

7. 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

8. 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

9. 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 10-11:** Adults ages 18 or older with moderately-to-severely active rheumatoid arthritis who are TIM-naïve and were failed by conventional DMARDs.

10. Does treating patients with upadacitinib plus a conventional DMARD offer one or more of the following potential “other benefits” in comparison to adalimumab plus a conventional DMARD? (Select all that apply.)

   a. This intervention offers reduced complexity that will significantly improve patient outcomes.
   b. This intervention will significantly reduce caregiver or broader family burden.
   c. This intervention offers a novel mechanism of action or approach that will allow successful treatment of many patients for whom other available treatments have failed.
   d. This intervention will have a significant impact on improving patients’ ability to return to work and/or their overall productivity.
   e. There are other important benefits or disadvantages that should have an important role in judgments of the value of this intervention: ____________.

11. Are any of the following contextual considerations important in assessing the long-term value for money at current pricing of upadacitinib? (Select all that apply.)

   a. This intervention is 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. This intervention is intended for the care of individuals with a condition that represents a particularly high lifetime burden of illness.
   c. Compared to adalimumab, there is significant uncertainty about the long-term risk of serious side effects of this intervention.
   d. Compared to adalimumab, there is significant uncertainty about the magnitude or durability of the long-term benefits of this intervention.
   e. There are additional contextual considerations that should have an important role in judgments of the value of this intervention: ____________.
Long-Term Value for Money

**Patient population for question 12:** Adults ages 18 or older with moderately-to-severely active rheumatoid arthritis who are naïve to TIMs.

12. Given the available evidence on comparative effectiveness, incremental cost-effectiveness using the net price estimate of 26% off the WAC, and considering other benefits, disadvantages, and contextual considerations, what is the long-term value for money of treatment with upadacitinib plus a conventional DMARD versus adalimumab plus a conventional DMARD?

a. Low long-term value for money at estimated pricing  
b. Intermediate long-term value for money at estimated pricing  
c. High long-term value for money at estimated pricing