



Targeted Immune Modulators for Ulcerative Colitis: Effectiveness and Value

Draft Questions for Deliberation and Voting: September 24, 2020 Public Meeting

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

Clinical Evidence

Patient population for all questions: Adults with moderate-to-severe UC.

Given that adalimumab, golimumab, infliximab, ustekinumab, and vedolizumab demonstrated superiority over conventional treatment in clinical trials, we will not vote on clinical evidence for these treatments versus conventional therapy.

1. Is the evidence adequate to demonstrate that the net health benefit of **vedolizumab** is superior to that provided by **adalimumab**?

Yes No

2. Is the evidence adequate to demonstrate that the net health benefit of **ustekinumab** is superior to that provided by **adalimumab**?

Yes No

3. Is the evidence adequate to distinguish the net health benefit among **tofacitinib**, **ustekinumab**, and **vedolizumab**?

Yes No

Potential Other Benefits and Contextual Considerations

4. When compared to conventional therapy, does treating patients with TIMs offer one or more of the following potential “other benefits”? (Select all that apply.)
 - a. These interventions offer reduced complexity that will significantly improve patient outcomes.
 - b. These interventions will significantly reduce caregiver or broader family burden.
 - c. 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.
 - d. These interventions 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 these interventions: _____.

5. Are any of the following contextual considerations important in assessing the long-term value for money of TIMs? (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. Compared to conventional therapy, there is significant uncertainty about the long-term risk of serious side effects of these interventions.
 - e. Compared to conventional therapy, 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 Money

6. 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 infliximab, infliximab-abda, and infliximab-dyyb versus conventional treatment?
 - a. Low long-term value for money at current pricing
 - b. Intermediate long-term value for money at current pricing
 - c. High long-term value for money at current pricing