



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 unless otherwise noted: 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. In patients who are biologic-naïve, is the evidence adequate to distinguish the net health benefit between **infliximab** and **adalimumab**?

Yes No

- 2a. If the answer to Q2 is Yes: Based on the available evidence, which therapy has a greater net health benefit in biologic-naïve patients: **infliximab** or **adalimumab**?

Infliximab Adalimumab

3. Is the evidence adequate to distinguish the net health benefit between **ustekinumab** and **adalimumab**?

Yes No

3a. If the answer to Q3 is Yes: Based on the available evidence, which therapy has a greater net health benefit: **ustekinumab** or **adalimumab**?

Ustekinumab Adalimumab

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

Yes No

5. In patients who are biologic-naïve, is the evidence adequate to distinguish the net health benefit between **vedolizumab** and **golimumab**?

Yes No

5a. If the answer to Q5 is Yes: Based on the available evidence, which therapy has a greater net health benefit in biologic-naïve patients: **vedolizumab** or **golimumab**?

Vedolizumab Golimumab

Potential Other Benefits and Contextual Considerations

6. 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: _____.

7. 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 Money¹

8. 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 **adalimumab** 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
9. 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 **golimumab** 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

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.

10. 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** 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

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 **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

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 **infliximab-abda** 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

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 **ustekinumab** 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

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 **vedolizumab** 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

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 **adalimumab** versus **infliximab**?
- Low long-term value for money at current pricing
 - Intermediate long-term value for money at current pricing
 - High long-term value for money at current pricing
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 **golimumab** versus **infliximab**?
- Low long-term value for money at current pricing
 - Intermediate long-term value for money at current pricing
 - High long-term value for money at current pricing
17. 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-dyyb** versus **infliximab**?
- Low long-term value for money at current pricing
 - Intermediate long-term value for money at current pricing
 - High long-term value for money at current pricing
18. 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-abda** versus **infliximab**?
- Low long-term value for money at current pricing
 - Intermediate long-term value for money at current pricing
 - High long-term value for money at current pricing
19. 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 **ustekinumab** versus **infliximab**?
- Low long-term value for money at current pricing
 - Intermediate long-term value for money at current pricing
 - High long-term value for money at current pricing

20. 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 **vedolizumab** versus **infliximab**?
- Low long-term value for money at current pricing
 - Intermediate long-term value for money at current pricing
 - High long-term value for money at current pricing
21. 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** versus **adalimumab**?
- Low long-term value for money at current pricing
 - Intermediate long-term value for money at current pricing
 - High long-term value for money at current pricing
22. 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 **ustekinumab** versus **adalimumab**?
- Low long-term value for money at current pricing
 - Intermediate long-term value for money at current pricing
 - High long-term value for money at current pricing
23. 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 **vedolizumab** versus **adalimumab**?
- Low long-term value for money at current pricing
 - Intermediate long-term value for money at current pricing
 - High long-term value for money at current pricing