

High cost drug treatment pathway

INFLAMMATORY BOWEL DISEASE in adults

GUIDELINE

Ulcerative colitis

Adult with **moderately to severely active ulcerative colitis** (defined normally, but not exclusively, by Truelove and Witts criteria). Other criteria, such as adapted Mayo score, may also be used.

Inadequate response, intolerance or contraindication to optimised conventional therapy including corticosteroids and azathioprine/6-mercaptopurine

When more than one treatment is suitable, the least expensive should be chosen

Adalimumab, infliximab, golimumab (TA329)
Tofacitinib (TA547), **filgotinib** (TA792), **upadacitinib** (TA856)
 Option if TNF α INHIBITOR therapy has failed, cannot be tolerated or is unsuitable: **ustekinumab** (TA633) or **mirikizumab** (TA925)
 Option if infliximab is not suitable or a biological treatment cannot be tolerated or is not working well enough: **ozanimod** (TA828)
Vedolizumab (TA342)

Adequate clinical response

Yes

Continue treatment for 12 months or until treatment failure (whichever is shorter). Treatment should only continue if there is clear evidence of response as determined by clinical symptoms, biological markers and investigation, including endoscopy if necessary. People should be reassessed at least every 12 months. A trial withdrawal should be considered for patients in stable clinical remission at 12 months.

No

Depending on clinical grounds consider an alternative therapy or surgery

Ulcerative Colitis¹

Post-surgery prophylaxis

High cost drugs should not be offered to maintain remission after surgery.

Sequential use

NICE does not make any recommendations on sequential use of biologics treatment for ulcerative colitis, although it recommends ustekinumab or mirikizumab if TNF α INHIBITOR therapy has failed, and ozanimod if infliximab is not suitable or a biological treatment cannot be tolerated or is not working well enough.

When more than one treatment is available, the least expensive should be chosen.

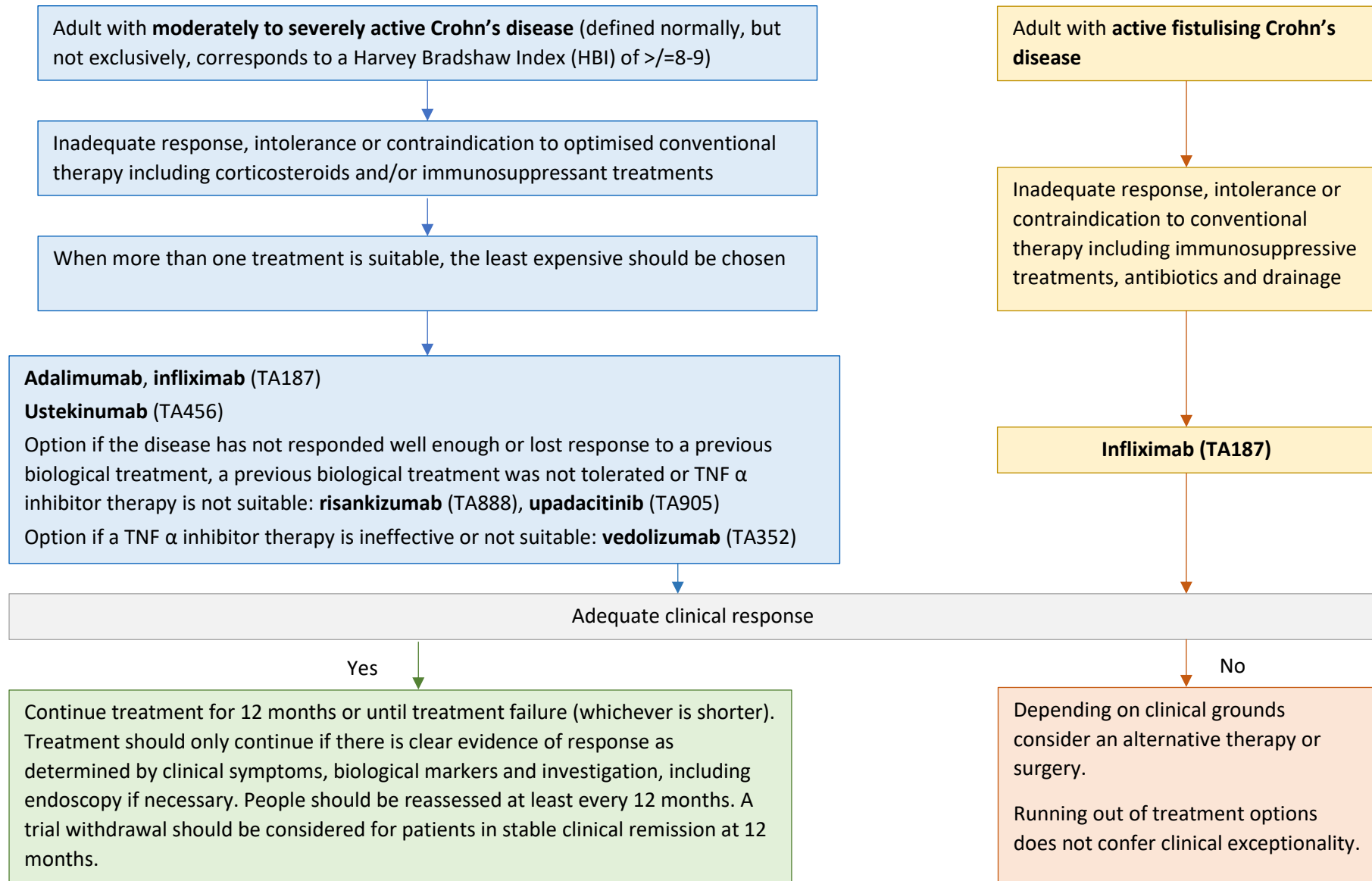
Acute exacerbations of ulcerative colitis

For acute exacerbations, NICE TA163² recommends that infliximab is used if IV ciclosporin is contraindicated or clinically inappropriate. For reasons of safety and efficacy, NHS Cheshire and Merseyside recognises that infliximab will normally be used in preference to ciclosporin, after steroid treatment has been unsuccessful, for this indication.

References

1. [Ulcerative colitis: management](#). NICE NG130 May 2019. Accessed 18/02/2020.
2. [Infliximab for acute exacerbations of ulcerative colitis](#) NICE TA163 December 2008. Accessed 3/02/2021
3. [NICE TA 329. Infliximab, adalimumab and golimumab for treating moderately to severely active ulcerative colitis after the failure of conventional therapy](#)
4. [NICE TA 547. Tofacitinib for moderately to severely active ulcerative colitis](#)
5. [NICE TA792. Filgotinib for treating moderately to severely active ulcerative colitis](#)
6. [TA856. Upadacitinib for treating moderately to severely active ulcerative colitis](#)
7. [TA342. Vedolizumab for treating moderately to severely active ulcerative colitis](#)
8. [TA633. Ustekinumab for treating moderately to severely active ulcerative colitis](#)
9. [TA828. Ozanimod for treating moderately to severely active ulcerative colitis](#)
10. [TA925. Mirikizumab for treating moderately to severely active ulcerative colitis](#)

Crohn's disease



Crohn's Disease¹¹

Post-surgery prophylaxis

Biologics should not be offered to maintain remission after complete macroscopic resection of ileocolonic Crohn's disease. Azathioprine should be considered, in combination with up to 3 months post-operative metronidazole. Biologics would only continue if surgery does not remove all the diseased area.

Subsequent disease flares

If the patient subsequently relapses post successful surgery, a biologic may be considered. The choice of biologic would usually be made at an MDT meeting, choosing the drug with the best chance of success and striving to use the most cost-effective agent.

Sequential use

NICE does not make any recommendations on sequential use of biologics although it recommends that ustekinumab and vedolizumab are used after failure of treatment with TNF α inhibitors and risankizumab and upadacitinib are used if the disease has not responded well enough or lost response to a previous biological treatment, a previous biological treatment was not tolerated or TNF α inhibitor therapy is not suitable.

When more than one treatment is available, the least expensive should be chosen.

Response to TNF α inhibitor therapy¹¹

For patients with primary nonresponse to one TNF α inhibitor the likelihood that they will respond to a second is small but is dependent on the clinical context. Switching to a drug that acts through a different mechanism is more likely to be successful.

Secondary loss of response to TNF α inhibitor therapy can occur as a consequence of immune-mediated neutralising antibodies to the drug (although there are likely to be other mechanisms including non-neutralising, drug-clearing antibodies, or non-immune-mediated mechanisms).

Measurement of drug and antibody levels may be helpful in guiding individual treatment choices and next steps¹².

References

11. [NICE NG129. Crohn's disease: management](#)
12. [British Society of Gastroenterology consensus guidelines on the management of inflammatory bowel disease in adults](#). June 2019. Accessed 18/02/2020.
13. [British Society of Gastroenterology consensus guidelines on the management of inflammatory bowel disease in adults](#). Gut BMJ 2021
14. [TA187. Infliximab and adalimumab for the treatment of Crohn's disease](#)
15. [TA456. Ustekinumab for moderately to severely active Crohn's disease after previous treatment](#)
16. [TA888. Risankizumab for previously treated moderately to severely active Crohn's disease](#)
17. [TA905. Upadacitinib for previously treated moderately to severely active Crohn's disease](#)
18. [TA352. Vedolizumab for treating moderately to severely active Crohn's disease after prior therapy](#)
19. [TA187. Infliximab and adalimumab for the treatment of Crohn's disease](#)