Adult (age\(\geq 18\) years) high-cost drug pathway for moderately to severely active ulcerative colitis

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North Central London Joint Formulary Committee
Adult high-cost drug pathway for active ulcerative colitis
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Document management

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Note 1: Moderately to severely active UC  
- Corresponds to a Mayo score of 6-12  
- If alternative disease severity scoring system used, evidence of correlation with disease severity and response criteria to be provided.

Note 2: Conventional immunosuppressive therapy  
Usual Adult maintenance treatment dose ranges:  
- Azathioprine - 2 mg/kg/day to 2.5 mg/kg/day,  
- Mercaptopurine - 0.75 mg/kg/day to 1.5 mg/kg/day

Note 3: Choice and Less expensive drug  
When considering both drug and administration costs, the treatment cost hierarchy is expected to be:  
- SC biosimilar (lowest cost)  
- IV biosimilar  
- SC originator  
- IV originator (highest cost)

Note 4: Response definitions  
Complete Mayo:  
- decrease in full Mayo score from baseline by ≥3 points and ≥30%, AND  
- decrease in rectal bleeding sub-score from baseline by ≥1 point, OR absolute rectal bleeding sub-score of 0 or 1.  
Partial Mayo (where further endoscopy not considered necessary/appropriate):  
- decrease in partial Mayo score from baseline of ≥2 points and ≥25% AND  
- decrease in rectal bleeding sub-score from baseline of ≥1 point OR absolute rectal bleeding sub-score of 0 or 1.  
If alternative disease severity scoring system used, evidence of correlation with disease severity and response criteria to be provided.

Note 5: Disease reassessment  
At 12 months after the start of treatment, people should have their disease reassessed to determine whether ongoing treatment is still clinically appropriate. Treatment should only be continued if there is clear evidence of ongoing adequate response (Note 4) and active disease. This should be determined by:  
- Clinical symptoms and  
- Biological markers and  
- Investigation, including endoscopy if necessary.  
Clinical Remission:  
- complete or partial Mayo score of ≤2 points and no individual subscore >1

Note 6: Trial Dose Escalation  
For patients who have responded to induction and maintenance treatment regime of a TNF inhibitor but then lost response an attempt to recapture response with a temporary period of increased dose / shortened interval between doses may be made:  
- 3 doses of infliximab® dose of 10mg/kg  
  8 weekly and then back to 5mg/kg; or  
- 3 doses of infliximab®, 5mg/kg given 4-6 weekly and then back to 8 weekly; or  
- Up to 12 weeks on weekly adalimumab 40mg then back to every other week.  
Adalimumab dose escalation is not routinely commissioned (submit tIFR)²

Note 7: Anti-TNF drug and antibody levels  
If response to treatment not seen, only partial response or loss of response; consider anti-TNF drug and antibody levels to guide further biologic therapy. See Appendix 1 for guidance on interpreting anti-TNF drug and antibody levels

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* In the absence of robust published evidence, a pragmatic view was taken by the IBD working group
† An unlicensed use/dose of the medicine. Clinically approved by NCL IFC and/or IBD working group
§ Licensed however not included within economic assessment of NICE TA342 therefore not routinely commissioned
* Deviation from NICE TA. Clinically approved by NCL IFC and IBD working group.
Appendix 1: Poor response or loss of response to anti-TNF therapy

- Poor response of loss of response to anti-TNF therapy
  - Confirm active IBD (faecal calprotectin, inflammatory markers and scope/radiology)
  - Exclude alternative pathology (stricture, cancer, infection, IBS)

- Anti-TNF trough level low or undetectable
  - Check compliance

- Anti-TNF antibodies detectable
  - Antibody level high
    - Either: Switch to another anti-TNF† Switch to vedolizumab†
  - Antibody level low
    - Add in/optimise immunosuppressant† Increase dose/frequency of anti-TNF† (see note 6)
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- Anti-TNF antibodies undetectable
  - Antibody level high
  - Antibody level low
  - Switch to vedolizumab

Appendix 2: Tofacitinib use in Ulcerative Colitis

Tofacitinib will be considered as a treatment choice for patients who have failed on (at least one) anti-TNF therapy and/or Vedolizumab, in line with NICE TA547. Tofacitinib will only be considered as first line treatment of ulcerative colitis where the most cost effective choices (anti-TNF’s) are contraindicated, or where the patient has a treatment-limiting needle phobia, resulting in an oral therapy being the most appropriate choice.

The place in therapy for tofacitinib will be reviewed in 6 months from the date of publication of this document, with the view to incorporate into the above clinical pathway.

Appendix 3: Clinical trials

An investigative medicinal product (IMP) will be considered part of the commissioned pathway, and subsequently reimbursed by NCL commissioners if all the following criteria are met:

- IMP has a positive NICE Technology Appraisal (NHS funding will commence 90 days after TA publication)
- Patient met NICE criteria when initiating IMP

Appendix 4: Review and Stop updates on Blueteq

Blueteq will be used for funding requests, as well as to record/capture patients that have stopped drug treatment as a result of clinical review and/or remission

Acknowledgements

This pathway is based on a version developed by Hertfordshire CCG and has been updated, with permission, for use within North Central London.