Lancashire & South Cumbria Medicines Management Group

Inflammatory Bowel Disease: High-Cost Drugs Commissioning Pathway Version 1.0 – May 2026

VERSION CONTROL		
Version	**Date**	**Amendments made**
Version 1.0	May 2026	New guidance.

Inflammatory Bowel Disease: High-Cost Drugs Commissioning Pathway

Background

- The Inflammatory Bowel Disease High-Cost Drugs Commissioning Pathway document summarises the NHS funding decisions for advanced therapy high-cost drugs according to the NICE technology appraisal guidance.
- When new high-cost drugs receive positive recommendation from NICE, guidance on their use will be included in upcoming pathway updates.
- For further guidance on clinical best practice and treatment decisions based on patient and disease factors, clinicians may wish to consult the latest guidance from the British Society of Gastroenterology.

Initiating and continuing treatment with a high-cost drug

- Choice of treatment to be made on an individual basis following discussion between clinician and patient, this must be clearly documented in the patient record.
- NICE recommends that treatment with a high-cost drug is initiated in patients whose disease has not responded to conventional therapy (including immunosuppressive and/or corticosteroid treatments), or who are intolerant of or have contraindications to conventional therapy.
- Treatment should normally be started with the least expensive drug (including biosimilars), taking into account administration costs and should be prescribed by brand name to support pharmacovigilance
- **Patients should be reviewed by a consultant at least annually to assess treatment efficacy.**
- Dose optimise for those who do respond to treatment
- Non-responders have little benefit from sustained treatment, discontinue if there is a complete lack of response

Please refer to the individual drug SPCs for detailed prescribing information

Inflammatory Bowel Disease
High Cost Drugs Commissioning Pathway
Moderately to Severely Active Crohn's Disease

- Routine use of high-cost drugs to prevent recurrence of Crohn's Disease following surgery is not recommended. In patients at high risk of recurrence (e.g. more than one resection, or penetrating or fistulising disease), prophylaxis with a biologic (e.g anti-TNFs, vedolizumab) should be considered where appropriate. 5-ASA and purine analogues are not suggested for post-surgical maintenance remission of Crohn's disease.
- Before withdrawal is considered, assessment of disease activity and confirmation of clinical remission using a combination of clinical, chemical, endoscopic/histologic and/or radiological investigations should be considered to inform the risks and benefits of stopping.

Step 1 **Anti-TNF therapy (dose optimisation or switching anti-TNF within step 1 is considered as one line of therapy)**

Infliximab
TNFα inhibitor
IV infusion or SC injection
Review response at 6 weeks

Adalimumab
TNFα inhibitor
SC injection
Review response at 12 weeks

- Secondary loss of response can occur due to antibody formation (see Figure 1).
- Dose escalation of anti-TNF treatment may be tried in some patients in light of secondary failure of anti-TNF treatment e.g. patient using adalimumab SC or infliximab IV (see Figure 1).
- A second anti-TNF drug may be tried in antibody mediated failure with the 1st anti-TNF drug (see Figure 1).
- An anti-TNF drug in combination with an immunosuppressant is recommended in suitable patients to increase efficacy, but does increase the risk of serious infection and lymphoma and patients should be appropriately counselled.
- Infliximab should be considered first-line for fistulising Crohn's disease.
- Use of infliximab SC should be considered when appropriate.
- When Infliximab / Adalimumab is used for induction and maintenance of remission for Crohn's disease, it is recommended this is done in combination with purine analogues. Consideration as to if or when purine analogues are started and stopped should be based on response and adverse event experience.
- Routine withdrawal of Infliximab therapy is not suggested after 1 year of stable remission in Crohn's disease.
- **Proceed to Step 2 if anti-TNF therapy has failed due to lack of efficacy or intolerance to anti-TNF drugs.**

Step 2 **Up to 4 lines of therapy available**

Ustekinumab
IL-12/23 inhibitor
IV infusion then SC injection
Review response at 16 weeks

Risankizumab
p19 subunit IL-23 inhibitor
IV infusion then SC injection
Review response at 16 weeks

Mirikizumab
p19 subunit IL-23 inhibitor
IV infusion then SC injection
Review response at 12 weeks

Guselkumab
IL-23 inhibitor
SC injection
Review response at 12 weeks

Upadacitinib
JAK inhibitor
Oral
Review response at 24 weeks

JAK inhibitors should only be used in patients >65 years, in current or past smokers, in those with other cardiovascular risk factors (such as diabetes or coronary artery disease), and in patients with other malignancy risk factors **if no suitable alternatives are available.**

Vedolizumab
Anti-integrin
IV infusion or SC injection
Review response at 14 weeks

Vedolizumab is not suggested for induction and maintenance of remission in patients with moderate to severe Crohn's disease (British Society of Gasroenterology). This does not preclude the use of the drug for the management of Crohn's disease where this has been agreed with the patient and the wider IBD MDT.

Failure of a fifth line of treatment constitutes the end of the commissioned pathway.

Inflammatory Bowel Disease
High Cost Drugs Commissioning Pathway
Moderately to Severely Active Ulcerative Colitis

- High-cost drugs should not be used routinely to prevent recurrence of ulcerative colitis following surgery (although should be considered if a patient has been left with a pouch).
- The overall treatment goal in ulcerative colitis is achieving remission and should be assessed biochemically or endoscopically and histologically. Maintenance therapy should be continued with the agent successful in achieving induction, with the important exception that corticosteroids are not recommended for long-term maintenance.
- In patients with ulcerative colitis, withdrawal of anti- TNF therapy, when used as monotherapy or combination therapy, is associated with a significant risk of relapse. Shared decision- making should be undertaken before withdrawal.

Step 1 **Anti-TNF therapy (dose optimisation or switching anti-TNF within step 1 is considered as one line of therapy)**

Infliximab
TNFα inhibitor
IV infusion or SC injection
Review response at 14 weeks

First line

- If there is evidence of efficacy with anti-TNF therapy, but there is antibody mediated loss of response (Figure 1), then consider adding in a thiopurine (if a patient is not already taking one and there is no CI/intolerance),
- An anti-TNF drug in combination with an immunosuppressant is recommended in suitable patients to increase efficacy, but does increase the risk of serious infection and lymphoma and patients should be appropriately counselled.
- Infliximab is recommended as an option for the treatment of acute exacerbations of severely active ulcerative colitis as an alternative to ciclosporin.
- Use of infliximab SC should be considered when appropriate.
- For patients at high risk of infection, with significant co-morbidities vedolizumab first-line may be appropriate.
- **Proceed to Step 2 if Step 1 therapy options have failed due to lack of efficacy or intolerance**

Golimumab
TNFα inhibitor
SC injection
Review response at 14 weeks

Second line

Step 2 **Up to 4 lines of therapy available**

Mirikizumab
p19 subunit IL-23 inhibitor
IV infusion then SC injection
Review response at 12 weeks

Risankizumab
p19 subunit IL-23 inhibitor
IV infusion then SC injection
Review response at 24 weeks

Ustekinumab
IL-12/23 inhibitor
IV infusion then SC injection
Review response at 16 weeks

Guselkumab
IL-23 inhibitor
SC injection
Review response at 12 weeks

Etrasimod
S1P receptor modulator
Oral

Ozanimod
S1P receptor modulator
Oral

Vedolizumab
Anti-integrin
IV infusion or SC injection
Review response at 10 weeks

Tofacitinib
JAK inhibitor
Oral
Review response at 16 weeks

Upadacitinib
JAK inhibitor
Oral
Review response at 16 weeks

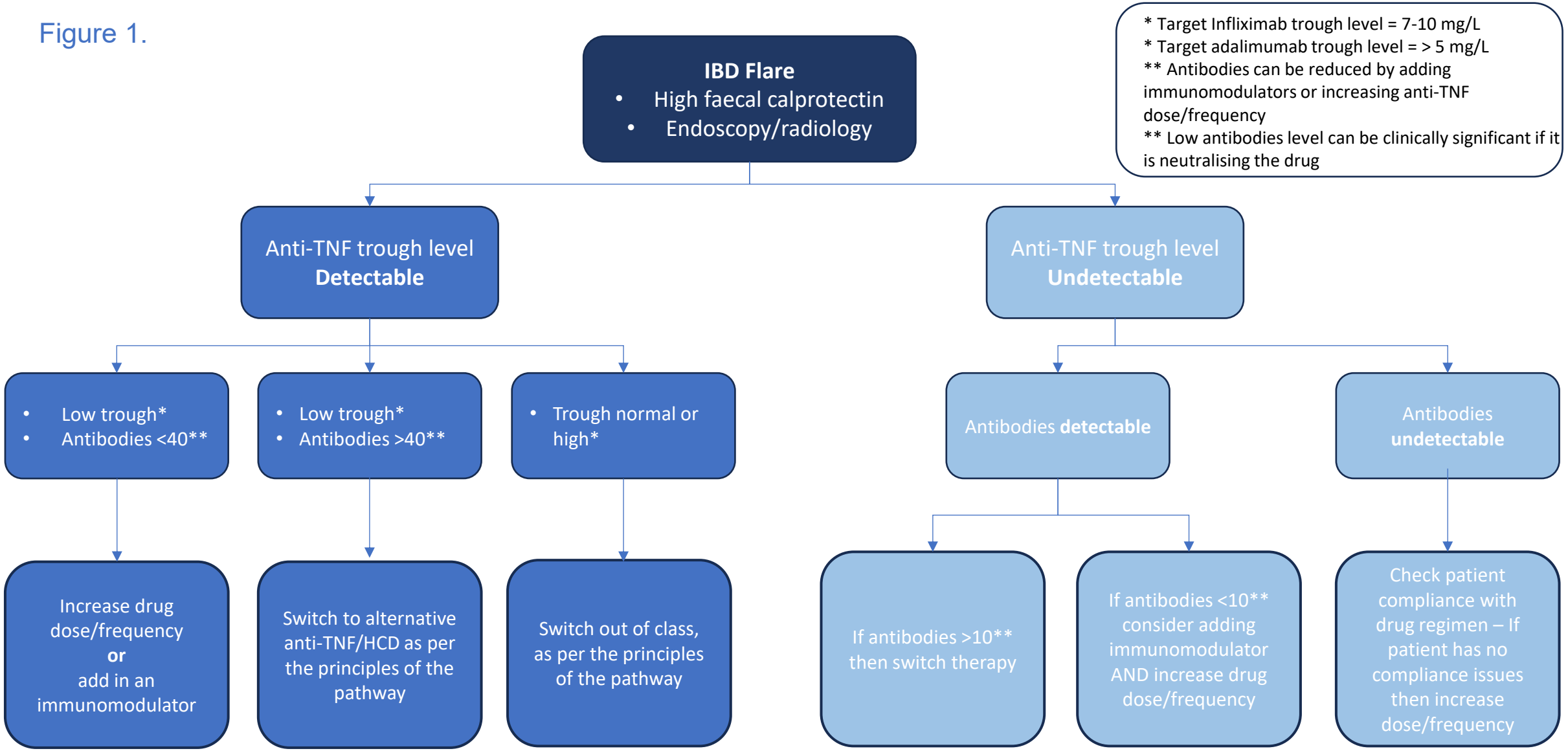
Filgotinib
JAK inhibitor
Oral
Review response at 22 weeks

JAK inhibitors should only be used in patients >65 years, in current or past smokers, in those with other cardiovascular risk factors (such as diabetes or coronary artery disease), and in patients with other malignancy risk factors **if no suitable alternatives are available**

Tofacitinib MHRA Alert

Failure of a fifth line of treatment constitutes the end of the commissioned pathway.

Figure 1.



Adapted from the Lancashire Teaching hospitals 'Biological therapy in inflammatory bowel disease prescribing policy'

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