

DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE (JAPC)

Guideline for the treatment of Crohn's Disease (Updated: June 2018)

Adult with active Crohn's disease

Does the adult have **severe** active Crohn's disease?

No

Does the adult have active **fistulising** Crohn's disease?

No

Has the patient's disease failed to respond to **or** is the patient intolerant of **or** does the patient have contraindications to conventional therapy, including:

- immunosuppressant's **and/or**
- Corticosteroid treatments?

Yes

Yes

First line treatment option:

- **Infliximab biosimilar (TA187)**

First line treatment option:

- **Adalimumab (TA187)**

Has treatment with a TNF Inhibitor failed or is a TNF inhibitor CI or not tolerated?

- **Adalimumab (TA187) (local decision)**

Has treatment with a TNF Inhibitor failed or is a TNF inhibitor CI or not tolerated? Treatment should be started with the least expensive drug:

- **Ustekinumab 12 weekly** is the cost effective choice (TA456) (See dosing schedule) Or
- **Vedolizumab (TA352)**

Treatment failure with TNF inhibitor.

First line treatment option:

- **Infliximab biosimilar (TA187)** as a planned course of treatment

Has treatment with a TNF Inhibitor failed or is a TNF inhibitor CI or not tolerated?

- **Adalimumab (TA187) (Local decision)**

Treatment failure with TNF inhibitor.

No

At any point **before 12 months** of treatment has passed, has treatment failed (including the need for surgery)?

At **12 months** after the start of treatment, reassess the disease. Is there evidence of active disease?

No

Is the patient in stable clinical remission?

Yes

Discuss the risks and benefits of continued treatment. Is a trial withdrawal considered appropriate?

Yes

Yes

No

No

Maintain treatment and reassess patient at least every 12 months.

Trial withdrawal from biologic drug used. Restart treatment if patient relapses after treatment is stopped.

For some centres TDM may be used for infliximab and Adalimumab to check response to the anti-TNF inhibitor See appendix 1.

Yes

Cease treatment with the biologic drug used.

Please Note:
Initiate a thiopurine alongside a biologic unless contraindication. Evidence shows early use of thiopurine reduces the likelihood of anti-tnf failure.

The CCG's will only commission 4 treatment options (3 switches) per patient - this includes 2 treatment failure and 1 intolerance.

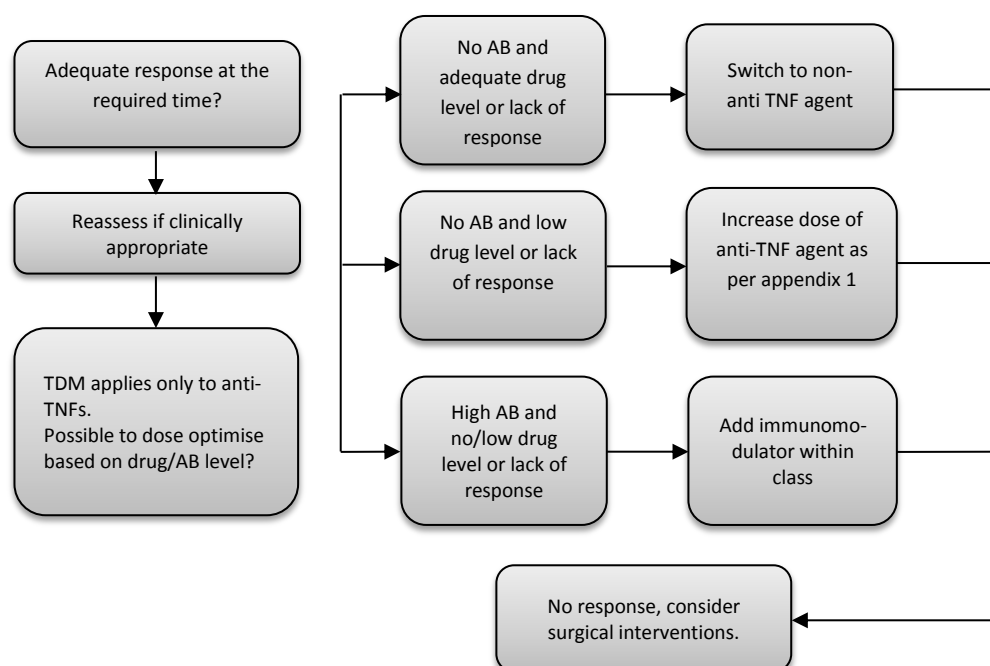
NICE approved treatment

Local variation to NICE

Date updated: June 2018

Review due: May 2020

Appendix 1- Therapeutic drug monitoring (TDM)



Clinical response includes clinical symptoms, biological markers and investigation, including endoscopy.

The CDAI is frequently used to assess disease severity. It is a composite of overall activity of Crohn's disease as assessed by clinicians, and has eight variables weighted according to their ability to predict disease activity. It gives a score ranging from 0 to over 600, based on a diary of symptoms kept by the patient for 1–7 days, and other measurements such as the patient's weight and haematocrit.

- CDAI score < 150 is considered to be remission,
- CDAI score > 220 is considered to define moderate to severe disease,
- CDAI score > 300 is considered to be severe disease.

Appendix 3 - Dosing schedule for Crohns disease

Biologic	Induction dose	Maintenance dose	Dose escalation	Adequate response	Further information		
Adalimumab (SC)	Week 0 – 80mg SC Week 2 – 40mg SC Or Rapid response: Week 0 – 160mg SC Week 2 – 80mg SC	40mg SC every other week thereafter.	Maintenance dose can be increased to 40 mg every week in people whose disease shows a decrease in response to treatment.	Week 12	Adalimumab is a recombinant human monoclonal antibody that binds specifically to tumour necrosis factor alpha (TNF- α)		
Infliximab (IV) (Biosimilar or originator)	Week 0, 2, 6 – 5mg/kg IV	5mg/kg IV every 8 weeks thereafter.	Dose escalation is an option for people whose disease has stopped responding on the basis on drug and antibody levels	Week 6	Infliximab is a chimeric human-murine IgG1 monoclonal antibody		
Vedolizumab (IV)	Week 0, 2, 6 – 300mg IV	300mg IV every 8 weeks thereafter	No	Week 14	Vedolizumab is a humanised IgG1 monoclonal antibody that binds to the human $\alpha 4\beta 7$ integrin.		
Ustekinumab (IV & SC)	Week 0 – 6mg/kg IV Initial intravenous dosing of ustekinumab	Week 8 - 90mg SC Then 90mg SC every 12 weeks thereafter.	Dose escalation can be increased to 8 weekly dosing for people whose disease has stopped responding. (Prescribers are reminded that 8 weekly dosing is the most expensive dosing schedule)	Week 16	Ustekinumab is a fully human monoclonal antibody that targets interleukin-12 (IL-12) and IL-23.		
	Body weight of patient					Dose	No. of vials
	≤55kg					260mg	2
	>55kg - ≤85kg					390mg	3
>85kg	520mg	4					