DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE (JAPC)

Treatment algorithm for Ulcerative Colitis
Updated: June 2018

Adult with moderately to severely active Ulcerative Colitis

Does the patient have an acute exacerbation of severely acute ulcerative colitis

Yes → Treat according to NICE TA163 (Infliximab)

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:
- Mercaptopurine/azathiopurine **and/or**
- Corticosteroid treatments?

First line treatment option:
- **Infliximab biosimilar (TA329) (Note 3)**

As part of a planned course of treatment

Has treatment with a TNF Inhibitor failed or is a TNF inhibitor CI or not tolerated?
- **Adalimumab** (TA329) *(Local decision)*

First line alternative treatment options for patients for whom Infliximab is clinically inappropriate.
Use the less expensive drug as a planned course of treatment (see note 1):
- Adalimumab (TA329) or
- Golimumab (TA329) or
- Vedolizumab* (TA342)

Vedolizumab* (TA342) may be given to patients who have had an inadequate response or lost response to, or who were intolerant to either conventional therapy or a TNF inhibitor.

*Continued therapy for patients with UC should be carefully reconsidered if no evidence of therapeutic benefit is observed by week 10.

At any point **before 12 months** of treatment has passed, has treatment failed (including the need for surgery)? (See appendix 1 for adequate response time)

Yes → Cease treatment with the biologic drug used.

No

At 12 months after the start of treatment, reassess the disease (see note 2). Is there evidence of response active disease?

Yes → Maintain treatment and reassess patient at least every 12 months.

No

Is the patient in stable clinical remission?

No → Maintain treatment and reassess patient at least every 12 months.

Yes

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

No → Maintain treatment and reassess patient at least every 12 months.

Yes

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

Note 1: Less expensive drug
As assessment of the less expensive drug should take into account:
- Drug administration costs
- Required dose
- Product price per dose

The assessment of the less expensive drug may need to be varied for individual patients because of differences in the method of administration and treatment schedules

Note 2: 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 active disease. This should be determined by
- Clinical symptoms and
- biological markers and
- investigation, including endoscopy if necessary

Note 3: Infliximab prescribing
Infliximab biosimilar should be prescribed by brand.

Please note:
Dose escalation of biologic drugs is not currently recommended by NICE

<u>The CCG's will only commission 4 treatment options (3 switches) per patient - this includes 2 treatment failures and 1 intolerance</u>

Date updated: June 2018
Review due: May 2020

NICE approved treatment

Local variation to NICE

Appendix 1- Dosing schedule in UC

Biologic		Induction phase	Maintenance phase	Adequate response time (weeks)
Adalimumab (SC)	Adalimumab is a recombinant human monoclonal antibody that binds specifically to tumour necrosis factor alpha (TNF-α)	Induction phase • Week 0 - 160mg SC. • Week 2 – 80mg SC	Maintenance phase • 40mg every other week thereafter.	2-8 weeks after starting treatment
Golimumab (SC) *Only recommended if the company provides the 100mg dose of golimumab at the same cost as the 50mg dose, as agreed in the patient access scheme.*	Human IgG1κ monoclonal antibody produced by a murine hybridoma cell line with recombinant DNA technology	Induction phase- **<u>if patient weighs <80kg</u>** • Week 0 - 200mg SC • Week 2 – 100mg SC	Maintenance phase • 50mg every 4 weeks thereafter.	12 -14 weeks after starting treatment
		Induction phase **<u>if patient weighs >80kg</u>** • Week 0 - 200mg SC • Week 2 – 100mg SC	Maintenance phase • 100mg every 4 weeks thereafter.	
Infliximab biosimilar IV (Inflectra)	Infliximab is a chimeric human-murine IgG1 monoclonal antibody	Induction phase • Week 0 - 5mg/kg IV • Week 2 – 5mg/kg IV • Week 6 - 5mg/kg IV	Maintenance phase • 5mg/kg IV every 8 weeks	Within the first 14 weeks
Infliximab originator IV (Remicade)	Infliximab is a chimeric human-murine IgG1 monoclonal antibody	Induction phase • Week 0 - 5mg/kg IV • Week 2 – 5mg/kg IV • Week 6 - 5mg/kg IV	Maintenance phase • 5mg/kg IV every 8 weeks	
Vedolizumab (IV)	Vedolizumab is a humanised IgG1 monoclonal antibody that binds to the human α4β7 integrin.	Induction Phase • Week 0 - 300mg IV • Week 2 - 300mg IV • Week 6 – 300mg IV	Maintenance phase • 300mg IV every 8 weeks thereafter	Observed by week 10.