This policy statement is approved by Halton, Knowsley, Liverpool, South Sefton, Southport and Formby, St Helens, Warrington, West Lancashire, and Wirral CCGs

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NHS
Pan Mersey
Area Prescribing Committee

Inflammatory Bowel Disease High Cost Drugs Treatment Pathway for Adults

Pan Mersey APC pathways for the initiation and maintenance of high cost drugs in the management of Ulcerative Colitis and Crohn's Disease.

GUIDANCE

Ulcerative Colitis

Conventional therapy
Aminosalicylates, Corticosteroids (for disease flares), Azathioprine, 6-mercaptopurine

↓

Not tolerated
Inadequate/loss of response
Contraindications

↓

Offer up to six lines of therapy, including vedolizumab, tofacitinib and ustekinumab according to NICE criteria, if this number of lines is clinically appropriate prior to surgery. When more than one treatment is appropriate, the least expensive should be chosen

TNF α INHIBITORS (TA329)	Adalimumab, Infliximab, Golimumab
ANTI-INTEGRIN (TA342)	Vedolizumab
JAK INHIBITOR (TA547, TA792)	Tofacitinib, Filgotinib
IL12/23 (TA633)	Ustekinumab
S1P RECEPTOR MODULATOR (TA828)	Ozanimod

↓ ↑

Clinical response: Assess response according to NICE criteria and at 12 months
Poor response: Consider an alternative drug or surgery
Not tolerated: Consider an alternative drug or surgery (does not constitute a line of treatment)
NB: Failure of fifth line treatment constitutes the end of the commissioned pathway and running out of treatment options does not confer clinical exceptionality.

Continuation of High Cost Drugs Therapy (NICE NG130)[1]

Therapy should be given as a planned course until treatment failure (including the need for surgery) or until 12 months after starting, whichever is shorter.
Continue only if there is clear evidence of ongoing clinical benefit as determined by clinical symptoms, biological markers and investigation, including endoscopy if necessary.
Reassess at least every 12 months to determine whether ongoing treatment is still clinically appropriate.

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Review date: February 2023 — Version: 1.4
(or earlier if there is significant new evidence relating to this recommendation)
APC administration provided by Midlands and Lancashire Commissioning Support Unit

Crohn's Disease

Conventional therapy
Aminosalicylates,
Corticosteroids (for disease flares),
Azathioprine, 6-mercaptopurine, methotrexate
Polymeric diet with or without corticosteroids

↓

Not tolerated
Inadequate or lost response
Medical contraindications

↓

TNF α INHIBITOR (TA187)
Assess response according to NICE criteria.
Adalimumab
Infliximab
In patients who experience intolerance, secondary failure or primary failure with a first TNF α inhibitor, when clinically appropriate, treatment with the second NICE-approved TNF α inhibitor may be offered.
IL12/23 (TA456)
May be used first line in elderly patients or close contacts of patients with TB
Assess response according to NICE criteria
Ustekinumab

↓

ANTI-INTEGRIN (TA352)
Assess response according to NICE criteria
To be used second line if a TNF α inhibitor is ineffective or not suitable
Vedolizumab

Clinical response: Assess response according to NICE criteria and at 12 months
Poor response: Consider an alternative drug.
Not tolerated: Consider an alternative drug (does not constitute a line of treatment).

Golimumab has not been included in clinical trials for Crohn's disease and is not licensed for use in Crohn's disease. Therefore, it should not be considered as a treatment option for Crohn's disease, even as an individual funding request.

NB: Failure of fourth line treatment constitutes the end of the commissioned pathway

Running out of treatment options does not confer clinical exceptionality.

Continuation of High Cost Drugs Therapy (NICE NG129)[2]

Therapy should be given as a planned course until treatment failure (including the need for surgery) or until 12 months after starting, whichever is shorter.

Continue only if there is clear evidence of ongoing clinical benefit as determined by clinical symptoms, biological markers and investigation, including endoscopy if necessary.

Reassess at least every 12 months to determine whether ongoing treatment is still clinically appropriate.

Patients who are in stable clinical remission should be considered for a trial withdrawal of therapy. If disease relapses after treatment is stopped, patients should have the option to restart treatment.

Additional Information

Ulcerative Colitis[1]

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.

Acute exacerbations of ulcerative colitis
For acute exacerbations, NICE TA163[2] recommends that infliximab is used if IV ciclosporin is contraindicated or clinically inappropriate. For reasons of safety and efficacy, Pan Mersey APC recognises that infliximab will normally be used in preference to ciclosporin, after steroid treatment has been unsuccessful, for this indication.

Crohn's Disease[3]

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 (10-20 patients per year in Pan Mersey), a biologic may be considered. The choice of biologic would 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.
When more than one treatment is available, the least expensive should be chosen.

Response to TNF α inhibitor therapy[4]
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 steps. However, NICE currently states that there is insufficient evidence to recommend their routine adoption across the NHS[5].

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. Crohn's disease: management. NICE NG129 May 2019. Accessed 18/02/2020.
4. British Society of Gastroenterology consensus guidelines on the management of inflammatory bowel disease in adults. June 2019. Accessed 18/02/2020.
5. Therapeutic monitoring of TNF-alpha inhibitors in Crohn's disease (LISA-TRACKER ELISA kits, IDKmonitor ELISA kits, and Promonitor ELISA kits). DG22 February 2016. Accessed 18/02/2020.