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Ulcerative Colitis Disease BSW STP Biologic / Biosimilar Commissioning Pathway

NICE Criteria to Start Treatment with biologic / biosimilar
Ref NICE CG166 June 2013

Patients with moderately to severely active UC, whose disease has responded inadequately to conventional therapy (including corticosteroids / mercaptopurine /azathioprine, or who cannot tolerate, or have medical contraindications for these are eligible for treatment with a biologic.

ONLY if a C/I or relative C/I to a TNF inhibitor

1st line Treatment Options (Anti-TNF)

Treatment should normally be started with the less expensive drug (taking into account drug administration costs, required dose and product price per dose)

TA329

Infliximab (TNF inhibitor) BIOSIMILAR (prescribe by br…) IV 5mg/kg at 0, 2, and 6 weeks then every 8 weeks. Review at week 12 to 14 (HBI, bloods +/- faecal calprotectin)
OR
Adalimumab (TNF inhibitor) 80mg loading then 40mg alternate weeks s/c. (OR Adalimumab (TNF inhibitor) 160mg loading then 80mg week 2 then 40mg every 2 weeks)

TA329

Golimumab

Adalimumab is cheaper than golimumab. If both drugs are suitable adalimumab should be used in preference (NICE TA 329 recommends least expensive drug)

TA342

Vedolizumab

As per NICE TA 342 and the SPC vedolizumab can be used as 1st line biologic. In practice it is anticipated that anti-TNFs will be 1st & 2nd line biologic options unless otherwise inappropriate as vedolizumab is the only biologic available for 3rd line use. Escalation to every 4 weeks (whilst the SPC) was not part of NICE costing model and requires an IFR

Good response

Continue and review at 12 months consider stopping + maintain immunosuppressant

Partial response

Short term dose escalation approved (locally agreed)

Primary Non response

2nd line Treatment Options

NICE does not make any specific recommendations regarding sequential use of anti-TNFs for UC. The greatest evidence base for 2nd line anti-TNFs relates to adalimumab.

Infliximab & golimumab as 2nd line treatments should be reserved for those patients who have had adalimumab as a 1st line anti-TNF ONLY.

TA329

Alternative TNF inhibitor
Adalimumab OR Infliximab BIOSIMILAR OR
Golimumab (TNF inhibitor) < 80mg/kg 200 mg s/c week 0 , then 100 mg at week 2, then 50 mg every 4 weeks. >80mg/kg mg, 200mg week 0 then 100 mg at week 2, then 100 mg every 4 weeks. Review at week 12-14.

OR

Vedolizumab (most expensive option)

Adalimumab
OR
Vedolizumab

3rd line Treatment Option

Use of an Anti-TNF as a 3rd line biologic for UC patients who have experienced treatment failure or intolerance to a 2nd biologic is not recommended

TA352

Vedolizumab IV 300mg at week 0, 2 and 6 then every 8 weeks. Review at week 14 to 16

Vedolizumab

Continuation of Biologic Treatment

Treat for 12 months or until treatment failure (including the need for surgery), whichever is shorter, then review and discuss the risks and benefits of continued treatment. Continue only if there is evidence of response 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. Consider a trial of withdrawal for patients who are in stable clinical remission. If disease relapses after treatment is stopped patients should have the option to start treatment again.

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Nb. Use of a biologics for post-surgery prophylaxis in UC is not recommended due to lack of evidence