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Crohn's Disease BSW ST Biologic Commissioning Pathway

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NICE Criteria to start treatment with Biologic / Biosimilar agents Ref NICE CG152 May16

Patients with severe active CD, which has responded inadequately to conventional therapy (steroids, 5-ASA, immunosuppressant) or who cannot take/tolerate, or have medical contraindications for these are eligible for treatment with a biologic.

Severe CD is defined as very poor general health & 1 or more symptoms e.g. weight loss, fever, severe abdominal pain and usually frequent (3–4 or more) diarrhoeal stools daily. This normally, but not exclusively, corresponds to a Crohn's Disease Activity Index (CDAI) score of 300 or more, or Harvey- Bradshaw score of 8 to 9 or more.

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

ONLY if C/I to adalimumab, infliximab, ustekinumab

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)

TA187

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

TA456 Ustekinumab

TA352 Vedolizumab

Good response

Continue and review at 12 months considerer stopping + maintain immunosuppressant

Partial response

Short term dose escalation agreed as per local guidance

Primary Non response

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.

2nd line Treatment Options

NICE TA 187 does not make any specific recommendations regarding sequential use of Anti-TNFs. In CD patients who experience intolerance, secondary failure or primary failure with a first Anti-TNF, treatment with a 2nd approved Anti-TNFs may be tried.i.e. infliximab, adalimumab or ustekinumab

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Adalimumab (TNF inhibitor) OR
Infliximab (TNF inhibitor) BIOSIMILAR
OR
Ustekinumab (IL12 & IL23 inhibitor) IV Loading Dose then 90mg s/c at week 8 and every 12 weeks.

≤55kg	260mg	2 vials of 130mg
> 55 kg to ≤ 85 kg	390mg	3 vials of 130mg
> 85 kg	520mg	4 vials of 130mg

3rd line Treatment Option

Use of an Anti-TNF as a 3rd line biologic for CD 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

Use of Biologics Post Surgery

Routine use of biologics as post surgery prophylaxis in CD is not recommended (insufficient evidence). In patients at high risk of recurrence (e.g. more than one resection, or penetrating or fistulising disease), prophylaxis with thiopurine should be considered where appropriate. An approved biologic may be considered in these high risk patients upon recurrence, or if thiopurine treatment is not tolerated