Crohns Disease

LMMG Recommended Biologic Commissioning Pathway

Lancashire Medicines Management Group NHS

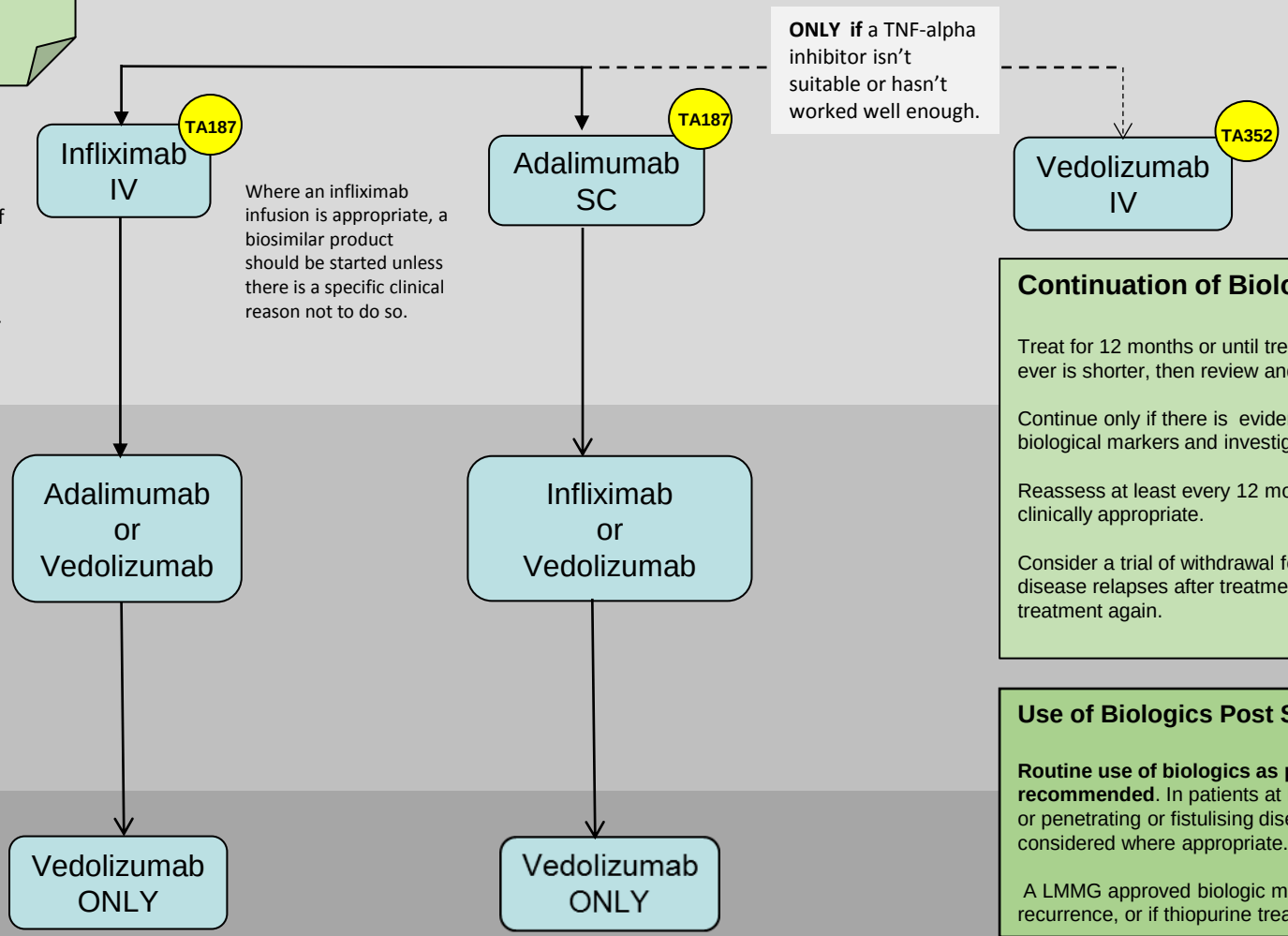
NICE Criteria to Start Treatment

Patients with severe active CD, which has responded inadequately to conventional therapy, 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 a Harvey-Bradshaw score of 8 to 9 or above.

1st line Treatment Options

The choice of treatment should be made on an individual basis after discussion between the clinician and patient about the advantages and disadvantages of the treatments available. Treatment **should normally be started with the less expensive drug** (taking into account drug administration costs, required dose and product price per dose). This may need to be varied for individual patients because of differences in the method of administration and treatment schedules.



2nd line Treatment Options

NICE TA 187 does not make any specific recommendations regarding sequential use of Anti-TNFs. LMMG recommends that in CD patients who experience intolerance, secondary failure or primary failure with a 1st TNF-alpha inhibitor, treatment with a second NICE TA 187 approved TNF-alpha inhibitor may be tried. i.e. infliximab or adalimumab

3rd line Treatment Options

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

Continuation of Biologic Treatment

Treat for 12 months or until treatment failure (including the need for surgery), which ever 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.

Use of Biologics Post Surgery

Routine use of biologics as post surgery prophylaxis in CD is not recommended. 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.

A LMMG approved biologic may be considered in these high risk patients upon recurrence, or if thiopurine treatment is not tolerated. **i.e. Red Colour Classification**

Failure of third line treatment constitutes the end of the commissioned biologics pathway

Midlands and Lancashire CSU
Version 1.0

Date Produced: July 2016
For Review: July 2019

Ulcerative Colitis

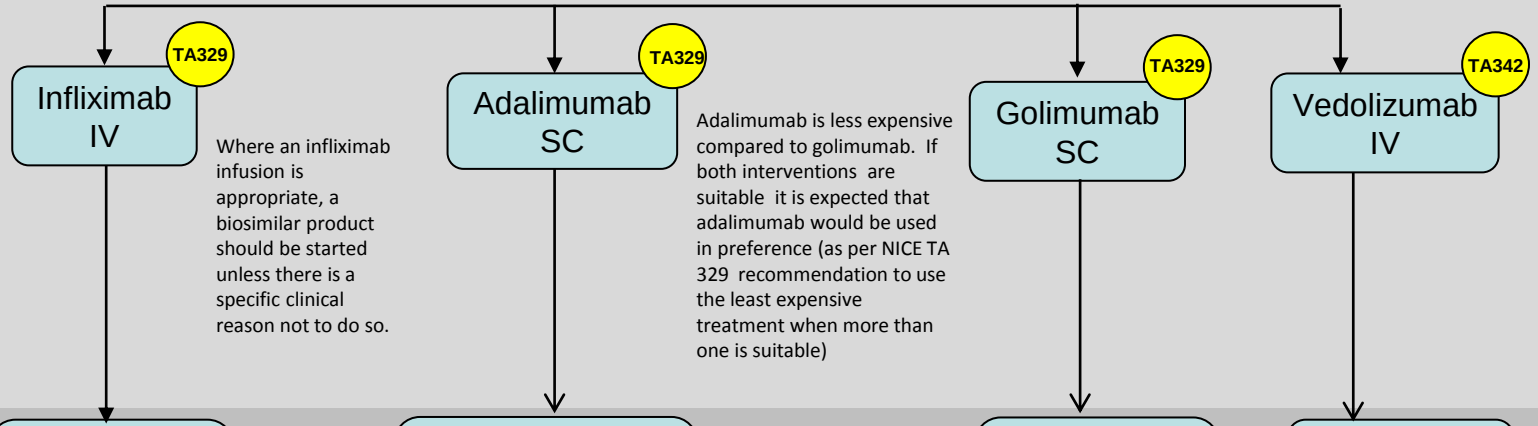
LMMG Recommended Biologic Commissioning Pathway

NICE Criteria to Start Treatment

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

1st line Treatment Options

The choice of treatment should be made on an individual basis after discussion between the clinician and patient about the advantages and disadvantages of the treatments available. This should take into consideration therapeutic need and whether or not the patient is likely to adhere to treatment. **If more than 1 treatment is suitable, the least expensive should be chosen** (taking into account administration costs, dosage & price per dose).



Where an infliximab infusion is appropriate, a biosimilar product should be started unless there is a specific clinical reason not to do so.

Adalimumab is less expensive compared to golimumab. If both interventions are suitable it is expected that adalimumab would be used in preference (as per NICE TA 329 recommendation to use the least expensive treatment when more than one is suitable)

As per NICE TA 342 and the SPC vedolizumab can be used as a 1st line biologic.

In practice it is anticipated that anti-TNFs will be used as 1st and 2nd line biologic treatment options unless otherwise inappropriate as vedolizumab is the only biologic available for 3rd line use.

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.

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

3rd line Treatment Options

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

Continuation of Biologic Treatment

Treat for 12 months or until treatment failure (including the need for surgery), which ever 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 on-going 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.

Nb. Use of a biologics for post surgery prophylaxis in UC is **not recommended**

Failure of third line treatment constitutes the end of the commissioned biologics pathway