East Berkshire Clinical Commissioning Group

Procedure Not Routinely Funded

Thames Valley Priorities Committee Commissioning Policy Statement

Policy No. TVPC93 — **Biologic drugs for the management of Crohn's disease**

Recommendation made by the Priorities Committee: **May 2019**

Date of issue: **October 2019**

Thames Valley Priorities Committee has considered the evidence of clinical and cost effectiveness; NICE Guidance: Crohn's disease: management; and local specialist advice. The Committee supports the use of biologic drugs as per NICE Guidance (NICE NG129)[1] and Technology Appraisal Guidance (TAs) 187[2] 456[3] and 352[4] within the pathway provided in Figure 1.

First line treatment is typically a biosimilar anti-TNF. Vedolizumab or ustekinumab may be more appropriate first line treatments only for patients who have documented relative and absolute contraindications, as per pathway, to anti-TNFs and /or ustekinumab, or for patients for whom the clinician considers will not respond or may lose response quickly to anti-TNFs. Documented factors include: obesity; smokers; patients unable to take an immunomodulator and patients carrying a specific gene which indicates that they are unlikely to respond to an anti-TNF drug.

In line with NICE guidance, if more than one agent is suitable at particular points in the treatment algorithm, the drug with the lowest acquisition cost is recommended. Where appropriate, a biosimilar product should be used in preference to the originator brand.

Thames Valley Priorities Committee supports the sequential use of up to three biologics. If a patient is required to switch from a biosimilar to an originator drug due to an adverse drug reaction, this will not be classed as a switch to an alternative biologic drug. A fourth biologic will be funded if the only remaining alternative treatment is more costly and invasive, for example surgery and total parenteral nutrition (TPN).

[1] https://www.nice.org.uk/guidance/ng129
[2] https://www.nice.org.uk/guidance/ta187
[3] https://www.nice.org.uk/guidance/ta456
[4] https://www.nice.org.uk/guidance/ta352

Additional exceptions to this will be either the switching of a biologic where there is a documented adverse reaction that necessitates discontinuation and where the patient has shown response to this drug, or switching to a biologic with a mode of action that has not been previously tried. In these cases only, the maximum number of sequential biologic treatments funded will be four.

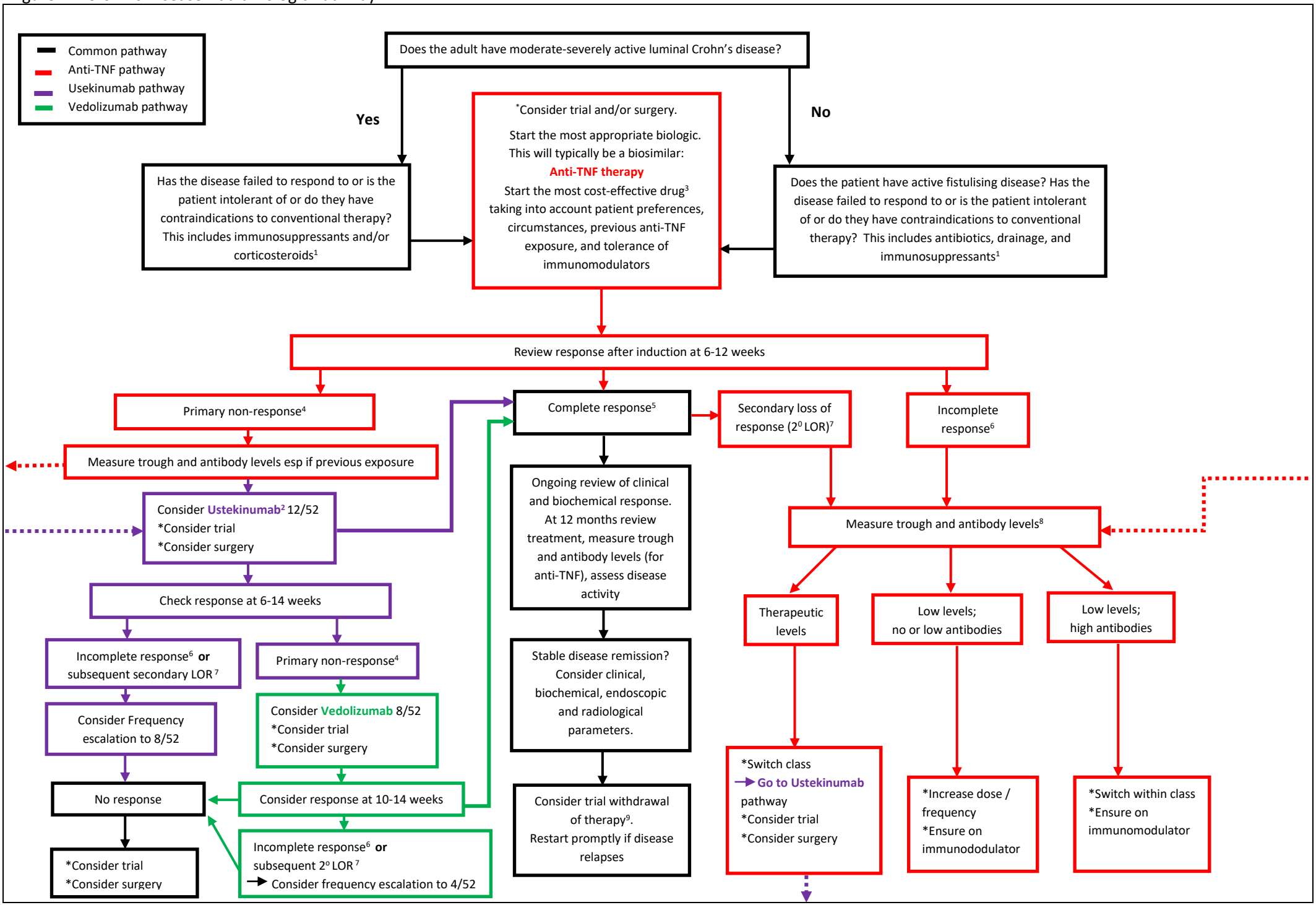
The evidence of clinical and cost-effectiveness is insufficient to support any further switching between these drugs and is therefore **not normally funded.**

This policy will be reviewed for update in light of new evidence, national guidance or local specialist advice. Note that this policy will also apply to all biologic therapies recommended by NICE TAGs for Crohn's disease that are published post May 2019.

NOTES:

- Potentially exceptional circumstances may be considered by a patient's CCG where there is evidence of significant health status impairment (e.g. inability to perform activities of daily living) and there is evidence that the intervention sought would improve the individual's health status.
- This policy will be reviewed in the light of new evidence or new national guidance, e.g., from NICE.
- Thames Valley clinical policies can be viewed at http://www.fundingrequests.cscsu.nhs.uk/

Figure 1: Crohn's Disease Adult Biologic Pathway



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1. Severe disease may require primary biologic therapy / top-down therapy. Indicators include: Upper GI disease, multifocal or extensive disease, severe perianal disease, profound weight loss.
2. Consider relative/absolute contraindication to anti-TNF and / or ustekinumab:
    a. Anti-TNF: TB, active infection, malignancy, heart failure, demyelination, elderly patient
    b. Ustekinumab: TB, active infection, malignancy, elderly patient
3. Use the most cost-effective biologic drug where clinically appropriate. An assessment of the cost-effectiveness of the drug should take into account drug administration & tariff cost, required dose, and patient acceptability.

Assessment of primary response between 6 weeks and 14 weeks post induction, depending on the drug used:

4. Primary non-response**:** No improvement in Harvey-Bradshaw (HB) score and no improvement in inflammatory markers
5. Complete response**:** Normalisation of HB score and inflammatory markers
6. Incomplete response**:** Partial improvement in HB score and / or partial improvement in inflammatory markers
7. Secondary loss of response is defined as situations where patients achieve remission after induction or maintenance therapy, but then have a rise in HB score of >3 points compared to their best previous score, or an HB score >8 on two consecutive assessments prior to drug administration. Objective evidence of active disease as a cause of apparent deterioration should be confirmed by investigation.
8. Stopping treatment**:** Disease activity should be fully assessed and an informed discussion had with the patient before stopping or withdrawing treatment. If the patient has continued response to treatment but has evidence of ongoing active disease, as determined by biological markers (CRP>5, faecal calprotectin>100) and / or evidence of endoscopic and histological disease activity, then treatment may be continued.
   In the event of a relapse following treatment withdrawal in a patient in remission, biologic therapy should be restarted within 4 weeks. Even if the patient achieves mucosal remission, stopping biologic therapy may not always be appropriate, for example in cases where there is a critical risk to small bowel length (i.e. at risk of short bowel syndrome), or in cases where cessation of treatment has already been shown to lead to relapse.