Oxfordshire Clinical Commissioning Group

Thames Valley Priorities Committee Commissioning Policy Statement

Policy No. 263a (TVPC 43) Use of biologic therapies and Janus-associated tyrosine kinases (JAK) inhibitors for ulcerative colitis in adults (18 years and over) – Interim statement

Recommendation made by the Priorities Committee: May 2016/ Updated March 2021[1]

Date of issue: **July2021**

Thames Valley Priorities Committee has considered the evidence of clinical and cost effectiveness and NICE technology appraisal (TA) guidance for the sequential use of biologic therapies and JAK inhibitors for ulcerative colitis. The Committee supports the use of biologics and JAK inhibitors as per NICE TAGs[2345] and attached algorithm.

First line treatment should be the most cost-effective drug taking account of clinical appropriateness. This is likely to be a tumour necrosis factor-alpha antagonist (anti-TNF) biosimilar.

As per NICE guidance, if more than one anti-TNF treatment is suitable, the least expensive should be chosen (taking into account tariff and price per dose). The choice of drug should be limited to the most cost effective within the options at any step of the pathway where appropriate.

Switching to another anti-TNF is a treatment option, if clinically appropriate, following a documented adverse drug reaction or after secondary failure of anti-TNF treatment.

Dose escalation is supported within the marketing authorisation when considered clinically appropriate for secondary loss of response.

Ustekinumab should be used in line with NICE guidance and is recommended as an option for treating moderately to severely active ulcerative colitis in adults when conventional therapy or a biological agent cannot be tolerated, or the disease has responded inadequately or lost response to treatment, only if:

- a tumour necrosis factor-alpha inhibitor has failed (that is the disease has responded inadequately or has lost response to treatment) or
- a tumour necrosis factor-alpha inhibitor cannot be tolerated or is not suitable

[1]
[2]
[3] https://www.nice.org.uk/guidance/ta342
[4] https://www.nice.org.uk/guidance/ta547
[5] https://www.nice.org.uk/guidance/ta633

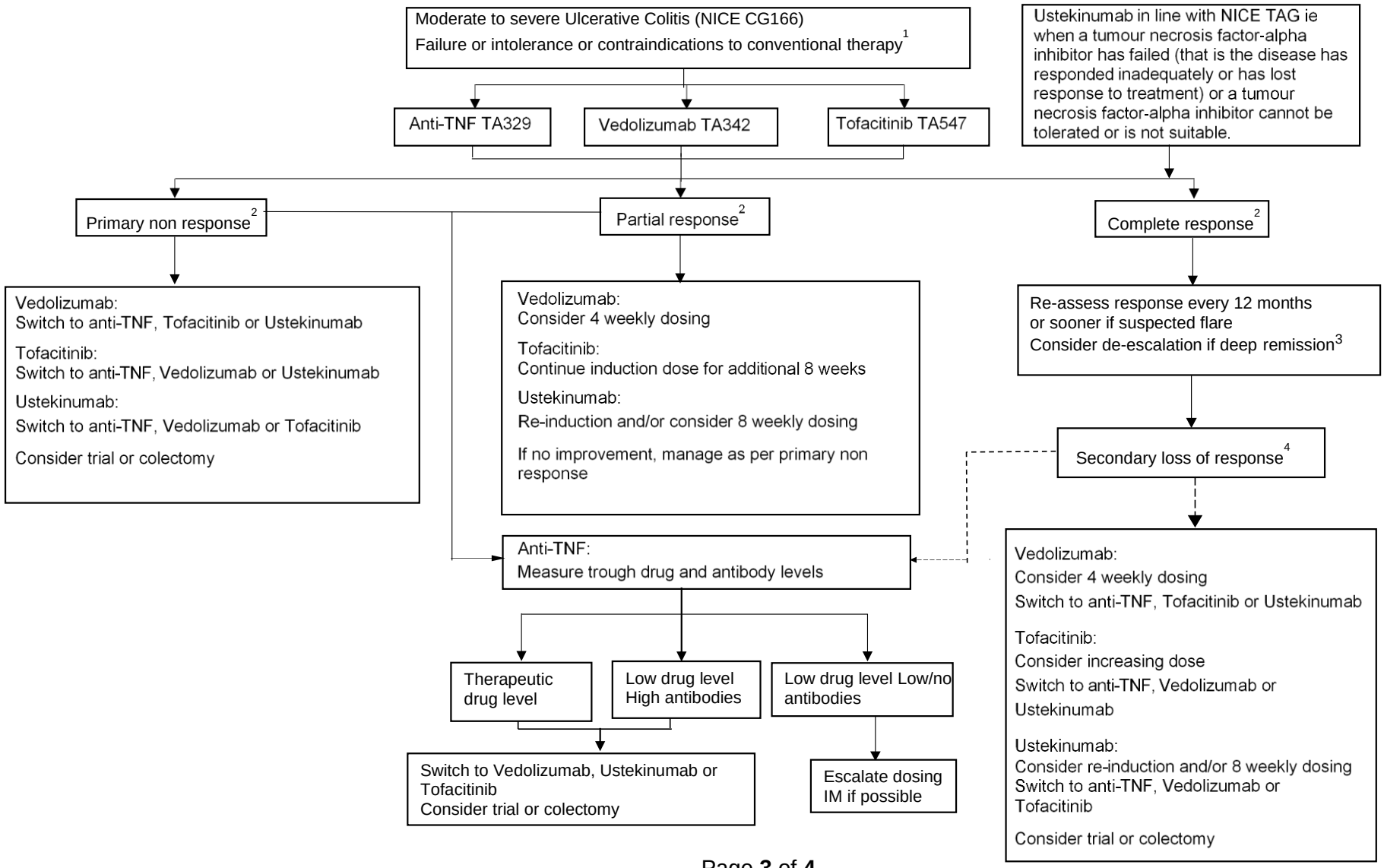
Treatment with any biologic drug or JAK inhibitor should only continue if there is clear evidence of ongoing clinical benefit.

Note that this policy will also apply to all biologic therapies and JAK inhibitors recommended by NICE TAGs for ulcerative colitis that are published post March 2021.

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/
- Oxfordshire CCG clinical polices can be viewed at http://www.oxfordshireccg.nhs.uk/professional-resources/policies.htm

Ulcerative Colitis Adult Advanced Therapy Pathway



Additional notes:

1. Start with the most cost effective drug taking into account patient preference and clinical context. Consider age, comorbidities, speed of onset, mode of delivery, extra-intestinal manifestations, tolerance of immunomodulator, obesity, smoking history and HLA status
   Contraindications to anti-TNF: tuberculosis, active infection, heart failure, malignancy, demyelinating disease, elderly. Contraindications to Vedolizumab: consider speed of onset and steroid responsiveness/tolerance
   Contraindications to Tofacitinib: tuberculosis, active infection, severe hepatic impairment, malignancy, significant anaemia, pregnancy and lactation, elderly. High dose contraindicated unless no alternative treatments if high risk of venous thromboembolism (VTE) including history of unprovoked VTE, use of combined oral contraceptive or age >65 years. Take into account current anticoagulation which may mitigate VTE risk.
   Contraindications to Ustekinumab: tuberculosis, active infection, malignancy, elderly
   If latent TB (LTBI) detected on screening, LTBI treatment should be initiated before starting advanced therapy

2. Assessment of primary response at 6-14 weeks, depending on the drug used.
   Primary non response defined as no improvement of Simple Clinical Colitis Activity Index (SCCAI) and/or inflammatory markers.
   Partial response defined as improvement but not normalisation of SCCAI and/or inflammatory markers.
   Complete response defined as normalisation of SCCAI and inflammatory markers.

3. De-escalation of treatment should be considered on a case by case basis, taking into account patient preference. Disease activity should be fully assessed prior to consideration. If the patient has continued response to treatment but 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. Even if a patient achieves mucosal remission, continuation of treatment may still be appropriate, for example in cases where previous de-escalation has inevitably led to relapse.

4. Secondary loss of response is defined as a clinical scenario where patients have achieved remission after induction or maintenance therapy but then develop a rise in their SCCAI and/or inflammatory markers with objective evidence of disease recurrence.