Oxfordshire Clinical Commissioning Group

Thames Valley Priorities Committee Commissioning Policy Statement

Policy No. 201e (TVPC51) Use of biological and immunomodulatory therapies in Rheumatoid Arthritis – INTERIM POLICY

Recommendation made by the Priorities Committee: **July 2018, updated March 2021**

Date of issue: **July 2021**

Thames Valley Priorities Committee has considered the evidence of clinical and cost effectiveness and NICE Guidance for the use of biological and immunomodulatory therapies in Rheumatoid Arthritis. The Committee supports these treatments as per NICE Guidance (NICE NG100[1] and Technology Appraisal Guidance (TAs) 195[2],225[3],247[4],375[5],415[6],466[7], 480[8],485[9], 665[10] and 676[11]) within the pathway provided in Figure 1.

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.

Dose escalation is supported within the marketing authorisation when considered clinically appropriate for secondary loss of response. Escalation of dose of biological or immunomodulatory therapies above their licensed starting dose is not normally funded.

---

[1] https://www.nice.org.uk/guidance/ng100
[2] https://www.nice.org.uk/guidance/ta195
[3] https://www.nice.org.uk/guidance/ta225
[4] https://www.nice.org.uk/guidance/ta247
[5] https://www.nice.org.uk/guidance/ta375
[6] https://www.nice.org.uk/guidance/ta415
[7] https://www.nice.org.uk/guidance/ta466
[8] https://www.nice.org.uk/guidance/ta480
[9] https://www.nice.org.uk/guidance/ta485
[10] https://www.nice.org.uk/guidance/ta665
[11] https://www.nice.org.uk/guidance/ta676

Thames Valley Priorities Committee supports the sequential use of up to four biologic drugs or JAK inhibitors as shown in figure 1. Due to the lack of national guidance and good quality evidence of clinical effectiveness of sequential use, the use of a 5th biologic or immunomodulatory drug is not normally funded.

When a change from drug is required only due to a documented local injection site reaction or infusion reaction, this will not be considered to be a switch to a subsequent biologic drug or JAK inhibitor.

If a patient is required to switch from a biosimilar to an originator drug or vice versa this will not be classed as a switch to an alternative biologic drug.

The evidence of clinical and cost-effectiveness is insufficient to support any further switching between these drugs, including additional switching between anti-TNFs and/or other biological or immunomodulatory agents, beyond that recommended by current NICE guidance and is therefore **not normally funded.**

Thames Valley Priorities Committee considered the evidence of clinical and cost effectiveness for the use of **rituximab in seronegative patients**. There is insufficient evidence to support the development of a separate treatment pathway for seronegative patients and it is recommended that seronegative patients are treated in line with NICE guidance as shown in Figure 1.

Thames Valley Priorities Committee supports the use of rituximab monotherapy as a first line biological option for patients in whom other therapies are contra-indicated or who have other co-morbidities (such as interstitial lung disease) as shown in Figure 1.

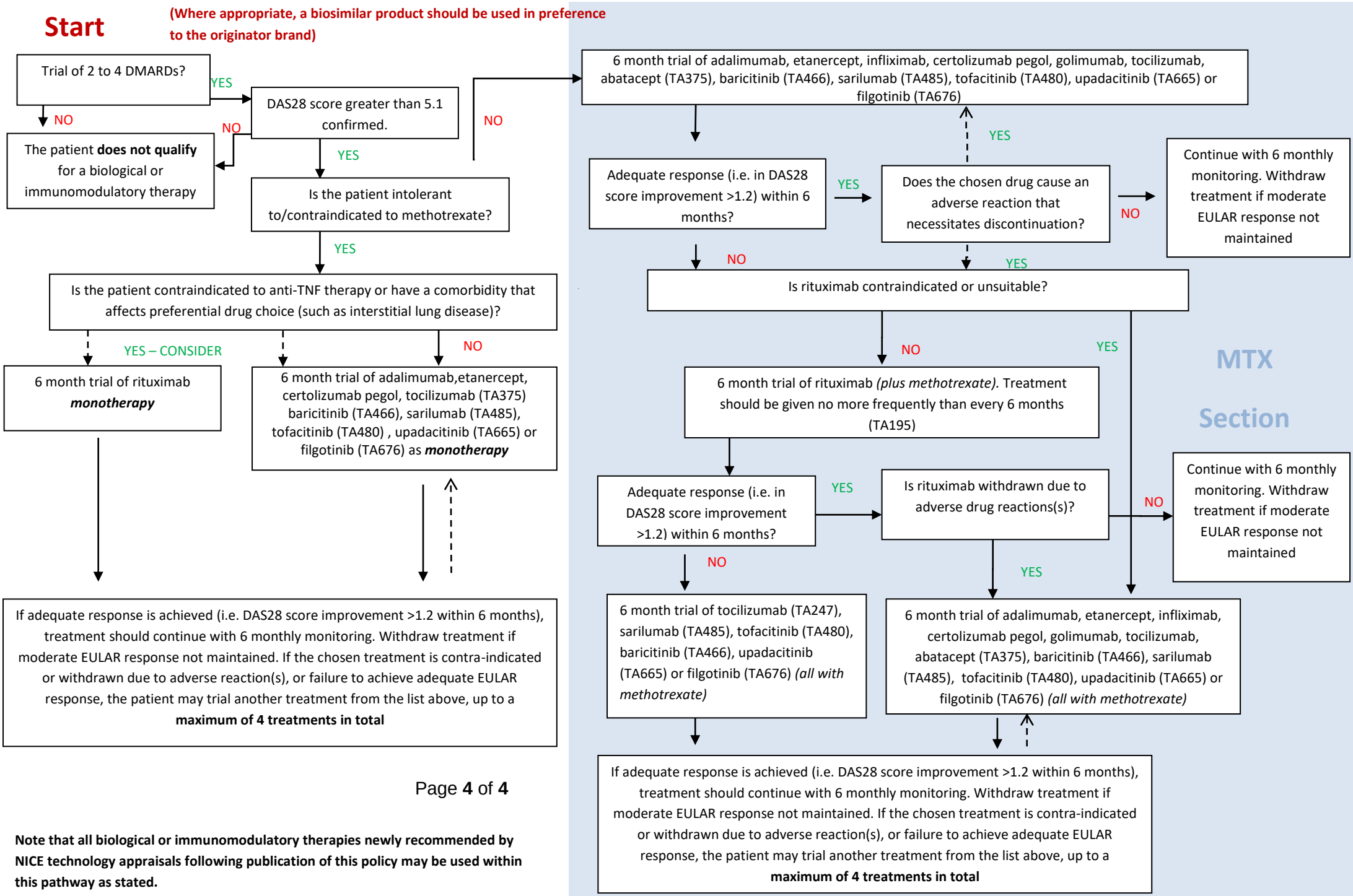
Monitoring: All patients receiving biological or immunomodulatory therapy should be monitored at six monthly intervals throughout treatment. Assessment at each six monthly review should include measurement of the DAS28 score. Treatment should only continue whilst an adequate response is maintained. This is defined as a DAS28 score which remains at least 1.2 points better than baseline (ie, the DAS28 score used to confirm eligibility for treatment) or a moderate response measured using European League Against Rheumatism (EULAR) criteria, Patients should be made aware of this exit criterion before they commence treatment and, as part of their consent to treatment, should agree to withdrawal of therapy if the threshold for an adequate response is not met. The only exception to continuation of treatment for an inadequate response would be if there is a clear reason for the decline in response (for example, a recent infection or surgery) and where the patient is expected to continue to respond as previously.

In line with NICE Clinical Guideline NG79, anakinra in the treatment of rheumatoid arthritis (at any point in the treatment pathway) is **not normally funded.**

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

Figure 1: Biological and immunomodulatory therapies for rheumatoid arthritis treatment pathway (based on Berkshire West APC policy).



Note that all biological or immunomodulatory therapies newly recommended by NICE technology appraisals following publication of this policy may be used within this pathway as stated.