



Berkshire West Clinical Commissioning Group

Thames Valley Priorities Committee Commissioning Policy Statement

Policy No. TVPC51 Use of biological and immunomodulatory therapies in Rheumatoid Arthritis

Recommendation made by the Priorities Committee: July 2018

Date of issue: November 2018

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 NG100¹ and Technology Appraisal Guidance (TAs) 195², 225³, 247⁴, 375⁵, 415⁶, 466⁷, 480⁸ and 485⁹) 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.

Thames Valley Priorities Committee supports the sequential use of up to three biological or immunomodulatory drugs in rheumatoid arthritis as shown in Figure 1.

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**.

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>

The one exception to this would be the optional switching of a biological or immunomodulatory drug within the same part of the pathway (for patients able to take methotrexate) where there is a documented adverse reaction to the **first drug trialled that necessitates discontinuation and the patient has shown response to this drug**. In this case only, the maximum number of sequential biological or immunomodulatory treatments would be four.

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, (see fig.1, and NICE TA195, TA225, TA247) or a moderate response measured using European League Against Rheumatism (EULAR) criteria, (see NICE TA375, TA415, TA466, TA480, TA485). 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.

Dose escalation: Escalation of dose of biological or immunomodulatory therapies above their licensed starting dose is **not normally funded**.

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.ccsu.nhs.uk/>

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

