Rituximab without methotrexate for rheumatoid arthritis

NHS Devon

Commissioning policy

The commissioning of rituximab without methotrexate is accepted in Devon as a first line biological treatment option for patients who have had an inadequate response to conventional DMARDs, who cannot receive methotrexate, and for whom TNF inhibitors are not clinically appropriate due to comorbidities which give rise to medical concerns.

The decision to offer rituximab is at the discretion of the treating clinician. The patient must be made fully aware of the unlicensed nature of the treatment and the rationale for treatment.

Rationale for the decision

Evidence from a randomised double-blind placebo-controlled trial has shown that significantly more patients receiving rituximab plus placebo achieved an ACR20 response than patients receiving methotrexate plus placebo. More patients receiving rituximab plus placebo achieved an ACR50 response and ACR70 response but the treatment difference was not significant. Data from the British Society of Rheumatology Biologics Register and from case series are also suggestive of clinical benefit for patients receiving rituximab without methotrexate as a first line biological therapy for rheumatoid arthritis.

British Society of Rheumatology guidance recommends that if methotrexate is contra-indicated, rituximab should be used in rheumatoid arthritis either alone, or with leflunomide.

Use of rituximab without methotrexate as a first line biological therapy for patients who have had an inadequate response to conventional DMARDs falls outside the licensed indication for rituximab. In deciding whether to use an unlicensed treatment in preference to a licensed treatment, a clinician needs to consider professional guidance, including guidance from the General Medical Council. The patient must be

made fully aware of the unlicensed nature of the treatment and the rationale for treatment. Each patient should sign an informed consent form.

Guidance notes on exceptionality

Where the circumstances of treatment for an individual patient do not meet the criteria described above exceptional funding can be sought. Individual cases will be reviewed by the appropriate panel of the ICB upon receipt of a completed application from the patient's GP, consultant or clinician. Applications cannot be considered from patients personally.

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