Rituximab in combination with methotrexate for rheumatoid arthritis

NHS Devon

Commissioning policy

The commissioning of rituximab in combination with methotrexate is accepted in Devon as a first line biological treatment option for patients with rheumatoid arthritis who have had an inadequate response to conventional DMARDs, including methotrexate, and for whom TNF inhibitors are not clinically appropriate due to co-morbidities 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

The efficacy of rituximab in combination with methotrexate as a first line biological therapy has been demonstrated in randomised double-blind placebo-controlled trials conducted in patients with an inadequate response to methotrexate. In the largest trial, significantly more patients receiving rituximab plus methotrexate achieved an ACR20 and ACR50 response than patients receiving methotrexate plus placebo. Similar outcomes were reported in favour of rituximab plus methotrexate for moderate or good EULAR responses, low disease activity and disease remission.

The total cost of treatment with rituximab in combination with methotrexate is anticipated to be comparable or less expensive than the total treatment costs for alternative treatment options for these patients. These costs take into account drug cost and administration cost.

British Society of Rheumatology guidance recommends rituximab could be given in rheumatoid arthritis before treatment with TNF inhibitor, particularly in patients who have an absolute or relative contra-indication to treatment with TNF-inhibitor.

Use of rituximab in combination with 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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