NHS

North East Treatment Advisory Group

Treatment Appraisal: Decision Summary

Date	11th October 2011
Appraisal	Rituximab (MabThera®) in rheumatoid arthritis: non-NICE approved indications
Details	The North East Treatment Advisory Group was requested to conduct an appraisal of the use of rituximab in rheumatoid arthritis in situations which have not been appraised by NICE. Specifically, use of rituximab as monotherapy, in combination with DMARDs other than methotrexate, and in combination with methotrexate prior to use of a tumour necrosis factor inhibitor. This appraisal was first considered in July 2011 and an appeal of part of the group's recommendation was heard in October 2011
Recommendation	The NHS North East Treatment Advisory Group has updated its recommendation on the use of rituximab in non-NICE indications for severe active rheumatoid arthritis following an appeal. **The group recommends rituximab in combination with methotrexate as first-line biological therapy in cases where there is an absolute contra-indication to tumour necrosis factor inhibitors.** **The group recommends rituximab monotherapy or rituximab in combination with other (non-methotrexate) disease-modifying anti-rheumatic drugs in cases in which conventional treatment with tumour necrosis factor inhibitors or methotrexate is deemed unsafe.** For example in cases of interstitial lung disease, neutropenia or where there is a history of malignancy. Rituximab in RA is only licensed for use in combination with methotrexate.
Clinical evidence summary	The group was satisfied that evidence for use of rituximab in severe rheumatoid arthritis was sufficient to support its use either in combination with methotrexate as a first-line biological therapy where TNF-inhibitors are specifically contra-indicated, or in combination with a DMARD other than methotrexate (particularly leflunomide) or as monotherapy in patients for whom TNF-inhibitors or methotrexate is considered to be clinically unsafe. The latter group has been prospectively identified as patients with interstitial lung disease, neutropenia, or where there is a relevant history of malignancy. The group acknowledged that evidence in these scenarios is of poorer quality than that for which rituximab is currently recommended for RA by NICE.
Cost analysis summary	Rituximab is one of the least costly biological drugs for severe RA and in practice costs may be even less than estimated as treatment intervals are usually extended beyond the minimum recommended.
Financial impact PbR: Excluded	At maximum dose frequency and minimum dose interval rituximab is estimated to cost £8,400 per patient per annum. This does not include provider admission costs. It was not possible to estimate an expected patient population. However, the patient population for which treatment is recommended by the group is expected to be of low volume with a consequent low financial impact.
Further research or information	The group request that all NHS North East treatment centres utilise a recognised method and criteria to diagnose interstitial lung disease.