NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

RPP decision paper

Review of TA308; Vasculitis (anti-neutrophil cytoplasmic antibody-associated) – rituximab (with glucocorticoids)

Final recommendation post consultation
The guidance should be transferred to the “static guidance list”.

1. Background

This guidance was issued in March 2014.

At the GE meeting of 21 March 2017 it was agreed that we would consult on the recommendations made in the GE proposal paper. A four week consultation has been conducted with consultees and commentators and the responses are presented below.

2. Proposal put to consultees and commentators

The guidance should be transferred to the “static guidance list”.

3. Rationale for selecting this proposal

There are no new data to suggest that a re-appraisal of rituximab compared with cyclophosphamide for induction of remission would result in a different incremental cost effectiveness ratio or recommendation.

The marketing authorisation for rituximab in combination with glucocorticoids is for the induction of remission in adult patients with severely active granulomatosis with polyangiitis (Wegener’s) (GPA) and microscopic polyangiitis (MPA). The summary of product

characteristics states that there were insufficient data available for rituximab maintenance therapy at the time the marketing authorisation was granted.

There are currently ongoing clinical trials of rituximab maintenance (after induction of remission) and of rituximab in a population with eosinophilic granulomatosis. NICE can only appraise technologies within their marketing authorisation and would only be able to appraise rituximab for maintenance therapy or for eosinophilic granulomatosis if the company decided to apply for a marketing authorisation to cover these indications. Technology appraisals on the "static guidance list" are reviewed every 5 years, and this time frame will allow a review proposal to be made once the outcome of these trials and the company's intentions regarding applying for an extension to the marketing authorisation are known. Should a marketing authorisation extension be sought sooner than 5 years, it is anticipated that this would be identified and considered through the NICE topic selection process.

4. Summary of consultee and commentator responses

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

Respondent: Roche Products Limited **Response to proposal:** Agree As noted in Appendix B – Proposal Paper there are a number of registered clinical trials that are relevant to this guidance which are ongoing, and we will continue to coordinate and update NICE with regards to how these will contribute evidence to future reviews of appraisal TA308.	**Comment from Technology Appraisals** Thank you for your comment and continued coordination with NICE.

Respondent: British Society of Rheumatology **Response to proposal:** Disagree The proposal to move the existing guidance to the static list, as a result from the review, should be reconsidered. The NICE website decides if technology appraisal guidance is static if a "previous full review which yielded a 'no update' decision and at that time no major ongoing studies/research was identified as due to be published in the near future (that is within the next 3-5 years)". Yet both the Rituximab Vasculitis Maintenance Study (RITAZAREM) and Rituximab Versus Azathioprine to Maintain Remission of ANCA-Associated Vasculitides (MAINRITSAN) trials are to be published in the next couple of years. In light of this we hope the proposal to move the guidance to the static list is reviewed.	**Comment from Technology Appraisals** Thank you for your comment. No new studies were found assessing the clinical effectiveness of rituximab for the induction of remission in adult patients with severely active granulomatosis with polyangiitis (Wegener's) (GPA) and microscopic polyangiitis (MPA). The use of rituximab as a maintainance treatment is not currently covered by its marketing authorisation. The maintenance trials are noted, and should these trials result in an extension to the marketing authorisation for rituximab, NICE would consider whether a technology appraisal of this extended use of rituximab is appropriate.

Paper signed off by: Linda Landells, 12 May 2017

Contributors to this paper:

Technical Lead: Mary Hughes

Project Manager: Samantha Shannon