Royal College of Nursing

Introduction

The Royal College of Nursing (RCN) was invited to review the Appraisal Consultation Document (ACD) for Belimumab for the treatment of active autoantibody-positive systemic lupus erythematosus.

Nurses caring for people with lupus were invited to review the consultation document on behalf of the RCN.

Appraisal Consultation Document – RCN Response

The Royal College of Nursing welcomes the opportunity to review the Appraisal Consultation Document (ACD) of the technology appraisal of Belimumab for the treatment of active autoantibody-positive systemic lupus erythematosus. We note that the Appraisal Consultation Document has not recommended this treatment as add-on therapy.

The RCN’s response to the four questions on which comments were requested is set out below:

i) **Has the relevant evidence been taken into account?**

   No comments to add at this stage.

ii) **Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence, and are the preliminary views on the resource impact and implications for the NHS appropriate?**
There is no doubt that the cost of Belimumab cannot be compared with that of conventional therapy and will of course, be at added cost to the NHS. An important issue is that the trial data reports that Belimumab helps to reduce steroid dosage and length of treatment with steroids. The use of long term steroids carry many potential side effects which can impact on quality of life and lead to numerous co-morbidities many of which will have cost and health implications for many years. Whilst Belimumab is not free of side effects, its comparators are greater and significantly impact on individuals’ quality of life, capacity to work, mental health status, personal relationships and life aspirations.

Clinically, there is a concern about the choices of medication available to lupus teams in the group of patients who are steroid dependent and not responding to conventional therapies, including immunosuppression. Belimumab has met the primary endpoint in both of its pivotal Phase 3 trials, it is FDA approved and approved by European commissioners. This then is a very sensible option for treatment in a group not responding to conventional therapy.

Rituximab did not meet its endpoint and therefore did not receive either a licence in lupus or NICE approval. Yet this document directly recommends a head to head trial between Belimumab which has met its primary endpoint and Rituximab which did not meet its endpoint. This will not realistically happen as drug companies would not consider it to be cost effective or in their best interests.

The only drugs currently holding a licence for lupus are steroids, Hydroxychloroquine and Belimumab. All other drugs used are off licence and therefore without NICE approval, this will result in clinicians having to apply with IFRs which may be rejected, resulting in loss of clinical time to the NHS and patient care.

Rituximab is widely used to treat lupus and every time this is planned, an IFR has to be completed. Patients understand that these drugs are off licence which does not provide them with any significant confidence in its effectiveness.
It is anticipated that following response to treatment with Belimumab that infusions can be reduced in frequency and even stopped when in remission. Costings should reflect this in the appraisal document and it is not clear that this has been considered in sufficient detail.

iii) Are the provisional recommendations of the Appraisal Committee sound and do they constitute a suitable basis for the preparation of guidance to the NHS?

We consider that the NICE appraisal committee should review its decision regarding Belimumab. The opportunity to provide this as a reasonable treatment option for those with active auto-antibody positive muco-cutaneous and musculoskeletal complications of lupus has to be re-considered in the light that these patients are currently on long term steroids and immunosuppression with little potential for stopping these drugs over time. These cause a significant number of side effects, which cannot always be prevented and then impact on quality of life when co-morbidities develop.

iv) Are there any equality related issues that need special consideration that are not covered in the ACD?

None that we are aware of at this stage. We would however, ask that any guidance issued should show that equality issues have been considered and that the guidance demonstrates an understanding of issues concerning patients’ age, faith, race, gender, disability, cultural and sexuality where appropriate.