Name | xxxxxxxxxxxxxxxxxxxxxx
---|---
Role | NHS Professional
Other role | 
Location | England
Conflict | no
Notes | NHS Bolton are one of the official consultees for this technology appraisal. Responses are representative of the organisation not from myself as an individual.

Comments on individual sections of the ACD:

**Section 1**
(Appraisal Committee's preliminary recommendations)

NHS Bolton would agree with the proposed recommendation based on the presented clinical and cost-effectiveness data. The ICER for the drug without a patient access scheme in place is not a cost-effective use of resources compared to standard care (ICER of £64,410 - £71,000 per QALY gained).

Although a patient access scheme has been submitted, the ICER still continues to be higher than that usually considered by NICE to be cost-effective use of NHS resources. The data presented did not provide a case for comparing belimumab against rituximab (current standard practice although unlicensed) in terms of cost-effectiveness again supporting the case that this is not a cost-effective use of NHS resources or affordable.

**Section 2**
(The technology)

NHS Bolton agrees that the use of this drug should be in patients who have a high-degree of disease activity only (despite the wider marketing authorisation).

With regard to dosing, more frequent doses are required for belimumab compared to rituximab which will lead to additional patient hospital attendances and hence cost. During the first 6 months of treatment (suggested review period) the patient will need to attend hospital on 7 occasions (more if additional monitoring is required), compared to current practice with rituximab this is a greater inconvenience for the patient. There is also the opportunity with rituximab to utilise homecare services, however NHS Bolton is not sure whether this option would be available to patients for belimumab infusions.

NHS Bolton would support the manufacturers proposed PAS (a discount on the list price) being offered, as this ensures minimal administrative burden for provider, commissioner and manufacturer. The current level of discount in the PAS however would seem insufficient to meet the required levels of cost effectiveness required.

**Section 3**
(The manufacturer's submission)

There was no direct comparison of efficacy made between belimumab and rituximab (current, standard care for this group of patients a relevant comparator).

No information in the trial data, identified if patients had received previous treatment with rituximab. In practice, patients who would fit the clinical criteria for belimumab may have previously received rituximab it is unknown whether safety or efficacy data is available to support any sequential use.

Belimumab did not demonstrate improved health-related quality of life benefits compared to standard care (when considering
functional assessment at week 52 comparing standard care and belimumab therapy).

The costs presented in the model for administration costs of belimumab are felt to be underestimated in relation to practice. It is more likely that the tariff of day case admission will be used, which will increase the costs. Additional costs of making up the infusion per individual patient (as based on weight) in a pharmacy aseptic unit would also need to be considered.

### Section 4
(Consideration of the evidence)

Patient populations in the BLISS studies did not include patient participants from the UK hence it is difficult to determine if the patients in the trial are representative of patients with SLE and high-disease activity in the UK. This would include age, sex, gender, medicines management, criteria for diagnosis etc.

The review time for belimumab in the model was at 24 weeks, based on an assessment of the SELENA-SELEDAI score. Experts suggested that if the score was shown to be less than 4 points (i.e. some benefit of treatment) they may still continue with belimumab? this would affect the % of patients stopping in practice when compared to the trial and costs would be higher than predicted, which could be an unexpected cost pressure to the payer.

NHS Bolton supports the development of new, novel agents however they must be cost-effective and affordable to the NHS. Budgets are no longer increasing. To fund drugs that are less cost-effective (e.g. by analysis of ICERs/ QALYs) than NICE deems cost-effective would be very difficult to justify, when decisions are being made to refuse treatments which have greater clinical evidence in some cases. To fund this drug, other services may need to be decommissioned and taking into account the cost-differential of rituximab, the currently used standard of care, Â the difference in affordability is likely to be still too great to justify use.

### Section 5
(Implementation)

These tools are useful when a technology is recommended for use.

### Section 6
(Proposed recommendations for further research)

No comments

### Section 7
(Related NICE guidance)

No comments

### Section 8
(Proposed date of review of guidance)

No comments

Date 10/21/2011 9:57:00 AM