Single technology appraisal: Belimumab for the treatment of active auto-antibody positive systemic lupus erythematosus

The Primary Care Rheumatology Society, representing the views of GPs advocating access to best possible care for patients who have SLE, wishes to appeal to the Committee’s final decision on Ground 2.

**Ground two: The Institute has formulated guidance which cannot reasonably be justified in the light of evidence submitted**

The Primary Care Rheumatology Society considers that the Institute has formulated guidance on Belimumab (BMB), which cannot reasonably be justified in the light of evidence submitted.

2.1. We consider that one of the main flaws to the guidance is the prominence given in the decision making process, to a comparison of Rituximab with Belimumab. This is highlighted in the statement from the Chief Executive (NICE website accessed May 9th 2012).

**Sir Andrew Dillon, NICE Chief Executive said:** "NICE's independent appraisal committee has looked very carefully at the evidence provided on the use of belimumab for treating systemic lupus erythematosus (SLE), including the views of people with the condition, those who represent them, and clinical specialists. The Committee concluded that compared with standard care, there was some evidence of the clinical effectiveness of belimumab. However, the evidence considered did not persuade the Committee that belimumab provided enough health benefit for patients in view of how much the NHS would need to pay for it compared to standard care, as the cost of the drug in relation to how well it works is very high. As some people with severe disease currently receive rituximab, it was also considered relevant to compare belimumab with rituximab although it isn't licensed for this use. However, there were no reliable data to show the relative efficacy of belimumab compared with rituximab, and no sound case presented to the Committee on the cost effectiveness of belimumab compared with rituximab. "Whilst recognising the severity of the disease, the Committee concluded that based on this evidence, belimumab could not be considered a good use of NHS resources compared with current clinical practice."

The formulation of the NICE guidance therefore relies heavily on there being

a) No reliable data to show the relative efficacy of Belimumab compared to Rituximab

b) No sound case on the cost effectiveness of Belimumab compared to Rituximab

The implication is that the Committee has made a judgement based on an assumption that current clinical practice across the whole NHS would include the use of Rituximab as part of current clinical practice. This is not currently the case; particularly as Rituximab is neither licensed nor in clinical trials proven to be effective, but is instead used for a small number of patients with severe disease in specialist units. We appeal
on the basis that making a decision to reject Belimumab because it offers no advantage over an unlicensed drug cannot be justified.

2.2. The NICE guidance, which indicates that there is no advantage of “licensed” Belimumab compared to “unlicensed” Rituxumab, will potentially lead doctors into a situation which conflicts with advice issued by the General Medical Council (2008) and the MHRA (2009), and therefore on this basis the NICE guidance cannot be justified. This prescribing advice states that

“Wherever possible, doctors should try to prescribe a licensed medicine for your condition. Before prescribing an unlicensed medicine, be satisfied that an alternative, licensed medicine would not meet the patient’s needs. Before prescribing a medicine off-label, be satisfied that such use would better serve the patient’s needs than an appropriately licensed alternative”.

By appearing to advocate the use of an unlicensed drug compared to a licensed drug, NICE is also potentially exceeding its powers.

2.3. The NICE guidance, which indicates that there is no advantage of “licensed” Belimumab compared to “unlicensed” Rituximab, will potentially lead to severe adverse unintended consequences for lupus patients who suffer from the most severe life and organ threatening manifestations of their disease. Not only will they not be able to access treatment with Belimumab, but it is likely that they will now find it much more difficult to access the comparator drug Rituximab. Access to this medication is usually at either PCT or IFR panel discretion, and a rejection of a licensed drug which has met trial endpoints is likely to make it much harder to obtain access to an unlicensed drug which has not met it’s trial endpoints. The guidance will therefore potentially lead to reduced patient access to Rituximab. This cannot be justified (as the NICE guidance remit is to only consider Belimumab) and in doing so we also consider that NICE has exceeded its powers.

The Primary Care Rheumatology Society also wishes to appeal to the Committee’s final decision on Ground 3.

**Ground three: NICE has exceed its powers.**

The Primary Care Rheumatology Society argues that the points set out in 2.2 and 2.3 above also demonstrate that NICE has exceeded its powers.

The Primary Care Rheumatology Society would like its submission to be considered at either a written or an oral hearing.