From:
Sent: 11 September 2008 08:43
To:
Cc:
Subject: Re: Appeal on Final Appraisal Determination – Adalimumab, etanercept and infliximab for the treatment of rheumatoid arthritis after failure of a previous TNF-a inhibitor
Importance: High

NHS
National Institute for Health and Clinical Excellence

Midcity Place
71 High Holborn
London
WC1V 6NA

Tel: 0845 003 7780
Fax: 0845 003 7784

Sent via email

www.nice.org.uk

Dear

Re: Appeal on Final Appraisal Determination – Adalimumab, etanercept and infliximab for the treatment of rheumatoid arthritis after failure of a previous TNF-α inhibitor

Thank you for your letter of 4 September and for reworking your appeal points. This letter represents my final assessment of their validity. I will adopt the new numbering contained in your letter of 4 September, and will not comment on points already accepted as valid.

Ground 1.2

I note the previous involvement of an appeal panel on this point and therefore agree it would be appropriate for this point to go forward.

Ground 1.3

I am afraid this still seems to me to be a perversity rather than a process issue, and as it will be considered under ground 2, I do not agree it is a valid ground 1 appeal point.

Ground 1.4

This is a valid ground 1 appeal point.

Ground 1.6

I am not persuaded this is a valid appeal point. It does not seem to me that the appraisal committee used rituximab as a primary comparator as such, rather, they appear to have considered treatment with rituximab as that had already been recommended for these patients by NICE. I assume they were concerned to see whether this appraisal was broadly consistent with the work carried out in the rituximab appraisal. Your point may have been arguable had rituximab been the primary comparator, but that appears to have been treatment with DMARDs. As I understand the FAD the recommendations stand or fall on that comparison, and not the brief comparison with rituximab. Therefore I do not think a close analysis of the treatment of rituximab is valid.

In so far as a really egregious treatment of rituximab might still have been unfair the appeal panel will be able to pick this up under your appeal point 1.7.

Ground 1.8

I am afraid that, as a process point, my view remains that this is not arguably a breach of published procedures.

Ground 2.1

I am confused as to exactly what data is in play here. Your own appeal letter stated that "the data from the BSRBR suitable for inclusion in the BRAM model was published after the further analysis...was performed." You now draw attention to a passage in the FAD referring to some data from the BSRBR, albeit it is not clear if this is the same data. I will allow the point to proceed, but the appeal panel will need clarity as to what data it is being argued was available, and should have been used.

Ground 2.4

I am not willing to accept an unsubstantiated claim of undue weight as an arguable case or perversity and so this point should not proceed.

Ground 2.5

A valid ground 2 appeal ground.

Ground 2.6

A valid ground 2 appeal ground

Ground 2.7

Withdrawn.

Ground 2.8

A valid ground 2 appeal

Ground 2.9

A valid ground 2 appeal

Therefore points 1.1, 1.2, 1.4, 1.5, 1.7, 2.1, 2.2, 2.3, 2.5, 2.6, 2.8 and 2.9 will be considered by the appeal panel.

Yours sincerely

Mark Taylor
Appeals Committee Chair
National Institute for Health and Clinical Excellence