Reviewer's report

Title: Patterns of Use, Dosing, and Economic Impact of Biologic Agent Use in Patients with Rheumatoid Arthritis

Version: 1 Date: 12 July 2004

Reviewer: Paul Emery

Reviewer's report:

This is a retrospective analysis of the direct cost of anti-TNF drugs used in RA undertaken by a particular reimbursement agency in the US. As such, it is a relatively crude analysis of infliximab versus etanercept, knowing that there is a licensed indication to increase dose on infliximab but not to etanercept. Not surprisingly the finding is that the dose of infliximab increases whereas etanercept (with its absence of indication for increased dosing) does not.

Points
• The numbers of patients are significant
• The inclusion criteria included 5 infusions or prescription of the index medication. No indication that the data collected is validated is included in the methodology.
• The authors suggest that they under-estimated the increase in infliximab because it would be impossible to increase the dose from 1.5 vs. to 1.7 vs. with no detectable change in the reimbursement. In fact it is also possible that the reverse is true, that they have over-estimated the change because of a small increase in either weight or dose might require the patient to move from 1.9 vs. to 2.1 vs. The reimbursement cost would appear to be much larger under these circumstances.
• Because of the reimbursement situation arrangement may artificially raise the cost of infliximab. In practice, in large units the vials are shared to minimize this effect.
• The patients are not closely matched for age (for very understandable reasons reimbursement etc.) however this may have a major impact on the likelihood of increasing dose.
• The lack of ability to distinguish switching and labelling patients according to their initial therapy is also a major limitation.

A positive side of this study is that it at least gives some indication of how frequently changes in dosage are occurring and some estimate of the direct cost of the drug.

The limitations of the study however need to be stressed in the abstract.

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Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)

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Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)

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Discretionary Revisions (which the author can choose to ignore)
What next?: Accept after minor essential revisions

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Acceptable

Statistical review: Yes