Comments on the ACD Received from the Public Through the NICE Website

Name	[redacted]
Role	NHS Professional
Other role	Deputy Director Patient Safety
Location	England
Conflict	No
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	
Section 2 (the technology)	The cost of golimumab depends on the dose. Dose escalation is a risk to commissioners. The cost of £9,294.96 per patient per year, which is similar to the annual costs of other TNF-a inhibitors, was modelled by the manufacturer, the recommended starting dose is 50mg given once a month, given subcutaneously. However the drug has marketing authorisation for an increased to 100mg a month in people weighing more than 100kg whose psoriatic arthritis shows inadequate response after three or four doses. People taking the 100mg dose would incur twice the annual cost and it is not clear now many would do so.
Section 3 (manufacturer's submission)	This technology is not a cost effective use of NHS resources. Golimumab is not as effective as the key comparator, etanercept. Indirect comparisons reporting quality of life change in Health Assessment Questionnaire [HAQ] score suggest that health related quality of life improves further with etanercept. The long term adverse effects of golimumab have not been adequately studied. The GO-REVEAL study was not sufficiently powered to detect differences in adverse event outcomes. The manufacturer did not provide any long term safety data for golimumab, though some data is available from trials of the drug for other indications. In addition golimumab is not included in the current British Society of Rheumatology Biologic Registry and so there is no mechanism for monitoring the number of severe adverse events that might occur.
Section 4 (consideration of the evidence)	There were limitations to the quality of the research: A single short term RCT of golimumab against placebo is not a 'sufficient' evidence base to inform this decision.
Section 5 (implementation)	The exact number of people who will be switched to golimumab or start this agent in preference to alternatives is unknown.
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	27/10/2010 15:52

Name	[redacted]
Role	NHS Professional
Other role	
Location	England
Conflict	No
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	We agree with the ACD: golimumab should not be recommended for the treatment of psoriatic arthritis.
Section 2 (the technology)	It is another anti-TNF inhibitor – it has not got a markedly different mechanism of action to the 3 anti-TNFs already licensed and approved by NICE. It has similar contra indications and cautions so would not allow different patient groups to be treated e.g. patients with co-existing moderate to severe heart failure. The recommended dose is 50 mg given once a month. The SPC states that in people who weigh more than 100 kg whose psoriatic arthritis does not show an adequate clinical response after three or four doses, the dose of golimumab may be increased to 100 mg once a month. The manufacturer's submission states that the cost of golimumab is £774.58 for a 50 mg pre-filled injection pen, and estimates an annual cost of £9294.96. People taking the 100mg dose would incur twice the annual cost and it is not clear how many would do so.
Section 3 (manufacturer's submission)	We agree with the ERG concerns about the adverse event data presented for golimumab. No long-term adverse event data had been presented as the GO-REVEAL trial only lasted for 24 weeks. In addition golimumab is not included in the current BSR Biologic Registry and so there is no mechanism for monitoring the number of severe adverse events that might occur. We do not feel that the manufacturer can conclude that golimumab has a safety profile comparable to that of the other TNF inhibitors as they have not presented any long term safety data - there is still uncertainty about the long-term adverse event profile. In the mixed treatment comparison there were differences among the trial populations in disease severity and number of previously tried DMARDs (with many participants having received only one previous DMARD). We agree with the ERG comments that the trial populations were not precisely representative of the population with active and progressive psoriatic arthritis for whom TNF inhibitors are recommended in BSR guidelines and in NICE TA199.
Section 4 (consideration of the evidence)	Golimumab is not a cost effective treatment option: golimumab was 'extendedly dominated' by a combination of etanercept plus palliative care and golimumab was not found to be as effective as the key comparator, etanercept. There were limitations on the quality of the evidence. GO-REVEAL is one placebo controlled trial. There are no head to head trials with other anti-TNFs. It only had a very small number of participants (405) and it only lasted 24 weeks.

Section 5 (implementation)	The exact number of people who will be switched to golimumab or start this agent in preference to alternatives is unknown. It is unlikely that golimumab, even if approved as an alternative, would completely replace the other TNF-a inhibitors as there is more efficacy and long term safety data available for these agents.
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	26/10/2010 16:20