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

NHS Professional England «Disclosure»	The recommendations in 1.5 and 1.6 state: 1.5 For people who cannot tolerate adalimumab, certolizumab pegol, etanercept or golimumab and who stop taking it before response can be assessed at 12 weeks, another TNF-alpha inhibitor is recommended within its marketing authorisation. 1.6 Treatment with another TNF-alpha inhibitor is not recommended for people whose disease has not responded to treatment with the first TNF-alpha inhibitor, or those who had an initial response which was then lost. These statements do not accomodate a patient who develops an intolerance to an anti-TNF after the intiial 12 week assessment. 1.5 suggests that this indication is not covered BUT 1.6 does not specifically relate to intolerance occuring beyond 12 weeks; it just relates to "non-responders" and those who had an "intitial response which was then lost". We have had a request for such a patient that developed intolerance beyond 12 weeks and it would be helpful if NICE could clarify the position for this group of patients. This is a common problem with many NICE TA's which often leave too many "grey areas" which require local interpretation. Thank you NO
Primary Cre Rheumatology Society England	In general, we welcome the conclusions of the ACD, especially the extension of the use of TNF-alpha inhibitors to treat non-radiographic axial spondylarthropathy. However, we are concerned at recommendation 1.6 â€œTreatment with another TNF-alpha inhibitor is not

Disclosure	recommended for people whose disease has not responded to treatment with the first TNF-alpha inhibitor, or those who had an initial response which was then lostâ€• . We note that the Committee considered the evidence for sequential use of another TNF-alpha inhibitor, and the conclusions contained in section 4.59. We note the conclusion that â€œsequential treatment with TNF-alpha inhibitors is likely to be beneficial, but that clinical data are limitedâ€• . It is our opinion that this conclusion could discriminate against people with ankylosing spondylitis compared with people with rheumatoid arthritis, another auto-immune rheumatological disorder. NICE TAG195 allows sequential treatment with TNF-alpha inhibitors in patients with RA who have not responded to a first TNF-alpha inhibitor, or whose initial response has been lost. In order to achieve equality between patient groups, we feel that sequential treatment should be considered in these circumstances. Steering committee member, Primary Care Rheumatology Society. No
Patient, Teacher	I am writing with regards to the Appraisal Committee's preliminary recommendations, Section 1 - point 1.6 titled 'Treatment with another TNF- alpha inhibitor is not recommended for people whose disease has not responded to treatment with the first TNF-alpha inhibitor, or those who had an initial response which was then lost': I am a young female of 30 years, who sufferers terribly with Ankylosing Spondylitis. I am currently on my first TNF blocker drug Golimumab, and have been so for over a year now. I have not responded particularly well to the drug - and i've suffered with re-current infections. My consultant Dr Andrew Keat is keen to move me to another TNF blocker, one which i take more regularly, with the view that it will give me more coverage. Therefore, i am outraged to read of your desire to remove this opportunity from patients like myself. Your report states that the response rates and benefits are reduced with 2nd and 3rd anti tnfâ€™s , yet the evidence provided does not in any way seem robust enough to support such a bold claim.

Disclosure	Furthermore, I know of thousands of patients who attend NASS members days annually who share such glorifying stories of successes with a 2nd TNF blocker. We know that all TNF blockers work in different ways, so why should it be a lucky dip for sufferers to get the right drug first time round? Beyond the statistics, i can tell you first hand that the reality of living with this chronic condition is bleak. Your preliminary decision to remove the right to try a second TNF after the 12 week window has past leaves sufferers like myself in absolute dismay. I am a young woman who dreams of a family one day - but without the right treatment, it is only a matter of time before i am forced to stop working, and left unable to live the life i rightly deserve. I urge you to reconsider this decision - it will leave young sufferers like myself with no hope at all. N/A
Patient England	I think the following are a positive move forward: 1) Offering four types of anti-TNF to patients 2) Using MRI results and not just X-ray results to make the decision to offer anti-TNF. This will enable earlier diagnosis and effective treatment plans to be made. The negatives of this report for me as an AS sufferer are: 1) Not being offered a different anit-TNF if the one you have tried does not work or stops working. I think this is short sighted because people respond to medications in different ways. Surely the aim is to help patients find the treatment that works best for them, even if it means trying out a few in the process. The long term gain for this would be far higher than the short term cost saving. Anti-TNF medication literally changes the quality of someone's life so patients should be given options regardless of whether they have tried one type of anti-TNF or not.

«Disclosure»	2) Patients should be offered MRI scans more regularly. I have only had one and that was 6 years ago. If my treatment plan is being aided by MRI results, surely you will need more updated results to see how the disease is progressing / not No
Pharmaceutical Industry» England «Disclosure»	We query why the patient access scheme for certolizumab pegol has not been mentioned within Section 1.1 of the appraisal consultation document of TNF-alpha inhibitors for ankylosing spondylitis and non-radiographic axial spondyloarthritis [ID694]. Our interpretation of this is that certolizumab pegol is recommended in ankylosing spondylitis and non-radiographic axial spondyloarthritis even without the patient access scheme? We note that in the Rheumatoid Arthritis appraisal consultation document [ID537] the â€œdiscount agreed in their patient access schemes is referred to for certolizumab pegol, golimumab, abatacept and tocilizumab at Section 1.1.» N/A
NHS Professional England	We are a group of clinicians working in the field of spondyloarthritis and conduct a large specialist clinic providing tertiary care for over 600 people with axial SpA. We have used TNF inhibitors (TNFi) for this condition for the last 15 years after conducting the first interventional studies worldwide looking at the efficacy of these agents. As such, our experience with both the disease area and the use of these drugs is vast and recognized at international level. We would like to comment on the eagerly anticipated appraisal consultation document (ACD) â€“TNF alpha inhibitors (TNFi) for ankylosing spondylitis and non-radiographic axial spondyloarthritis (including a

	review of TA143 and TA 233). We welcome the majority of the conclusions, in particular the treatment of those individuals who suffer from axial SpA on its non-radiographic form as they represent a neglected group with no treatment options up to now. We are, however, extremely concerned about the ACD positioning on the â€œnoâ€• recommendation of switching or treatment with another TNFi for those people whose disease has not responded to treatment with the first TNFi, or those who had an initial response which was then lost (1.6). In particular, we feel that the available evidence does not support this statement, rather the opposite. We would like to highlight the following: 1. Switching is cost-neutral in real life. We believe that there are other interpretations to the data outlined on Point 4.32 (Page 32) which discusses the model presented by Pfizer on pairwise comparison of TNFi versus conventional care. This, in our opinion, is not ideal as there is no such a thing as â€œconventional careâ€• in axSpA. Conventional care in axSpA refers to physiotherapy and NSAID use which has limited evidence beyond symptomatic relief. Risk of cardiovascular, renal and gastrointestinal toxicity is substantial. There are a paucity of data on the long term impact of NAIDs. Once the decision to start a biologic drug is made, it is assumed that an expense will be incurred and this will continue. This is so as current data suggest that drug free remission is unlikely with the majority experiencing a relapse that will require re-starting treatment. Whether this is the initial agent or a new one, the cost will vary minimally and it is assumed to be nearly equal. This is particularly so, since infliximab is currently not supported by NICE. As such switching in axial SpA is cost-neutral. Comment»

«Disclosure»	The Rheumatology Department at LTHT conducts clinical trials sponsored by pharmaceutical companies who manufacture biologic treatments for people suffering with axial Spondyloarthritis.