NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Patient/carer organisation statement (MTA)

TNF-alpha inhibitors for ankylosing spondylitis and axial spondyloarthritis without radiographic evidence of ankylosing spondylitis (including a review of technology appraisal 143 and technology appraisal 233)

Please sign and return to:
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Thank you for agreeing to give us your views on the treatment(s) being evaluated by NICE in this appraisal and how it/they could be used in the NHS. Patients, carers and patient organisations can provide a unique perspective on conditions and their treatment that is not typically available from other sources. We are interested in hearing about:

- the experience of having the condition or caring for someone with the condition
- the experience of receiving NHS care for the condition
- the experience of having specific treatments for the condition
- the outcomes of treatment that are important to patients or carers (which might differ from those measured in clinical studies, and including health-related quality of life)
- the acceptability of different treatments and how they are given
- expectations about the risks and benefits of the treatment(s).

To help you give your views, we have provided a questionnaire. You do not have to answer every question — the questions are there as prompts to guide you. The length of your response should not normally exceed 10 pages. If you think your response will be significantly longer than this, please contact the NICE project team to discuss.

When answering the questions from section 3 onwards, please make sure to say which treatment (s) you are commenting on.

1. About you and your organisation

Your name: [redacted]

Name of your organisation: National Ankylosing Spondylitis Society (NASS)

Your position in the organisation: Chief Executive

Brief description of the organisation

The National Ankylosing Spondylitis Society (NASS) was founded in 1976 by a group of patients, doctors and physiotherapists at the Royal National Hospital for Rheumatic Diseases in Bath.

The 3 main aims of NASS are:

- To seek a cure for ankylosing spondylitis (AS) and related conditions, and improve their treatment in the UK;
- To promote awareness of these conditions in the UK; and
- To provide guidance, advice and information for people affected by these conditions including their families, their carers and their employers.

NASS is the only registered charity in the UK dedicated to the needs of people with ankylosing spondylitis (including axial spondyloarthritis) in the UK to date.

NASS is a membership organisation. We have 6,300 members, the vast majority of whom have AS or are a friend or family member of someone with AS. Within England NASS has approximately 5,400 members.

The NASS head office is based in Surrey where we currently have 5 full time members of staff and 1 part time staff member. However we have a network of 91 local branches spread throughout the UK, of which 77 are based in England.

The branches provide regular physiotherapy, hydrotherapy and gym sessions that are supervised by physiotherapists with an interest in AS. Most branches meet weekly on weekday evenings. Although the main aim of meeting is for exercise, most branches also have an educational and social aspect.

NASS wanted to represent the views of people living with ankylosing spondylitis and axial spondyloarthritis in our submission. We emailed a link to a survey on the issues to all members in England for whom we have an email address (approximately 3,800). We additionally posted a link to the survey on the NASS website, advertised the survey in our monthly E-Newsletter and asked all our branch contacts to ensure branch members were aware of the research.

The survey was set up to allow only one entry per IP address. The survey was only for people with a diagnosis of axial spondyloarthritis or ankylosing spondylitis who were living in England.

The introduction to the survey explained that NICE were reviewing the anti TNF guidelines and had asked NASS to get involved as a patient organisation. It explained NASS would use the views given in the survey to write our submission. We additionally explained that it did not matter whether or not people were using or interested in using anti TNF therapy. People were asked to try to answer all the questions even if they were not sure and were asked to share any personal experiences that might be useful. Respondents were assured all their replies would be completely anonymous.

608 completed the survey.

2. Living with the condition

What is it like to live with the condition or what do carers experience when caring for someone with the condition?

Axial Spondyloarthritis (axial SpA) refers to inflammatory disease where the main symptom is back pain, and where the x-ray changes of sacroiliitis *may or may not* be present. Within axial SpA there are two groups:

Ankylosing Spondylitis (AS): Where the x-ray changes are clearly present.

Non-radiographic axial spondyloarthritis (nr-axSpA): Where x-ray changes are *not* present but you have symptoms.

Around 7 in 10 in this group have visible inflammation which shows on an MRI. 3 in 10 may not have any change visible on the MRI despite symptoms of back pain and other symptoms of inflammatory disease including:

- Episodes of uveitis (inflammation in the eyes)
- Crohn's disease or ulcerative colitis (inflammatory bowel disease)
- Psoriasis
- Inflammation in the heel of the foot
- Inflammation in the fingers or toes
- Elevated markers of inflammation in blood tests
- HLA-B27+

We will not make the distinction between the two subsets of axial SpA in this document because most NASS members are currently told or have been told in the past that their diagnosis is ankylosing spondylitis. They are not commonly aware of the differentiation between x-ray and MRI changes unless they have been told they are not eligible for anti TNF therapy on these grounds. As a patient organisation we cannot distinguish between these two different sub-groups in our contacts with patients, carers or families.

Axial SpA is an inflammatory condition of the spine which often produces pain, stiffness, deformity and disability throughout adult life. It is a chronic progressive disease. It is characterised by periods of fluctuating intensity, leading to slowly increasing spinal and peripheral joint damage.

The key symptom in early disease is inflammatory back pain (IBP). The onset of back pain and stiffness is usually gradual, being especially severe at night and following immobility. For many people sleep is disturbed, often causing them to get out of bed in the night to move around so as to improve their back pain and stiffness. Pain and stiffness in AS are commonly at their worst first thing in the morning and may improve considerably with stretching and light exercise.

Persistence of the disease leads to progressive spinal stiffness which may be accompanied by deformity. Up to 25% of people with axial SpA eventually develop complete fusion of the spine which leads to substantial disability and restriction.

50% of people with axial SpA also suffer from associated disorders at sites distant from the spine. In particular, 40% experience episodic eye inflammation (iritis), 16% develop psoriasis and 10% inflammatory bowel disease.

Symptoms of axial SpA usually begin in adolescence or early adulthood, a critical period in terms of education, work and establishment of social frameworks and relationships.

Symptoms are often present for a long time (7-10 years) before the diagnosis is made.

Although most people with axial SpA live a normal lifespan, there is an increased risk of premature death from cardiovascular disease in particular.

Since many people with axial SpA are neither deformed nor have peripheral joint abnormalities, much of the burden of living with axial SpA is invisible. The spectrum of severity means that although many people with axial SpA live active and rewarding lives, others experience progressive spinal pain, immobility and functional impairment.

Work disability is a major problem with more than 50% of people who are affected suffering work instability. The average age of diagnosis is 24, a prime time for establishing a career. In addition, one-third of people with axial SpA give up work before normal retirement age and another 15% reduce or change their work because of axial SpA. The work capacity of people with axial SpA in the middle decades of life is similar to that of people with rheumatoid arthritis.

Being unable to work has important consequences for the individual and his/her family through both loss of earnings and the loss of self-esteem that a career and income provide.

People with axial SpA are more likely to be divorced or never to have married and women with axial SpA are less likely to have children.

Many people with axial SpA suffer with issues including depression, fatigue and poor sleep during their lives. All of these problems exert a profound influence on their quality of life.

3. Current practice in treating the condition

Which treatment outcomes are important to patients or carers? (That is, what would patients or carers like treatment to achieve?) Which of these are most important? If possible, please explain why.

When speaking to people with axial spondyloarthritis, they are clear that they want their symptoms to be improved by treatment. In particular they hope to have significantly less pain and stiffness. This would mean that they could enjoy a better quality of life including an improved family life, social life and an increased ability to be economically active.

People with axial spondyloarthritis often suffer a great deal with fatigue and they often hope that their fatigue will be reduced through treatment. Where fatigue is exacerbated by disturbed sleep due to pain and stiffness, the improvement in fatigue is often a secondary affect.

In summer 2012 we conducted a quick poll via the NASS website. We asked:

'If there was a new treatment for your AS what single thing would you most like it to do for you?'

A total of 277 people took part and the responses were as follows:

Prevent further damage to your spine and joints	**44%**
Relieve your pain	**27%**
Reduce fatigue	**19%**
Give you a sense of being well	**6%**
Improve your social life and give you the ability to interact normally with your family and friends	**4%**

This indicates that, once people's symptoms are controlled, they hope to avoid further progression of disease.

What is your organisation's experience of currently available NHS care and of specific treatments for the condition? How acceptable are these different treatments and which are preferred and why?

In our survey of people with axial spondyloarthritis living in England, 48% were currently taking anti TNF therapy. This is a higher proportion than in our survey of 1630 people with axial spondyloarthritis in summer 2013 when a third (33%) were taking anti TNF therapy. We would hypothesise that people on anti TNF therapy had a greater interest in this survey and a greater confidence in considering the issues than those not taking anti TNF therapy.

The anti TNF therapies currently being used are adalimumab (27%), etanercept (15%), golimumab (4%) and infliximab (2%).

Those on anti TNF therapy reported that it had made a big difference to their life. They noted it had significantly reduced symptoms of pain and stiffness and had led to improvements in mobility. It had also reduced extra-articular symptoms such as uveitis. The result of these improved symptoms was a significantly improved quality of life.

Life changing , no aching , reduction in pain, reduction in joint swelling. I can lead active life and no longer use a stick. No longer concerned about having to move house for a bungalow.

It kept me in work for 12 years longer than I would have otherwise managed.

I can WALK again. My disease is not active. I have managed to get my life back. Without Humira I would not be married to my wife and enjoying watching my step children grow up.

Prior to taking the TNF, I felt the condition was not manageable and couldn't see a point in living a life with so much pain. The difference now is that I can enjoy life and not be absorbed by my condition.

It has made EVERY difference. Without TNF I was unable to function, had constant pain, the inflammation was constant, the stiffness was unbearable, I had no energy, I could not perform at work well, I had to take time off work, I felt down, I had difficulty sleeping and I did not want to live like this. TNF changed all this, I have no more pain, I am able to function like a normal human being. TNF gave me my life back.

Anti TNF has, quite literally, given me my life back. It has given my daughter her mummy back. It has given me the ability to share my daughter's childhood with her. Before anti TNF treatment, I couldn't walk easily without crutches or a stick, I was waking at least twice a night needing pain relief, I was unable to put my own socks on, I could not help my child up if she fell. With anti TNF treatment, I am in considerably less pain, I can ride a bike, fly a kite in the park, I can run with my daughter as she rides a bike, I can swim with her, play with her and simply enjoy both mine and her life. Anti TNF has not only controlled my ankylosing spondylitis symptoms, it has stopped ankylosing spondylitis controlling me, and for that, my husband, daughter and I are forever grateful.

The benefits of anti TNF therapy were seen as being reduced pain and stiffness, improved mobility, reduction in attacks of uveitis and reduced levels of fatigue. Again, these improvements in symptoms lead directly to an improved quality of life. People reported that they were able to independently manage activities of daily living that were previously problematic and be economically active. They were also better able to carry out the exercises that are vital for optimising outcome in axial spondyloarthritis. A number noted they had been able to significantly cut down on their use of other painkilling medications.

No major flare ups. Much reduced overall level of pain. Increased mobility. No uveitis since starting. Much reduced level of psoriasis.

It has flattened out flares in AS. I also haven't had iritis since starting this treatment.

Allowed me to live a normal life without pain, no longer have to plan how to dress in a morning (used to struggle with socks and tie.) Have taken up old hobbies. No longer concerned about employability and effect on ability to work.

It has meant that I'm able to exercise much more consistently and have gained movement and strength I had forgotten was possible.

Pain reduction and the release of stiffness mean I can walk, do yoga and hydrotherapy, so I am able to increase my fitness & so my general health improves.

It means I can work a full week and enjoy it.

I can now (most significantly) walk further than the end of my road (!) go to work, enjoy social occasions much more, enjoy a physical relationship with my partner, play tennis, ride a bike, I could go on!

I had lost my job and a lot of my friends because I was unable to do much for myself but now with such reduced pain I have a full time job, a fiancee and a very happy life.

My husband has MS and I am his carer. Without anti TNF drugs this probably would have been impossible and we would have had to bring in outside carers, which neither of us wanted as his MS is progressive and he requires a lot of intimate care.

Less worry about medication and less side effects from the drug "cocktail" I was on prior to Humira.

The perceived downsides of anti TNF therapy centred around the fact that it is an injection rather than an oral medication, the impact of the medication on the immune system and concerns over the potential long term side effects and risks. Overall, the majority clearly felt that the downsides were considerably outweighed by the benefits.

I dislike injections so a weekly injection isn't something to look forward to but the benefits outweigh the fear of injections.

I am still not able to give myself the injection, and I find the injections very painful still. I don't like the fact I am now dependent on fortnightly injections.

The injection itself. I dread doing it as it REALLY stings and I am usually left with slight inflammation at the injection site.

I have developed vasculitis as a consequence which causes skin blotches, bruising and also feet swelling which means I need crutches at times, I also have other infections such folliculitis and I get a sore throat, fatigue and other symptoms every month. However, the benefits outweigh these side effects. I can manage these side effects with some other drugs and lifestyle changes, I cannot manage the pain without TNF.

I tend to get more chest infections and longer lasting colds.

There are risks, as there are with any medication, and some of them are concerning. My immune system is not as strong as it should be if I was healthy. But the benefits far, far outweigh the downsides.

I've had 3 episodes of tonsillitis this year and never had it before starting Humira. It definitely makes it easier to get sick and you can't take the injection if you are sick so you are always stopping and starting.

Takes longer to recover from minor infections. Some of the potential side effects are a bit frightening.

Prior to starting anti TNF I was worried about my immune system being affected and the slight risk of increase in cancer (my dad passed from cancer). But to date have had no downsides.

Worried what harm it may have caused to my immune system in the long run.

4. Patient views on whether infliximab should be made available to people with ankylosing spondylitis

91% of patients believed that infliximab should be made available for people with ankylosing spondylitis.

The main advantage or benefit of infliximab over the currently available anti TNF therapies for ankylosing spondylitis was perceived to be the mode of administration. The iv infusion was perceived as offering another option or alternative for people with ankylosing spondylitis.

The mode of administration would mean that patients would not have to self inject. This was regarded as being potentially advantageous to some patients. It also meant that people would not have to store anti TNF therapy in the fridge which was seen as an inconvenience by some.

The 8 week dosing regimen of infliximab was also seen as an advantage. Patients compared this favourably to the 4 week, 2 week and 1 week dosing options currently available at the moment.

The fact that the infusion would be administered by a health professional rather than self administered was seen as advantageous for some. Patients felt that they would be more closely monitored by health professionals rather than left to manage alone.

It would give AS patients a greater range of medication options ensuring individuals can find the best option for themselves.

It's another option and when you're living with a condition like AS you need options.

I wouldn't be dependent on fortnightly injections, so it would give me more freedom. I also wouldn't have to rely on my sister to administer it for me!

Not having to self-inject. Longer gaps between administration would possibly make travel easier.

Travelling away from home would be much easier to arrange without having to carry the anti TNF syringes in refrigerated conditions and also avoiding twice weekly injections. An eight week infusion via drip would be much easier to organise my life.

Self injection doesn't suit everyone, nor do they have the facilities to store the meds

I'll get half my fridge back!

Supervised administration. No self injection. No carrying of cooling boxes when going away. Nowhere near as intrusive to life as others.

When patients considered the potential disadvantages of making infliximab available to people with ankylosing spondylitis they expressed concerns about the increased pressure on NHS time and staff. They noted that more pressure would be placed on outpatient clinics and were concerned that missed appointments might lead to further cost to the NHS.

Some feared that waiting lists and administrative issues might mean infusions were delayed leading to a return of symptoms. There was some feeling that it was better to be in control of exactly when and where medication was administered rather than being given an appointment time and date that may not be convenient.

Patients also noted that there would be a need to travel to outpatient clinics. This was seen as potentially difficult and costly for some patients. It would also mean additional time spent at hospitals for patients. It was noted that working people wouldn't want to take time off every 8 weeks for an outpatient visit.

The necessity of hospital treatment in outpatients departments means that it is expensive to administer.

Putting more pressure onto outpatients where I can inject myself with Adalimumab.

More strain on the NHS due to it being an outpatient infusion so staff required for administration.

Extra hospital visits with travel time and waiting.

Having to attend an outpatient clinic on a regular basis, which must be time consuming. Better to be in control at home with self-injection.

It has to be administered in a clinic. This could cause problems for people with limited mobility, limited access to transport or on reduced incomes.

The types of people that patients felt might particularly benefit from access to infliximab include:

- People scared of needles/self-injection
- People with memory problems
- People with learning difficulties
- People with anxiety disorders/depression
- People with dexterity problems
- Children
- Elderly
- Working people who cannot receive deliveries of anti TNF therapy
- People who have to travel a lot
- People with injection site reactions from other anti TNF therapy

5. Patient views on whether certolizumab pegol should be made available to people with ankylosing spondylitis

91% of people believed that NICE should make certolizumab pegol available to people with ankylosing spondylitis. The view of the majority was that certolizumab pegol would increase the options available for people with ankylosing spondylitis in England.

More options for treatment the better. It's a young person's disease and we have a long road to go on. If it works then it should be available.

All drugs and treatments that could positively impact upon someone's life should be made available. What suits one person may not suit another - and people should have access to the widest amount of treatments possible.

If these drugs work and improve people's quality of life they should be approved

By increasing the choice of anti TNFs, patients are more likely to find one that works for them or one that has the least side effects. They may all be anti TNFs but I'm sure they work slightly differently. Hence some will work better for some patients and some will have fewer side effects for some patient.

Useful to have as wide a range of drugs available as possible.

6. *Patient views on whether adalimumab and certolizumab pegol should be made available to people with non-radiographic axial spondyloarthritis*

93% of people believe that NICE should make adalimumab and certolizumab pegol available for the treatment of non-radiographic axial spondyloarthritis.

One of the main perceived benefits of making adalimumab and certolizumab pegol available for this indication was that it would allow patients who have not responded to anti inflammatories the opportunity to improve their symptoms, resulting in a better quality of life. At the moment these patients lack effective treatment options. They often struggle with pain and stiffness, which has a huge impact on their ability to have a family life and social life as well as their ability to remain economically active.

Because the changes do not show up on an x-ray, it does not mean the pain is not the same.

Enable people to have better quality of life without suffering, enable people to continue work without relying on benefits. Axial is just as debilitating as AS and people suffer just the same.

Getting pain under control early will reduce inflammation, enable patients to take on greater activity and self management. These patients have very real pain, impacting their quality of life.

This is a group who have been poorly served in the past

We still have a lot to learn about AS. At some point this group of people are likely to be detected on x-ray and MRI. It seems logical if you have diagnosed these people, and they are ill, to offer them treatment with an anti-TNF - get them better faster, possibly slow the development of disease, get them back to work, or allow them to contribute more fully in the workplace. And allow them to contribute more fully in raising a family.

I am one of those patients. I appreciate these therapies are costly but the NICE criteria means that access to anti TNFs occurs far too late in the disease continuum. Earlier access would help slow down the progression of the condition and allow patients like me, in my early 40's, to still be able to do things that every person of my age should still be able to do. Come NICE, you can do it! Be caring, be brave, be patient-focused!

I had to wait two and half years with uncontrolled symptoms until there was sufficient x-ray evidence to suggest use of an anti-TNF. If this type of drug could be used sooner it would mean that the condition could be effectively treated so reducing the impact on work, being active and also reduce permanent damage to joints.

People hope that using these anti TNF therapies earlier on in the disease, before there are changes on x-ray, will result in a reduction in long term damage.

I am in this group and if it means I don't have to wait until irreversible damage has been done, I want to take whatever I can. Prevention must be the way forward for a condition where there is no cure?

It seems counter-productive to force people to wait until their disease has progressed significantly, possibly causing disability, before allowing them to use a treatment which could prevent their disease progressing to the stage where they have bone damage and fusion.

7. Patient views on whether NICE guidance should change so that if the first anti TNF does not help with symptoms within the first 12 weeks, people can try a second anti TNF

97% of people with axial spondyloarthritis believed that NICE guidance should change so that if the first anti TNF does not help with symptoms within the first 12 weeks, people can try a second anti TNF.

It was noted that this change would significantly reduce fears and anxiety when first starting on anti TNF therapy. Currently people know this is their one chance of finding if anti TNF therapy will work for them and improve their symptoms and quality of life. This leads to high levels of anxiety. Knowing there was a 'second chance' if the first anti TNF did not help would be very helpful, especially as there is currently no alternative treatment.

It would also offer a lifeline to the estimated 2 in 10 people who do not respond to anti TNF therapy. If the second anti TNF therapy did benefit these people it would not only help with symptoms but could potentially significantly improve quality of life and allow people to remain economically active.

When asked which drug I would like - it was like playing Russian roulette. If I pick the wrong one I'm dead!

It would relieve the worry and fear associated with the first drug treatment - that there would be no other option if this one failed.

It was very, very stressful going forward with Humira as my one chance.

If someone is ill then they should be entitled to find the best drug for them, not just gamble on one drug and get no further help if it does not work!

I think 12 weeks is too short a window to make a decision that can have a massive impact on someone's quality of life. An opportunity to try a second one must be given to allow doctors to decide what would be the best decision for the patient.

If we thought this way about antibiotics then we'd have a very small population. People and their conditions do not all respond the same way or to the same degree with medication. Increased chance of a higher quality of life. Increased chance of being able to give back to the community and to society. Why would you deny this?

It allows them to find a treatment that suits them rather than having to rely on pot luck of hitting the right one first.

Any family of drugs can work better on some patients than others, surely it is common sense to allow an alternative TNF therapy.

Not all drugs suit all people, it is common sense that more than one drug should be tried to ensure that patients get the best treatment available to help them live a full life.

AS sufferers should be given every opportunity to find a treatment which would be effective or sufficiently effective so as to be able to lead a normal or near normal life.

From personal experience the use of an anti-TNF has made a massive difference in terms of quality of life and being able to work, so the benefits of using this type of drug outweighs the negative. To have the option of trying different anti TNFs would therefore increase quality of life and this would surely save in terms of the cost of care in the long run.

Studies have shown that switching is effective. Other countries successfully manage their AS patients this way. NICE is denying AS patients optimal medical care.

This is very disappointing and frustrating as an AS patient. There may be a rationale if you are a budget holder, but, isn't the aim ultimately to help patients lead better lives? Particularly with AS which affects patients differently and it is therefore difficult to predict what therapy each patient is going to respond best to. Switching would be a useful way to successfully manage this condition.

Anecdotally I am aware that some AS patients have reported that alternative anti TNFs work for them when previous anti TNFs have failed. As a principle, if I was starting anti TNF I would want the option to switch if one wasn't working. A one strike you are out policy seems unreasonable.

Every patient reacts differently to medications, anti TNF included. I have spoken to quite a few patients who all say that one anti TNF did not work for them but another one did! If they had not been allowed to try a second anti TNF they would be severely limited in what they could do now.

8. Patient views on whether NICE guidance should change so that if the effectiveness of one anti TNF wears off over time, a second can be tried

98% of people believed that NICE guidance should change so that if the effectiveness of one anti TNF therapy wears off over time, a second can be tried.

It was noted by many that the stakes are high for people with severe axial spondyloarthritis who need to be on anti TNF therapy. It is likely that the pain, stiffness and loss of mobility would return if the efficacy of anti TNF therapy wears off and the treatment is halted. This would mean a return to a low quality of life, family and social problems and the ability to work might well be curtailed. Thus, it was agreed that a second chance was essential.

Anti-TNF has hugely improved my life but if it does wear off I will become disabled again, so, having the option to change to another drug could be a life line and give AS sufferers hope for their future.

The benefits when anti TNF is successful are so great that seeking the right alternative medication is hugely beneficial to the individual and to the NHS in avoiding escalating cost in treating unresponsive patients.

The relief received from AS symptoms with anti TNF are indescribable to those who do not suffer. I cannot imagine life without it so switching to another drug to see if it regains effectiveness is essential to AS sufferers.

If a secondary drug works and stops people being incapacitated- surely that is cheaper for the State and better for the individual.

Individuals believed that if their anti TNF therapy stopped being effective and they were denied a chance to try a second option, this would have a profoundly negative impact on their life. Indeed, people on anti TNF do fear this possibility.

If my anti TNF was taken away and I was offered no alternative I don't know how I would cope. The thought of it actually keeps me awake at night sometimes.

It gives people hope that even if the first one does lose effectiveness there are other options. It may stop the feeling that this one drug is their only hope. For people who do find the effectiveness changes over time this would be very distressing and could lead to people feeling depressed if there is no other treatment for them and nothing to try.

It is hard enough to live with this condition. To know there is going be help after the first wears off will give everyone a massive psychological boost. Take that option away and depression will become rife throughout AS sufferers. We need hope.

People noted that axial spondyloarthritis is a lifelong condition and that there are currently no alternative options to anti TNF therapy. Thus, they argued that it was only reasonable to people with axial spondyloarthritis to be allowed the option of switching anti TNF therapy as needed. Some noted that this is allowed under the NICE guidelines for rheumatoid arthritis and questioned why people with axial spondyloarthritis should be comparatively disadvantaged.

This is a lifelong condition so give us lifelong treatment options. Why should we be left to suffer down the road when one treatment is not working to its full potential anymore? Give us the option to try another.

This is very common in rheumatoid arthritis patients so I cannot understand why this is not accepted as a likely event for AS patients.

I have been severely affected by ankylosing spondylitis. The only effective treatment has been an anti TNF. If this stops working there are no more options. Surely having the option of extending the benefits (quality of life, being active) of using this type of drug far outweigh the cost of care in the long run.

I've had this condition for over 30 years - I've had many treatments and anti TNF is the best. Some become less effective over time so there should be an option to try another. I assume everyone else needs to carry on working just like I do?

A second chance. If the first had remained effective then they would be able to continue so it seems sensible that they could move to a different one rather than being condemned to revert to other treatments which presumably have already been tried and found wanting.

It is well known that some medications have diminished efficacy over time and therefore can mean that an AS sufferer that has enjoyed better disease management and reduction in symptoms could revert back to being in pain but more frustratingly knowing that there could be other anti TNF treatments that could work but he/she is denied access too. It comes back to the fact that anti TNF can give a person with AS their quality of life back.

Some people were currently in the position of feeling the efficacy of their anti TNF had worn off to some extent and would like the opportunity to see if a different anti TNF might give them greater efficacy.

Optimal control of the inflammatory process is required for the best long term outcome. This cannot be achieved when patients are stuck with one particular type of Anti TNF which may be less effective than another. I've been taking etanercept for 10 years now. It still works to reduce pain and inflammation, but not as well as when I first started using it. I would very much like the opportunity to try another type of Anti-TNF as it could potentially lead to me being able to return to work.

Other people had been able to change anti TNF and reported good experiences. These people felt very strongly that had they not been allowed this opportunity, they would have a much poorer quality of life.

This is a VERY important point. I am on my third TNF. I started with Remicade which worked like magic however wore off after 1.5 years! Same happened with Humira, it wore off after 2 years. Luckily I lived in Germany where they show lots of support and flexibility towards patients like me and I was able to change TNF therapies. Today I am on Enbrel and thank goodness it has worked perfectly for many years now. However I would like to be assured that if by any chance (based on my previous experience) Enbrel stops working, that I can change to an alternative as I cannot imagine life without TNF. It would be going back to hell.

I myself have experience of being on one anti TNF for 18 months and it started to wear off, I have now been on my current anti TNF for nearly 3 years but without having been able to change I would still be in a lot of pain.

I am on my second TNF and I found it hugely beneficial. It should be available to all.

This helped me. The effectiveness of infliximab wore off over time. So my doctor put me on another anti TNF treatment. I think everybody should get this chance.

9. Research evidence on patient or carer views of the treatment

Is your organisation familiar with the published research literature for the treatment(s)?

☐ Yes x☐ **No**

If you answered 'no', please skip the rest of section 7 and move on to section 8.

Please comment on whether patients' experience of using the treatment(s) as part of their routine NHS care reflects the experiences of patients in the clinical trials.

Do you think the clinical trials have captured outcomes that are important to patients? Are you aware of any limitations in the assessment of the treatment(s) in clinical trials?

If already available in the NHS, are there any side effects associated with treatment(s) being appraised that were not apparent in the clinical trials but have emerged during routine NHS care?

Are you aware of any relevant research on patient or carer views of the condition or existing treatments (for example, qualitative studies, surveys and polls)?

X☐ **Yes** ☐ No

If yes, please provide references to the relevant studies.

The NASS survey of 608 people with AS / axial spondyloarthritis is attached.

10. Equality

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Protected characteristics are: age; being or becoming a transsexual person; being married or in a civil partnership; being pregnant or having a child; disability; race including colour, nationality, ethnic or national origin; religion, belief or lack of religion/belief; sex; sexual orientation.

Please let us know if you think that recommendations from this appraisal could have an adverse impact on any particular groups of people, such as:

- excluding from full consideration any people protected by the equality legislation who fall within the patient population for which the treatment is/will be licensed;
- having a different impact on people protected by the equality legislation than on the wider population, e.g. by making it more difficult in practice for a specific group to access the treatment;
- any adverse impact on people with a particular disability or disabilities.

Please let us know if you think that there are any potential equality issues that should be considered in this appraisal.

No

Are there groups of patients who would have difficulties using the treatment(s) being appraised or currently available treatments? Please tell us what evidence you think would help the Committee to identify and consider such impacts.

No

11. Other issues

Do you consider the treatment(s) being appraised to be innovative?

☐ Yes X☐ **No**

If yes, please explain what makes it significantly different from other treatments for the condition. (If this applies to more than one treatment that is being appraised, please give reasons for each one.)

Are there any other issues that you would like the Appraisal Committee to consider?

No

12. Key messages

In no more than 5 bullet points, please summarise the key messages of your submission.

- NICE guidance should change so that if the first anti TNF does not help with symptoms during the first 12 weeks, people can try a second anti TNF.
- NICE guidance should change so that if the effectiveness of one anti TNF wears off over time, a second can be tried.
- Adalimumab and certolizumab pegol should be made available to people with non-radiographic axial spondyloarthritis.
- Certolizumab pegol should be made available to people with ankylosing spondylitis.
- Infliximab should be made available to people with ankylosing spondylitis.