National Ankylosing Spondylitis Society (NASS)

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)

Comments on the appraisal consultation document (ACD)

Summary

NASS is satisfied with the ACD recommendation that adalimumab, certolizumab pegol, etanercept and golimumab are treatment options for active AS, but would still additionally request infliximab is recommended as an option.

NASS is very satisfied with the ACD recommendation that adalimumab, certolizumab pegol and etanercept are treatment options for non-radiographic axial spondyloarthritis.

NASS is very concerned that the ACD not recommended treatment with another anti TNF for people whose disease has not responded to treatment with the first anti TNF, or those who had an initial response which was then lost.

Representing the views of people in England with AS and axial spondyloarthritis

In order to fully represent the views of patients with regard to the ACD, NASS conducted a survey of people with ankylosing spondylitis and axial spondyloarthritis without radiographic evidence of ankylosing spondylitis living in England.

The survey was conducted via Survey Monkey. It comprised 15 questions. The survey opened on 2 June 2015 and closed at midday on 10 June 2015. Information about the NICE ACD was provided along with a link to the survey via:

- NASS website (ww.nass.co.uk)
- NASS E-News
- Emails out to NASS members
- NASS Facebook page
- NASS Twitter account

Only one entry was allowed via each IP address.

918 people took part in the survey. However, 44 were excluded as they did not live in England and a further 10 were excluded as they did not have AS or non radiographic axial SpA. Thus the number taking part in the main survey was 858.

Adalimumab, certolizumab pegol, etanercept and golimumab are recommended as treatment options for active ankylosing spondylitis (AS)

NASS is happy to see that adalimumab, certolizumab pegol, etanercept and golimumab are recommended as treatment options for active ankylosing spondylitis (AS) in the ACD. 93% of people in the NASS survey were very or quite satisfied with this decision.

Adalimumab, certolizumab pegol and etanercept are recommended as treatment options for non-radiographic axial spondyloarthritis

NASS is additionally very pleased to see that the Appraisal Committee has also recommended adalimumab, certolizumab pegol and etanercept as treatment options for non-radiographic axial spondyloarthritis. We know that this will make a very big difference to people living with non-radiographic axial spondyloarthritis who are either unable to take anti inflammatories or are not getting sufficient effect from this class of drugs. In the NASS survey, 94% stated they were very or quite satisfied with this decision.

Infliximab is not recommended for the treatment of AS

NASS is disappointed that NICE has not recommended making infliximab available to people with AS, especially as a number of biosimilar versions of infliximab have entered the market at a significantly lower cost. We would note that the cost effectiveness analysis was based upon the NHS list price and our understanding is that the tender process has resulted in a significantly lower price. This would alter the cost /benefit ratio.

77% of people in the survey who had an opinion on this issue, felt very or quite dissatisfied with this decision.

525 people commented on the reasons for their response, analysing these responses, the main reason behind this dissatisfaction was that people felt AS is a complex condition and they wanted their clinician to be able to choose the best option for them. As there are so few options currently available for the treatment of AS, people felt their rheumatologist should be able to choose from they currently licensed and available options. It was noted that the different mode of administration could make this the best option for some people.

It reduces options. My own personal experience is that infliximab can greatly reduce pain, stiffness, fatigue and iritis attacks. It should be available based on the recommendation of the treating rheumatologist.

I have been on infliximab for 10 years for AS and it has transformed my life. The regime (6-weekly infusions) allows working and travel options (between infusions) that alternatives that I know of do not.

I think that for some AS patients this is one of the most effective treatments where importantly you are monitored in hospital for any side effects, also the gap between treatments is a good period of time.

It seems unfair that patients with RA can have this drug but AS suffers can't. Both these diseases are equally debilitating, therefore both should have equal opportunity to all anti TNFs.

I was on etanercept and could not inject myself on a regular basis and ended up in a very sad state. I am now on infliximab and have an infusion every six weeks, I have been on this treatment for the last 8 years. Under the new rules I wouldn't have had this opportunity.

Treatment with another anti TNF is not recommended for people whose disease has not responded to treatment with the first anti TNF, or those who had an initial response which was then lost

NASS is very concerned that NICE has specifically stated that treatment with another anti TNF is not recommended for people whose disease has not responded to treatment with the first anti TNF, or those who had an initial response which was then lost.

We want to highlight that no restriction has been placed on the switching of anti TNF therapy in the psoriatic arthritis guidelines (TA199). This decision was taken in the absence of any evidence about the switching of anti TNF therapy in psoriatic arthritis. NASS feels this sets a precedent. If TA199 is silent on the issue of switching anti TNF in the absence of evidence, the ankylosing spondylitis guidelines should also be silent on the issue.

92% of people in the survey were very or quite dissatisfied with this decision, with the vast majority of these feeling very dissatisfied. 586 commented on the reasons for their response.

Many of the people taking part in the survey started their anti TNF as a last option when NSAIDs either no longer helped with the pain or stiffness or had caused side effects such as stomach bleeds or kidney problems. There was huge concern that if their anti TNF had stopped working effectively and they were not allowed to try a second, there would simply be no other treatments available for them. This is effectively condemning people with severe, active AS to a life without access to treatment.

During the period of 16 years that I took NSAIDS I had three stomach bleeds. Four years ago I was offered Humira which had an almost immediate effect. Within 6 weeks of starting the treatment I was no longer on any painkillers or NSAIDS and have not had to take these again over the four year period. As you can imagine, if the effects of Humira were to cease, I could not imagine a life back on the old regime particularly if there were alternative anti-TNF treatments which could possibly give me another four years without NSAIDS and painkillers. I feel that this particular recommendation should not be a blanket decision but decided on an individual basis.

I am allergic to NSAIDs so Enbrel is my only course of treatment. If it stops being effective I have virtually no other treatment options available to me. I work and have two small children. I need to be as mobile as possible in order to keep working and look after my children. If I

am left with no treatment through not being able to try an alternative anti TNF it will have a major impact on my life and the life of my family. I want to remain independent and contribute to society, not be a drain upon it.

If my anti-TNF stopped working, it would be horrible to think that I wouldn't be allowed to try another option, that I would have to live with the pain without at least trying to see if there was another option that could help!

If you have exhausted all other forms of medication for arthritis and they have been unsuccessful, before being given anti TNF medication what are you supposed to return to?

Those currently taking an anti TNF highlighted the beneficial effect it had on their lives, noting that effective treatment meant they were able to continue working and making a positive contribution to society. They also noted that the cost of a 12 week trial of a second anti TNF for a patient would be relatively small compared with the potential benefit.

Currently on Humira which has been miraculous for me and enabled me to keep working. If this drug stopped working I would have no alternative which concerns me greatly.

Why cannot patients at least try a different anti-TNF therapy? If it doesn't work it can be stopped and the overall cost to the NHS would be minimal, whilst if it does work the patient's quality of life would be significantly improved.

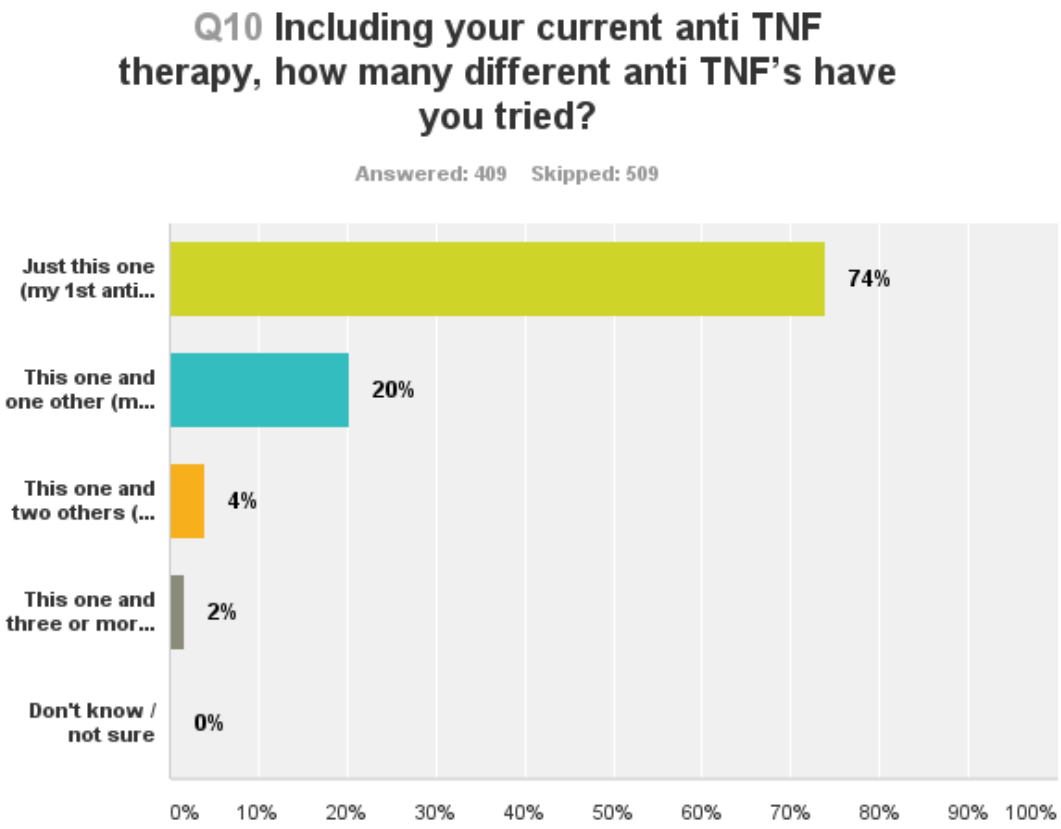
It's way too simplistic and goes against current research findings. It is unlikely to be financially efficient. There is already appearing research which will enable much better clarification of why a particular TNF may fail or become ineffective over time in a particular individual allowing greater fine tuning of prescription and therefore cost efficacy. A blanket ban on prescription of an alternate TNF will prevent appropriate clinical assessment & treatment leading to higher subsequent disease management costs when the condition is not properly controlled.

While understanding the difficulties in balancing the cost of treatment against therapeutic benefit, I believe a restriction of only trying one anti TNF drug is unreasonably restrictive and unnecessarily harsh.

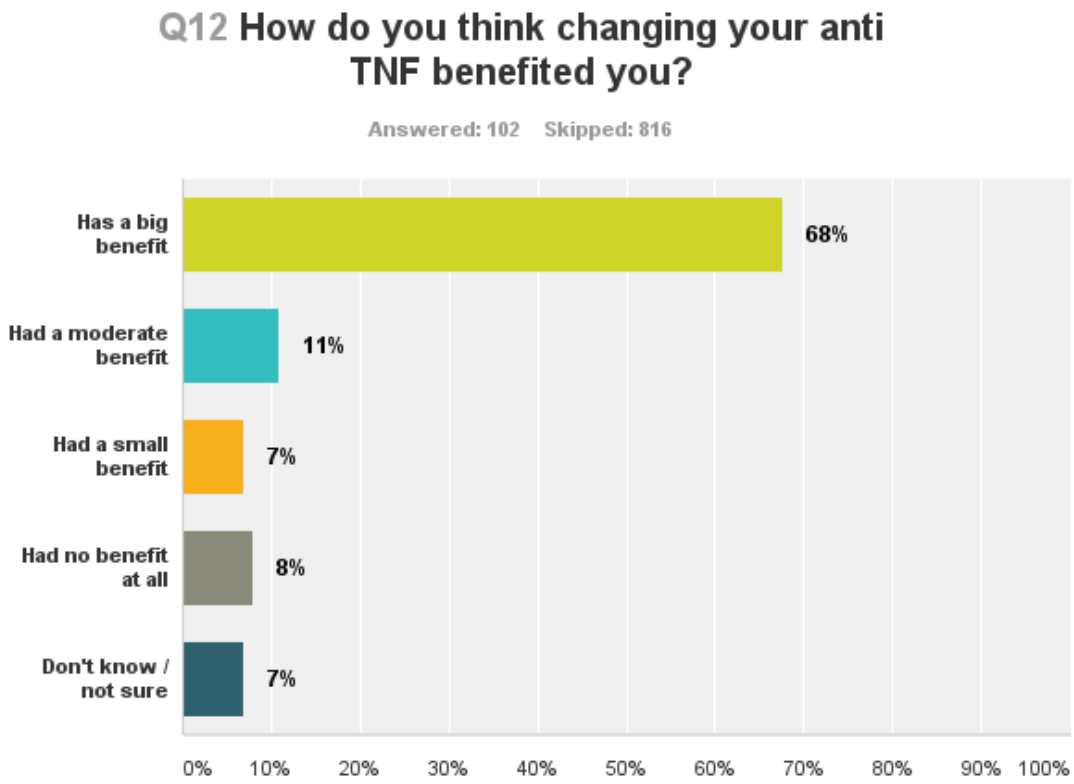
Because of Humira, I have my life back - I was previously often unable to walk and in immense pain. I lost my career and things were looking pretty bleak. I'm now in full time work and have my life back, which is amazing. The thought of going back to how I was and there being a drug which could work but I can't access is horrifying. It isn't even as though I can buy it outside the NHS, it isn't available.

We asked respondents if they were currently taking, or had previously taken, anti TNF therapy. More than half (57%) were currently on anti TNF, one in eleven had previously taken it (9%) and the remainder (34%) had never been on anti TNF

We then asked those currently taking anti TNF therapy, how many anti TNF’s, including their current one, they had tried. The majority (74%) have only tried one anti TNF, but a quarter have tried two or more.



The main reasons for trying a different anti TNF were side effects (57%) and loss of efficacy (53%). Those who had changed anti TNF were asked about the level of benefit they experienced. As the chart indicates, four in five (79%) felt that switching anti TNF had a moderate to large benefit for them.



Ninety five people commented on how changing anti TNF helped them. It can clearly be seen from this representative selection of comments, what diverse and complex problems people have with both their condition and the anti TNF therapy. This is why NASS believe it is so important to allow rheumatology consultants the flexibility to work with their patients to find the best possible solution for them.

My first anti TNF, etanercept, appeared to make my associated eye conditions (especially uveitis) much worse. Also my AS symptoms continued.

The first anti TNF coincided with my suffering from continuous bouts of uveitis, which prior to taking it I had never experienced. It was some years later that it was decided that I might benefit from a second drug. At this point I was caring for my spouse, who is bed bound with MS, and still working. The benefits of the drug were almost instantaneous and have enabled me to continue working until I have been forced to retire due to my spouses deteriorating health. I am still able to be a full time carer for him, which I am certain would not have been possible had I not been given a second drug.

When I was on my first anti TNF I spent long periods on antibiotics to treat the boils which were a result of the treatment. Since changing I have not experienced the same problem.

The first anti TNF was by infusion every 8 weeks and the effect wore off after 5-6 weeks. Second anti TNF (Enbrel) was a weekly subcut. self injection at home. The benefit is now continuous.

I experienced side effects on Humira with little improvement in my pain/stiffness. I felt generally unwell whilst taking it. Simponi was started 70 days after finishing Humira. Now after two doses I am beginning to experience significantly less pain and stiffness and feel generally well for the first time in many years.

The Humira wore off after a few years. Simponi helps me to access work and support my family rather than being a burden.

The first anti TNF had no positive effect on my life. I was still in pain, still had morning stiffness, and still couldn't control my life. After changing anti TNF to Enbrel from Humira, I found gradually that my morning stiffness faded somewhat, and I gained more control of the pain, although so much damage had already been done from 12 years of misdiagnosis.

My first anti TNF gave me some help. The second anti TNF was a massive help and improvement.