Multiple Technology Appraisal (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) [ID694]

Initial comments from the National Ankylosing Spondylitis Society (NASS) on Assessment Report

Anti TNF therapies available for ankylosing spondylitis (AS)

The Assessment Report correctly highlights that, in AS, conventional therapies are currently very limited. The only current options are non-steroidal anti-inflammatory drugs (NSAIDs), exercise and education. Anti TNF therapy is the only class of drugs available to people with AS, outside of these conventional therapies.

Given that the Assessment Report notes that anti TNFs can be assumed to have a class effect, with the treatments being equally effective, it is very important that people have the broadest possible range of options to choose from with guidance from their rheumatology team. Currently people with AS have only three anti TNFs available as options under NICE guidance, although five have a license for AS.

Nine in ten (91%) of NASS members living in England want to see infliximab made available an option. This is because infliximab is the only anti TNF which can be administered as an iv infusion which was perceived as advantageous to some people. In particular NASS members highlighted that people frightened of needles / self injecting; people with memory problems; people with learning difficulties; people with other mental health problems; people with dexterity problems and some elderly people may all potentially benefit from access to infliximab.

We recently had a call on the NASS Helpline from a lady who was visually impaired. Her consultant wanted to prescribe her infliximab but her CCG turned the request down as infliximab is not approved by NICE. Including infliximab as an option for AS within NICE guidance will allow consultant rheumatologists to choose the best option for their patients.

Nine in ten (91%) of NASS members living in England also want to see certolizumab pegol available as an option for people with AS. This would increase the options available for people with AS and avoid issues of postcode prescribing.

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.

Treatment options for non-radiographic axSpA

The Assessment Report highlights that current treatment options for people with nr-axSpA are currently very limited. It is limited to non-steroidal anti-inflammatory drugs (NSAIDs), exercise and education.

It is very important to highlight that there is no evidence that levels of pain and stiffness are less for people with nr-axSpA or that quality of life measures are better. Those people with nr-axSpA for whom conventional therapies are not working are currently left to struggle. This 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, nr-axSpA is just as debilitating as AS and people suffer just the same.

These patients are currently poorly served under current NICE guidance. The clear message that current NICE guidance sends is that these patients need to hope that their disease progresses so they can access effective therapy. The NASS Helpline has had callers who have told us that they have stopped exercising and lost mobility and flexibility in a bid to qualify for anti TNF therapy. Inability to access anti TNF therapy, even where a consultant rheumatologist has recommended it and applied to a CCG for funding, causes a great deal of emotional trauma to patients who are struggling to continue with their lives.

This comment was recently posted on the NASS facebook page.

I'm fighting for funding for any anti TNF despite my consultant recommending it and it being deemed a clinical need! All because my MRI shows the requisite sacroiliac joint inflammation and changes but my basic x-rays are less clearly defined. I'm on naproxen, Tramadol, morphine etc and struggling each day to keep working because of the pain and fatigue. No end in sight.

We have also been working with NASS member Martin over the past 2 years to try and help him access the anti TNF therapy his consultant has tried to prescribe to him on a number of occasions, with the CCG refusing funding on every occasion.

Martin is 44 and works as a police officer. He has two young children. He has evidence of inflammation on MRI but no changes on x-ray. Martin has regular physiotherapy and takes etoricoxib, co-codamol and Tramadol. However, these treatments do not go far enough to help him with his pain, stiffness and mobility problems.

He is no longer able to serve as an active police officer and has had to accept a desk job. This role is now under threat due to budget cuts. His marriage has failed due to the strain of his medical condition and he is now divorced. He is suffering from high levels of fatigue and is depressed. Martin's mood is worsened by the knowledge that there is a treatment that his consultant rheumatologist believes could help and wants to prescribe but that his CCG will not fund due to lack of NICE guidance.

NASS is concerned by the implication within the Assessment Report (pages 218-219) that this group of patients should continue to be denied a treatment with proven efficacy on the grounds that ‘there is some uncertainty regarding the definition of the nr-axSPA patient population who would benefit most from these anti-TNFs.’ These patients need early access to treatment and should not be penalised because the population is difficult to predict.

The Assessment Report additionally notes that ‘the potential extra cost to the NHS of providing anti-TNFs for patients with nr-axSpA is unclear...’. NASS would note that the Scottish Medicines Consortium made anti TNF therapy available for nr-axSpA around 12 months ago. It would perhaps be useful to approach NHS Scotland for data on increased cost / uptake over the past 12 months compared to previous years.

Sequential treatment with anti TNF

The Assessment Report clearly highlights that, although there is good data to show sustained efficacy of anti TNF therapy in axial spondyloarthritis, there are clearly a proportion of patients who experienced decreased efficacy or loss of efficacy. The Assessment Report additionally indicates that the results of studies based on registry data demonstrate that sequential treatment can be worthwhile.

98% of NASS members living in England want to see sequential treatment with anti TNF therapy being allowed under NICE guidance. We would note that it is very 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. There are currently no alternative options to anti TNF therapy. This would mean a return to a low quality of life, family and social problems and the ability to work might well be curtailed, meaning further options to access this therapy is essential. Axial SpA is a lifelong condition. A person might be diagnosed in their late teenage years. Assuming efficacy lasting 5 years and patients being allowed to try other anti TNF options, a person may 'run out' of options in time. It is essential that this young population are able to access alternative anti TNF therapies, they need hope that they will be able to continue with quality of life once their first therapy has lost efficacy.

NASS also want to highlight that sequential treatment with anti TNF is allowed under the NICE guidelines for rheumatoid arthritis, leaving people with axial spondyloarthritis comparatively disadvantaged.

We speak to people who have been able to change anti TNF and reported good experiences. These people feel very strongly that had they not been allowed this opportunity, they would have a much poorer quality of life. Indeed, there do seem to be large numbers of patients in England whose CCG has allowed them to try a second, third or even fourth anti TNF, while other CCGs will refuse a move to a second anti TNF. Thus we are seeing a return to postcode prescribing leading to inequalities in provision.

A NASS member commented:

My son's consultant recommended a change of anti TNF but this was turned down because of guidelines saying the CCG doesn't have to approve a change. This is despite some CCGs approving changes and evidence of patient improvements being seen by consultants. Why is there such variation in decisions, especially when changing over does not result in extra cost?