NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Patient/carer expert 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 return to:
Technology Appraisal Administrator, Marcia Miller, Committee A
Email: TACommA@nice.org.uk Fax: (0) 20 7061 9721
or by Post: NICE, 10 Spring Gardens, London, SW1A 2BU

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, including health-related quality of life)
- preferences for different treatments and how they are given
- expectations about the risks and benefits of the treatment(s).

We have already asked your nominating organisation to provide an organisation's view. We are asking you to give your views as an individual whether you are:

- a patient
- a carer (who may be voicing views for a patient who is unable to) or
- somebody who works or volunteers for a patient organisation.

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 response area will expand as you type. 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 specify which treatment (s) you are commenting on.

About you

Your name: [redacted]

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

Do you know if your nominating organisation has submitted a statement?

X Yes ☐ No

Do you wish to agree with your nominating organisation's statement?

X Yes ☐ No

(We would encourage you to complete this form even if you agree with your nominating organisation's statement.)

Are you:

- a patient with the condition?

X Yes ☐ No

- a carer of a patient with the condition?

☐ Yes X No

- a patient organisation employee or volunteer?

X Yes ☐ No

Do you have experience of the treatment (s) being appraised (that is, those included in the title)?

X Yes ☐ No

If yes, please tell us which one(s)

Humira (Adalimumub)

If you wrote the submission from the patient organisation and do not have anything to add, tick here ☐ (If you tick this box, the rest of this form will be deleted after submission.)

Living with the condition

What is your experience of living with the condition as a patient or carer?

a. I developed Ankylosing Spondylitis (AS) in 1990, although with hindsight, symptoms go back further. I started getting severe back pains; initially diagnosed as another slipped disk. I was diagnosed by a Royal Navy rheumatologist at the RN Hospital at Haslar. After pain worsened & spread over next 2 years to include feet, ankles, wrists, neck, sternum, ribs etc, was diagnosed with AS which was erratic in nature at first, but worsened rapidly in 1991/93 after which I suffered from several attacks of Iritis (inflammation of the iris of the eye)
b. Iritis/Uveitis. Since 1990s I have had 5 bouts of inflammation of the iris (both eyes) required hospital treatment, drops, creams and even injections. I have not had an attack since going on the Anti-TNF drugs (see **g** below). I was at first unaware that Iritis is associated with A.S
c. AS steadily worsened with frequent periods of severe hip, neck, back and sacro-iliac joint pain. I was often exhausted. I had various steroid injections into hip, knee & intramuscular, alterations to medication & increased specialist exercise. Joined the National Ankylosing Spondylitis Society (NASS) Portsmouth branch in 1995. This arranges weekly physio & hydrotherapy sessions which I still attend. I also swim twice a week too.
d. Anti-inflammatory NSAID drug. I had been a on a variety of these, none of which seemed to help at all. Eventually one (Froben) seemed to work for a while – especially in conjunction with Salazopyrine.
e. I tried to remain active, but by 2000, my A.S, meant that I had to give up all sport apart from swimming as well as severalty curtailing my Scout Leader activities.
f. A.S. had worsened significantly by 2003, there were periods where I could barely walk, so was given Arthrogram hip procedure in 2005.
g. Anti-TNF drug. I was given the chance to join a last stage clinical trial for the biologic Anti-TNF drug Adalimumab (Humira) in Sept 2006. This was extremely successful and I am generally much more flexible with less pain than I was in 2006. Having access to this treatment meant that I was able to continue to manage a high-profile 24/7 operational MoD logistics organisation with some 150 staff. Being treated with Humira enabled me to remain at work for another 8 years before a number of other medical conditions meant I had to be retired on ill-health grounds.

Current practice in treating the condition

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

The key thing is to be able to remain active, be as self-reliant *as possible* and if possible to continue to work. Ideally, one should be as pain free as possible. When you stop being active, then everything then becomes "a drag", you become "down"/depressed/frustrated and demotivated, and end-up in a downward spiral. You then lose the interest in trying to help yourself by not exercising and/or not trying to manage your own condition. This then becomes a greater burden on the NHS and the taxpayer as you are much more difficult to help or treat for your A.S. and also become more likely to suffer from another health condition. In my view and those of many HCPs and AS sufferers too, and AS patient needs to make a real effort to keep mobile and to exercise, this combined with the drug are very powerful weapons to tackle AS.

Education is also vitally important as that enables the AS patient to understand their own condition, how they can manage it better and to get information on the best methods to exercise, best foods to eat, available medications and have access to support groups (eg NASS) .

What is your experience of currently available NHS care and of specific treatments? How acceptable are these treatments – which did you prefer and why?

I have been very fortunate in being supported by a really good rheumatology department at Queen Alexandra Hospital in Portsmouth. That dept. has a superb integration with the local physiotherapy and hydrotherapy departments. That means that AS patients have access to a top class set of clinic and treatments as well as education session. There are also dedicated daytime AS hydro and physiotherapy session for newly diagnosed patients and for a number of patients in need of "encouragement."

All the departments work closely with the NASS (Portsmouth) branch that provides self-funded physiotherapist-led hydrotherapy and gym based exercise sessions during the evening.

The daytime services physio sessions are excellent, and I would say that all patients really do benefit from them, but because of the huge demand from hydrotherapy these AS sessions are limited to a 6-week period only. Clearly with nearly 500 AS sufferers in the area, such dedicated treatments are limited in number. The education and patient involvement methods employed by Queen Alexandra Hospital (and NASS as a national organisation) have been excellent too and really encouraged and inspired me to be more proactive in fighting my AS.

As Chairman of the local NASS branch and now a NASS Trustee I have spoken to numerous AS patients and I can say that we are very fortunate in the Portsmouth area as our experience is certainly ***not shared*** across the UK.

I feel that the crucial integrated approach developed by my hospital has been vital in my treatment and condition management. I have really had benefit from the hydrotherapy treatments during bad "flares" and from the excellent advice from the local physio and rheumatology team into exercises and ways of coping with things.

The classic fall-back treatment of prescribing NSAIDs to AS sufferers can be quite effective too, although I know of people where these have had little or no effect at all. To be the most effective a patients should really have regular steady dose of anti-inflammatory: however, although that is proven to be the most effective way of having NSAIDs, it can lead to other problems. For example, 4 of our NASS exercise group cannot take any NSAIDs due to problems with their stomachs, and I myself have to severely limit the amount I take as I now have only one functioning kidney. The renal and rheumatology depts. Have both agreed that the long term use of the NSAIDs I have had to use over the last 25 years may have been the cause of left kidney ceasing to work.

Finally, in addition to the way that I have been looked after by Queen Alexandra Hospital, I will always be thankful that I was asked to undertake the clinical trial into the use of the biologic anti-TNF drug Humira in treating A.S. Essentially that changed my life. It enabled me to stay in work for another 8 years, and if it had not been for a variety of other medical problems, I would still be at work now. The anti-TNF drug also really improved my quality of life outside work; I was able to continue my voluntary work as a Scout Leader, with the church and with NASS, or be able to care for my elderly and unwell parents. Without access to the drug, I would have been in a very difficult place; emotionally, practically and physically.

Your views on whether infliximab should be made available to people with ankylosing spondylitis

I concur with the views of NASS expressed in their "Patient/carer organisation statement (MTA).

However, just to say that, yes I think it should be. Not every patient reacts the same way to the various biologic rugs. The potential benefits to the AS sufferer and to society that might be gained from the use of this drug surely support the use where patients may not have responded particularly well to Adalimumab (Humira). It must be remembered that if the use of Infliximab treatment ***does not*** prove beneficial, the patient can be taken off the drug, thereby ensuring that costs are kept down. Whereas if the patient responds well, the overall societal cost benefits would surely outweigh the cost of the drug.

Potential advantages of infliximab over the other anti TNF therapies?

I concur with the views of NASS expressed in their "Patient/carer organisation statement (MTA).

Potential disadvantages of making infliximab available

I concur with the views of NASS expressed in their "Patient/carer organisation statement (MTA).

Groups of people with AS who you think would particularly benefit from infliximab?

I concur with the views of NASS expressed in their "Patient/carer organisation statement (MTA).

Views on whether certolizumab pegol should be made available to people with ankylosing spondylitis

Reasons for making it available

I concur with the views of NASS expressed in their "Patient/carer organisation statement (MTA).

However, just to say that, yes I think it should be. Not every patient reacts the same way to the various biologic rugs. The potential benefits to the AS sufferer and to society that might be gained from the use of this drug surely support the use where patients may not have responded particularly well to Adalimumab (Humira). It must be remembered that if the use of certolizumab pegol treatment ***does not*** prove beneficial, the patient can be taken off the drug, thereby ensuring that costs are kept down. Whereas if the patient responds well, the overall societal cost benefits would surely outweigh the cost of the drug.

Views on whether adalimumab and certolizumab pegol should be made available to people with non-radiographic axial spondyloarthritis

I concur with the views of NASS expressed in their "Patient/carer organisation statement (MTA).

Potential advantages of making them available

I concur with the views of NASS expressed in their "Patient/carer organisation statement (MTA).

Potential disadvantages of making them available

I concur with the views of NASS expressed in their "Patient/carer organisation statement (MTA).

Groups of people who might particularly benefit from this availability

I concur with the views of NASS expressed in their "Patient/carer organisation statement (MTA).

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

Yes, I think they should, as do all the 40 members of my NASS branch. Some people react very differently to different anti-TNF drugs, as the drugs do not all work in the same way. There is some evidence to this effect.

Potential advantages

More patients could be successfully treated with all the health and societal improvements to the individual, their family and work. It could also potentially keep people in gainful employment with less on-cost to the taxpayer.

Potential disadvantages

There would be more admins work at rheumatology depts. As they would have to assess the progress and then arrange for the different drugs, but I believe that this would be more than outweighed by the potential benefits.

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

I concur with the views of NASS expressed in their "Patient/carer organisation statement (MTA).

Potential advantages

I concur with the views of NASS expressed in their "Patient/carer organisation statement (MTA).

Potential disadvantages

I concur with the views of NASS expressed in their "Patient/carer organisation statement (MTA).

Research evidence on patient or carer views of the treatment

Are you 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 your experience of using the treatment(s) as part of routine NHS care reflects the experience 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 the 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?

☐ Yes ☐ No

If yes, please provide references to the relevant studies.

Equality

NICE is committed to promoting equality of opportunity and eliminating discrimination. Please let us know if you think that recommendations from this appraisal could have an adverse impact on any particular groups of people, who they are and why.

N/A

Other issues

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

X Yes ☐ 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.)

There simply is at present nothing else available to patients or health care professionals that works the same way. Therefore, although the drugs has been around for a number of years, I regard that as still being innovative.

Is there anything else that you would like the Appraisal Committee to consider?

No.

Key messages

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

- TNF inhibitors have had a proven positive record in treating sufferers of AS
- In my view, there is nothing (at present) as effective as this treatment
- The drugs can make significant reductions in overall costs to the taxpayer by keeping people in work, and improving their quality of life
- If one drug is not that effective, patients should be able to swap to another.
- The pathway for the use of TNF inhibitors needs to be clear for all stakeholders.