NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Single technology appraisal (STA)

Abatacept for the treatment of rheumatoid arthritis only after the failure of conventional DMARDs

Thank you for agreeing to give us your views on the technology and the way it should be used in the NHS.

Patients and patient advocates can provide a unique perspective on the technology, which is not typically available from the published literature.

To help you give your views, we have provided a template. The questions are there as prompts to guide you. You do not have to answer every question. Please do not exceed the 8-page limit.

About you

Your name: Ailsa Bosworth

Name of your organisation: National Rheumatoid Arthritis Society (NRAS)

Are you (tick all that apply):

- a patient with the condition for which NICE is considering this technology?
- a carer of a patient with the condition for which NICE is considering this technology?
- an employee of a patient organisation that represents patients with the condition for which NICE is considering the technology? If so, give your position in the organisation where appropriate (e.g. policy officer, trustee, member, etc)
- other? (please specify)

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Single technology appraisal (STA)

What do patients and/or carers consider to be the advantages and disadvantages of the technology for the condition?

1. **Advantages**
(a) Please list the specific aspect(s) of the condition that you expect the technology to help with. For each aspect you list please describe, if possible, what difference you expect the technology to make.

The gold standard treatment for newly diagnosed patients with RA is combination DMARD therapy including Methotrexate as the anchor drug. Bridging steroids are likely to be given to relieve symptoms and control the disease during the first few weeks on treatment until the MTX takes effect. If patients are diagnosed and treated early, this regimen can be as successful as biologic therapy in controlling the disease, however, many people are not diagnosed within the 'window of opportunity' (12 weeks from symptom onset) and can have sustained irreversible damage prior to commencement of treatment and for some, conventional DMARDs do not adequately control the symptoms and the progress of the disease. Under these circumstances, in order to avoid further irreversible damage, getting onto a biologic quickly is extremely important. As a patient who has been on biologic therapy for 10 years and as someone who was inadequately treated 30 years ago when diagnosed, I would advocate for and support the BSR guidelines which recommend lowering the criteria for access to biologic therapy from a DAS of >5.1 to a DAS of >3.2 as it has been shown that people with DAS scores which fall between 3.2 and 5.1 do just as badly over time as those with higher DAS scores.
With 7 biologic drugs available currently, we need to start gaining clinical experience of putting people on biologics other than purely the Anti-TNFs post DMARD failure. I appreciate that we have no head to head data to show that abatacept would be more effective than a TNF, yet we know that approximately 30% of people who go onto Anti-TNFs are primary non-responders and it may be that this group are more likely to respond to a biologic with a different mode of action. In the absence of bio-markers to determine which therapy is going to be most beneficial to which individual patient, we need to start gaining clinical experience of enabling clinicians to decide in consultation with their patients whichever of the available drugs might be best suited to that individual.
We know from RCT data that abatacept is a clinically effective drug and is cost effective and can suppress inflammation and control the disease in patients who fail conventional DMARDs.

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Single technology appraisal (STA)

(b) Please list any short-term and/or long-term benefits that patients expect to gain from using the technology. These might include the effect of the technology on:

- the course and/or outcome of the condition
- physical symptoms
- pain
- level of disability
- mental health
- quality of life (lifestyle, work, social functioning etc.)
- other quality of life issues not listed above
- other people (for example family, friends, employers)
- other issues not listed above.

In trial data when comparing Abatacept at 10mg with MTX to placebo, this has been shown to lead to sustained, significant, and clinically meaningful long-term improvements in physical function over 12 months with good safety data when compared to placebo. This is likely to lead to improved physical symptoms such as pain and fatigue, reduced levels of disability and increased quality of life which can include enabling people to get back to work or remain in employment and better look after their families.

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Single technology appraisal (STA)

What do patients and/or carers consider to be the advantages and disadvantages of the technology for the condition? (continued)

2. **Disadvantages**

Please list any problems with or concerns you have about the technology. Disadvantages might include:

- aspects of the condition that the technology cannot help with or might make worse.
- difficulties in taking or using the technology
- side effects (please describe which side effects patients might be willing to accept or tolerate and which would be difficult to accept or tolerate)
- impact on others (for example family, friends, employers)
- financial impact on the patient and/or their family (for example cost of travel needed to access the technology, or the cost of paying a carer).

Generally speaking, there is no widespread reporting of side effects from biologic therapies. They either work very well, work well, or work to some degree or don't work. Unlike conventional DMARDs such as Methotrexate, Leflunomide, etc. which can cause side effects such as nausea, headaches, vomiting, diarrhoea, biologics do not cause such side effects. Abatacept is given via monthly IV infusion which some people prefer because it is given in a hospital setting where they can benefit from health professional advice. Others prefer to be able to self inject at home. Preferred mode of administration is very much down to the individual and their own lifestyle. I might argue that for working people, a monthly IV may cause difficulties with getting time off work but once people are in a routine and can arrange appointments perhaps either early or late to minimise time away from work, this can be accommodated. Travel to and from the hospital may be an issue dependent upon whether public transport has to be taken.

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Single technology appraisal (STA)

3. Are there differences in opinion between patients about the usefulness or otherwise of this technology? If so, please describe them.

Not that I am aware of

4. Are there any groups of patients who might benefit **more** from the technology than others? Are there any groups of patients who might benefit **less** from the technology than others?

Abatacept is equally effective for people who are both sero positive and sero negative and therefore it could be argued that this therapy could be preferable to Rituximab which has been shown to be less effective in people who are sero-negative.

Comparing the technology with alternative available treatments or technologies

NICE is interested in your views on how the technology compares with with existing treatments for this condition in the UK.

(i) Please list any current standard practice (alternatives if any) used in the UK.

Currently the pathway is that Anti-TNF would be used first post DMARD failure. Other DMARDs not yet used following failure of MTX are technically a comparator, however, when someone is being considered for biologic therapies, they have usually failed on MTX and at least 2 other DMARDs, making a further DMARD the least attractive option from both patient and clinician perspective, because failure on MTX is more likely to lead to failure on other DMARDs. Allowing disease to remain uncontrolled is expensive in the long term as damage is irreversible and disability can be quite rapid leading to hospitalisation, flares, more visits to GP, outpatient clinic, and ultimately surgery.

(ii) If you think that the new technology has any **advantages** for patients over other current standard practice, please describe them. Advantages might include:

- improvement in the condition overall
- improvement in certain aspects of the condition

- ease of use (for example tablets rather than injection)
- where the technology has to be used (for example at home rather than in hospital)
- side effects (please describe nature and number of problems, frequency, duration, severity etc.)

I would definitely say that going from failure on DMARDs including MTX to abatacept would be advantageous as the likelihood of getting the disease under control will be greater going down that pathway than by going onto other DMARDs not yet used for the reasons stipulated above. With no head to head trial data comparing abatacept with other biologics, I cannot say whether there would be advantage in going onto abatacept by comparison with a TNF, however, as stated earlier, we need to gain clinical experience of putting patients onto a variety of biologics post DMARD failure.

(iii) If you think that the new technology has any **disadvantages** for patients compared with current standard practice, please describe them. Disadvantages might include:

- worsening of the condition overall
- worsening of specific aspects of the condition
- difficulty in use (for example injection rather than tablets)
- where the technology has to be used (for example in hospital rather than at home)
- side effects (for example nature or number of problems, how often, for how long, how severe).

Current standard practice would be to go from failed DMARDs to A.TNF and I am not able to say whether there would be any disadvantage in going onto abatacept instead any more than I can say there would be advantage for the reasons outlined above.

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Single technology appraisal (STA)

Research evidence on patient or carer views of the technology

If you are familiar with the evidence base for the technology, please comment on whether patients' experience of using the technology as part of their routine NHS care reflects that observed under clinical trial conditions.

Abatacept has not been used for very long in the NHS and I am therefore not able to comment

Are there any adverse effects that were not apparent in the clinical trials but have come to light since, during routine NHS care?

Not that I am aware of

Are you aware of any research carried out on patient or carer views of the condition or existing treatments that is relevant to an appraisal of this technology? If yes, please provide references to the relevant studies.

We have done a number of member surveys over the years which reinforce the findings of the National Audit Office report into RA services which showed a wide variation in access to good care around England. The Kings Fund Report (Feb. 2009) is also relevant.
We have survey data on nearly 1000 patients across the UK which shows that nearly a third of people who lose their job due to their RA, do so within 12 months' of diagnosis and that rises to 50% by 6 years. We have also published a report on the Economic Burden of RA in 2010 and a report Entitled 'The Year of RA, One Year On' which compiles the results of a survey of rheumatologists and patients carried out in spring 2010 to determine what, if anything, had changed in regard to delivery of care since the launch of the NICE RA Guidelines in 2009, the IA commissioning pathway, launched in July 2010 and which resides on the DH website, and the NAO Report.

References

National Collaborating Centre for Chronic Conditions. Rheumatoid Arthritis: national clinical guideline for amangement and treatment in adults. London: Royal College of Physicians, February, 2009

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Single technology appraisal (STA)

Department of Health. Elective Care Commissioning Pathways. November 2010

House of Commons Committee of Public Accounts. Mintues of Evidence. Services for people with RA. 23rd November, 2010

House of Commons Committee of Public Accounts. Services for people with RA. Tenth Report of Session 2009-10, Feb. 2010#

The Kings' Fund. Perceptions of Patients and Professionals on rheumatoid arthritis care. Jan 2009.

National Audit Office. Services for people with rheumatoid arthritis. July 2009

NRAS. The Economic Burden of RA, March 2010

NRAS. The Year of RA: One Year On. November, 2010

NRAS: I Want to Work: Employment and Rheumatoid Arthritis, A National Picture, 2007

NRAS: RA and Work: Employment and Rheumatoid Arthritis in Scotland, A National Picture, 2010

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Single technology appraisal (STA)

Availability of this technology to patients in the NHS

What key differences, if any, would it make to patients and/or carers if this technology was made available on the NHS?

It would give clinicians and patients more choice over which therapy to use post DMARD failure and there may be instances where use of Anti-TNF is contra-indicated and for those patients access to abatacept could make a huge difference, particularly for those patients who are sero-negative and for whom Rituximab may not be the best option.

What implications would it have for patients and/or carers if the technology was **not** made available to patients on the NHS?

For the sub group mentioned above, it could be that there were not an option available other than failed DMARDs or greater doses of steroids with all the unacceptable side effects associated with long term steroid use.

Are there groups of patients that have difficulties using the technology?

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Single technology appraisal (STA)

Other Issues

Please include here any other issues you would like the Appraisal Committee to consider when appraising this technology.