Patient/carer organisation statement template

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: [redacted]

Name of your organisation: National Rheumatoid Arthritis Society

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) I am CEO of NRAS
- other? (please specify)

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 data from the trials on golimumab appears to be robust and positive and this therapy has been shown to be effective in a wide range of disease sub-sets and profiles in people with moderate to severe RA.

Different biologic therapies including golimumab have been shown to be very effective in controlling inflammation, synovitis, disease progression and reducing radiological damage, specifically in patients who have failed standard DMARD therapy. Golimumab has been shown to be effective in patients who are MTX non-responders with sustained results.

Golimumab has been shown to be effective in controlling signs and symptoms of the disease in addition to slowing radiological damage and has shown improved physical function, HRQoL and productivity.

(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.

As with other biologic therapies, patients could expect to experience a fairly rapid lessening of symptoms such as pain, swollen and tender joints, inflammation, fatigue which would lead to better quality of life, greater independence, ability to enjoy and participate in family and social events and enable a person to remain working or potentially go back to work. In 2007 we undertook a survey of employment and rheumatoid arthritis. Seven hundred and eighty two people responded of whom 229 people had given up work or retired early because of their rheumatoid arthritis. Disturbingly, over a quarter had had to stop working within one year of diagnosis. This research gives readers a greater understanding of the huge impact rheumatoid arthritis has on peoples' lives, work being one measure of their ability to be active within society.

Longer term this would lead to better outcomes for an individual, less irreversible damage, less surgery, less flares, in hospital stays, less disability. It is widely known that RA can lead to depression and isolation. This is much less likely to be the case if the disease is well controlled so that people can enjoy a better quality of life. There is also evidence to suggest that biologic therapies lessen fatigue and CV risk.

Ref: National Rheumatoid Arthritis Society Survey 2007: Employment and rheumatoid Arthritis. A national picture. www.nras.org.uk

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).

As this technology can be self administered by sub-cutaneous injection, patients are likely to find it fairly easy and straight forward to manage the administration of this therapy after learning how to self-inject which can, to begin with, be challenging for some.
I am not aware of any reported side effects which would cause patients an on-going problem in using the therapy. The side effects such as increased risk of infection etc. and others which are usually associated with biologic therapies apply to this drug as to other biologic anti-TNF therapies but should be unlikely to cause someone in need of treatment to refuse to take it.

Occasionally there can be injection site reactions but these usually pass. There may be some people who will need a partner to inject for them but in my experience the majority of people self injecting are able to do it themselves.

I believe the manufacturers are or have developed a pen to make self injecting easier.

The advantage with Golimumab is that it is a monthly injection as opposed to some of the alternatives which are more frequently given which is likely to be preferable to patients.

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

I am not aware of any. As this drug is not yet in routine use in the NHS I wouldn't anticipate there being any significant knowledge of this drug amongst existing patients with the exception of NRAS members and others who are more informed about the pipeline of therapies in RA.

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?

I am not aware of any sub-groups in whom this technology is more or less suitable.

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.

There are four existing Anti-TNF therapies currently available for use following failure of standard DMARD therapy including MTX. Whilst TNFs are generally considered by NICE in a 'class' way, it should be stated that they all work differently and due to the heterogeneity of RA, one cannot assume that because drug A works for one patient that it will automatically work for the next. This is why we need access to the range of biologic therapies but clear starting and stopping rules.

(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.)

Golimumab has been shown to be effective in all the trials as previously stated and to improve QoL for patients who have failed standard DMARD therapy. We know that approx. 30% - 50% of patients will either fail immediately or will ultimately fail on the above 4 existing TNF therapies and it is vital that we have other biologic therapies available to treat these patients who, by the nature of their eligibility for TNF in the first place, demonstrates the serious and refractory nature of their disease.

Golimumab has been shown to give sustained benefit over the longer term and is a welcome addition to the armamentarium of biologic therapies necessary to treat people with moderate to severe RA. This technology has the advantage of being able

to be administered by the patient in their own home and I am not aware of any side effects which would cause anyone to refuse to take it.

Currently for patients who are sero-negative (about 25-30% of all RA patients), the only option after failing one anti-TNF is Rituximab which has been shown to be much less effective in this group of patients. Therefore golimumab would be a suitable option.

(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).

I am not aware of any.

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.

The technology is not in routine clinical use yet.

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

See my comment above.

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.

Biologic therapies have literally been life saving for many thousands of people who have failed on all standard therapies and whose quality of life had been reduced dramatically due to their uncontrolled disease which causes severe pain, ultimate loss of function and disability. We have much anecdotal evidence of this via our members, volunteers and helpline calls. This is also reflected in our annual surveys.

National Rheumatoid Arthritis Society – Beyond the Pain, 2004
National Rheumatoid Arthritis Society – I want to work, 2007
National Rheumatoid Arthritis Society – RA and Work, 2010
National Rheumatoid Arthritis Society – DMARDS and Biologics – Monitoring, Information and Education: Experiences of People with RA – 2005
National Rheumatoid Arthritis Society – ARMA Standards of Care: Patients Experiences: Meeting the Standards of Care for People with Inflammatory Arthritis – a national pilot survey of NRAS members, 2006

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?

As referenced above, RA is a heterogenous disease and we do not know which patient will respond to which drug. 30-50% of people will either fail immediately or ultimately on their first Anti-TNF and they then need a range of other biologics to move onto. RA can be diagnosed at any age – I was thirty and have lived with RA for 30 years. During a lifetime if one fails on standard DMARD therapy, a whole range of biologic drugs will be necessary. We cannot survive with access to only 2! Just like all drugs, there can come a point where efficacy is lost and then you need access to something else.

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

There will undoubtedly be a section of the RA population for whom golimumab will work extremely well and potentially more effectively than some other biologic therapies. As mentioned previously we need a RANGE of therapies to be able to access over a lifetime of disease.

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

The technology is not it routine clinical use yet and I am not aware of any.

Other Issues

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