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: Julie Chandler

Name of your organisation: Psoriasis and Psoriatic Arthritis Alliance - PAPAA

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)

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.

Psoriatic arthritis is associated with the skin disease psoriasis. Psoriasis causes significant distress and psychological impact on the individual's life, employment and social activities. The development of psoriatic arthritis often comes as a shock and a blow, as awareness at primary care level is often low, which is not helped by the intermittent symptoms, which leave the patient bemused as to the cause, this therefore makes diagnosis difficult.

The main impact of psoriatic arthritis is pain within the joints, commonly affecting the toes, which can hinder walking, and fingers which impacts on personal care, such as dressing or preparing food. For those who are reliant on the use of their hands for work, such as keyboard operators, surgeons, artists, chefs etc one or two tender swollen joints could have a huge impact on their overall quality of life. Larger joints can also be affected, as can tendons and connective tissue. The impact on large joints can affect mobility and independence.

Once diagnosis is established, treatments are used to reduce inflammation and therefore pain. Progression of psoriatic arthritis can lead to joint destruction in a small number of the severer cases, with loss of bone or the fusion of joints which again makes mobility difficult and therefore impacts on all aspects of social care.

Although, given the issues and impact of psoriasis, it is our experience that once an individual develops psoriatic arthritis, the impact of psoriasis is outweighed by the pain and disability associated with psoriatic arthritis.

It would be hoped that this technology would address the inflammatory process, within the joints and connective disease and slow down disease progression, which in turn would reduce future disability and the need for corrective surgery such as joint replacement.

(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.

The only study (GO-REVEAL study) carried out by the manufacturer indicated that an ACR20 - a 20% improvement in swollen joint count, tender joint count, and at least 3 of the following 5 assessments: patient's assessment of pain, patient's global assessment of disease activity, physician's global assessment of disease activity, patient's assessment of physical function using the Health Assessment Questionnaire (HAQ) and CRP - was achieved at week 14 in 48% of those on the active agent. There also appeared to be some improvement in the skin and nail psoriasis as a secondary end point, which might be seen as an overall benefit for some patients.

From a patient perspective, it would be hoped that this data would be translated into a reduction of the number of swollen joints and associated pain. With the main problems of psoriatic arthritis being joint pain, improving this aspect significantly, would tend to lead to the improvement of other aspects such as quality of life, employment etc. if the benefits are sustained over a significant period of time, which would be an important aspect for patients, this would allow decisions to be made regarding long-term activities. If you live with a condition which fluctuates and is uncontrollable, this can hinder progression in education, employment and personal relationships. Good long-term outcome data can be a comfort and an advantage for patients particularly when making a decision to undertake treatment with a secondary agent such as golimumab.

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).

The disadvantages of these technologies have to be the adverse events and long-term safety profiles. These are toxic drugs, which although appear to be effective in a small trial population have be shown to have adverse events, although the trial suggests that the safety profile is similar to other agents, this should not be seen as an endorsement of presumed safety. Currently there is limited data being collected for the use biologic agents in psoriatic arthritis, as data is not collect by either the British Association of Dermatologists Biologics Interventions Register (BADBIR) or the British Society for Rheumatology Biologics Register (BSRBR) – this does appear to leave a long-term safety data-free zone.

It also has to be added that given these technologies are expensive in relation to other second line DMARDs , (although comparable in price with similar biologic agents). This might have a disadvantageous impact on their use, as any doubt regarding benefit and potential risks might steer a prescriber to use an agent which although is cost-effective, may not necessarily the most effective.

Self injecting might cause some individuals a problem. As would storage if an individual's personal circumstance dictates. Travelling with a treatment that is an injection, particularly through security sensitive situations and then keeping the product at correct temperatures might in some instances be a problem.

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

I'm not aware of any such differences at this stage apart from preference regarding delivery via IM v IV.

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?

If the data for the skin and nail psoriasis shows significant improvement then this might influence choice, therefore people with both psoriatic arthritis and psoriasis might benefit more from this technology.

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.

Other licensed alternative agents for psoriatic arthritis in this class include: etanercept, adalimumab and infliximab,

(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.)

This technology is used once a month, so less injections than etanercept (twice a week) adalimumab (every two weeks) and infliximab (at two weeks, then at six to eight weeks)

Although less frequent injections would make people with the condition happier, the efficacy of the technology would need to be comparable. This technology does not appear to have been trialled against similar agents. So this comparison would be difficult to judge.

(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).

The disadvantages will be long-term adverse events profile and high cost. Patients are already using similar treatment delivery methods for other agents

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.

I cannot comment on this, but it appears to be used in the same manner as other similar products.

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

Can't comment

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.

Not aware, therefore can't comment

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 provide alternate options, although given the limited trial evidence it would still be unknown which patients would benefit. It would be more useful if patients who were likely to respond to this treatment could be identified before prescribing.

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

Psoriatic arthritis has a number of treatments now licensed in this class. I suspect that unless it is proven to be superior or more cost effective by being targeted at particular groups, who are seen to benefit more than existing treatments can, it would not change current practice.

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

Those that can't self inject for some reason. This could be overcome by assiatnce from someone else – this may have a cost implication.

Other Issues

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

I would like the committee to consider the issue of long-term safety data collection in a register that is specifically geared towards psoriatic arthritis. The current registers do not capture this and use tools which are not appropriate in psoriatic arthritis. The psoriasis register acknowledges arthritis but doesn't measure any related data.