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:

PAPAA – The Psoriasis and Psoriatic Arthritis Alliance

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.

Psoriasis is a condition which affects those with it in many differing ways. For the majority, the condition is often mild but an irritating condition that may cause in some cases significant inconvenience and psychological issues. These individuals will often develop coping strategies that may be in conjunction with a prescription via a GP, with OTC remedies or avoidance of situations because of visible psoriasis. Although the severity of disease may not necessarily equate to the psychological impact or location, these Individuals might feel that the impact of the disease is greater than the clinical diagnosis of mild.

For people who have severer disease with widespread scaly skin, which is red and thick or who have developed associated psoriatic arthritis (benefit has been noted in trials with ustekinumab) this treatment could provide further choice, and relief, within the current selection of similar technologies.

This technology in a published trial (evaluating the Efficacy and Safety of Ustekinumab Compared to Etanercept in the Treatment of Subjects with Moderate to Severe Plaque Psoriasis (ACCEPT) has shown that ustekinumab achieved PASI 75 within 12 weeks, this would include reduction of skin scales, redeness and skin thickness.

Scaly skin is the most commonly complained problem by patients, the reduction of this element removes a burden that patients face. The sheer volume of skin and the deposits this leaves wherever a person with severe psoriasis goes is not only embarrassing but psychologically damaging. It will also dictate behaviour and limit opportunities both socially and within employment. The associated element of scaly skin is the pain and itch associated with a tight thick skin and subsequent scratch and then bleeding of these areas, which in turn adds to the circle of psychological impact.

The reduction of redness and thickness also relieves the burden of the disease and the subsequent need for coping strategies.

The traditional treatments for mild psoriasis are generally those that are topical in nature and the associated time and messy nature of these treatments. Although effective in many cases are disliked by patients and leads to poor compliance. Moderate to severe disease is generally treated in a secondary care situation and opens patients to more aggressive treatments which although more effective have more significant risk. The ease of less time consuming treatments will appeal to patients, but adequate risk/benefit analysis should be part of the process, with benefit for improved psychological issues being included.

The delivery of ustekinumab appears to be easier with studies suggesting 3-4 injections per annum, this would go a long way in providing patients with freedom from being tied to daily/weekly treatments and therefore could provide better compliance and effective use of available funds.

(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 use of the technology could provide long term relief with the need for fewer treatment episodes. If trials are an indication towards 'real' life scenarios then potentially severe psoriasis could become less of an impact on individual lives, therefore improving not only physical symptoms but social functioning and employment opportunities. The release from the burden of being tied to a disease 365 days of the year will also provide significant psychological changes. If there is evidence that this technology improves psoriatic arthritis symptoms as well, this could impact of levels of disability that this condition has.

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 new technologies are the unknown long term safety issues, which are only now emerging with other similar treatments. The need for vigilant monitoring both in the short term and subsequent years needs to be paramount so that any potential adverse events can be easily identified.

Therefore the use should be weighed against potential known side effects in relation to the benefit received by the individual patient. Cost of these treatments may be an issue that may be a disadvantage for prescribers, given that it may be difficult to identify which treatment will be most effective in individual cases.

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

The usefulness for a patient will be the end result – "Does it get rid of my psoriasis?"

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?

There may be advantages for those who find regular (daily or weekly) treatment difficult to complete such as visits to outpatient treatment centres for PUVA, particularly if employed in an occupation that takes them away from there usual home location. Less time needed to attend appointments might be advantageous, although monitoring would still be needed.

Co-morbidity risks might make the use of these technologies less useful in some cases.

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.

Current therapies include topical applications (steroids, vitamin D analogues tar, dithranol etc.) UVA, UVB,PUVA , acitretin, methotrexate, ciclosporin, etanercept, efalizumab, infiximab, adalimumab.

(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.)

The advantages would be the ease of use and the need for less often treatments. Use for those who also get benefit if they also have psoriatic arthritis.

(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 could be unknown side effects, lack of long-term safety data, age and impact on people wishing to have children or start a family. The potential impact on the immune system and the related issues of a suppressed immune system.

Those individuals who are phobic of injections or unable to self inject may need assistance if they have some form of disability such as psoriatic arthrtis, this could therefore require extra support. So might not necessarily be advantageous over other treatment methods.

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.

Unable 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?

Unable to 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.

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 further choice and treatment options.

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

There would be less choice, although psoriasis does already have other similarly effective technologies available.

Without the introduction of newer technologies, patients may not get any benefit of improved care with 'older' treatments being used because they are already approved even though they are less effective or have problematical safety issues. There might also be less of an incentive on manufacturers to improve/develop treatments that are more targeted in psoriasis or improve the safety profiles of existing treatments.

Choice and healthy competition amongst manufacturers might improve cost of treatments and therefore lead to wider use and availability with the need to provide improved long term safety data, which would reassure clinicians and patients when deciding which treatment to try.

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

Patients who are phobic or who cannot self inject, although assistance would solve this issue.

Other Issues

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

Nothing to add.