# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## Patient/carer organisation submission (STA)

## Secukinumab for treating moderate to severe plaque psoriasis (ID718)

Thank you for agreeing to give us your views on this treatment that is being appraised by NICE and how it 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, and including health-related quality of life)
- the acceptability of different treatments and how they are given
- expectations about the risks and benefits of the treatment.

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 length of your response should not normally exceed 10 pages.

## *1. About you and your organisation*

**Your name:** [redacted]

**Name of your organisation:** Psoriasis Association

**Your position in the organisation:** [redacted]

**Brief description of the organisation:** Patient Support Organisation and Charity. The Psoriasis Association currently has around 2500 members who help to fund the organisation via an annual fee. Other sources of income include fundraising (individuals, legacies and trusts), investments and unrestricted educational grants from the Pharmaceutical Industry for projects.

In addition to traditional members, the Psoriasis Association regularly communicates with, or offers a platform enabling people whose lives are affected by the condition to communicate with one another via online forums on their own websites (4,000 registered users), Facebook Group (1, 600 members) and Twitter (4, 200 followers). The main Psoriasis Association website averages 45, 000 visits per month.

(For example: who funds the organisation? How many members does the organisation have?)

We are asking for your collective view as an organisation and will be asking patient experts for their individual input separately. If you have the condition, or care for someone with the condition, you may wish to complete a patient expert questionnaire to give your individual views as well.

## *2. Living with the condition*

**What is it like to live with the condition or what do carers experience when caring for someone with the condition?**

Psoriasis is a lifelong condition with varying degrees of severity. The patients for whom this treatment is intended, those with moderate to severe disease, will have a degree of psoriasis that will not only be visible to others, but also be itchy, painful and produce excess scales. The scales are unsightly, and can cause problems with employment and work colleagues in many industries.

Owing to the highly visible nature of psoriasis, and its unsightliness, patients can often adopt negative coping mechanisms such as avoiding social situations (in the hope of avoiding negative reactions from members of the general public). This can mean that the condition itself is isolating and lonely. This can in turn lead to adopting unhealthy lifestyle choices, such as alcohol and drug use, lack of exercise and smoking.

Patients with moderate to severe psoriasis have usually been through a long journey of treatment trial and error and expense. When psoriasis is first diagnosed, patients will usually be prescribed topical treatments (creams and ointments). Our latest membership survey found that people were spending on average two hours every day treating their (mild) psoriasis. This involves regularly moisturising the skin (essential in order to keep the skin comfortable, to help with itch and to reduce flakes from falling – having to share a desk at work can be very difficult for people with psoriasis), and applying creams and ointments with more active ingredients. The majority of respondents in our membership survey reported psoriasis impacting on their choice of clothing, from regularly "covering up" in the summer months in long sleeves and long trousers, to the colour of clothing on the top half of the body (men report frequently having light suits for work to help conceal the shedding of scales, whilst women consciously sought certain fabrics so as not to have clothing ruined by treatments). It is often unsustainable to treat psoriasis with topical treatments alone, and patients will need more help to cope with a flare, or to maintain the condition at a manageable level. The traditional next stage has been Ultraviolet Light Therapy, but for some patients this form of treatment is not considered owing to the time commitment required (attending the Dermatology Department three times per week for 10 weeks). Traditional systemic treatments for psoriasis would then be considered if the psoriasis was deemed to be moderate to severe in nature. It is vitally important however to measure, record and treat not only the physical symptoms of psoriasis, but the psychological impact the condition can have. Being a lifelong condition, the psychological impact may not initially be realised, which is why it is important for this assessment to be made over the course of the disease.

Psoriasis in high impact areas such as the hands, feet, face or genitals is not only a problem for people owing to the visibility of the condition. Deep cracks to the fingertips (not to mention nail psoriasis) can be disabling for those whose trade requires use of the hands and fingers (e.g. musicians, artists, mechanics, not to forget general office-based administration roles). Psoriasis on the feet can make walking difficult, even wearing shoes. Psoriasis on the face can be especially distressing, and we know people avoid intimate relationships so as not to have to expose genital psoriasis. For those in steady relationships, sexual relationships can be difficult owing to the pain experienced by genital psoriasis. People report deliberately not having children in case they too develop psoriasis. For those with moderate – severe psoriasis who do want children, their choice of treatment is limited owing to the teratogenicity of traditional systemic medications.

Psoriasis therefore can affect every stage of life to varying degrees – from bullying in school, through to difficulty writing in exams, choice of career, having children, holidays and long-term relationships. Access to treatments that are appropriate, suitable and reliable is vital.

## *3. Current practice in treating the condition*

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

The Psoriasis Association surveyed 173 patients, online in 2012. The top responses when asked “What is the most important treatment objective for your psoriasis?” were:-

1. Be able to live a normal everyday life (31.3%)
2. Long-term clearance (25%)
3. Total clearance now (18.8%)

The Psoriasis Association 2009 Membership Survey (1,564 completed surveys) asked what patients wanted most from their treatments. Rated 1 as not important and 4 as very important, the following were the top responses:-

1. Clearance in visible areas (mean = 3.51, standard deviation = 0.85)
2. General improvements in wellbeing (mean = 3.43, standard deviation = 0.80)
3. Clearance of scales (mean = 3.38, standard deviation = 0.75)

**What is your organisation's experience of currently available NHS care and of specific treatments for the condition? How acceptable are these treatments and which are preferred and why?**

Sadly the treatment, and access to treatments for people with psoriasis differs markedly across the country. Many people become frustrated with the health service as accessing treatment when required (i.e. at the beginning of a flare-up) can be extremely difficult. Patients with moderately severe psoriasis are often the most poorly treated – they report frustrations at not being referred on to specialist care, often being stuck at the GP with a Special Interest level, on sub-optimal topical treatments. Those with severe psoriasis, for whom other treatments have failed often report good relationships with their Dermatologist and Dermatology Nurse Specialist overseeing their biologic interventions. There is currently a major unmet need for systemic therapies for psoriasis that is moderate in severity, is too extensive for topical treatments, yet not severe enough to warrant biologics.

## *4. What do patients or carers consider to be the advantages of the treatment being appraised?*

Benefits of a treatment might include its effect on:

- the course and/or outcome of the condition
- physical symptoms
- pain
- level of disability
- mental health
- quality of life (such as lifestyle and work)
- other people (for example, family, friends and employers)
- ease of use (for example, tablets rather than injection)
- where the treatment has to be used (for example, at home rather than in hospital)

- any other issues not listed above

**Please list the benefits that patients or carers expect to gain from using the treatment being appraised.**

Following a period of training in injection technique, patients will be in a position to largely self-manage their treatment at home. The results of the trials of Secukinumab would indicate that patients should experience a high level of psoriasis clearance whilst using this treatment, allowing them to lead normal lives. Whilst there is data up to 52 weeks use of Secukinumab, further long-term data will be welcomed when feasible – the 52 week data is encouraging, and we know from patient surveys that long-term clearance is of great importance. Being able to lead a normal life is of great importance also, and it would appear that this treatment could offer that hope for many people suffering with psoriasis for whom a suitable treatment has not yet been found.

**Please explain any advantages that patients or carers think this treatment has over other NHS treatments in England.**

Secukinumab may work faster than other biologics currently approved for moderate – severe psoriasis, and for some people the speed in which the treatment can get the psoriasis under control is of great importance.

**If you know of any differences in opinion between patients or carers about the benefits of the treatment being appraised, please tell us about them.**

N/A

## *5. What do patients and/or carers consider to be the disadvantages of the treatment being appraised?*

Disadvantages of a treatment might include:

- aspects of the condition that the treatment cannot help with or might make worse
- difficulties in taking or using the treatment (for example, injection rather than tablets)
- side effects (for example, type or number of problems, how often, for how long, how severe. Please describe which side effects patients might be willing to accept or tolerate and which would be difficult to accept or tolerate)
- where the treatment has to be used (for example, in hospital rather than at home)

- impact on others (for example, family, friends and employers)
- financial impact on the patient and/or their family (for example, the cost of travel to hospital or paying a carer)
- any other issues not listed above

**Please list any concerns patients or carers have about current NHS treatments in England.**

Please see comments above regarding access to services at the beginning of a flare (re-accessing of services).

**Please list any concerns patients or carers have about the treatment being appraised.**

Long-term safety data – but this can only come with time.

**If you know of any differences in opinion between patients or carers about the disadvantages of the treatment being appraised, please tell us about them.**

## *6. Patient population*

**Are there any groups of patients who might benefit more from the treatment than others? If so, please describe them and explain why.**

Those for whom all other treatments have failed. Plus those for whom existing biologics are not considered, yet whose psoriasis is extensive in nature and / or difficult to treat.

**Are there any groups of patients who might benefit less from the treatment than others? If so, please describe them and explain why.**

## *7. Research evidence on patient or carer views of the treatment*

**Is your organisation familiar with the published research literature for the treatment?**

X Yes

**If you answered 'no', please skip the rest of section 7 and move on to section 8.**

**Please comment on whether patients' experience of using the treatment as part of their routine NHS care reflects the experiences of patients in the clinical trials.**

It is too early to comment on this aspect

**Do you think the clinical trials have captured outcomes that are important to patients? Are you aware of any limitations in how the treatment has been assessed in clinical trials?**

Itch is a big problem for patients with psoriasis, yet it is infrequently measured in clinical trials, and often overlooked in the clinical setting. A reduction in itch would be a significant improvement in psoriasis symptoms for many people.

**If the treatment being appraised is already available in the NHS, are there any side effects 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 (for example, qualitative studies, surveys and polls)?**

☐ Yes

**If yes, please provide references to the relevant studies.**


1. Bundy, C *et al* Psoriasis: snapshots of the unspoken: using novel methods to explore patients' personal models of psoriasis and the impact on well-being. *British Journal of Dermatology* 2014; **171** (4): 825-831

2. Anstey, A *et al* Extending psychosocial assessment of patients with psoriasis in the UK, using a self-rated, web-based survey. *Clinical and Experimental Dermatology* 2012; **37** (7): 735–740

3. Nash, A *et al* Psoriasis today: experiences of healthcare and impact on quality of life in a major UK cohort. *Primary Health Care Research and Development* 2014; http://dx.doi.org/10.1017/S1463423614000450


## *8. Equality*

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Protected characteristics are: age; being or becoming a transsexual person; being married or in a civil partnership;

being pregnant or having a child; disability; race including colour, nationality, ethnic or national origin; religion, belief or lack of religion/belief; sex; sexual orientation.

Please let us know if you think that recommendations from this appraisal could have an adverse impact on any particular groups of people, such as:

- excluding from full consideration any people protected by the equality legislation who fall within the patient population for which the treatment is/will be licensed;
- having a different impact on people protected by the equality legislation than on the wider population, e.g. by making it more difficult in practice for a specific group to access the treatment;
- any adverse impact on people with a particular disability or disabilities.

**Please let us know if you think that there are any potential equality issues that should be considered in this appraisal.**

**Are there groups of patients who would have difficulties using the treatment or currently available treatments? Please tell us what evidence you think would help the Committee to identify and consider such impacts.**

Those who may have psoriatic arthritis (or other forms of arthritis) affecting their fingers could find using the pre-filled syringe difficult, as could those with a needle phobia. It would be hoped that the manufacturer has factored in additional support for those who require it.

People who must travel, for work or domestic purposes, over extended periods have experienced difficulties and enforced treatment breaks as the injections are unstable over long journeys e.g. to Australia.

## *9. Other issues*

**Do you consider the treatment to be innovative?**

X☐ Yes

**If yes, please explain what makes it significantly different from other treatments for the condition.**

Secukinumab inhibits the protein interleukin-17A which is found in high concentrations in skin affected by psoriasis. This is the first treatment to target this protein.

**Are there any other issues that you would like the Appraisal Committee**

**to consider?**

## *10. Key messages*

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

- Psoriasis is a lifelong condition in which individuals respond differently to different treatments. For this reason a range of treatment options for all degrees of severity is required.
- There is currently unmet need in the treatment of people with moderate psoriasis (for whom topical treatments nor biologics are suitable).
- High impact sites such as the face, hands, feet and genitals should not be overlooked when defining treatment criteria (these sites will not produce a high PASI score).
- Itch should be considered as a treatment outcome.
-