**Healthcare professional group/clinical specialist statement**

Thank you for agreeing to give us a statement on your organisation's view of the technology and the way it should be used in the NHS.

Healthcare professionals can provide a unique perspective on the technology within the context of current clinical practice which is not typically available from the published literature.

To help you in making your statement, we have provided a template. The questions are there as prompts to guide you. It is not essential that you answer all of them.

Please do not exceed the 8-page limit.

**About you**

**Your name: Ms. Karina Jackson**

**Name of your organisation (if applicable): British Dermatological Nursing Group**

**Are you (tick all that apply):**

- ✓a specialist in the treatment of people with the condition for which NICE is considering this technology?

- ✓other? (please specify) Nursing representative on the Biological therapy Working Group, a sub-group of the British Association of Dermatologists and invited to represent the British Dermatological Nursing Group

**What is the expected place of the technology in current practice?**

How is the condition currently treated in the NHS?
*Severe psoriasis is currently managed with a range of systemic therapies such as methotrexate, ciclosporin, acitretin, photochemotherapy (PUVA) and biological drugs such as efalizumab, etanercept and infliximab via secondary or tertiary care specialists. This may be supported or substituted when necessary, by intensive topical therapy under specialist nursing supervision as an in-patient or day patient in secondary care. Patients with severe psoriasis may suffer considerable disability through their extensive skin disease, which have a significant psycho-social impact. Support through specialist nursing*

Is there significant geographical variation in current practice?
*No, but larger dermatology centres with tertiary services for severe psoriasis will have more experience and potentially more resources to use newer therapies.*

Are there differences of opinion between professionals as to what current practice should be?
*No. The British Association of Dermatologists published guidelines on the use of biological therapies in psoriasis (Smith et al 21005) and these have been adopted nationally by dermatologists. These will be further reviewed in 2007.*

What are the current alternatives (if any) to the technology, and what are their respective advantages and disadvantages?
*Alternatives include the other biological therapies and other standard systemic therapies (as detailed above). However the criteria for use of biological therapies is failure to respond to or intolerance / contraindication to standard systemic therapies, so standard therapies are likely to be exhausted by this point in the patient's treatment journey.*
*The sub-cutaneous injection biological therapies (efalizumab and etanercept) licensed for treatment of severe psoriasis are not as fast acting as inflximab nor are they as effective in terms of rapidity of effect. This has not been demonstrated in head to head trials but comparative efficacy data clearly demonstrates are more rapid response to therapy in infliximab above all other biological therapies to date. Sub-cutaneous injections are however more convenient to the patient as they are self administered at home, requiring fewer visits to secondary care. Other advantages of infliximab are treatment compliance, less frequent injections (every 8 weeks once established on therapy) and potential social aspects of care, coming into contact with the specialist team and other patients with severe psoriasis. There is a risk of infusion reaction and complications of intravenous cannulation, although in practice we do not experience this often.*

Are there any subgroups of patients with the condition who have a different prognosis from the typical patient?

Are there differences in the capacity of different subgroups to benefit from or to be put at risk by the technology?

In what setting should/could the technology be used – for example, primary or secondary care, specialist clinics?
*Infliximab is administered by IV infusion. This should ideally be undertaken in a specialist secondary care setting that specialises in dermatology. If a general infusion treatment centre is used this should be supported with specialist supervision from the dermatology medical and nursing team. It would be inappropriate to deliver treatment in primary care in the absence of specialist supervision.*

Would there be any requirements for additional professional input (for example, community care, specialist nursing, other healthcare professionals)?
*As above. The infliximab infusion is only one element of the patient's care and management. Specialist nursing care is an essential component in the holistic management of severe psoriasis. Additionally undertaking disease severity scoring (PASI) and subjective quality of life assessment will become a requirement for the UK psoriasis biologicals registry. Trained specialist nurses will be required to undertake these assessments along with other disease specific data.*

If the technology is already available, is there variation in how it is being used in the NHS?
*There may be minor variations in terms of the depth of pre-treatment screening and patient monitoring during and post infusion. Guidance is available in the drug SPC. There is also some practice of prescribing concomitant methotrexate when not contraindicated, in line with rheumatology practice.*

Is it always used within its licensed indications?
*No.*

If not, under what circumstances does this occur?
*Pustular psoriasis is a rarer sub-type of psoriasis which can be difficult to manage and life threatening if generalised and uncontrolled. Infliximab is not licensed for this type of psoriasis. There is no evidence of the safety and efficacy of infliximab in pustular psoriasis (neither is there for any other biological drug for this indication) however case report evidence shows favourable disease severity outcomes and no difference in side effect profile or risk (Smith et al 2006).*
*Inflixmab has also been used to treat severe acral disease (not yet published)*

Please tell us about any relevant **clinical guidelines** and comment on the appropriateness of the methodology used in developing the guideline and the specific evidence that underpinned the various recommendations.

British Association of Dermatologists guideline.
Smith CH, Anstey AV, Barker JN, Burden AD, Chalmers RJ, Chandler D, Finlay AY, Griffiths CE, Jackson K, McHugh NJ, McKenna KE, Reynolds NJ, Ormerod AD
British Association of Dermatologists guidelines for use of biological interventions in psoriasis 2005. Br J Dermatol. 2005 Sep;153(3):486-97

NICE is particularly interested in your views on how the technology, when it becomes available, will compare with current alternatives used in the UK. Will the technology be easier or more difficult to use, and are there any practical implications (for example, concomitant treatments, other additional clinical requirements, patient acceptability/ease of use or the need for additional tests) surrounding its future use?
*Once infliximab is approved for use the practical implications will be access to specialists with experience in the prescribing, monitoring and supervising treatment with specialist nursing support. There is also the issue of IV administration equipment, pharmacy support and clinical space to deliver the therapy.*

If appropriate, please give your view on the nature of any rules, informal or formal, for starting and stopping the use of the technology; this might include any requirements for additional testing to identify appropriate subgroups for treatment or to assess response and the potential for discontinuation.

If you are familiar with the evidence base for the technology, please comment on whether the use of the technology under clinical trial conditions reflects that observed in clinical practice. Do the circumstances in which the trials were conducted reflect current UK practice, and if not, how could the results be extrapolated to a UK setting? What, in your view, are the most important outcomes, and were they measured in the trials? If surrogate measures of outcome were used, do they adequately predict long-term outcomes?

What is the relative significance of any side effects or adverse reactions? In what ways do these affect the management of the condition and the patient's quality of life? Are there any adverse effects that were not apparent in clinical trials but have come to light subsequently during routine clinical practice?

**Any additional sources of evidence**

Can you provide information about any relevant evidence that might not be found by a technology-focused systematic review of the available trial evidence? This could be information on recent and informal unpublished evidence, or information from registries and other nationally coordinated clinical audits. Any such information must include sufficient detail to allow a judgement to be made as to the quality of the evidence and to allow potential sources of bias to be determined.

**Implementation issues**

The NHS is required by the Department of Health and the Welsh Assembly Government to provide funding and resources for medicines and treatments that have been recommended by NICE technology appraisal guidance. This provision has to be made within 3 months from the date of publication of the guidance.

If the technology is unlikely to be available in sufficient quantity, or the staff and facilities to fulfil the general nature of the guidance cannot be put in place within 3 months, NICE may advise the Department of Health and the Welsh Assembly Government to vary this direction.

Please note that NICE cannot suggest such a variation on the basis of budgetary constraints alone.

How would possible NICE guidance on this technology affect the delivery of care for patients with this condition? Would NHS staff need extra education and training? Would any additional resources be required (for example, facilities or equipment)?
*Nursing staff delivering the therapy will need to be able to cannulate the patient and administer the infusions safely. This may require local training. As before, clinical space (with access to oxygen, suction and emergency equipment) and IV administration equipment will be required and this will ideally be within a dermatology specialist department or with immediate support from the specialist team. The medical and nursing staff will need to be able to recognise and treat anaphylaxis or other infusion reactions. They will need to be able to undertake disease severity scoring and quality of life measures for the purpose of the biologicals registry.*