Professional organisation statement template

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: Michael J. Tidman

Name of your organisation British Association of Dermatologists

Who are you?

- The British Association of Dermatologists represents UK dermatologists, who, whilst not usually involved primarily in the management of psoriatic arthritis, often manage the cutaneous aspects of psoriasis in patients afflicted with psoriatic arthritis. The scope of the appraisal includes, as an outcome measure, an assessment of the effect of golimumab on concomitant cutaneous psoriasis.
- In accepting this invitation to participate in this appraisal process for golimumab in the treatment of psoriatic arthritis, opinions were sought from the Therapy & Guidelines sub-committee (Chair: M.J.Tidman), the Audit & Clinical Standards sub-committee and the Biologics register sub-committee of the BAD.

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

How is the condition currently treated in the NHS?
This is outlined in Appendix A. The development of the TNF-α inhibitors represent a significant advance in the management of recalcitrant psoriasis, both cutaneous and articular.

Is there significant geographical variation in current practice?
We are not aware of any such variation in the UK.

Are there differences of opinion between professionals as to what current practice should be?
Not that we are aware of in relation to psoriatic arthritis.

What are the current alternatives (if any) to the technology, and what are their respective advantages and disadvantages?
Other TNF-α inhibitors include adalimumab, etanercept and infliximab. We are not aware of significant differences between them in relation to psoriatic arthritis.

Are there any subgroups of patients with the condition who have a different prognosis from the typical patient?
None that are known to us in the context of psoriatic arthritis.

Are there differences in the capacity of different subgroups to benefit from or to be put at risk by the technology?
We are not aware of any such differences.

In what setting should/could the technology be used – for example, primary or secondary care, specialist clinics?
This technology should be supervised in specialist clinics in secondary care.

Would there be any requirements for additional professional input (for example, community care, specialist nursing, other healthcare professionals)?
Probably not, over and above the professional input already in place for other biologic therapies.

If the technology is already available, is there variation in how it is being used in the NHS? Is it always used within its licensed indications? If not, under what circumstances does this occur?
Golimumab is not yet generally available to the NHS, and is only available to registered users.

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.
The SIGN guideline on the management of psoriasis and psoriatic arthritis is due to be published in November 2010.

The advantages and disadvantages of the technology

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?

It is anticipated that golimumab, when it becomes available, will differ little from established biologic agents in respect of ease of use and practical implications for its future use.

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.

We are not aware of any such rules in the context of psoriatic arthritis.

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?

We are not sufficiently familiar with the evidence base for the efficacy of golimumab in psoriatic arthritis to comment.

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?

We are not sufficiently familiar with the side effect profile for golimumab in psoriatic arthritis to comment.

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.

No additional sources of information are known to us.

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)?

It is likely that golimumab is sufficiently similar to the other biologic agents available for the treatment of psoriatic arthritis that, if NICE technology appraisal guidance were to recommend golimumab, there would be little affect on the delivery of care to patients with psoriatic arthritis.