

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: [REDACTED]

Name of your organisation

British Thoracic Society

Are you (tick all that apply):

- a specialist in the treatment of people with the condition for which NICE is considering this technology? YES
- a specialist in the clinical evidence base that is to support the technology (e.g. involved in clinical trials for the technology)? NO
- an employee of a healthcare professional organisation that represents clinicians treating the condition for which NICE is considering the technology? If so, what is your position in the organisation where appropriate (e.g. policy officer, trustee, member etc.)? YES CF CLINIC DIRECTOR
- other? (please specify)

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

How is the condition currently treated in the NHS? Is there significant geographical variation in current practice? Are there differences of opinion between professionals as to what current practice should be? What are the current alternatives (if any) to the technology, and what are their respective advantages and disadvantages?

The condition is currently treated as stated in the final scope document. There is variation in practice, but this relates to the experience of individual clinicians, including the ability to obtain funding for expensive therapies, rather than geography. The alternative treatments are as stated in the scoping document. However, response to individual treatments in CF is variable, such that the more available, the better the chance of improving outcome – this new therapy will add to the number of therapies available, thus allowing more effective treatment to the group as a whole.

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?

There is no risk from this technology. Some patients with CF deteriorate more quickly than others, for reasons unknown. It is not clear whether this new technology will have a part in preventing this.

In what setting should/could the technology be used – for example, primary or secondary care, specialist clinics? Would there be any requirements for additional professional input (for example, community care, specialist nursing, other healthcare professionals)?

This should only be used as part of a multidisciplinary team approach to CF care, currently practised in specialist tertiary clinics. Patients will use this in the community as part of their chronic disease management plan.

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?

I am not aware that the technology is already available, other than for patients who undertook the original trials.

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.

There are several sets of guidelines looking at nebulised therapy in CF patients – all these are consensus documents produced by experts in the field reviewing the published literature and grading it according to its scientific rigour.

These guidelines include:

UK CF Trust:

- Standards of Care - Standards for the Clinical Care of Children and Adults with Cystic Fibrosis in the UK 2001. May 2001.
- Antibiotic Treatment for Cystic Fibrosis. Third edition. May 2009.

Cystic Fibrosis Worldwide: Standards of care for patients with cystic fibrosis: a European Consensus 2005

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?

The new technology will be used in tandem with existing inhaled mucolytic treatments, and in some cases will replace them. It is unlikely that CF patients will be asked to use all 3 at the same time.

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.

CF patients starting this treatment should have objective measures of its utility made, including quality of life measures.

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?

Not applicable to me

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?

Side-effects of this medication are those related to local irritative effects only.

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

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)?

There should be no problems with supply or staff training but if this medication is expensive funding streams would need to be agreed with purchasers which may delay its commencement.