Appendix G - professional organisation submission template

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Single Technology Appraisal (STA)

Nintedanib for treating idiopathic pulmonary fibrosis [ID752]

Thank you for agreeing to make a submission 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 submission, 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)?
- 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)?
- other? (please specify) **Representative of the British Thoracic Society**

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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?

Currently, pirfenidone = standard practice in specialist centres if FVC 50-80%. Advantages of nintedanib – lower tablet burden, no skin rashes, fewer nausea side effects, impact (small) on acute exacerbations. Disadvantages –no overt mortality signal, diarrhoea side effects. Patients excluded if on anti-coagulant therapy. Desperate need for 2nd agent in view of toxicity profile of pirfenidone. Pirfenidone represented a step-change in the management of IPF, and nintedanib is at least as good as pirfenidone.

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?
False classification into mild/moderate/severe unhelpful. Patients with *progressive* disease at any severity even if 'normal' or indeed "supra-normal FVC" should be commenced on Rx.

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)?
Specialist ILD centres only, need ILD nurse

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?
Used until recently in patient access scheme ("Individual patient supply programme") and clinical trials. Inequality of access in UK to access scheme (local contract issues)

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.

No clinical guideline recommending nintedanib at present.

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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?
Easier to use than pirfenidone – fewer tablets, fewer side effects (esp rash and nausea). Similar blood test monitoring to pirfenidone.
Anti-coagulation therapy contra-indicated. Care needed with multiple ant-platelet agents.

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.
It is imperative there is no upper cap on FVC – this was incredibly unhelpful with pirfenidone. The stopping rule for pirfenidone was not based on medical evidence nor expert opinion and patients have suffered as a consequence.

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?
The nintedanib clinical trials were pragmatic studies, and thus particularly generalisable. The INPULSIS study which has provided the evidence for the use of nintedanib for IPF very much followed UK clinical practice. They permitted a wide range of patients into study- any FVC>50%; definite and probable cases of IPF. Its protocol was well matched to the UK.
We strongly believe that the FVC change is a clear surrogate for mortality – it is likely therefore that nintedanib will have a similar magnitude of (mortality) effect to pirfenidone (once the statistical techniques are teased out).

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?
Diarrhoea in 60% reported – at least once in a year, mostly very mild. This is borne out in our clinical experience and can be managed by the additional use of loperamide. It is well tolerated, with minimal additional side effects seen (communication from centres currently using in UK).

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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.

Not as such – evidence from sources listed. Data submitted to national meetings suggests nintedanib is beneficial.

Implementation issues

The NHS is required by the Department of Health 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 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)?

Most specialist centres are prescribing nintedanib through the individual patient supply programme and many patients remain on the drug via the open label phase of prior clinical trials (demonstration of efficacy); as such most specialist centres will have clinical experience of using the therapy ,and in addition ILD nurses will already have systems for dealing with patient side effects.

Equality

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NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that this appraisal:

- could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which [the treatment(s)] is/are/will be licensed;
- could lead to recommendations that have 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 technology;
- could lead to recommendations that have any adverse impact on people with a particular disability or disabilities.

Please tell us what evidence should be obtained to enable the Committee to identify and consider such impacts.

We have no concerns.