NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Single Technology Appraisal (STA)

Nintedanib for treating idiopathic pulmonary fibrosis [ID752]

Thank you for agreeing to give us a statement on your 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: Dr Toby Maher

Name of your organisation:

1) **Chair, Specialised Respiratory Medicine, Clinical Reference Group, NHS England**
2) **Consultant Respiratory Physician and NIHR Clinician Scientist, Royal Brompton Hospital, London**

Are you (tick all that apply):

- a specialist in the treatment of people with the condition for which NICE is considering this technology? x
- a specialist in the clinical evidence base that is to support the technology (e.g. involved in clinical trials for the technology)? x
- 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.)? x Chair, Specialised Respiratory Medicine, Clinical Reference Group, NHS England
- other? (please specify)

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

Patients with idiopathic pulmonary fibrosis in England are generally diagnosed and their initial treatment managed in Specialist Interstitial Lung Disease Centres. Diagnosis and management is usually in accordance with the NICE guidelines on IPF. The only pharmacotherapy currently available is pirfenidone and this is used for patients as per the NICE Pirfenidone TA. Because of the lung function criteria stipulated in this TA less than half of patients have access to treatment. The remainder have, in some cases, the option of clinical trials, otherwise the only available treatments are symptom based and palliative.

If nintedanib is approved for the treatment of IPF then I would anticipate that initiation of treatment in England would be through existing specialist centres with subsequent monitoring and management of complications occurring through shared care patient pathways with secondary care services.

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The advantages and disadvantages of the technology

IPF has a median survival of only 3 years and therefore represents a huge unmet medical need. The only current alternative to nintedanib is pirfenidone. Based on clinical trial evidence the two drugs have similar efficacy. Both have some tolerability issues but these differ. Pirfenidone causes nausea and photosensitive rash in up to a quarter of patients whilst nintedanib predominantly causes diarrhoea. Nintedanib has a slight advantage in being a twice daily, two tablet regimen compared to pirfenidone's three times daily, 9 tablet regimen. Approximately a quarter of patients are unable to tolerate pirfenidone therapy and for these patients there is no existing alternative treatment.

At present there are no means for stratifying patients in to those who may respond best to one or other of the available therapies. In my opinion the inclusion criteria for treatment should mirror those used in the phase 3 trials i.e. a diagnosis of IPF and an FVC>50% predicted. I participated in the clinical trials (as UK Lead Investigator) and I believe that the circumstances of the trial mirror clinical practice for this patient group.

The best trial measure for IPF outcomes is serial change in FVC. However, in the clinic setting this measure is less well suited to determining individual patient response to therapy. One of the major challenges in treating IPF is that because therapy is simply expected to slow disease worsening, the treating clinician can anticipate that treated patients' FVC will continue to decline. As such, there is no effective way to determine whether treatment is working at the level of the individual (because FVC will get worse over time even when treatment is successful – albeit at a slower rate than it would have done without treatment). This lack of a specific measurement of treatment effectiveness makes it difficult to develop stopping rules for nintedanib.

In terms of side effects it is anticipated that, like pirfenidone, those of nintedanib will lead to a proportion of patients being unable to tolerate long term treatment. However, the anticipation remains that the majority of patients will not get side effects and thus slowing the rate of disease decline will lead to improved survival and prolongation of the time spent without significant respiratory restriction and thus prolonged maintenance of quality of life.

In the period of time since nintedanib has been approved in the US and Europe, no new adverse events or side effects have come to light

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Equality and Diversity

n/a

Any additional sources of evidence

n/a

Implementation issues

In England, the existence of specialist ILD services should ensure that the necessary infrastructure is in place to deliver this technology to patients with IPF

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