NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Proposed Health Technology Appraisal

Nintedanib for treating idiopathic pulmonary fibrosis

Draft scope (pre-referral)

Draft remit/appraisal objective

To appraise the clinical and cost effectiveness of nintedanib within its licensed indication for treating idiopathic pulmonary fibrosis.

Background

Idiopathic pulmonary fibrosis (IPF) is a chronic, progressive lung disease in which scarring (fibrosis) occurs. The cause of IPF is unknown although it is thought to be related to an abnormal immune response to an unknown cause. It is a difficult disease to diagnose and requires a multidisciplinary team. Most people with IPF experience symptoms of breathlessness, which may initially be only on exertion. Cough, with or without sputum, is a common symptom. Over time, these symptoms are associated with a decline in lung function, reduced quality of life and death.

The median survival for people with IPF in the UK is approximately 3 years from the time of diagnosis. However, about 20% of people with IPF survive for more than 5 years. The rate of disease progression can vary greatly. Prognosis is difficult to estimate at the time of diagnosis and may only become apparent after a period of careful follow-up.

The incidence of IPF is approximately 8 to 9 per 100,000 person-years, which equates to more than 5,000 new diagnoses each year in the UK. The incidence is higher in men than women, and increases with age (median age of presentation is 70 years). IPF co-exists with chronic obstructive pulmonary disease in around 8-15% of people.

The aim of treatment is to manage the symptoms and slow progression. NICE clinical guideline No. 163 on the diagnosis and management of suspected idiopathic pulmonary fibrosis recommends that best supportive care (including symptom relief, management of co-morbidities, withdrawal of therapies suspected to be ineffective or causing harm and end of life care) should be offered to people from diagnosis and be tailored according to disease severity, rate of progression and the person's preference. If pharmacological treatment is considered appropriate, the guideline recommends use of pirfenidone if a person's forced vital capacity (FVC) is between 50% and 80% of their expected value in line with recommendations in NICE technology appraisal guidance No. 282. Pirfenidone treatment should be stopped if the person's FVC falls by 10% or more within 12 months after treatment started. Oral N-acetylcysteine is not currently licensed for IPF but is used in clinical practice. Lung transplantation is an option if there are no contraindications.

The technology

Nintedanib (brand name unknown, Boehringer Ingelheim) targets 3 growth factor receptors involved in pulmonary fibrosis. The mechanism of nintedanib is not fully understood but it is thought that by blocking the signalling pathways involved in fibrotic processes, nintedanib may reduce disease progression by slowing the decline of lung function. It is administered orally.

Nintedanib does not currently have a UK marketing authorisation for treating IPF. It is being studied in clinical trials compared with placebo in adults who have been diagnosed with IPF.

Intervention(s)	Nintedanib
Population(s)	Adults with idiopathic pulmonary fibrosis

Comparators	• Best supportive care
	• Pharmacological interventions including:
	  ○ Pirfenidone (where appropriate)
	  ○ N-acetylcysteine

Outcomes	The outcome measures to be considered include: • pulmonary function parameters • physical function • exacerbation rate • progression-free survival • mortality • adverse effects of treatment • health-related quality of life.
Economic analysis	The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year. The reference case stipulates that the time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared. Costs will be considered from an NHS and Personal Social Services perspective. The availability of any patient access schemes for the intervention or comparator technologies should be taken into account.

Other considerations	Guidance will only be issued in accordance with the marketing authorisation or CE marking. Where the wording of the therapeutic indication does not include specific treatment combinations, guidance will be issued in the context of the evidence that has underpinned the marketing authorisation granted by the regulator.
Related NICE recommendations and NICE Pathways	Related Technology Appraisals: Technology Appraisal No. 282, April 2013, 'Pirfenidone for treating idiopathic pulmonary fibrosis'. Review Proposal Date TBC. Related Guidelines: Clinical Guideline No.163, July 2013, 'Idiopathic pulmonary fibrosis: The diagnosis and management of suspected idiopathic pulmonary fibrosis'. Review Proposal Date TBC. Related Quality Standards: Quality Standard in progress, 'Idiopathic pulmonary fibrosis'. Expected Publication Date January 2015. http://www.nice.org.uk/guidance/qualitystandards/qualitystandards.jsp Related NICE Pathways: NICE pathway: Idiopathic pulmonary fibrosis, Pathway created June 2013. http://pathways.nice.org.uk/pathways/idiopathic-pulmonary-fibrosis
Related National Policy	National Service Frameworks: Older People Department of Health, November 2013, 'NHS Outcomes Framework 2014-2015'.

Questions for consultation

Have all relevant comparators for nintedanib been included in the scope?

- Which treatments are considered to be established clinical practice in the NHS for IPF?

Are there any subgroups of people in whom nintedanib is expected to be more clinically effective and cost effective or other groups that should be examined separately?

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 the

proposed remit and scope may need changing in order to meet these aims. In particular, please tell us if the proposed remit and scope:

- could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which nintedanib 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 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.

Where do you consider nintedanib will fit in the existing NICE pathway 'idiopathic pulmonary fibrosis'?

Do you consider nintedanib to be innovative in its potential to make a significant and substantial impact on health-related benefits and how it might improve the way that current need is met (is this a 'step-change' in the management of the condition)?

Do you consider that the use of nintedanib can result in any potential significant and substantial health-related benefits that are unlikely to be included in the QALY calculation?

Please identify the nature of the data which you understand to be available to enable the Appraisal Committee to take account of these benefits.

NICE intends to appraise this technology through its Single Technology Appraisal (STA) Process. We welcome comments on the appropriateness of appraising this topic through this process. (Information on the Institute's Technology Appraisal processes is available at http://www.nice.org.uk/aboutnice/howwework/devnicetech/technologyappraisalprocessguides/technology_appraisal_process_guides.jsp).