**NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE**

**Health Technology Evaluation**

# Nerandomilast for treating idiopathic pulmonary fibrosis or progressive pulmonary fibrosis ID6446

**Draft scope**

## Draft remit/evaluation objective

To appraise the clinical and cost effectiveness of nerandomilast within its marketing authorisation for treating idiopathic pulmonary fibrosis or progressive pulmonary fibrosis.

## Background

Interstitial lung disease (ILD) is an overarching term used to describe a large group of many different and often rare disorders that cause inflammation or scarring (fibrosis) of the functional lung tissue. Some ILDs progress and become fibrotic and are referred to as progressive fibrosing ILD (PF-ILD).

Idiopathic pulmonary fibrosis (IPF) is a chronic PF-ILD of unknown cause. It is a difficult disease to diagnose and requires a multidisciplinary team. Progressive pulmonary fibrosis (PPF) is a form of PF-ILD occurring in cases other than IPF. It is defined based on clinical symptoms, lung function and chest imaging, regardless of the underlying condition.[1]

IPF and PPF have similar pathogenetic mechanisms and disease behaviours.[1] The most common symptoms are breathlessness (which may initially be only on exertion), cough, fatigue and chest pain. Over time, these symptoms are associated with a decline in lung function, reduced quality of life, disability and shortened life expectancy.

In the UK around 32,500 people are living with IPF, a prevalence of around 50 per 100,000.[2] There are around 6,000 new cases of IPF diagnosed every year.[2] The prevalence of PPF is difficult to measure as data are usually for specific conditions. Sarcoidosis and connective tissue disease-associated ILD (CTD-ILD) are common types of PPF. The prevalence of sarcoidosis is around 230 per 100,000 and it is estimated that 3,393 people were diagnosed with the condition in England in 2023.[3] The estimated incidence rate of CTD-ILD is 7.96 per 100,000 person-years.[4]

Established clinical management for IPF includes treatment with antifibrotic therapy alongside pulmonary rehabilitation and cessation of smoking and drugs associated with pulmonary toxicity.[5] For PPF, established clinical management may include antifibrotic therapy, immunosuppresants, corticosteroids, infliximab or rituximab.[6] NICE technology appraisals 379 and 864 recommend nintedanib for treating idiopathic pulmonary fibrosis. NICE technology appraisal 747 recommends nintedanib for treating chronic progressive fibrosing interstitial lung diseases . NICE technology appraisal 504 recommends pirfenidone for treating idiopathic pulmonary fibrosis.

## The technology

Nerandomilast (brand name unknown, Boehringer Ingelheim) does not currently have a marketing authorisation in the UK for treating idiopathic pulmonary fibrosis or progressive pulmonary fibrosis. It has been studied in double-blind, randomised clinical trials for treating idiopathic pulmonary fibrosis and other types of progressive fibrosing interstitial lung diseases.

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| **Intervention(s)** | Nerandomilast |
| **Population(s)** | People with idiopathic pulmonary fibrosis or progressive pulmonary fibrosis |
| **Subgroups** | If the evidence allows the following subgroups will be considered:<br>• Idiopathic pulmonary fibrosis<br>• Progressive pulmonary fibrosis<br>• Disease severity defined by Forced Vital Capacity (FVC) (such as above or below 80% FVC) |
| **Comparators** | Established clinical management without nerandomilast, including but not limited to:<br>For idiopathic pulmonary fibrosis:<br>• nintedanib<br>• pirfenidone<br>• best supportive care.<br>For progressive pulmonary fibrosis:<br>• nintedanib<br>• immunosuppressants, such as azathioprine, cyclophosphamide or mycophenolate<br>• corticosteroids<br>• infliximab<br>• rituximab<br>• best supportive care. |

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| **Outcomes** | The outcome measures to be considered include:<br>• pulmonary function<br>• physical function<br>• exacerbation rate<br>• progression-free survival<br>• lung transplantation<br>• mortality<br>• adverse effects of treatment<br>• 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.<br>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.<br>Costs will be considered from an NHS and Personal Social Services perspective.<br>The availability of any commercial arrangements for the intervention, comparator and subsequent treatment technologies will be taken into account.<br>The availability and cost of biosimilar and generic products should be taken into account. |
| **Other considerations** | Guidance will only be issued in accordance with the marketing authorisation. Where the wording of the therapeutic indication does not include specific treatment combinations, guidance will be issued only in the context of the evidence that has underpinned the marketing authorisation granted by the regulator. |
| **Related NICE recommendations** | **Related technology appraisals:**<br>Nintedanib for treating idiopathic pulmonary fibrosis when forced vital capacity is above 80% predicted (2023) NICE technology appraisal guidance 864<br>Nintedanib for treating progressive fibrosing interstitial lung diseases. (2021) NICE Technology appraisal guidance 747. Review date to be confirmed.<br>Pirfenidone for treating idiopathic pulmonary fibrosis (2018) NICE technology appraisal guidance 504<br>Nintedanib for treating idiopathic pulmonary fibrosis (2016) NICE technology appraisal guidance 379 |

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| | **Related technology appraisals in development:**<br>Nintedanib for treating fibrosing interstitial lung disease in people aged 6 to 17. NICE technology appraisal guidance [ID6194] Publication expected: to be confirmed<br>**Related NICE guidelines:**<br>Idiopathic pulmonary fibrosis in adults: diagnosis and management (2013) NICE Clinical Guideline 163. Last updated: 23 May 2017 |

**Questions for consultation**

Where do you consider nerandomilast will fit into the existing care pathway for idiopathic pulmonary fibrosis and progressive pulmonary fibrosis?

To what extent does the definition of 'progressive pulmonary fibrosis' align with the definition of 'progressive fibrosing interstitial lung disease excluding idiopathic pulmonary fibrosis'?

To what extent do the comparators listed in the scope reflect established clinical management?

What is considered best supportive care for idiopathic pulmonary fibrosis?

What is considered best supportive care for progressive pulmonary fibrosis?

Please select from the following, will nerandomilast be:

A. Prescribed in primary care with routine follow-up in primary care
B. Prescribed in secondary care with routine follow-up in primary care
C. Prescribed in secondary care with routine follow-up in secondary care
D. Other (please give details):

For comparators and subsequent treatments, please detail if the setting for prescribing and routine follow-up differs from the intervention.

Would nerandomilast be a candidate for managed access?

Do you consider that the use of nerandomilast can result in any potential 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 committee to take account of these benefits.

Please indicate if any of the treatments in the scope are used in NHS practice differently than advised in their Summary of Product Characteristics. For example, if the dose or dosing schedule for a treatment is different in clinical practice. If so, please indicate the reasons for different usage of the treatment(s) in NHS practice. If stakeholders consider this a relevant issue, please provide references for data on the efficacy of any treatments in the pathway used differently than advised in the Summary of Product Characteristics.

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 nerandomilast 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.

NICE intends to evaluate this technology through its Single Technology Appraisal process. (Information on NICE's health technology evaluation processes is available at https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/changes-to-health-technology-evaluation).

**References**

1. Kang HK, Song JW. Progressive Pulmonary Fibrosis: Where Are We Now? Tuberc Respir Dis (Seoul). 2024 Apr;87(2):123-133. doi: 10.4046/trd.2023.0119. Epub 2023 Dec 18.

2. Snell N, Strachan D, Hubbard R, et al P272 Epidemiology of idiopathic pulmonary fibrosis in the uk: findings from the british lung foundation's 'respiratory health of the nation' project Thorax 2016;71:A236.

3. Bechman, Katie et al. Incidence, prevalence, and mortality of sarcoidosis in England: a population-based study. The Lancet Regional Health – Europe, Volume 53, 101283

4. Gonnelli F, Eleangovan N, Smith U, Heatley H, Navarantam V, Corte TJ, Price DB, Carter V, Bonifazi M, Fermoyle CC, Hubbard R. Incidence and survival of interstitial lung diseases in the UK in 2010-2019. ERJ Open Res. 2025 Mar 3;11(2):00823-2024. doi: 10.1183/23120541.00823-2024.

5. BMJ Best Practice. Idiopathic pulmonary fibrosis. Available at: https://bestpractice.bmj.com/topics/en-gb/446/treatment-algorithm. Accessed August 2025

6. BMJ Best Practice. Sarcoidosis. Available at: Sarcoidosis - Treatment algorithm | BMJ Best Practice. Accessed August 2025