NICE National Institute for Health and Care Excellence

Putting NICE guidance into practice

Resource impact report:
Nintedanib for treating idiopathic pulmonary fibrosis when forced vital capacity is above 80% (TA864)

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Summary

NICE has recommended nintedanib as an option for treating idiopathic pulmonary fibrosis in adults, only if: they have a forced vital capacity of above 80% of predicted. Nintedanib is only recommended if the company provides it according to the commercial arrangement.

We estimate that:

- 5,300 people with idiopathic pulmonary fibrosis (IPF) are currently eligible to start treatment with nintedanib (prevalent population, including people diagnosed within the last year).
- 1,700 people who are newly diagnosed each year with IPF are eligible to start treatment with nintedanib after adjusting for population growth (incident population).
- 1,300 people will receive treatment with nintedanib from year 2027/28 onwards once market share has reached 63%. This is shown in table 1.
- The average treatment period for people who continue treatment is 2 years.
- Around 36% of people discontinue treatment in their first year, with an average treatment duration of 10 months.
- Around 5,400 additional monitoring appointments are needed in England from year 2027/28 onwards for people receiving nintedanib (see table 2 below).

Table 1 Estimated number of people in England receiving nintedanib

	2023/24	2024/25	2025/26	2026/27	2027/28
Market share for nintedanib (%)	30	40	50	60	63
Population starting treatment with nintedanib each year	1,600	700	800	1,000	1,000
People who receive a full year of treatment treatment each year*	1,000	1,400	900	1,200	1,300

*This includes people continuing treatment from the previous year and adjusts for people who discontinue treatment. Further analysis is given in the resource impact template.

Table 2 Estimated number of additional monitoring appointments

	2023/24	2024/25	2025/26	2026/27	2027/28
Number of appointments*	4,400	5,900	3,900	4,800	5,400

*The uptake from the eligible population currently diagnosed and awaiting treatment is profiled in the first 2 years of the guidance being implemented, after which uptake is assumed to be from newly diagnosed cases. This results in more appointments in the short term. Further analysis is given in the resource impact template.

This report is supported by a local resource impact template because the list price of nintedanib has a discount that is commercial in confidence. The discounted price of nintedanib can be put into the template and other variables may be amended.

This technology is commissioned by NHS England. Providers are Specialist Respiratory Centres.

1 Nintedanib

1.1 NICE has recommended nintedanib as an option for treating idiopathic pulmonary fibrosis in adults, only if: they have a forced vital capacity of above 80% of predicted. Nintedanib is only recommended if the company provides it according to the commercial arrangement.

1.2 The recommendation is not intended to affect treatment with nintedanib that was started in the NHS before this guidance was published. People having treatment outside this recommendation may continue without change to the funding arrangements in place for them before this guidance was published, until they and their NHS clinician consider it appropriate to stop.

1.3 Currently, the only option for people with idiopathic pulmonary fibrosis with a forced vital capacity (FVC) above 80% of predicted is best supportive care.

1.4 Nintedanib is currently recommended for people who have FVC between 50% and 80% (TA379). A further option for this group is pirfenidone (TA504). This appraisal only focusses on the population who have FVC>80%.

1.5 Clinical trial evidence suggests that nintedanib slows the decline of lung function compared with placebo in people with idiopathic pulmonary fibrosis with an FVC above 80%. In addition, long-term evidence suggests that the effect of nintedanib is maintained over time. This will, in time, increase the prevalence of people who have IPF with FVC>80%.

2 Resource impact of the guidance

We estimate that:

- 5,300 people with idiopathic pulmonary fibrosis (IPF) are currently eligible to start treatment with nintedanib (prevalent population, including people diagnosed within the last year).
- 1,700 people who are newly diagnosed each year with IPF are eligible to start treatment with nintedanib after adjusting for population growth (incident population).
- 1,300 people will receive treatment with nintedanib from year 2027/28 onwards once market share has reached 63%. This is shown in table 3.
- The average treatment period for people who continue treatment is 2 years.
- Around 36% of people discontinue treatment in their first year, with an average treatment duration of 10 months.
- Around 5,400 additional monitoring appointments are needed in England from year 2027/28 onwards for people receiving nintedanib (see table 4 below).

2.1 The current treatment and future uptake figure assumptions are based on clinical expert opinion and are shown in the resource impact template. Table 3 shows the number of people in England who are estimated to receive nintedanib by financial year.

Table 3 Estimated number of people receiving nintedanib using NICE assumptions

	2023/24	2024/25	2025/26	2026/27	2027/28
Market share for nintedanib (%)	20	30	40	50	63
Population starting treatment with nintedanib each year	1,600	700	800	1,000	1,000
People who receive a full year of treatment each year*	1,000	1,400	900	1,200	1,300

*This includes people continuing treatment from the previous year and adjusts for people who discontinue treatment. Further analysis is given in the resource impact template.

Table 4 Estimated number of additional monitoring appointments

	2023/24	2024/25	2025/26	2026/27	2027/28
Number of appointments*	4,400	5,900	3,900	4,800	5,400

*The uptake from the eligible population currently diagnosed and awaiting treatment is profiled in the first 2 years of the guidance being implemented, after which uptake is assumed be from newly diagnosed cases. This results in more appointments in the short term. Further analysis is given in the resource impact template.

2.2 This report is supported by a local resource impact template. Nintedanib has a commercial arrangement (simple patient access scheme). This makes nintedanib available to the NHS with a discount. The size of the discount is commercial in confidence. It is the company's responsibility to let relevant NHS organisations know details of the discount.

Savings and benefits

2.3 Early intervention from the point of diagnosis or when deemed appropriate by the treating clinician has the benefit of slowing decline in lung function and reduces the rate at which symptoms, functional capacity and quality of life worsen.

3 Implications for commissioners

3.1 This technology is commissioned by NHS England. Providers are Specialist Respiratory Centres. Integrated care systems commission existing secondary and primary care services supporting the local care of people with IPF as determined by the Specialised Respiratory Centres.

3.2 More frequent monitoring is needed for people receiving nintedanib than for people receiving best supportive care. Based on standard care for people with FVC between 50% and 80% who receive nintedanib, this is at monthly intervals for at least 3 months by a specialist hospital team and if stable, every 3 months thereafter by local hospitals. The same level of monitoring is also required for people with FVC >80%. People receiving best supportive care require 3 visits per year. This may have a

significant local capacity impact for some specialist respiratory services.

3.3 Because the treatment slows the decline in lung function, having this treatment option at an earlier stage of the disease will, in time, increase the prevalence of people who have IPF with FVC>80%. This effect has not been modelled in the resource impact template.

3.4 Nintedanib falls within the programme budgeting category 11X 'Problems of the respiratory system – other'.

4 How we estimated the resource impact

The population

4.1 The prevalence of IPF is estimated to be 0.06% (adjusted for England population, around 26,400 people) [British Lung Foundation IPF statistics]. Based on clinical opinion, 20% of this population (5,300 people) currently have FVC of >80% and be eligible to start treatment in year 1 (2023/24).

4.2 The incidence of IPF is estimated to be 0.01% (adjusting for England population, around 4,200 people) [British Thoracic Society Annual Report 2019]. Around 40% of this population (1,700 people) present with FVC>80% [IPF in the UK British Thoracic Society electronic registry 2013 to 2019] and eligible to start treatment from 2027/28 after adjusting for population growth.

Table 5 Number of people eligible for treatment in England

Population	Proportion of previous row (%)	Number of people (prevalence)	Proportion of previous row (%)	Number of people (incidence)
Adult population 2022/23		44,456,850		
Adult population forecast in 2026/27				46,263,200
Prevalence of IPF[1] / Incidence of IPF[2]	0.06	26,400	0.01	4,200
Percentage of people diagnosed with FVC>80%[3]	20	5,300	39.5	1,700
Total number of people eligible to start treatment with nintedanib		5,300		1,700
Total number of people estimated to start treatment with nintedanib in 2023/4[4]	30	**1,600**		
Total number of people estimated to start treatment with nintedanib from 2027/28[5]			63	**1,000**

[1] British Lung Foundation IPF statistics 2004-2012
[2] British Thoracic Society Annual Report 2019
[3] For people currently diagnosed (prevalent population) this is based on clinical expert opinion. For people newly diagnosed: [IPF in the UK British Thoracic Society electronic registry 2013 to 2019]
[4] Clinical expert opinion including currently diagnosed people awaiting treatment.
[5] Company estimate.

Assumptions

4.3 The resource impact template assumes that:

- In the first year, there is a prevalent population eligible for treatment (which includes people who have been diagnosed with IPF in the last year). From year two onwards the eligible population is based on incidence only.
- 20% of people in the prevalent population are expected to have FVC >80% and 39.5% of people in the incident population are expected to have FVC >80%.
- 30% of people currently diagnosed who have FVC >80% receive treatment in 2023/24, this considers the part year effect of people starting treatment in year

- Around 36% of people discontinue treatment within their first year.
- People who discontinue receive an average of 10 months treatment.
- People revert to best supportive care if they discontinue nintedanib and their FVC is still greater than 80%. If there FVC is between 50% and 80%, treatment options include nintedanib (TA379) and pirfenidone (TA504)
- No additional monitoring visits are assumed in year for people who discontinue and revert to best supportive care. This is because 5 attendances are assumed to take place in the first year of treatment with nintedanib.
- The average length of treatment for people who don't discontinue within their first year is 2 years (INPULSIS studies)
- 22% of people receive nintedanib through secondary care prescribing (collected at monitoring appointments) with 78% receiving nintedanib via homecare. A weighted average cost is assumed in the resource impact template.

About this resource impact report

This resource impact report accompanies the NICE guidance on Nintedanib for treating idiopathic pulmonary fibrosis when forced vital capacity is above 80% [TA864] and should be read with it.