

1	<p>Treatment & Condition</p> <p>Nintedanib (Ofev[®]) for treating idiopathic pulmonary fibrosis</p>																					
2	<p>Associated appraisal body & Summary of ruling</p> <p>NICE technology appraisal guidance [TA379] (January 2016)</p> <p>Nintedanib (Ofev[®]) is recommended as an option for treating idiopathic pulmonary fibrosis, only if:</p> <ul style="list-style-type: none"> • the person has a forced vital capacity (FVC) between 50% and 80% of predicted; • the company provides nintedanib with the discount agreed in the patient access scheme; and, • treatment is stopped if disease progresses (a confirmed decline in per-cent predicted FVC of 10% or more) in any 12-month period. 																					
3	<p>Number of people in Northern Ireland expected to take up service/therapy (including new cases per year)</p> <p>The table below is based on the Resource Impact Report that accompanies NICE TA379.</p> <table border="1" data-bbox="245 1144 1437 1827"> <thead> <tr> <th colspan="3" data-bbox="245 1144 1437 1245">Estimated number of people eligible for treatment with nintedanib in Northern Ireland</th> </tr> <tr> <th data-bbox="245 1245 1054 1346">Population</th> <th data-bbox="1054 1245 1235 1346">Proportion</th> <th data-bbox="1235 1245 1437 1346">Number of people</th> </tr> </thead> <tbody> <tr> <td data-bbox="245 1346 1054 1417">Total NI population</td> <td data-bbox="1054 1346 1235 1417"></td> <td data-bbox="1235 1346 1437 1417">1,840,498</td> </tr> <tr> <td data-bbox="245 1417 1054 1489">Prevalence of IPF</td> <td data-bbox="1054 1417 1235 1489">0.0234%</td> <td data-bbox="1235 1417 1437 1489">431</td> </tr> <tr> <td data-bbox="245 1489 1054 1624">Number of people eligible for treatment with nintedanib - proportion with forced vital capacity (FVC) between 50% and 80% of predicted</td> <td data-bbox="1054 1489 1235 1624">50%</td> <td data-bbox="1235 1489 1437 1624">215</td> </tr> <tr> <td data-bbox="245 1624 1054 1758">Proportion continuing treatment (no confirmed decline in percent predicted FVC of 10% or more in any 12-month period)</td> <td data-bbox="1054 1624 1235 1758">70%</td> <td data-bbox="1235 1624 1437 1758">151</td> </tr> <tr> <td data-bbox="245 1758 1054 1827">Uptake for treatment with nintedanib</td> <td data-bbox="1054 1758 1235 1827">51%</td> <td data-bbox="1235 1758 1437 1827">77</td> </tr> </tbody> </table> <p>Therefore it is estimated that 215 people are eligible for treatment with nintedanib each year. This reduces to 151 people once discontinuation due to disease progression is taken into consideration. Of these, 77 people will continue treatment long-term.</p>	Estimated number of people eligible for treatment with nintedanib in Northern Ireland			Population	Proportion	Number of people	Total NI population		1,840,498	Prevalence of IPF	0.0234%	431	Number of people eligible for treatment with nintedanib - proportion with forced vital capacity (FVC) between 50% and 80% of predicted	50%	215	Proportion continuing treatment (no confirmed decline in percent predicted FVC of 10% or more in any 12-month period)	70%	151	Uptake for treatment with nintedanib	51%	77
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4	<p>Patient Access Scheme availability</p> <p>The company that manufacturers nintedanib has agreed a patient access scheme with the Department of Health. This scheme provides a simple discount to the list price of nintedanib, with the discount applied at the point of purchase or invoice. The level of the discount is commercial in confidence.</p>
5	<p>Costs <i>(before PAS if applicable)</i></p>
5.1	<p>Drug cost per patient per annum (for new and prevalent cases)</p> <p>The recommended dosage of nintedanib is 150mg, given orally, twice daily. The list price of nintedanib is £2,151 for 60 capsules. This equates to a daily cost of £71.70 (2 capsules per day) and an annual cost per patient of £26,171</p> <p>The company has agreed a patient access scheme with the Department of Health. This scheme provides a simple discount to the list price of nintedanib, with the discount applied at the point of purchase or invoice. The level of the discount is commercial in confidence.</p>
5.2	<p>Infrastructure costs per patient per annum</p> <p>Any additional infrastructure costs associated with the introduction of these therapies will be dealt with as part of the routine commissioning process.</p>
5.3	<p>Current in year costs</p> <p>The current in year costs are estimated at £30k.</p>
5.4	<p>Recurrent overall costs per annum before PAS <i>(including additional costs)</i></p> <p>According to the Resource Impact Template that accompanies NICE TA379 and, before application of the PAS discounts for both nintedanib and pirfenidone and assuming no patients are receiving nintedanib at baseline, the recurrent cost per annum in Northern Ireland will reach steady state by year 5 and will be £474k.</p>
5.5	<p>Opportunities for cost savings and how these will be secured</p> <p>Cost savings are not anticipated</p>
6	<p>Expected implementation period</p> <p>There is no barrier to immediate implementation for new patients</p>
7	<p>Commissioning arrangements</p> <p>This regimen will be formally commissioned by the HSCB/PHA via the Specialist Services Commissioning Team initially on a cost-per-case (CPC) basis for a period of 12 months. After this time, numbers of patients who received or are receiving treatment will be reviewed and consideration will be given to moving to recurrent funding to support this regimen.</p>

8	Monitoring arrangements Trusts will be required to provide Specialist Services Commissioning Team on a quarterly basis commencing 2016/17 with the following information: <ul style="list-style-type: none">• the number of patients that have been given the drug and the cost of the drug per patient;• confirmation that each patient complies with the NICE requirements for this treatment;• confirmation that each patient has been reviewed within 12 months of commencing treatment to determine if there is evidence of disease progression (a decline in per cent predicted FVC of 10% or more); and,• the number of patients ceasing treatment.
9	DHSSPS Legislative/Policy Caveats This advice does not override or replace the individual responsibility of health professionals to make appropriate decisions in the circumstances of their individual patients, in consultation with the patient and/or guardian or carer. This would, for example, include situations where individual patients have other conditions or complications that need to be taken into account in determining whether the NICE guidance is fully appropriate in their case.