

1	<p><b>Treatment &amp; Condition</b></p> <p>Roflumilast for treating severe chronic obstructive pulmonary disease in adults with chronic bronchitis.</p>
2	<p><b>Associated appraisal body &amp; Summary of ruling</b></p> <p>NICE Technology Appraisal guidance TA 461 (July 2017)</p> <p>Roflumilast, as an add-on to bronchodilator therapy, <b>is recommended</b> as an option for treating severe chronic obstructive pulmonary disease in adults with chronic bronchitis, only if:</p> <ul style="list-style-type: none"> <li>• the disease is severe, defined as a forced expiratory volume in 1 second (FEV1) after a bronchodilator of less than 50% of predicted normal, <b>and</b></li> <li>• the person has had 2 or more exacerbations in the previous 12 months despite triple inhaled therapy with a long-acting muscarinic antagonist, a long-acting beta-2 agonist and an inhaled corticosteroid.</li> </ul> <p>Treatment with roflumilast should be started by a specialist in respiratory medicine.</p>
3	<p><b>Number of people in Northern Ireland expected to take up service/therapy</b> <i>(including new cases per year)</i></p> <p>Based on available research, it is difficult to provide an estimate; however a paper from the US showed that 25% of COPD patients were on triple therapy, indicating that approximately 10,000 people in NI could be on triple therapy.</p> <p>Many of these would be likely to meet the recommended indications for treatment with roflumilast, however many treatments in the US are used more aggressively than in the UK, where the therapy has to be initiated by a respiratory consultant.</p>
4	<p><b>Patient Access Scheme availability</b></p> <p><b>(Yes/<u>No</u>)</b></p> <p>The company do not offer a patient access scheme.</p>
5	<p><b>Costs</b> <i>(before PAS if applicable)</i></p> <p>Recommended dose is one 500mcg tablet daily.</p> <p>1 x 30 tablets = £37.71.</p>

5.1	<p><b>Drug cost per patient per annum (for new and prevalent cases)</b></p> <p>Annual costs of treatment = £458.80 per patient</p>
5.2	<p><b>Infrastructure costs per patient per annum</b></p> <p>None</p>
5.3	<p><b>Current in year costs</b></p> <p>In year costs will depend on the number of patients seen. In 2017-18 costs are estimated at £40,000</p>
5.4	<p><b>Recurrent overall costs per annum (including additional costs)</b></p> <p>NICE does not expect this guidance to have a significant impact on resources; that is, it will be £9,100 per 100,000 population approximately £164,000 per annum.</p> <p>This is because the expected uptake of the technology is small because the therapy should only be started by specialists in secondary care, and the unit cost for the intervention is small.</p>
5.5	<p><b>Opportunities for cost savings and how these will be secured</b></p> <p>None</p>
6	<p><b>Expected implementation period</b></p> <p>There is no impediment to implementation of this guidance.</p>
7	<p><b>Commissioning arrangements</b></p> <p>The HSCB will commission this technology to compliment the ongoing implementation of the regional Respiratory Service Framework.</p>
8	<p><b>Monitoring arrangements</b></p> <p>The HSCB will incorporate information on this regime into the existing monthly monitoring arrangements.</p>
9	<p><b>DoH Legislative/Policy Caveats</b></p> <p>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</p>

	complications that need to be taken into account in determining whether the NICE guidance is fully appropriate in their case.
--	---