

NICE TA 276 – Colistimethate sodium and tobramycin dry powders for inhalation for treating pseudomonas lung infection in cystic fibrosis

<p>1</p>	<p>Summary of NICE TA 276</p> <p>NICE recommends tobramycin dry powder for inhalation (DPI) as an option for treating chronic pulmonary infection caused by <i>Pseudomonas aeruginosa</i> in people with cystic fibrosis only if:</p> <ul style="list-style-type: none"> • nebulised tobramycin is considered an appropriate treatment, that is, when colistimethate sodium is contraindicated, is not tolerated or has not produced an adequate clinical response and • the manufacturer provides tobramycin DPI with the discount agreed as part of the patient access scheme to primary, secondary and tertiary care in the NHS <p>NICE recommends colistimethate sodium DPI as an option for treating chronic pulmonary infection caused by <i>P. aeruginosa</i> in people with cystic fibrosis only if:</p> <ul style="list-style-type: none"> • they would clinically benefit from continued colistimethate sodium but do not tolerate it in its nebulised form and thus tobramycin therapy would otherwise be considered and • the manufacturer provides colistimethate sodium DPI with the discount agreed as part of the patient access scheme to primary, secondary and tertiary care in the NHS <p>People currently using tobramycin DPI or colistimethate sodium DPI that is not recommended according to the above criteria should be able to continue treatment until they and their clinician consider it appropriate to stop. For children and young people this decision should be made jointly by the clinician, the child or young person and their parents or carers.</p>
<p>2</p>	<p>Number of people in Northern Ireland expected to take up service/therapy (new cases per year)</p> <p>The DHSSPSNI have advised that around 140 people per annum will be eligible for these regimes. Of these it is estimated by NICE that up to 40% of people currently taking nebulised colistimethate and 20% of patients currently taking nebulised tobramycin will transfer to DPIs. In addition, following discussion with local clinicians, it is estimated that there are around a further 20 people with a <i>P.aeruginosa</i> who are currently not on treatment. Of these, local clinical advice would suggest that approximately half of these patients may opt for treatment with DPIs. See Table 1.</p>

Table 1			
	Number of people in NI	Drug cost per patient per year*	Number of people likely to change to DPI
Nebulised colistimethate	64	£1,971 to £5,037	40% = 26
Nebulised tobramycin	36	£7,737	20% = 7
Both colistimethate and tobramycin (alternate mths)	40	£4954 to £6386	Unknown
Currently not on treatment	20 adults	0	50% (estimate) = 10
Total	160		43

*sourced from the NICE Costing Statement

The HSCB/PHA will support the introduction of TA276 using local clinical data on the basis that local clinicians are best placed to take account of local variations which contribute to this uptake of these treatments in Northern Ireland. This position will be closely monitored and will be subject to review over the next 18-24 months.

3 Costs

3.1 Cost per patient per annum

Tobramycin DPI costs £11,667 per patient per annum.

Colistimethate DPI costs £12,629 per patient per annum

The NICE Costing Statement for England that accompanies TA 276 indicates that implementation of this guidance is not expected to have a significant impact on NHS resources because the uptake and cost of colistimethate DPI and tobramycin DPI is not anticipated to be significantly different from the cost of the current treatment practice. However the incidence of Cystic Fibrosis in N. Ireland is higher than England.

The manufacturers of these two products have agreed a patient access scheme which makes both products available with a discount. The size of the discount is commercial in confidence. Belfast Trust will be expected to avail of this scheme.

While there may be the potential for some additional costs to arise from the cohort of patients currently not on treatment it is not possible to confirm this at present. The HSCB/PHA will closely monitor uptake of regime and expenditure in this regard in the context of the overall expenditure on the treatment of P.aeruginosa in people with cystic fibrosis.

<p>3.2</p>	<p>In year cost per patient per annum (for new and prevalent cases)</p> <p>Assuming all patients take up the new treatment between now and March 2014, the estimated in year cost before the patient access scheme discount (PAS) will be £200k. The PAS will reduce this significantly.</p> <p>The manufacturers of these two products have agreed a patient access scheme which makes both products available with a discount. The size of the discount is commercial in confidence. Belfast Trust will be expected to avail of this scheme.</p> <p>While there may be the potential for some additional costs to arise from the cohort of patients currently not on treatment it is not possible to confirm this at present. The HSCB/PHA will closely monitor uptake of regime and expenditure in the context of the overall expenditure on the treatment of P.aeruginosa in people with cystic fibrosis.</p>
<p>3.3</p>	<p>Cost savings and how these will be secured</p> <p>It is anticipated that there will be cost savings associated with a reduction in hospital admissions, demand for physiotherapy and use of other antibacterials.</p> <p>A number of new regimes including Ivacaftor and Mannitol dry powder have recently been made available to support cystic fibrosis care in Northern Ireland. In response to this the HSCB/PHA have put in place specific monitoring arrangements to ensure compliance with NICE and quantify reductions in the use of antibiotics, inpatient admissions and other services with the aim of identifying savings. Colistimethate and tobramycin DPIs will now be included within these monitoring arrangements which will be reviewed by senior medical, pharmacy and commissioning personnel within the HSCB/PHA on a regular basis.</p>
<p>3.4</p>	<p>Recurrent overall cost</p> <p>The additional cost before the patient access scheme (PAS) is estimated at £469k. The PAS will reduce this significantly.</p> <p>The manufacturers of these two products have agreed a patient access scheme which makes both products available with a discount. The size of the discount is commercial in confidence. Belfast Trust will be expected to avail of this scheme.</p> <p>While there may be the potential for some additional costs to arise from the cohort of patients currently not on treatment it is not possible to confirm this at present. The HSCB/PHA will closely monitor uptake of regime and expenditure in this regard in the context of the overall expenditure on the treatment of P.aeruginosa in people with cystic fibrosis.</p>

4	<p>Expected implementation period</p> <p>There is no impediment to immediate implementation for patients.</p>
5	<p>Commissioning arrangements</p> <p>This regime will be formally commissioned by the HSCB/PHA via the Specialist Services Commissioning Team.</p>
6	<p>Monitoring arrangements</p> <p>Belfast Trust will be required to provide Specialist Services Commissioning Team on a quarterly basis commencing 2013/14 with details of patients commencing treatment to include the number of patients that have been given the drug and the cost of the drug per patient and confirmation that each patient complies with the NICE requirements for this treatment. Other monitoring returns will be included to identify trends in the use of antibiotics, volume of inpatient admissions and other services as deemed appropriate. It will also be included in their Annual Report for Cystic Fibrosis.</p>
7	<p>DHSSPS Legislative/Policy Caveats</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 complications that need to be taken into account in determining whether the NICE guidance is fully appropriate in their case.</p>