

Colistimethate sodium powder and tobramycin powder for inhalation for the treatment of chronic *Pseudomonas aeruginosa* lung infection in cystic fibrosis

Addendum (2) to Assessment Report: Economic analysis of a proposed Patient Access Scheme for colistimethate sodium DPI

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A2.1 Introduction

In August 2012, Forest submitted a proposal for a Patient Access Scheme (PAS) for colistimethate sodium DPI. This document also included the agreed NHS list price for the drug; this was not available during the period in which the main Assessment Report was produced. This short addendum details the expected cost-effectiveness of colistimethate sodium DPI versus nebulised tobramycin for the treatment of *Pseudomonas aeruginosa* lung infection in patients with cystic fibrosis, based on the agreed list price and the proposed PAS. The submission states that the proposed PAS will take the form of a simple price discount and that orders will be placed either via the patient's homecare company or direct with manufacturer who will invoice accordingly. The agreed NHS list price is reported to be £968.80 per box (56 doses) which corresponds to a price per dose of £17.30. The proposed PAS price is [REDACTED] per box, which corresponds to a price per dose of [REDACTED].

A2.2 Methods

The analysis was undertaken using the model as described in the full Assessment Report. Within the Reference Case analysis, only the parameter used to represent the price of colistimethate sodium DPI was amended. All other assumptions and parameters are the same as those reported in the full Assessment Report.

In addition to the Reference Case analysis, a sensitivity analysis is presented to reflect the lower price of nebulised tobramycin was based on estimates from the Commercial Medicines Unit (CMU) Electronic Market Information Tool (E-MIT). In September 2012, this estimated cost to the NHS was £970.12 per pack, whereas the BNF list price is £1187.20.

A2.3 Cost-effectiveness results

A2.3.1 Reference Case analysis

Table A13 presents the central estimates of cost-effectiveness for colistimethate sodium DPI versus nebulised tobramycin based on the probabilistic Reference Case model. The base case analysis suggested that colistimethate sodium DPI produces fewer QALYs than nebulised tobramycin and obviously the proposed PAS does not change this situation. The results of this additional analysis suggest that based on the agreed NHS price, colistimethate sodium DPI is dominated by nebulised tobramycin. When the proposed PAS is incorporated into the analysis, the incremental cost-effectiveness of nebulised tobramycin versus colistimethate sodium DPI is approximately £52,700 per QALY gained. It should be noted that the ICER lies on the South-West quadrant of the cost-effectiveness plane (colistimethate sodium DPI is less effective and less expensive than nebulised tobramycin).

Table A13 Cost-effectiveness results for colistimethate sodium DPI versus nebulised tobramycin using the agreed NHS price and the proposed PAS – Reference Case model

Colistimethate price per dose	QALYs			Costs			ICER
	Coli DPI	Tobi neb	Inc.	Coli DPI	Tobi neb	Inc.	
Without PAS							
£17.30 per dose	9.48	9.61	-0.13	£167,982.95	£110,518.68	£57,464.27	dominated
With PAS							
██████████	9.48	9.61	-0.13	£103,592.27	£110,518.68	-£6,926.41	£52,672

Table A14 presents the central estimates of cost-effectiveness for colistimethate sodium DPI versus nebulised tobramycin based on the short-term “within trial” model (excluding the unobserved extrapolation period). This analysis again suggests that based on the agreed NHS price, colistimethate sodium DPI is expected to be dominated by nebulised tobramycin. When the proposed PAS is incorporated into the analysis, the incremental cost-effectiveness of nebulised tobramycin versus colistimethate sodium DPI is around £113,600 per QALY gained (note that again the ICER lies in the South-West quadrant of the cost-effectiveness plane).

Table A14 Cost-effectiveness results for colistimethate sodium DPI versus nebulised tobramycin using the agreed NHS price and the proposed PAS – short-term “within trial” analysis

Colistimethate price per dose	QALYs			Costs			ICER
	Coli DPI	Tobi neb	Inc.	Coli DPI	Tobi neb	Inc.	
Without PAS							
£17.30 per dose	0.35	0.35	-0.00	£6,204.75	£4,075.35	£2,129.40	dominated
With PAS							
██████████	0.35	0.35	-0.00	£3,826.41	£4,075.35	-£248.93	£113,644

Table A15 presents a summary of the probabilistic sensitivity analysis for the two pricing scenarios using the Reference Case model. Based on the agreed NHS price, the probability that colistimethate sodium DPI produces more net benefit than nebulised tobramycin is approximately zero. When the proposed PAS is included in the analysis, the probability that colistimethate sodium DPI produces more net benefit than nebulised tobramycin is approximately 0.79 at a threshold of £20,000 per QALY gained, and 0.66 at a threshold of £30,000 per QALY gained.

Table A15 Probability that colistimethate sodium DPI produces the greatest net benefit (Reference Case Model)

Scenario	Probability colistimethate sodium DPI produces greatest net benefit at threshold λ (Reference Case model)	
	λ =£20,000/QALY gained	λ =£30,000/QALY gained
Without PAS	0.00	0.00
With PAS	0.79	0.66

A2.3.2 Additional sensitivity analysis using E-MIT price

Table A16 shows the results of the economic analysis with and without the proposed PAS, taking into account the cost of nebulised tobramycin based on current estimates from E-MIT.

Table A16 Cost-effectiveness results for colistimethate sodium DPI versus nebulised tobramycin using E-MIT price for nebulised tobramycin

Colistimethate price per dose	QALYs			Costs			ICER
	Coli DPI	Tobi neb	Inc.	Coli DPI	Tobi neb	Inc.	
Without PAS							
£17.30 per dose	9.48	9.61	-0.13	£167,982.95	£92,944.08	£75,038.86	dominated
With PAS							
██████████	9.48	9.61	-0.13	£103,592.27	£92,944.08	£10,648.18	dominated

The inclusion of E-MIT estimates of the price paid by the NHS for nebulised tobramycin indicate that despite the proposed PAS, colistimethate sodium DPI remains dominated by nebulised tobramycin.

A2.4 Conclusions

Based on the agreed NHS price, colistimethate sodium is expected to be dominated by nebulised tobramycin. When the proposed PAS is included in the Reference Case analysis, the incremental cost-effectiveness of nebulised tobramycin versus colistimethate sodium DPI is expected be around £52,700 per QALY gained (i.e. colistimethate sodium DPI is less effective but also less expensive than nebulised tobramycin). When the cost of nebulised tobramycin is based on estimates from E-MIT, colistimethate sodium DPI is expected to be dominated by nebulised tobramycin, irrespective of whether the proposed PAS is incorporated into the analysis. It should be noted that the economic analysis presented here includes a comparison only against nebulised tobramycin, hence the relative cost-effectiveness of colistimethate sodium DPI versus any other comparator is unclear.