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Clinical Standards
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NICE Cystic fibrosis (pseudomonas lung infection) - colistimethate sodium and tobramycin

Appraisal Consultation Document (ACD)

Name	With thanks to: Dr Jeremy Hull (consultant in paediatric respiratory medicine, response on behalf of the British Paediatric Respiratory Society)

Section number Indicate **section number** If relevant	**Comments** If possible, please provide evidence (citations) to support your statements
Page 10	I would be grateful for clarification on the statement on page 10 that: For the primary end point of mean difference in change in FEV1% predicted after 24 weeks of treatment using logarithmic analysis, the results from the ITT population were -1.16% (95% CI −3.15 to 0.84) suggesting that colistimethate sodium DPI was marginally less efficacious than tobramycin nebuliser solution (because the non-inferiority criteria were not met). Surely if the confidence intervals range between -3.15 and 0.84, then there are no differences between the two treatments in terms of FEV1. This does appear to be critical since the basis by which NICE has not recommended the use of Colobreathe is that it is less efficacious than nebulised tobramycin. This impression of lack of efficacy seems to be re-inforced by the slightly higher exacerbation rate – but once again this does not seem to be statistically different between the 2 groups.

You may add extra rows as needed.

Evaluation report

The evaluation report includes statements from professional and patient groups and manufacturers, and is also available for comment.

Page number Indicate **page number** If relevant	**Comments** If possible, please provide evidence (citations) to support your statements

You may add extra rows as needed.

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