Table 44: Clinical evidence profile: Comparison 4.2. Tobramycin inhalation powder versus Tobramycin inhalation solution

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Tobramycin inhalation powder (TOBI DPI)	Tobramycin inhalation solution (TOBI neb)	Relative (95% CI)	Absolute	Quality	Importance
Lung function: % mean change in FEV_1% predicted (follow-up: 4 weeks; range of scores: 0-100; Better indicated by higher values)												
1 (Konstan 2011a/EAGER trial)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	308	209	-	MD 0.8 lower (3.90 lower to 2.30 higher)	LOW	IMPORTANT
Lung function: % mean change in FEV_1% predicted (follow-up: 20 weeks; range of scores: 0-100; Better indicated by higher values)												
1 (Konstan 2011a/EAGER trial)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	308	209	-	MD 1.10 higher (2.33 lower to 4.53 higher)	LOW	IMPORTANT
Lung function: % mean change in FEV_1% predicted (follow-up: 24 weeks; range of scores: 0-100; Better indicated by higher values)												
1 (Konstan 2011a/EAGER trial)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	308	209	-	MD 2.20 lower (1.11 to 5.51 lower)	LOW	IMPORTANT
Number of patients with 1 or more exacerbations												
NMA outcome												
Suppression of the organism: mean change in *P aeruginosa* sputum density log10 CFU (follow-up 4 weeks; Better indicated by higher values)												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Tobramycin inhalation powder (TOBI DPI)	Tobramycin inhalation solution (TOBI neb)	Relative (95% CI)	Absolute		
1 (Konstan 2011a/EAGER trial)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	308	209	-	MD 0.44 lower (0.79 to 0.09 lower)	MODERATE	IMPORTANT
Suppression of the organism: mean change in *P aeruginosa* sputum density log10 CFU (follow-up 20 weeks; Better indicated by higher values)												
1 (Konstan 2011a/EAGER trial)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[3]	none	308	209	-	MD 0.84 lower (1.17 to 0.51 lower)	LOW	IMPORTANT
Adverse events: any mild or moderate adverse (follow-up 24 weeks)												
1 (Konstan 2011a/EAGER trial)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	226/308 (73.4%)	143/209 (68.4%)	RR 1.07 (0.96 to 1.2)	48 more per 1000 (from 27 fewer to 137 more)	MODERATE	IMPORTANT
Adverse events: any serious adverse (follow-up 24 weeks)												
1 (Konstan 2011a/E	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[3]	none	84/308 (27.3%)	61/209 (29.2%)	RR 0.93 (0.71	20 fewer per 1000	LOW	IMPORTANT

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Tobramycin inhalation powder (TOBI DPI)	Tobramycin inhalation solution (TOBI neb)	Relative (95% CI)	Absolute		
AGER trial)									to 1.24)	(from 85 fewer to 70 more)		
Mild adverse events: productive cough (follow-up 24 weeks)												
1 (Konstan 2011a/EAGER trial)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	very serious[4]	none	56/308 (18.2%)	41/209 (19.6%)	RR 0.93 (0.64 to 1.33)	14 fewer per 1000 (from 71 fewer to 65 more)	VERY LOW	IMPORTANT
Mild adverse events: headache (follow-up 24 weeks)												
1 (Konstan 2011a/EAGER trial)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	very serious[4]	none	35/308 (11.4%)	25/209 (12%)	RR 0.95 (0.59 to 1.54)	6 fewer per 1000 (from 49 fewer to 65 more)	VERY LOW	IMPORTANT
Mild adverse events: vomiting (follow-up 24 weeks)												
1 (Konstan 2011a/E	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	very serious[4]	none	19/308 (6.2%)	12/209 (5.7%)	RR 1.07 (0.53	4 more per 1000 (from	VERY LOW	IMPORTANT

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Tobramycin inhalation powder (TOBI DPI)	Tobramycin inhalation solution (TOBI neb)	Relative (95% CI)	Absolute	Quality	Importance
AGER trial)									to 2.17)	27 fewer to 67 more)		
Serious adverse events: dyspnoea (follow-up 24 weeks)												
1 (Konstan 2011a/EAGER trial)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	very serious[4]	none	48/308 (15.6%)	26/209 (12.4%)	RR 1.25 (0.8 to 1.95)	31 more per 1000 (from 25 fewer to 118 more)	VERY LOW	IMPORTANT
Serious adverse events: haemoptysis (follow-up 24 weeks)												
1 (Konstan 2011a/EAGER trial)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	very serious[4]	none	40/308 (13%)	26/209 (12.4%)	RR 1.04 (0.66 to 1.66)	5 more per 1000 (from 42 fewer to 82 more)	VERY LOW	IMPORTANT

Abbreviations: CFU: colony forming units; CI: confidence interval; FEV_1: forced expiratory volume in 1 second; MD: mean difference; RR: risk ratio
1 The quality of the evidence was downgraded by 1 as this was an open trial, and randomisations was unclear
2 The quality of the evidence was downgraded by 1 as the 95% CI crossed 1 clinical MID
3 The quality of the evidence was downgraded by 1 as the 95% CI crossed 1 default MID
4 The quality of the evidence was downgraded by 2 as the 95% CI crossed 2 default MIDs