NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

GUIDANCE EXECUTIVE (GE)

Review of TA266; Mannitol dry powder for inhalation for treating cystic fibrosis, and TA276; Colistimethate sodium and tobramycin dry powders for inhalation for treating pseudomonas lung infection in cystic fibrosis

Final recommendation post consultation
The guidance should be incorporated into an ongoing clinical guideline and the guidance moved to the static list.

1. Background

TA266 was published in November 2012, and TA276 was published in March 2013.

At the GE meeting of 5 May 2015 it was agreed that we would consult on the recommendations made in the GE proposal paper. A four week consultation has been conducted with consultees and commentators and the responses are presented below.

2. Proposal put to consultees and commentators

The guidance should be incorporated into an ongoing clinical guideline and the guidance moved to the static list.

3. Rationale for selecting this proposal

There is no new evidence that is likely to lead to a change in the recommendations in the original guidance (TA266 and TA276). It is therefore appropriate for the guidance to be incorporated into the ongoing clinical guideline (Cystic fibrosis: diagnosis and management of cystic fibrosis) and the guidance moved to the static list.

4. Summary of consultee and commentator responses

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

Respondent: British Thoracic Society **Response to proposal:** Agree The Society confirms that the proposal to incorporate the guidance noted above into the NICE CF Clinical Guideline is appropriate.	**Comment from Technology Appraisals** Comment noted.

Respondent: Novartis **Response to proposal:** Agree There is no new evidence that will lead to a change in the recommendations for Tobi (tobramycin) (Tobi 300 mg/5 ml Nebuliser Solution; TOBI Podhaler 28 mg inhalation powder, hard capsules) in TA276. Additionally, there has been no change to the marketing authorisation for Tobi 300 mg/5 ml Nebuliser Solution or TOBI Podhaler 28 mg inhalation powder, hard capsules) since the publication of TA276. Novartis agrees that the guidance in TA276 should be incorporated into the on-going clinical guideline (Cystic fibrosis: diagnosis and management of cystic fibrosis) and the guidance TA276 moved to the static list.	**Comment from Technology Appraisals** Comment noted.

Respondent: Royal College of Physicians **Response to proposal:** Agree The RCP wishes to endorse the submission by the BTS.	**Comment from Technology Appraisals** Comment noted.

Respondent: Chiesi **Response to proposal:** Agree Chiesi Ltd. has looked further into the new evidence for Bronchitol®(mannitol) and at this stage has made an informed decision to retain Bronchitol on the static list. However, as part of the obligation to conduct post-authorisation measures, Pharmaxis the Marketing Authorisation Holder is further investigating the efficacy and safety of Bronchitol in children and adolescents with cystic fibrosis https://clinicaltrials.gov/ct2/show/NCT01883531). The final study results (final study report) should be provided to the CHMP and EMA by June 2016. Based on the outcome of these results, Chiesi Ltd. will be in contact to discuss the possibility of submitting more evidence that may potentially extend the current adult indication in the treatment of cystic fibrosis.	**Comment from Technology Appraisals** Comment noted.

Paper signed off by: Helen Knight, 10 July 2015

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