Appendix D – Clinical specialist statement template

Colistimethate sodium powder and tobramycin powder for inhalation for the treatment of pseudomonas lung infection in cystic fibrosis

Thank you for agreeing to give us a statement on your organisation's view of the technology and the way it should be used in the NHS.

Healthcare professionals can provide a unique perspective on the technology within the context of current clinical practice which is not typically available from the published literature.

To help you in making your statement, we have provided a template. The questions are there as prompts to guide you. It is not essential that you answer all of them.

Please do not exceed the 8-page limit.

About you

Your name: Jeremy Hull

Name of your organisation John Radcliffe Hospital, Oxford

Are you (tick all that apply):

- I am a specialist in the treatment of people with the condition for which NICE is considering this technology.

What is the expected place of the technology in current practice?
The advantages and disadvantages of the technology
Any additional sources of evidence

Inhaled antibiotic therapy is used in 2 distinct ways in patients with cystic fibrosis (CF): 1. as short term treatment (1-3 months) to eradicate new infection with Pseudomonas and 2. and long term treatment to suppress chronic established airway Pseudomonas infection. The trials of TIP (the EAGER and EVOLVE trials) have been directed towards the second type of use. There are no published data I could find for Colistimethate, but I suspect it will also be direct towards the second type of use.

Current practice is to use nebulised solutions of the same 2 drugs – colistin and tobramycin. Which is used depends on local practice. The trials evidence is stronger for tobramycin (as TOBI or Bramitob). TOBI and Bramitob are both more expensive than colistin, and many units in the UK continue to use colistin for this reason. Retrospective clinical studies suggest that colistin is as effective as tobramycin.

The advantage of dry powder inhalers is convenience to the patients. The time taken for CF patients to complete their daily treatments is often in excess of 2 hours per day. This can impact on quality of life and compliance. Use of dry powder formulations will reduce treatment times by around 30mins per day. There are no disadvantages – the trials with TIP show equal efficacy and side effect profile compared with tobramycin nebulised solution.

To use a dry powder inhaler requires a coordinated inspiratory manoeuvre of sufficient force. This means it is only suitable for adults and children over the age of 6 years.

The dry powder treatments will be used for suppressive treatment in the same way that nebulised drugs are used at present. These drugs are usually introduced once the patient has chronic infection with Pseudomonas – most usually defined as 3 or more Pseudomonas positive airway samples per year. Once started treatment usually continues for life. Occasionally if the patient is very well, with no cough and normal or near normal lung function and has been free of Pseudomonas for more than 12 months, the inhaled antibiotic may be stopped, at least for a trial period.

Implementation issues
None. The patients using the device will be under the care of a CF team. The team will provide instruction on use. It is likely to be easier to use than the existing nebulised treatments.