NICE Multiple Technology Appraisal (MTA)

Colistimethate sodium powder and tobramycin powder for inhalation for the treatment of pseudomonas lung infection in cystic fibrosis [ID342]

Cystic Fibrosis Trust response

The Cystic Fibrosis Trust is the UK national charity for people living with cystic fibrosis (CF). The Trust funds world-leading medical research, ensures safe and appropriate clinical care, and offers direct support for people with CF and their families.

CF is an inherited and progressive life-limiting disease which affects internal organs (particularly the lungs and digestive system) by clogging them with thick sticky mucus. This makes it harder to breathe and to digest food. The mucus in the lungs provides an ideal environment for pathogenic bacteria, promoting recurrent and increasingly frequent respiratory infections. In 2010, the average age at death was only 29.

Response to the consultation

The CF Trust welcomes the initial recommendation from the NICE, following a Multi Technology Appraisal, that tobramycin dry powder for inhalation (Tobi Podhaler, Novartis) for CF should be an option for use in people with CF.

We are pleased that tobramycin dry powder will be recommended for people with CF. It is really good news for the CF community as tobramycin has been found to be effective in treating lung infections in adults and children over the age of six.

It is however, very disappointing that NICE have so far taken the view not to recommend Colobreathe (colistimethate sodium dry powder for inhalation, Forest Laboratories). Colobreathe also treats pseudomonas infections and offers significant patient benefits over current treatment. These benefits include:

- An alternate inhaled treatment option for patients who are contraindicated for tobramycin
- Treatment burden is reduced because the drug is administered by inhaler rather than by nebuliser.
- Promotes adherence as quick and easy to administer compared to the current nebulised form of colomycin
- Treatment is more likely to be effective as patients will take a full dose because of more convenient inhaled delivery mechanism

There is a great need for further choice of treatments for CF to become available, particularly treatments that are quick and easy to use such as dry powder antibiotics.

People with CF have a huge burden of care, often having to do hours of treatments and physiotherapy a day. Each treatment that becomes available and is proven to be effective in treating infections and symptoms of CF is a huge step forward in helping people with CF to stay well.

Colobreathe is delivered by an inhaler (like an asthma inhaler), which is an efficient way of delivering the treatment, making it quicker and easier to take than the current nebulised form of colomycin. The new inhaler device makes it much more likely that the full dose of the active ingredient will be administered to the patient, largely due to the ease and speed of the delivery system but also due to less of the drug escaping into the air during nebulisation.

It is crucial for this treatment to be an available prescribing option for those people that do not tolerate or struggle to comply with nebulised therapy. If Colobreathe is not recommended tobramycin will be the only option, which is not appropriate for some due to ototoxicity caused by the effects of aminoglycosides or other contraindications to taking tobramycin.

Limiting treatment options available will make it more difficult for clinicians to consider what might be the most appropriate treatment for an individual patient and may impinge on their decision to recommend alternating treatments on a monthly basis, as many do currently with the nebulised forms of tobramycin and colomycin. With only one antibiotic available in dry powder form, there is a risk of over reliance on one antibiotic treatment, and a reduction in adherence during the monthly periods assigned to nebulised antibiotic therapies.

This prescribing method is clearly outlined in the response by Dr R I Ketchell, Consultant Physician and Director of the Adult Cystic Fibrosis Centre, Wales to this NICE consultation.

It must also be taken into account that those who do well on colomycin should have the option of reducing their treatment burden through moving onto a more effective and less time consuming delivery method. This should especially be the case if they are not adhering well because of the treatment burden.

In CF, the overall burden of care is immense, time consuming and exhausting for the patient. Effective innovations must be supported if we are going to help people with CF improve their quality of life and live longer. Innovative dry powder inhalers represent a step change in CF medicine.

The CF Trust supports both therapies and would like NICE to recommend both as prescribing options for CF specialist clinicians.

Therefore, the Cystic Fibrosis Trust is of the opinion that the provisional recommendations from NICE regarding Colobreathe are not a sound and suitable basis for guidance to the NHS and serves to severely limit clinicians' prescribing options.

Cystic Fibrosis Trust

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