SHARED CARE GUIDELINES FOR PRESCRIBING COLOMYCIN

INDICATION

Lung damage associated with persistent infection by P*seudomonas aeruginosa* is the major cause of morbidity and mortality in people with Cystic Fibrosis (CF). Nebulised antipseudomonal antibiotic treatment controls the burden of chronic infection and has been shown to improve lung function, slow the rate of respiratory decline and reduce the frequency of exacerbations of infection in people with CF. This reduces the need for intravenous antibiotic treatment and hospitalisation. In addition, repeated courses of intravenous antibiotics mean that CF patients are at a high risk of developing antibiotic-related toxicity. This can be avoided with nebulised antibiotics, which are able to achieve high local concentrations with low systemic absorption and toxicity.

Nebulised colomycin is indicated for eradication of recent pulmonary colonisation with Pseudomonas *aeruginosa*, with oral ciprofloxacin (20-50mg/kg/day in two divided doses, Maximum 750mg bd), for a period of three months. It is also indicated as long term use for chronic pulmonary *Pseudomonas aeruginosa* infection (2 or more isolates in a 6 month period).

At current prices an individual vial of 1 million units = £1.68, 2 million units = £3.09.

AREAS OF RESPONSIBILITY FOR SHARED CARE

This shared care agreement outlines suggested ways in which the responsibilities for managing the prescribing of colomycin can be shared between the specialist and general practitioner (GP). GPs are invited to participate. If the GP is not confident to undertake these roles, then he or she is under no obligation to do so. In such an event, the total clinical responsibility for the patient for the diagnosed condition remains with the specialist. If a specialist asks the GP to prescribe this drug, the GP should reply to this request as soon as practicable.

Sharing of care assumes communication between the specialist, GP and patient. The intention to share care is usually explained to the patient by the doctor initiating treatment. It is important that patients are consulted about treatment and are in agreement with it.

The doctor who prescribes the medication legally assumes clinical responsibility for the drug and the consequences of its use.

REFERRAL AND INITIATION

Shared Care is only appropriate if it provides the optimum solution for the patient.

- Patients will only be referred to the GP once the GP has agreed in each individual case

Specialist Responsibilities	
1	To assess the patient and establish the diagnosis, determine a management strategy and ensure appropriate follow-up in conjunction with the GP.
2	Where appropriate: o to assess suitability of the patient for treatment and perform a “test dose” with lung function monitoring; o to initiate and supply at least 28 days treatment; o to train the patient/carer in the use of the nebuliser system; o to provide and maintain a suitable compressor, nebuliser and nebulising pots; o to supply initial sundries; o obtain consent from the patient’s GP to continue prescribing once treatment has been stabilised; o monitor the patient and their therapy at appropriate intervals.

3	Ensure that patients know what to do and who to contact if they experience adverse events or an exacerbation of their condition.
4	To provide the GP with appropriate prescribing information and any additional information requested.
5	To be available for advice if the patient's condition changes.
6	To ensure that procedures are in place for the rapid re-referral of the patient by the GP.
7	To ensure the patient has given informed consent to their treatment.
8	To liaise with the GP on any suggested changes in prescribed therapy.
9	To discontinue treatment if no longer thought to be beneficial.

General Practitioner Responsibilities	
1	Initially, to refer the patient for specialist advice.
2	Where appropriate, to continue to prescribe colomycin and diluents.
4	To deal with general health issues of the patient.
5	To liaise with the consultant regarding any complications of treatment.

Patient's role (or that of carer)	
1	Report to the specialist or GP if he or she does not have a clear understanding of the treatment.
2	Attend appropriate consultant and GP appointments
3	Share any concerns in relation to treatment with colomycin
4	Use written and other information on the medication.
5	Seek help urgently if suspect side effects, or otherwise unwell.

SUPPORTING INFORMATION

Dosage and Administration[3]
Colomycin – initial eradication:
Adults and children >1 year: 2 million units nebulised twice a day for 3 months
Children <1 year 1-2 million units nebulised twice a day for 3 months

Colomycin - maintenance
Children <1 year 1 million units twice daily
Adults and children >1 year: 2 million units twice daily

Before nebulising a dose of colomycin, the patient should either inhale or nebulise a dose of bronchodilator. Each vial of colomycin should then be reconstituted with 2-4ml 0.9% sodium chloride solution and poured into the nebuliser. Alternatively, water for injections may be used.

Monitoring
Through the hospital consultant: regular cough swabs/sputum samples, regular respiratory function monitoring and monitoring symptoms.

Contraindications
Colomycin is contraindicated:

- in patients with a known hypersensitivity to the drug
- in patients with myasthenia gravis
- in pregnancy and if breast-feeding, unless the benefits outweigh the risks

Special Warnings
Colomycin should be used with extreme caution in patients with porphyria.

Side Effects
Transpulmonary absorption of colomycin is generally considered to be negligible; therefore, there is a low risk of systemic toxicity. Nebulised colomycin causes bronchoconstriction in

some patients, which may lead to discontinuation. This may be relieved in some patients by using an inhaled bronchodilator prior to nebulisation.
Sore throat or mouth has been reported and may be due to *Candida albicans* infection or hypersensitivity. Skin rash may also indicate hypersensitivity, if this occurs treatment should be withdrawn
The summary of product characteristics should be consulted for full information with respect to adverse effects and drug interactions.

Drug Interactions
Nebulised antibiotics should not be given within an hour of dornase-alfa (Pulmozyme®).

The manufacturer's summary of product characteristics (SPC) and the most current edition of the British National Formulary should be consulted for full information on contra-indications, warnings, side-effects and drug interactions.

References

1. Colomycin injection (Forest Laboratories UK Ltd) Summary of Product Characteristics. October 2008.
2. BCAP Prescribing and Therapeutics Committee Shared Care Guidance for the prescription of nebulised colistin (colomycin)
3. Leeds Shared Care Guidance for the use of colistimethate sodium (colistin, colomycin).

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