Nebulised colistimethate Sodium (*Colomycin®*) (Amber with Shared care)

Shared Care Guidelines: For long term prophylaxis in patients with non-Cystic Fibrosis (non-CF) bronchiectasis who are chronically colonised with *Pseudomonas aeruginosa*

Colomycin® is licensed for use in patients with cystic fibrosis. Use in non-CF bronchiectasis is outside of the product license but well established and recommended in national guidance from the British Thoracic Society (BTS)[1]. See also NICE Evidence summary on use [ESUOM25][2].

This shared care policy only relates to use of Colomycin® (referred to as colistimethate for remainder of protocol). Colomycin® should be prescribed by brand to reduce risk of supplying alternative products with different licensing and/or at higher cost.

AREAS OF RESPONSIBILITY FOR THE SHARING OF CARE

This shared care agreement outlines suggested ways in which the responsibilities for managing the prescribing of colistemethate and non-CF bronchiectasis 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. Patients with the condition are under regular specialist follow-up, which provides an opportunity to discuss drug therapy.

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

RESPONSIBILITIES and ROLES

	Specialist responsibilities
1	To diagnose *Pseudomonas aeruginosa* colonisation in non-CF bronchiectasis patients.
2	Discuss the benefits and side effects of treatment with the patient.
3	Initiate treatment and ensure first test dose is carried out before a continuous prescription is requested.
4	To supply the initial 3 months of treatment.
5	To provide the nebuliser system and train the patient/carer in the use of the nebuliser and preparation of the medication.
6	To co-ordinate servicing/maintenance of the nebuliser system
7	To monitor for response and adverse drug reactions during the test dose and the initiation period.
8	Ask the GP whether he or she is willing to participate in shared care and agree with the GP as to who will discuss the shared care arrangement with the patient.
9	Supply GP with summary within 14 days of a hospital out-patient review or in-patient stay.
10	Review the patient's condition and monitor response to treatment at regular intervals with interval determined by patients clinical need
11	Give advice to the GP on when to stop treatment.
12	Report adverse events to the MHRA
13	Ensure that clear backup arrangements exist for GPs to obtain advice and support.
14	Supply all equipment needed to nebulise the medicine

	General Practitioner responsibilities
1	Reply to the request for shared care as soon as practicable.
2	Prescribe medicine at the dose recommended.
3	Refer promptly to specialist when any loss of clinical efficacy is suspected (e.g. worsening of disease-related symptoms, new symptoms suggestive of disease recurrence or progression) or intolerance to therapy occurs.
4	Report to and seek advice from the specialist on any aspect of patient care that is of concern to the GP and may affect treatment.
5	Stop treatment on the advice of the specialist.
6	Report adverse events to the specialist and MHRA

Patient's role	
1	Report to the specialist or GP if he or she does not have a clear understanding of the treatment.
2	Share any concerns in relation to treatment with medicine.
3	Report any adverse effects to the specialist or GP whilst taking the medicine.
4	Store the medication appropriately

BACK-UP ADVICE AND SUPPORT

Contact details	Telephone No.	Bleep:	Email address:
Specialist:	01225 825344		ruh-tr.respiratorynursespecialist@nhs.net
Hospital Pharmacy Dept:	01225 825361		ruh-tr.medicines-information@nhs.net
Other:			

SUPPORTING INFORMATION

Summary of condition and licensed indications.

Use in context of this SCP relates to;

- Long term prophylaxis in patients with non-CF bronchiectasis who are chronically colonised with *Pseudomonas aeruginosa*

Treatment Aims (Therapeutic plan)

Pseudomonas aeruginosa is a pathogen that causes severe lung damage in patients who become colonised. Patients with non-CF bronchiectasis are at risk of significant morbidity and mortality from the damage caused by this pathogen. Nebulised antipseudomonal antibiotic treatment has been shown to slow the rate of respiratory decline and reduce the frequency of infective exacerbations in these patients. Nebulised antibiotics are able to achieve high local concentrations with low systemic absorption and toxicity as opposed to intravenous antibiotics, where there is a high risk of developing adverse effects from systemic absorption. Use of Colomycin® in patients with non-CF bronchiectasis is outside the product license (currently limited to use in CF-bronchiectasis) but use is consistent with BTS recommendations established as appropriate for shared care.

Treatment Schedule (including dosage and administration)

Colistimethate comes in vials of either 1 or 2 million units.

Dose

Eradication – 1-2 million units nebulised twice a day for 3 months (***not managed under shared care***)
Prophylaxis – 1-2 million units twice a day on either a continuous or alternative month basis

Each vial needs to be diluted with up to 4 ml of sodium chloride 0.9% (prescribed as solution for injection). Diluents should be prescribed alongside the colistimethate vials.

Before administration of nebulised colistimethate, the patient may administer a bronchodilator, either nebulised salbutamol 2.5mg or 2 puffs of a salbutamol inhaler. Advice on use of pre-treatment bronchodilator will be provided by secondary care team prior to establishing shared care arrangements.

Nebuliser Systems

Ombra or Pari Boy compressors and AeroEclipse nebuliser kits are supplies by the hospital. The nebuliser kit is replaced every 6 months for those patients on continuous treatment

Contra-indications

Hypersensitivity to colistimethate sodium (colistin) or to polymyxin B.

Precautions for Use

Coughing and bronchospasm may occur on inhalation of antibiotics. Patient should always use a bronchodilator before administration of colistimethate

Bronchial hyper reactivity in response to colistimethate sodium may develop with continued use over time. If signs are shown, treatment should be stopped, and the patient referred back to the specialist.

Colistimethate sodium should be used with extreme caution in patients with myasthenia gravis because of potential for drug induced neuromuscular blockade

Colistimethate sodium should be used with extreme caution in patients with porphyria.

During pregnancy or breast-feeding patients should be managed by secondary care (although nebulised use unlikely to represent safety concern).

Side-effects
The most common undesirable effects following nebulisation of colistimethate sodium are coughing and bronchospasm in approximately 10% of patients. Patients may also experience pharyngolaryngeal pain or discomfort, dyspnoea and apnoea.

Refer to the SPC or BNF for a full list of adverse effects.

Monitoring
Monitoring is undertaken by the Respiratory team every 3 months. This can take place by telephone or in person and will monitor for adverse reactions, clinical health of the patient and need for further supplies of equipment.

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

Drug interactions are unlikely to occur with nebulised colistimethate, however there are reports of serum levels ranging from 0 – 4mg/l (therapeutic) following nebulised colistimethate so the possibility and consequences of systemic absorption should be considered.

Concomitant use of colistimethate with other medicinal products of neurotoxic and/or nephrotoxic potential should be avoided. These include the aminoglycoside antibiotics such as gentamicin, amikacin, netilmicin and tobramycin. There may be an increased risk of nephrotoxicity if given concomitantly with cephalosporin antibiotics.

Neuromuscular blocking drugs and ether should be used with extreme caution in patients receiving colistimethate.

Cost
At current prices, one year's treatment with medicine at the dose is £1,450

References

1. British Thoracic Society Guidelines for bronchiectasis in adults. Thorax. 2019 Jan;74(Suppl 1):1-69 available via https://thorax.bmj.com/content/74/Suppl_1/1.long
2. NICE Evidence summary (ESUOM25] non-cystic fibrosis bronchiectasis: colistimethate sodium access via https://www.nice.org.uk/advice/esuom25/chapter/Key-points-from-the-evidence accessed Nov 19
3. Electronic BNF accessed May 2019
4. Summary of Product Characteristics for Colomycin 1MU for nebulisation accessed electronically June 2019
5. Sheffield Area Prescribing Group Shared Care Protocol for nebulised Colomycin and Tobramycin July 2018
6. Herefordshire CCG Shared care Protocol for nebulised Colomycin June 2017

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Document details
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