NORFOLK AND WAVENEY STP THERAPEUTICS ADVISORY GROUP (TAG)

SHARED CARE AGREEMENT

Shared care guidelines for Nebulised Colistin for Bronchiectasis (Non-Cystic Fibrosis)
Monitoring level Amber 0 – Prescribe drug and perform basic monitoring eg annual review

Generic and Proprietary/Brand Name	
Colistimethate sodium (Colistin) / Colomycin Powder for Injection, Infusion or Inhalation	
Indications for shared care	
Long-term management of chronic pulmonary infection due to Pseudomonas aeruginosa in adult and paediatric patients with non-cystic fibrosis bronchiectasis.	
Specialist Prescribing and Monitoring Responsibilities – summary. Full details in main body of document	**GP / Community Team - Primary Care Prescribing and Monitoring Responsibilities – summary. Full details in main body of document**
Prescribing: • Administration of the first (test) dose with lung function monitoring • Training the patient/carer in use of nebulised antibiotics • Prescription and supply (via hospital pharmacy) of the first month of colistin and diluents • Supply and ongoing maintenance of an appropriate nebuliser/compressor system • On-going supply of plastic syringes to measure diluent volumes • Assess response to treatment and to discontinue if no benefit • Ongoing clinical and microbiological review **Initial specialist monitoring:** • Spirometry pre and post the initial (test) dose. **Ongoing specialist monitoring:** • Sputum microbiology	**Prescribing:** • On-going prescription of colistin and diluents (in plastic ampoules) **Monitoring:** • On-going compliance and tolerance
Patient Information	
Specialist will provide information following initiation	
Specialist Contact Details	
• Specialist Clinical Pharmacist, NNUH, Tel: 01603 287139 • Specialist Cystic Fibrosis Nurses, NNUH, Tel: 01603 289634	

GENERAL PRINCIPLES FOR SHARED CARE PRESCRIBING

- Shared Care is only appropriate if it provides the optimum solution for the patient.
- GPs are **invited** to participate. If GPs are not confident to undertake these roles, they are 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 if they are unwilling to do so.**
- Prescribing responsibility will only be transferred when it is agreed by the consultant and the patient's GP and when the patient's condition is stable or predictable.
- Safe prescribing must be accompanied by effective monitoring.
- **The doctor who prescribes the medication legally assumes clinical responsibility for the drug and the consequences of its use.**

Background to Treatment

Regular administration of nebulised antibiotics to patients with bronchiectasis has been shown to significantly reduce the density of P.aeruginosa in the lung and the frequency of respiratory exacerbations.

Additional benefits include improved lung function, slower rate of lung function decline, decreased hospital admission rates and reduced need for IV antibiotics.

Administration directly to the lung allows high local concentrations be achieved with low systemic absorption and toxicity.

Licensed use and agreed local off-label use

Treatment by inhalation of Pseudomonas aeruginosa lung infection

Criteria for Patient Selection

Patients with bronchiectasis who grow Pseudomonas aeruginosa in their sputum or cough swab and who have required repeated admissions to hospital for IV treatment

Form and strength of preparation

- Colistin 1,000,000 units (= 1 mega unit) per vial
- Colistin 2,000,000 units (= 2 mega units) per vial

Side Effects and Management

Link to BNF

Link to SPC

- Inhalation may induce coughing or bronchospasm.
- Sore throat has also been reported.
- Due to negligible systemic absorption of colistin from the lung, the risk of systemic toxicity is low.
- Skin rashes have occurred during nebulised treatment. They may be a sign of hypersensitivity and will require treatment to be stopped

Drug Interactions

Link to BNF

Link to SPC

- Trans-pulmonary absorption of colistin is considered to be negligible; therefore no significant interactions with systemic medication are anticipated.
- There are no known interactions with other inhaled/nebulised therapies.

Cautions and Contraindications

Link to BNF

Link to SPC

- Bronchospasm can occur. As a precaution the first (test) dose must be given under supervision, with lung function tests before and after to ensure continued suitability.
- Hypersensitivity to colistin or polymyxin B
- Patients with myasthenia gravis

Initiation of therapy and ongoing dose regimen

Treatment should only be initiated by a respiratory physician.

Initiation:

- Initial (test) dose will be given in hospital by a respiratory nurse with spirometry before and after to assess tolerability.
- In children who are too young to perform spirometry, assessment of tolerability will be made clinically by the specialist nurse who is administering the test dose.

Maintenance:

Child (1 month – 2 years): 500,000 units -1 mega unit BD

Child (2-18 years): 1-2 mega units BD

Adult: 2 mega units BD

Reconstitution:

The method used for the test dose should be continued. Any change in the diluents used will require the test dose to be repeated.

- **Method 1:** 5ml sodium chloride 0.9%
- **Method 2:** 2ml water + 2ml sodium chloride 0.9% (least likely to cause bronchoconstriction)

Administration Information

Long-term

If patients need pre-treatment with nebulised salbutamol 2.5mg, this can be mixed directly with colistin (immediately prior to use) and nebulised.

Reference:

Roberts GW, Badcock NR, Jarvinen AO (1992) Cystic Fibrosis Inhalation Therapy: Stability of a Combined Salbutamol/Colistin Solution. Australian Journal of Hospital Pharmacy. 22(5):378-80

Baseline assessment and ongoing monitoring – by Specialist

Initial specialist monitoring:

- Spirometry pre and post the initial (test) dose.

Ongoing specialist monitoring:

- Sputum microbiology

GP / Community Team or other Primary Care monitoring responsibilities

- On-going compliance and tolerance

Consultant / Specialist prescribing responsibilities

- Administration of the first (test) dose with lung function monitoring

- Training the patient/carer in use of nebulised antibiotics
- Prescription and supply (via hospital pharmacy) of the first month of colistin and diluents
- Supply and ongoing maintenance of an appropriate nebuliser/compressor system
- On-going supply of plastic syringes to measure diluent volumes
- Assess response to treatment and to discontinue if no benefit
- Ongoing clinical and microbiological review

GP prescribing responsibilities

- On-going prescription of colistin and diluents (in plastic ampoules)

Additional Information

- **Diluents**

  Diluents must be supplied in **5ml plastic ampoules** for ease of use and to avoid the risks associated with breaking glass ampoules. Where part ampoules need to be used, volumes do not need to be measured accurately using a syringe, they can be estimated from the original volume in the vial.

  Recommended method of reconstitution:

  The method used for the test dose should be continued. Any change in the diluents used will require the test dose to be repeated.

  - **Method 1:** 5ml sodium chloride 0.9%
  - **Method 2:** 2ml water + 2ml sodium chloride 0.9% (least likely to cause bronchoconstriction)

- **Nebuliser and associated equipment (Pari LC or eFlow)**

  This will be supplied by the hospital, and will be serviced / replaced when required.

- **Expiratory filters**

These are used while patients are in hospital to minimise risks of antibiotic resistance and staff sensitisation due to repeated exposure. **At home the use of expiratory filters is not considered to be necessary provided the patient nebulises alone in a well ventilated room**. If a particular patient wants to use filters they may be purchased direct from PARI Medical Limited. It is recommended that pets are not present in the room when nebulisation occurs.

Indications for referral back to Specialist

- Suspected side-effects / adverse reactions
- Deterioration in clinical status

Further information and supporting documents

- British Thoracic Society guideline for non-CF bronchiectasis. M C Pasteur, D Bilton, A T Hill. Thorax July 2010
- British Thoracic Society. Nebuliser treatment best practice guideline. Thorax. 1997 Vol 52 suppl 2

Author(s) and Organisation	• Last reviewed in consultation with Jack Johnson, Cystic Fibrosis Specialist Pharmacist, NNUH • Transferred to new template by Jen Carroll, TAG Lead Technician, NWICB
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Document history:

Version	Date	Author / Editor	Status	Comment
1.	July 2013	Helen Willimott Specialist Clinical Pharmacist, Respiratory Medicine, Norfolk and Norwich University Hospitals NHS Foundation Trust / Fiona Marshall TAG Lead Pharmacist	Superseded	For consideration by the TAG July 2013. Draft approved by the TAG (July 2013) subject to clarification that on-going supplies of plastic syringes for measuring diluents will be provided by the hospital since they are not available for GPs to prescribe on FP10 prescription forms.
2.0	Aug 2015	Helen Willimott Specialist Clinical Pharmacist, Respiratory Medicine, Norfolk and Norwich University Hospitals NHS Foundation Trust - TBC / Fiona Marshall TAG Lead Pharmacist	Draft	Reformatted in current TAG Shared Care Agreement template. Hyperlinks to manufacturer's SPC inserted. Advice on diluents and recommended methods of reconstitution repeated in appropriate sections of the document for easier reading. Sent to the NNUH for review ahead of consideration by the TAG.
2.1	Nov 2015	Specialist Clinical Pharmacist, Respiratory Medicine, Norfolk and Norwich University Hospitals NHS Foundation Trust	Current	No changes recommended by the NNUH. Supported by the TAG and approved by the N&W D&TCG on behalf of the CCGs.
3.0	Nov 2018 – Jan 2019	Reviewed in consultation with Jack Johnson, Cystic Fibrosis Specialist Pharmacist, NNUH / / Fiona Marshall TAG Lead Pharmacist	Draft for consultation	Logos updated as per AGEM CSU. Checked against current SPC. Supported by the TAG – January 2019 in the interim until NICE CG 117 is considered further by local specialists.
4.0	Aug 2021	Jen Carroll, TAG Lead Technician	FINAL	Discussed at August 2021 TAG meeting. Review dates extended

				for a year from meeting due to covid pressures
5,0	March 2024	Jen Carroll, TAG Lead Technician	Final	SCA moved to new template ready for publication on KNoW. Content not yet reviewed but remains current