SHARED CARE AGREEMENT

Name of medicine colistimethate sodium

Indication for chronic pulmonary *Pseudomonas aeruginosa* infection in children and adults with cystic fibrosis and adults with non-cystic fibrosis bronchiectasis

Version: **4.0** Approval date: **April 2023** Review date: **April 2026**

The Shared Care Agreement (SCA) is intended to facilitate the accessibility and safe prescribing of complex treatments across the secondary/primary care interface. It does not contain all of the relevant product information, which should be sought using the current British National Formulary and manufacturer's Summary of Product Characteristics. The SCA must be used in conjunction with the NHS Lothian Procedure for the Shared Care of Medicines, available here.

Roles and Responsibilities

Listed below are specific responsibilities that are additional to those included in the NHS Lothian Policy and Procedures for Shared Care. Please refer to the policy for core roles and responsibilities that apply to all Shared Care Agreements.

Consultant

- Initiating and supplying:
  - the first 28 days of treatment for patients with cystic fibrosis and for patients with non-cystic fibrosis (non-CF) bronchiectasis
- Training of patient/carer in the use of the medicine
- Promoting patient compliance/adherence
- Checking renal function at baseline and:
  - annually thereafter for CF patients
  - every 6-12 months for non-CF bronchiectasis patients
- Lung function assessment before and after first dose to check for bronchospasm
- Ongoing monitoring of clinical parameters including lung function.

General Practitioners and primary care non-medical prescribers

- Prescribing colistimethate sodium and plastic ampoules of water for injections and sodium chloride 0.9% after the initial 28 days (CF patients) or 3 months (non-CF bronchiectasis patients)
- Continue to prescribe the specified brand of colistimethate to ensure compatibility with the patient's nebuliser.

Patient, Relatives, Carers

- As listed in NHS Lothian Policy and Procedures for the Shared Care of Medicines

Support and Advice for the GP and primary care non-medical prescribers

Paediatric Cystic Fibrosis Service

Dr Don Urquhart, Consultant Paediatrician	Tel: 0131 312 1124
CF secretary	Tel: 0131 312 0453

Adult Cystic Fibrosis Service

Specialist Cystic Fibrosis Nurses, WGH	Tel: 0131 537 1762
Dr Usma Koser, Consultant Physician, WGH	Tel: 0131 537 1783
Dr Helen Rodgers, Consultant Physician, WGH	Tel: 0131 537 1783
Dr Crichton Ramsay, Consultant Physician, WGH	Tel: 0131 537 1783
Douglas McCabe, Respiratory Pharmacist, WGH	Tel: 07816 172703

Adult non-CF Bronchiectasis Service

Kim Turnbull, Bronchiectasis Specialist Nurse, RIE	Tel: 0131 242 1878
Respiratory Nurse Specialists, RIE	Tel: 0131 242 1878
Dr Anna Lithgow, Consultant Physician	Tel: 0131 242 1921
Dr Eilise Ryan, Consultant Physician	Tel: 0131 242 1921
David Bissett, Lead Respiratory Pharmacist, RIE	Tel: 0131 536 1000 Bleep: 5744
Jill Gill, Lead Physiotherapist, Adult bronchiectasis, RIE	Tel: 0131 242 1904 Bleep: 5417

Key information on the medicine

Refer to the current edition of the British National Formulary (BNF), available at www.bnf.org, and Summary of Product Characteristics (SPC), available at www.medicines.org.uk for detailed product and prescribing information.

Background to disease and use of drug for the given indication

Lung damage associated with persistent infection by *Pseudomonas aeruginosa* is the major cause of morbidity and mortality in people with cystic fibrosis (CF) and non-CF bronchiectasis.

In CF patients, inhaled antipseudomonal antibiotic treatment controls the burden of infection and has been shown in randomised controlled trials to improve lung function, slow the rate of respiratory decline and reduce the frequency of exacerbations of infection. This reduces the need for intravenous antibiotic treatment, hospital admission and the risk of developing antibiotic-related toxicity.

In patients with non-CF bronchiectasis, trials with long-term nebulised colistimethate sodium have demonstrated an improvement in the quality of life of patients colonised with *Pseudomonas aeruginosa* who have one or more exacerbation per year and can extend the time to first exacerbation.

Indication

Cystic Fibrosis

Colomycin® 1 million unit vial and 2 million unit vial by nebulisation is indicated in adults and children for the management of chronic infection due to *Pseudomonas aeruginosa* in patients with CF. Colomycin® powder is dissolved in 2-4 ml of water for injections or sodium chloride 0.9% injection for use in a nebuliser.

A mixture of 2ml water for injections and 2ml sodium chloride 0.9% added to Colomycin® 2 million unit vial gives an approximately isotonic solution, which may reduce adverse effects in some patients.

Promixin® 1 million unit vial is indicated for the treatment by nebulisation of colonisation and infections of the lung due to susceptible *Pseudomonas aeruginosa* in patients with CF.

This is not an approved Lothian Joint Formulary choice and should only be used with an iNeb® device. This should not be prescribed in place of Colomycin® unless specifically recommended by the CF clinic.

Colobreathe® dry powder for inhalation is indicated for the management of chronic pulmonary infections due to *Pseudomonas aeruginosa* in patients with CF aged 6 years and older.

Non-CF Bronchiectasis

Colomycin® 1 million unit vial and 2 million unit vial by nebulisation is indicated for the treatment of patients with recurrent chest infection (≥3 annually) who are chronically colonised with *Pseudomonas aeruginosa*. The dose will be stated by the specialist and is usually 1 million units twice daily but may occasionally be increased to 2 million units twice daily. Colomycin® powder 1 million units is dissolved in 4 ml of sodium chloride 0.9% injection for use in a nebuliser.

Additional items required for administration by nebulisation:

Colistimethate sodium vials require reconstitution before inhalation. Please ensure patients are also prescribed the following items:

- Water for Injection 5ml e.g. Mini-Plasco® ampoules (B.Braun Medical Ltd)
- Sodium chloride, 0.9% solution for injection 5ml e.g. Mini-Plasco® ampoules (B.Braun Medical Ltd)
- It is important that plastic ampoules, rather than glass ampoules are prescribed.

Dosage and Administration

Please refer to www.bnf.org and www.medicines.org.uk

Monitoring

There are no specific monitoring requirements for the GP. All monitoring will be carried out in the specialist clinics including regular monitoring of lung function, adherence and adverse effects.

Cautions, contraindications - Refer to current Summary of Product Characteristics (SPC): www.medicines.org.uk

Fertility, Pregnancy and Lactation
Refer to current Summary of Product Characteristics: www.medicines.org.uk for full detail.
Vaccination - NA
Adverse effects - Refer to current Summary of Product Characteristics (SPC): www.medicines.org.uk

Drug interactions - Refer to current Summary of Product Characteristics (SPC): www.medicines.org.uk

The presence of this SCA does not compel a primary care prescriber to prescribe if they feel that it is out with the scope of their competencies (as per GMC guidance on safe prescribing) or resources, as ultimate responsibility lies with the prescribing, not the recommending, clinician.

For office use only:

Approved by the General Practice Prescribing Committee (GPPC) on 06 June 2023