**DRUG:**

**Inhaled antibiotics (Adults and Paediatrics) in Cystic Fibrosis. EXISTING ESTABLISHED PATIENTS ONLY**

- **Colistimethate** (Colomycin®, Promixin®)
- **Tobramycin** (Tobi®, Bramitob®)

**Introduction**

Inhaled antibiotics can be used for a short course (up to 3 months) alongside oral/IV antibiotic for the eradication of pulmonary *Pseudomonas aeruginosa* infection.

They can also be used long term for chronic pulmonary *Pseudomonas aeruginosa* infection.

Formulations are typically unlicensed in children under 6 years of age (with the exception of colomycin). Specialist commissioning group policy states however that, ‘Treatments are typically not licensed for use in children under the age of 6 years, but such use is commonplace and clinically appropriate’.


Patients may be prescribed any of the following agents (see table). Until further notice existing patients established on Colistimethate (Colomycin®) or Tobramycin (Tobi®, Bramitob®) should continue to have treatment prescribed by primary care. All new patients and patients on alternative formulations or antibiotics should have treatment initiated and continued by secondary care.

<table>
<thead>
<tr>
<th>Medication</th>
<th>Brand</th>
<th>Route</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Prescribe by brand name to avoid confusion</strong></td>
<td></td>
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<tr>
<td>Existing established patients – GP to continue to prescribe until further notice. New patients – all prescribing from secondary care</td>
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<tr>
<td>Colistimethate</td>
<td>Colomycin®</td>
<td>Nebulised</td>
</tr>
<tr>
<td>Colistimethate</td>
<td>Promixin®</td>
<td>Nebulised</td>
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<tr>
<td>Tobramycin</td>
<td>Tobi®</td>
<td>Nebulised</td>
</tr>
<tr>
<td>Tobramycin</td>
<td>Bramitob®</td>
<td>Nebulised</td>
</tr>
<tr>
<td>No existing patients on treatment. All prescriptions from secondary care</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Colistimethate</td>
<td>Colobreath®</td>
<td>Dry powder inhaler</td>
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</tbody>
</table>
Prescribing information

<table>
<thead>
<tr>
<th>Drug</th>
<th>Formulation</th>
<th>Standard dose (local policy)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tobramycin</td>
<td>Tobi Podhaler®</td>
<td>Dry powder inhaler</td>
</tr>
<tr>
<td>Aztreonam Lysine</td>
<td>Cayston®</td>
<td>Nebulised</td>
</tr>
</tbody>
</table>

Disease monitoring will be undertaken by secondary care, but as there is no additional monitoring specific to the drug, full shared care guidelines are not required. Prescribing information (side effect, drug interactions) can be found in the BNF and in the SPC at www.medicines.org.uk/EMC. The following shortened shared care guideline outlines the responsibility of the Specialist, GP and patient.

**Colistimethate (Colomycin®, Promixin®)**

**Formulation**

**Colomycin®**
- Powder for solution for injection, infusion or inhalation
  - 1 million units/vial
  - 2 million units/vial

**Promixin®**
- Powder for nebuliser solution
  - 1 million units/vial

**Standard dose (local policy)**

**Children <2 years of age**
- 1 million units twice daily
- The powder is usually reconstituted with 4mL sodium chloride 0.9% (as per Leeds policy)

**Children ≥ 2 years and adults**
- 2 million units twice daily
- The powder is usually reconstituted with 2mL water for injection and 2mL sodium chloride 0.9% to give a final volume of 4mL (as per Leeds policy)

**Promixin®**
- Powder for nebuliser solution
  - 1 million units/vial

**Children ≥ 2 years and adults**
- 1 million units twice daily
- The powder is usually reconstituted with 1mL water for injection

**Tobramycin (Tobi®, Bramitob®)**

**Formulation**

**Tobi®**
- Nebuliser solution
  - 300mg/5mL

**Bramitob®**
- Nebuliser solution
  - 300mg/4mL

**Standard dose (local policy)**

**Children ≥ 6 years and adults**
- 300mg twice daily for 28 days and then 28 days off treatment
- (Leeds regional guidance states the above dose can be used in all ages over 6 months)

Responsibilities of the specialist initiating treatment:

**General:**
- To assess suitability of the patient for treatment and to perform a ‘test dose’ with lung function monitoring or other suitable monitoring where lung function is not possible.
- To ensure that the patient/carer has received counselling and understands the therapy, its benefits, limitations, continued monitoring (where applicable), adverse effects, and is aware of actions to take if adverse effects are suspected.
• To train the patient/carer in the use of the antibiotic by the route indicated (i.e. nebuliser or dry powder inhaler)
• Inform the GP of the information provided to the patient.
• To review the patient at agreed intervals to carry out disease monitoring and copy all relevant results to the GP.
• To inform GP of the expected length of treatment e.g. for three months or long-term, and the required dilution prior to administration.
• Formally hand over to GP by letter and patient informed - send a copy (either electronically or paper copy) of the Shared Care Guideline to the GP and ask whether they are willing to participate in shared care – this should already have been done.

Prescribing:
• **NEW PATIENTS** – initiate treatment and maintain prescribing responsibility, do not transfer care to the GP
• **ESTABLISHED PATIENTS** – GPs may continue to prescribe Colistimethate (Colomycin®, Promixin®) or Tobramycin (Tobi®, Bramitob®) where shared care is already established
  • Prescribe by brand name.
  • When required to provide and maintain a suitable nebuliser system or to refer to community equipment services where this is normal practice.

Disease & drug monitoring:
• Discuss shared care arrangement with patient – this should already have been done as the patients are established on treatment.
• Support and advise GPs as required.
• Assess response to treatment including monitoring long-term efficacy and initiate any dose changes as clinically appropriate including discontinuation of treatment.
• To monitor for adverse drug reactions and report them to the GP and where appropriate the Commission on Human Medicines/MHRA (Yellow card scheme)

Responsibilities of other prescribers (GPs):

**General and Prescribing:**

**Existing patients**
• Continue to prescribe inhaled antibiotic prescriptions (Colomycin®, Promixin®, Tobi® or Bramitob®) for existing patients as recommended by the specialist.
• Prescribe by brand name.
• Ensure continued prescribing remains clinically appropriate for the expected duration of time, at dose advised by initiating team.
• Notify Consultant if treatment is discontinued.
• Ensure there are no drug interactions or contraindications with any other medications initiated in primary care

**New patients**
• New patients initiated on alternative formulations of colistimethate, tobramycin or different antibiotics will have all their prescriptions organised by secondary care as this treatment is now commissioned
by NHS England.
- Notify Consultant of any changes made to treatment supplied by primary care.
- Notify Consultant if treatment is discontinued.
- Ensure there are no drug interactions with any other medications initiated in primary care.

### Disease & drug monitoring:
- There is no routine blood monitoring required. GP to monitor for adverse effects, drug interactions etc.
- Refer back to the specialist if the patient’s condition deteriorates.
- Stop treatment on the advice of the specialist.
- Urgent drug discontinuation/ referral to specialist as clinically appropriate
- Identify adverse effects and report these to the specialist and where appropriate to the Commission on Human Medicines/MHRA (Yellow card scheme).

### General:
- To inhale the antibiotic as prescribed.
- Report any possible side effects to their GP or specialist.
- To report any queries or problems with inhaled antibiotics promptly to either the GP or specialist team as appropriate.
- Ensure they have adequate supply of medication.
- Attend appointments.
- Discuss any plans to conceive with specialist
- Discuss any plans to breast feed with specialist
- Inform GP/specialist if unexpected pregnancy is suspected.

### Disease & drug monitoring:
As above – contact GP or initiating team if side effects develop and attend appointments including those for routine blood tests/investigations.

### Specialist to GP:
- The specialist will already have informed the GP that they have initiated inhaled antibiotics and when there are any subsequent changes in treatment – standard clinic letter.
- Inform the GP of the information provided to the patient

### GP to Specialist:
- Irrespective of whether you accept prescribing responsibility or not, you should inform the consultant of relevant medical information regarding the patient and changes to the patient’s medication regime irrespective of indication.
- Notify Consultant if treatment with inhaled antibiotics is discontinued.
Contact names & details:
If you have any concerns regarding individual patients, see consultant letter for medical contact details or contact one of the following.
For people with Cystic Fibrosis:

<table>
<thead>
<tr>
<th>Name</th>
<th>Title/Location</th>
<th>Telephone / Bleep</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tracey Daniels</td>
<td>Specialist physiotherapist for CF</td>
<td>01904 725601/5528 <a href="mailto:tracey.daniels2@york.nhs.uk">tracey.daniels2@york.nhs.uk</a></td>
</tr>
<tr>
<td>Andrew Booth</td>
<td>Specialist nurse</td>
<td>01904 725601 <a href="mailto:andrew.booth2@york.nhs.uk">andrew.booth2@york.nhs.uk</a></td>
</tr>
<tr>
<td>Dr Rebecca Thomas</td>
<td>Consultant Respiratory Physician</td>
<td>01904 726045 <a href="mailto:rebecca.thomas@york.nhs.uk">rebecca.thomas@york.nhs.uk</a></td>
</tr>
<tr>
<td>Dr Murray Wheeler</td>
<td>Consultant Paediatrician</td>
<td>01904 725510 <a href="mailto:Murray.wheeler@york.nhs.uk">Murray.wheeler@york.nhs.uk</a></td>
</tr>
<tr>
<td>Julie Naylor</td>
<td>Paediatric specialist CF nurse</td>
<td>01904 721356 <a href="mailto:Julie.Naylor@york.nhs.uk">Julie.Naylor@york.nhs.uk</a></td>
</tr>
</tbody>
</table>

References:
- British National Formulary 66 (Sept 2013)

This information is not inclusive of all prescribing information and potential adverse effects. Please refer to the SPC (data sheet) or BNF for further prescribing information.

The original Microsoft Word file of this document is located on:
York Teaching Hospital NHS Foundation Trust Pharmacy Department X:\MEDICINES INFORMATION\Shared Care Guidelines\Approved Shared Care Guidelines\INHALED ANTIBIOTICS IN CYSTIC FIBROSIS Shared Care Guideline V1

Shared Care Guidelines are also available electronically via http://nww.nyypct.nhs.uk/Directorates/PublicHealth/MedicinesManagement/SharedCare_YorkTrust.htm

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