Basingstoke, Southampton and Winchester District Prescribing Committee

Shared Care Guideline: **Nebulised Tobramycin**

Name of patient treated under this guideline:

This shared care guideline has been produced to support the seamless transfer of prescribing and patient monitoring from secondary to primary care, and provides an information resource to support clinicians providing care to the patient. It does not replace discussion about sharing care on an individual patient basis.

This guideline was prepared using information available at the time of preparation, but users should always refer to the manufacturer's current edition of the Summary of Product Characteristics (SPC or "data sheet") for more details.

1.0 Status of nebulised tobramycin

Nebulised tobramycin is an "amber" drug using our local traffic light system. This means that treatment will usually be initiated in secondary care. The key principle is that the GP is provided with information and given the opportunity to accept (or decline) prescribing responsibility before the transfer occurs.

2.0 Licensed Indications and Dose

Tobramycin nebuliser solution is licensed for the long-term management of chronic pulmonary infection due to *Pseudomonas aeruginosa* in cystic fibrosis (CF) patients aged 6 years and older.

Tobramycin nebuliser solution is presented as 300mg/5ml (Tobi®) or 300mg/4ml (Bramitob®) in single use ampoules. It is not for parenteral use. The ampoules should be stored in a refrigerator at 2-8^{o}C, although the ampoules may be stored at room temperature (up to 25^{o}C) for 28days. The solution should not be mixed with any other drug.

The recommended dose for adults and children is 300mg nebulised twice daily using a PARI LC PLUS® (supplied free by the company) for 28 days, followed by a 28day break. This cycle should continue for as long as clinical benefit is seen.

3.0 Referral Criteria

Consultants will consider tobramycin nebuliser solution for any patient with cystic fibrosis who is chronically colonised with *Pseudomonas aeruginosa.*

4.0 Patient Selection

Patients will be selected on the basis of their pulmonary microbiology and ability to use a nebuliser system.

5.0 Safety Issues

5.1 Contra-indications (see BNF or SPC)

- Patients with a known hypersensitivity to aminoglycosides should not receive tobramycin nebuliser solution.
- Use of other nephrotoxic and ototoxic drugs should be avoided. This includes, diuretics, etacrynic acid ciclosporin, tacrolimus, polymixins and anticholinesterases.

5.2 Cautions (see BNF or SPC)

- The first dose should be given under supervision in hospital in case of bronchospasm.
- Measure lung function before and after nebulisation – if bronchospasm occurs, repeat using a bronchodilator e.g. salbutamol
- Other inhaled drugs should be administered before tobramycin.
- Monitor renal function before treatment and at least annually.
- Severe haemoptysis.
- Neuromuscular disorders.
- Pregnancy.

5.3 Common Side Effects (See BNF or SPC)

- Respiratory: increased coughing, voice alteration
- Gastrointestinal: vomiting, abdominal pain
- Sensory: tinnitus, hearing loss

5.4 Drug Interactions (see BNF or SPC)

- No known interactions.

5.5 Pre-treatment Assessment

- Pulmonary microbiology
- Renal function
- Patient should be taught how to use the nebuliser and compressor system.
- Patient should be given relevant information and advice

5.6 Routine Safety Monitoring

- Pulmonary microbiology (2-3 monthly)
- Renal function (annually)
- Audiology (annually)

6.0 Role of Consultant

The decision to use tobramycin nebuliser solution 300mg will be made by a consultant specialising in CF.

1. To assess the suitability of the patient for tobramycin nebuliser solution.
2. To discuss relevant safety issues with patients, and to make them aware of cautions or side effects.
3. Assessment of renal function prior to commencing treatment and annually thereafter.
4. Annual audiology assessment.
5. Supervision of first dose with evaluation for the development of bronchospasm
6. To ask the GP in writing whether they are willing to participate in shared care, this should include a copy of the shared care guideline. This correspondence should occur prior to initiating treatment.
7. To initiate therapy.
8. To monitor pulmonary microbiology for the development of paseudomonas resistance or other non-sensitive pathogens.

9. Prompt communication in writing with the GP of any changes in treatment and assessment of response and occurrence of adverse effects.
10. Advice on when to stop treatment.

7.0 Role of GP

1. To reply to the consultant accepting shared care if appropriate.
2. To ensure all other practice staff are aware of the shared care guideline.
3. Prescribing of tobramycin nebuliser solution once informed by the specialist that the patient has responded and is tolerating treatment.
4. To write the prescription in accordance with this shared care guideline.
5. Report adverse events to CF specialist and Medicines and Healthcare products Regulatory Agency.
6. If the patient reports tinnitus or hearing loss during treatment, refer to specialist for audiological assessment and advice regarding continuation of treatment.
7. Report to and seek advice from the specialist on any aspect of patient care that is of concern and may affect treatment.

8.0 Role of Patient or Parent

1. Report any adverse effects to the GP whilst taking nebulised tobramycin.
2. Ensure they have a clear understanding of their treatment.
3. Ensure correct storage and administration of the nebuliser solution.

9.0 Role of the Specialist Physiotherapist

1. To make sure all patients have an appropriate nebuliser system.
2. To administer the test dose of tobramycin nebuliser solution.
3. To monitor lung function pre and post dose.

10.0 Further Information

Southampton University Hospitals 023-80777222	
Lead Consultant	Gary Connett (Paeds) Mary Carroll (Adults)
Lead Nurse	Judi Maddison (Paeds) Tessa Hodson (Adults)
Lead Pharmacist	Amanda Bevan (Paeds) Caron Underhill (Adults)
Medicines Information	023-80796908/9

Royal Hampshire County Hospital 01962-863535	
Lead Consultant	Keith Foote (Paeds)
Lead Nurse	
Lead Pharmacist	Malcolm Irons
Medicines Information	01962-824294

North Hampshire Hospital 01256-473202	
Lead Consultant	Preya Ilangovan (Paeds)
Lead Nurse	
Lead Pharmacist	P Smith
Medicines Information	01256-473202

Lead Author: Amanda Bevan
Reviewed by: Gary Connett, Julian Legg, Mary Carroll, Julia Nightingale.
Approved by DPC: (Martin Stephens, Chair)
Review date: July 2012.