Share Care Protocol

Shared Care Guideline for Bramitob 300mg/4ml Nebuliser Solution		Reference Number
Author(s)/Originator(s): (please state author name and department) Nicola Jones, Specialist Cystic Fibrosis Pharmacist, Manchester Adults Cystic Fibrosis Centre, University Hospital South Manchester		**To be read in conjunction with the following documents:** Current Summary of Product characteristics (http://www.medicines.org.uk) BNF
Date approved by Commissioners: *dd/mm/yyyy*	**Review Date:** *dd/mm/yyyy*	

Please complete all sections

1. Licensed Indications	Management of chronic pulmonary infection due to *Pseudomonas aeruginosa* in patients with cystic fibrosis aged 6 years and older.
2. Therapeutic use & background	Lung damage associated with persistent infection by *Pseudomonas aeruginosa* is the major cause of morbidity and mortality in people with cystic fibrosis (CF). Nebulised anti-pseudomonal antibiotic treatment controls the burden of infection and has been shown to improve lung function, slow the rate of respiratory decline and reduce the frequency of exacerbations of infection in CF. This reduces the need for intravenous antibiotic treatment and hospitalisation. Nebulised antibiotics reduce the risk of developing antibiotic-related toxicity compared to intravenous antibiotics as they achieve high local concentrations with low systemic absorption and toxicity.
3. Contraindications (please note this does not replace the SPC or BNF and should be read in conjunction with it).	Administration of Bramitob is contraindicated in all patients with hypersensitivity to tobramycin, to any other aminoglycosides or to any of the excipients. It is also contraindicated in patients receiving potent diuretics, such as furosemide or ethacrynic acid, which have proved to be ototoxic.
4. Prescribing in pregnancy and lactation	**Pregnancy** There is no adequate data from the use of tobramycin administered by inhalation in pregnant women. Animal studies do not indicate a teratogenic effect of parenteral tobramycin, as shown in preclinical data. However, aminoglycosides can cause foetal harm (e.g., congenital deafness) when high systemic concentrations are achieved in a

	pregnant woman. If Bramitob is used during pregnancy, or if the patient becomes pregnant while taking Bramitob, she should be informed of the potential hazard to the foetus. **Lactation** Systemic tobramycin is excreted in breast milk. It is not known if inhaled tobramycin will result in serum concentrations high enough for tobramycin to be detected in breast milk. Because of the potential risk for ototoxicity and nephrotoxicity with tobramycin in infants, a decision should be made whether to terminate nursing or discontinue Bramitob therapy. This drug can be prescribed in the pregnant and breastfeeding patient where the benefits to the mother outweigh the risks to the foetus or baby. Under these circumstances prescribing should be the responsibility of the specialist CF team.
5. Dosage regimen for continuing care	Route of administration: Nebulisaton Preparations available – nebuliser solution only
	Insert dose to be prescribed including units, frequency and duration of treatment. Please prescribe: Bramitob 300mg BD for 28 days. The dose interval should be as close as possible to 12 hours. A cycle of 28 days on followed by 28 days off treatment should be maintained for as long as clinical benefit is seen.
	Is titration required: ~~**Yes**~~ **No**
	n/a
	Adjunctive treatment regime The patient should continue their standard regimen of chest physiotherapy. The use of appropriate bronchodilators should continue as deemed clinically appropriate. If patients are receiving several different respiratory therapies it is recommended that they take them in the following order: 1) bronchodilator 2) chest physiotherapy, 3) other inhaled medicinal products, 4) and lastly, Bramitob.
	Conditions requiring dose reduction *Elderly patients* Tobramycin should be used with caution in elderly patients who may have reduced renal function.

	Patients with renal impairment Tobramycin should be used with caution in patients with known or suspected renal, dysfunction. Bramitob should be discontinued in the case of nephrotoxicity until serum concentration of tobramycin fall below 2 µg/mL *Patients with hepatic insufficiency* No changes in dose are required in hepatic insufficiency
	Usual response time Response will be assessed at the specialist centre at the patients' routine appointments
	Duration of treatment : ongoing until terminated by the specialist CF team
	Treatment to be terminated by the specialist CF team
	NB. All dose adjustments will be the responsibility of the initiating specialist care unless directions have been specified in the medical letter to the GP.
6.Drug Interactions ***For a comprehensive list consult the BNF or Summary of Product Characteristics***	The following drugs must <u>not</u> be prescribed without consultation with the specialist: Concurrent and/or sequential use of Bramitob with other medicinal products with nephrotoxic or ototoxic potential should be avoided. Some diuretics can enhance aminoglycoside toxicity by altering antibiotic concentrations in serum and tissue. Bramitob should not be administered concomitantly with furosemide, ethacrynic acid, urea or mannitol. Other medicinal products that have been reported to increase the <u>potential toxicity of parenterally administered aminoglycosides</u> include: Amphotericin B, cephalotin, ciclosporin, tacrolimus, polymyxins (risk of increased nephrotoxicity); platinum compounds (risk increased nephrotoxicity and ototoxicity). Anticholinesterases, botulinum toxin: Due to their neuromuscular effects, the combination with tobramycin should be avoided.
	The following drugs may be prescribed with caution: See above.
7. Adverse drug reactions *For a comprehensive list*	**Specialist to detail below the action to be taken upon occurrence of a particular adverse event as appropriate. Most serious toxicity is seen with long-term use and may therefore present first to GPs.**

(including rare and very rare adverse effects), or if significance of possible adverse event uncertain, consult Summary of Product Characteristics or BNF	**Adverse event** System – symptom/sign	**Action to be taken** Include whether drug should be stopped prior to contacting secondary care specialist	**By whom**
	Nervous system disorders: Headache-uncommon (≥1/1,000 to <1/100)	Patient to be advised to contact specialist CF centre on 0161 291 2015 in hours or 0161 291 4732 out of hours or GP to stop therapy and contact the specialist centre	GP or patient
	Infections & Infestation: Oral candidiasis-uncommon (≥1/1,000 to <1/100)	As above	GP or patient
	Ear and labyrinth disorders: Vertigo, hypoacusis, deafness neurosensory-uncommon (≥1/1,000 to <1/100)	As above	GP or patient
	Respiratory, thoracic and mediastinal disorders: Cough, productive cough, dysphonia- common (≥1/100 and <1/10) Forced expiratory volume decreased, dyspnoea, rales, haemoptysis, oropharyngeal pain- uncommon (≥1/1,000 to <1/100);	As above	GP or patient
	Gastrointestinal disorders: Salivary hypersecretion, glossitis, abdominal pain upper, nausea- uncommon (≥1/1,000 to <1/100)	As above	GP or patient
	Skin and subcutaneous tissue disorders: Rash-uncommon (≥1/1,000 to <1/100)	As above	GP or patient

	General disorders and administration site conditions: Asthenia, chest discomfort, mucosal dryness - uncommon (≥1/1,000 to <1/100)	As above	GP or patient
	Investigations: Transaminases increased - uncommon (≥1/1,000 to <1/100)	As above	GP or patient
	The patient should be advised to report any of the following signs or symptoms to their GP without delay: Any of the above, contact specialist CF centre on 0161 291 2015 in hours or 0161 291 4732 out of hours or GP		
	Other important co morbidities (e.g. Chickenpox exposure). Include advice on management and prevention and who will be responsible for this in each case: n/a		
	Any adverse reaction to a black triangle drug or serious reaction to an established drug should be reported to the MHRA via the "Yellow Card" scheme. Yes		
8.Baseline investigations	Baseline pulmonary function tests, audiology and renal tests will be performed by the specialist centre.		
9. Ongoing monitoring requirements to be undertaken by GP	**Is monitoring required?**	**Yes or No (if yes complete following section)** *[insert]*	

Monitoring	**Frequency**	**Results**	**Action**	**By whom**
n/a	*n/a*	*n/a*	*n/a*	*n/a*

10. Pharmaceutical aspects	Store in a refrigerator (2-8°C). Store in the original package in order to protect from light. May be stored outside a refrigerator but below 25°C for up 3 months. Bramitob should not be mixed or diluted with any other drug. After first opening the single-dose container: use immediately. Discard the used single-dose container immediately.

11. Secondary care contact information	**If stopping medication or needing advice please contact:**
	Prof AK Webb / Dr A Jones / Dr R Bright-Thomas / Dr A Brennan
	Contact number: *0161 291 2016*
	Hospital: *University Hospital of South Manchester*
12. Criteria for shared care	Prescribing responsibility will only be transferred when ▪ Treatment is for a specified indication and duration. ▪ Treatment has been initiated and established by the secondary care specialist. ▪ The patient's initial reaction to and progress on the drug is satisfactory. ▪ The GP has agreed in writing in each individual case that shared care is appropriate. ▪ The patient's general physical, mental and social circumstances are such that he/she would benefit from shared care arrangements

13. Responsibilities of initiating specialist	Continue treatment and prescribe until dose is stable Undertake baseline monitoring. Dose adjustments. Monitor patient's initial reaction to and progress on the drug. Ensure that the patient has an adequate supply of medication until GP supply can be arranged. Continue to monitor and supervise the patient according to this protocol, while the patient remains on this drug, and agree to review the patient promptly if contacted by the GP Provide GP with diagnosis, relevant clinical information and baseline results, treatment to date and treatment plan, duration of treatment before consultant review. Provide GP with details of outpatient consultations within 14 days of seeing the patient *or* inform GP if the patient does not attend appointment Provide GP with advice on when to stop this drug. Provide patient with relevant drug information to enable Informed consent to therapy Provide patient with relevant drug information to enable understanding of potential side effects and appropriate action Provide patient with relevant drug information to enable understanding of the role of monitoring. Provide patient with monitoring booklet where appropriate. ----------
14. Responsibilities of the GP	Continue treatment as directed by the specialist Ensure no drug interactions with concomitant medicines To monitor and prescribe in collaboration with the specialist according to this protocol To ensure that the monitoring and dosage record is kept up to date To undertake influenza vaccine annually and ensure pneumococcal vaccine administered once since birth as directed by the initiating consultant, the BNF or Green Book Symptoms or results are appropriately actioned, recorded and communicated to secondary care when necessary. ----------
15. Responsibilities of the patient	To take medication as directed by the prescriber, or to contact the GP if not taking medication To attend hospital and GP clinic appointments, bring monitoring booklet (if issued) Failure to attend will result in medication being stopped (on specialist advice). To report adverse effects to their Specialist or GP.

16.Additional Responsibilities	**List any special considerations**	**Action required**	**By whom**	**Date**
	Tolerability to be assessed by specialist centre	***Clinical assessment***	***Clinicians at specialist centre***	***4 weeks after start of treatment and then at each clinic visit thereafter***
	Effectiveness to be assessed by specialist centre	***Clinical assessment***	***Clinicians at specialist centre***	***4 weeks after start of treatment and then at each clinic visit thereafter***
	Adherence to treatment	***Discussion with patient – and communication between specialist centre and GP***	***Clinicians at specialist centre and GP***	***4 weeks after start of treatment and then at each clinic visit thereafter by specialist centre or following a routine appointment or review by GP***
17. Supporting documentation	The SCG must be accompanied by a patient information leaflet.			
18. Patient monitoring booklet	The patient must receive a monitoring booklet from the specialist upon initiation of treatment. The patient must bring this booklet to all specialist and GP appointments where it will be updated by the health professional conducting the appointment. The patient must also produce the booklet to any health professional involved in other aspects of their care e.g. pharmacists and dentists.			
19. Shared care agreement form	Attached below			

Shared Care Agreement Form

Specialist request

***IMPORTANT: ACTION NEEDED**

Dear Dr *[insert Doctors name here]*

Patient name: *[insert Patients name here]*
Date of birth: *[insert date of birth]*
Diagnosis: *[insert diagnosis here]*

This patient is suitable for treatment with *[insert drug name]* for the treatment of *[insert indication]*

This drug has been accepted for Shared Care according to the enclosed protocol (as agreed by Trust / LHB / AWMSG). I am therefore requesting your agreement to share the care of this patient.

Treatment was started on *[insert date started]* *[insert dose].*

If you are in agreement, please undertake monitoring and treatment from *[insert date]*
NB: date must be at least 1 month from initiation of treatment.

Baseline tests: *[insert information]*

Next review with this department: *[insert date]*
You will be sent a written summary within 14 days. The medical staff of the department are available at all times to give you advice. The patient will not be discharged from out-patient follow-up while taking *[insert text here]*.

Please use the reply slip overleaf and return it as soon as possible.

Thank you.

Yours

[insert Specialist name]

Shared Care Agreement Form

GP Response

Dear Dr *[insert Doctors name]*

Patient *[insert Patients name]*

Identifier *[insert patient date of birth/address]*

I have received your request for shared care of this patient who has been advised to start *[insert text here]*

A I am willing to undertake shared care for this patient as set out in the protocol

B I wish to discuss this request with you

C I am unable to undertake shared care of this patient.

GP signature Date

GP address/practice stamp