Shared Care Protocol

Shared Care Guideline for Cayston 75mg (Aztronam lysine powder and solvent for nebuliser solution)		Reference Number
Author(s)/Originator(s): (please state author name and department) Katrina Cox, 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	Cayston is indicated for the suppressive therapy of chronic pulmonary infections due to *Pseudomonas aeruginosa* in patients with cystic fibrosis (CF) aged 6 years and older.
2. Therapeutic use & background	Lung damage associated with persistent infection with *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 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).	Hypersensitivity to the active substance or to any of the following excipients: *Powder vial* - L-Lysine *Solvent ampoule* - sodium chloride and water for injections
4. Prescribing in pregnancy and lactation	There are no data from the use of aztreonam in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive. Systemic concentration of aztreonam following inhaled administration of Cayston is low compared to a standard dose of aztreonam for injection (approximately 1% of the concentration resulting from a dose of 500 mg aztreonam for injection). Cayston should not be used during pregnancy unless the clinical condition of the woman requires treatment with aztreonam. Following administration of aztreonam for injection, aztreonam is excreted in human milk at very low concentrations. Systemic concentration of aztreonam following inhaled administration of Cayston is approximately 1% of the concentration resulting from a standard dose of aztreonam for injection. Therefore, and because of low oral absorption,

	aztreonam exposure in breast-fed infants due to mothers receiving Cayston is likely to be extremely low. Cayston can be used during breast-feeding. This drug can be prescribed in the pregnant and breastfeeding patient. 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: Cayston 75mg TDS for 28 days, followed by 28 days off Cayston. Doses should be taken at least 4 hours apart. Cayston may be taken in repeated cycles of 28 days on therapy followed by 28 days off Cayston therapy.		
	Is titration required	~~**Yes**~~	**No**
	n/a		
	Adjunctive treatment regime Patients should use a bronchodilator before each dose of Cayston. Short acting bronchodilators can be taken between 15 minutes and 4 hours and long acting bronchodilators can be taken between 30 minutes and 12 hours prior to each dose of Cayston. For patients taking multiple inhaled therapies, the recommended order of administration is as follows: 1. bronchodilator 2. mucolytics 3. and lastly, Cayston.		
	Conditions requiring dose reduction *Elderly population* Clinical studies of Cayston did not include Cayston-treated patients aged 65 years and older to determine whether they respond differently from younger patients. If Cayston is to be prescribed to the elderly then the posology is the same as for adults. *Renal impairment* Aztreonam is known to be excreted renally and therefore administration of Cayston in		

	patients with renal impairment (serum creatinine > 2 times upper limit of normal) should be undertaken with caution. No dose adjustment is necessary in cases of renal impairment since the systemic concentration of aztreonam following inhaled administration of Cayston is very low (approximately 1% of the concentration resulting from a dose of 500 mg aztreonam for injection). *Hepatic impairment* There are no data on the use of Cayston in patients with severe hepatic impairment (ALT or AST greater than 5 times the upper limit of normal). No dose adjustment is necessary in cases of hepatic impairment.
	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: No interaction studies have been performed. However, no evidence of any drug interactions with Cayston were identified from clinical studies in which Cayston was taken concomitantly with bronchodilators, dornase alfa, pancreatic enzymes, azithromycin, tobramycin, oral steroids (less than 10 mg daily/20 mg every other day) and inhaled steroids.
	The following drugs may be prescribed with caution: See above
7. Adverse drug reactions *For a comprehensive list (including rare and very rare adverse effects), or if significance of possible*	**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.**

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**
	Very common: cough, nasal congestion, wheezing, pharyngolaryngeal pain, dyspnoea Common: bronchospasm, chest discomfort, rhinorrhoea, haemoptysis	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
	Common: rash	As above	GP or patient
	Common: arthralgia	As above	GP or patient
	Common: pyrexia	As above	GP or patient
	Common: lung function test decreased	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 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)** None by GP	

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

10. Pharmaceutical aspects	Powder vial and solvent ampoule: Store in a refrigerator (2°C - 8°C). May be stored outside a refrigerator but below 25°C for up to 28 days. After reconstitution, immediate use of Cayston is recommended. If not used immediately, the reconstituted solution must be stored at 2°C - 8°C and used within 8 hours. In-use storage times and conditions prior to use are the responsibility of the user.
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 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

Patient name:
Date of birth:
Diagnosis: Cystic Fibrosis

This patient is suitable for treatment with Cayston 75mg (Aztronam lysine powder and solvent for nebuliser solution) for suppressive therapy of chronic pulmonary infections due to *Pseudomonas aeruginosa* in patients with cystic fibrosis (CF) aged 6 years and older.

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]* Cayston 75mg (Aztronam lysine powder and solvent for nebuliser solution) TDS.

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: *See information above in SCP above.*

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 Cayston 75mg (Aztronam lysine powder and solvent for nebuliser solution) TDS.

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