Shared Care Template

Shared Care Guideline for Pulmozyme 2500 U/ 2.5 ml, nebuliser solution	Reference Number
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Date approved by Commissioners: *dd/mm/yyyy*	**Review Date:** *dd/mm/yyyy*

Please complete all sections

1. Licensed Indications	Pulmozyme is indicated for the management of cystic fibrosis patients with a forced vital capacity (FVC) of greater than 40% of predicted and over 5 years of age to improve pulmonary function.
2. Therapeutic use & background	Recombinant human DNase is a genetically engineered version of a naturally occurring human enzyme which cleaves extracellular DNA. Retention of viscous purulent secretions in the airways contributes both to reduced pulmonary function and to exacerbations of infection. Purulent secretions contain very high concentrations of extracellular DNA, a viscous polyanion released by degenerating leukocytes, which accumulate in response to infection. *In vitro*, dornase alfa hydrolyses DNA in sputum and greatly reduces the viscoelasticity of cystic fibrosis sputum.
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 excipients: Sodium Chloride Calcium Chloride Dihydrate Water for Injections
4. Prescribing in pregnancy and lactation	*Pregnancy* The safety of dornase alfa has not been established in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, or embryofoetal development (see section 5.3). Caution should be exercised when prescribing dornase alfa to pregnant women.

	Lactation When dornase alfa is administered to humans according to the dosage recommendation, there is minimal systemic absorption; therefore no measurable concentrations of dornase alfa would be expected in human milk. Nevertheless, caution should be exercised when dornase alfa is administered to a breast-feeding woman. 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: 2.5 mg (corresponding to 2500 U) deoxyriboniuclease I by inhalation once daily. Inhale the contents of one ampoule (2.5 ml of solution) undiluted using a recommended jet nebuliser/compressor system. Some patients over the age of 21 years may benefit from twice daily dosage.		
	Is titration required	~~**Yes**~~	**No**
	n/a		
	Adjunctive treatment regime Patients should continue their regular medical care, including their standard regimen of chest physiotherapy.		
	Conditions requiring dose reduction None		
	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: None listed in SPC Pulmozyme can be effectively and safely used in conjunction with standard cystic fibrosis therapies such as antibiotics, bronchodilators, pancreatic enzymes, vitamins, inhaled and systemic corticosteroids, and analgesics.
	The following drugs may be prescribed with caution: As above

7. Adverse drug reactions

For a comprehensive list (including rare and very rare adverse effects), or if significance of possible adverse event uncertain, consult Summary of Product Characteristics or BNF

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 System – symptom/sign	**Action to be taken** Include whether drug should be stopped prior to contacting secondary care specialist	**By whom**
Conjunctivitis rare (< 1/1000).	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
Dysphonia, dyspnea, pharyngitis, laryngitis, rhinitis (all non-infectious) rare (< 1/1000).	As above	GP or patient
Dyspepsia rare (< 1/1000).	As above	GP or patient
Rash, urticaria rare (< 1/1000).	As above	GP or patient
Chest pain (pleuritic/non-cardiac), pyrexia rare (< 1/1000).	As above	GP or patient

	Patients who experience adverse events common to cystic fibrosis can, in general, safely continue administration of Pulmozyme as evidenced by the high percentage of patients completing clinical trials with Pulmozyme.
	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	Store in a refrigerator (2°C - 8°C). Keep the ampoule in the outer carton in order to protect from light. A single brief exposure to elevated temperatures (less than or equal to 24 hours at up to 30°C) does not affect product stability.
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:

This patient is suitable for treatment with Pulmozyme 2500 U/ 2.5 ml, nebuliser solution for the treatment of retention of viscous purulent secretions in the airways in patients with Cystic Fibrosis.

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]* Pulmozyme 2500 U/ 2.5 ml *OD or BD (Please ring).*

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 Pulmozyme 2500 U/ 2.5 ml.

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

Thank you.

Yours

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 Pulmozyme 2500 U/ 2.5 ml.

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