### DRUG:

**DORNASE ALFA (PULMOZYME®) (Adults and Paediatrics) in Cystic Fibrosis**

**EXISTING ESTABLISHED PATIENTS ONLY**

### Introduction

Dornase Alpha reduces sputum viscosity and aids sputum removal. It is indicated to improve pulmonary function in people with cystic fibrosis over the age of 5 years who have a forced vital capacity (FVC) of greater than 40% of predicted. It is occasionally used in children under 5yrs of age (unlicensed).


Until further notice existing patients will continue to have treatment prescribed by their GP, but new patients should have treatment initiated and continued by secondary care.

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](http://www.medicines.org.uk/EMC). The following shortened shared care guideline outlines the responsibility of the Specialist, GP and patient.

### Prescribing information

Dornase alfa nebuliser solution 2500 units (corresponding to 2.5milligrammes)/2.5millilitres

**ADULT and CHILD** over 5 years, by inhalation of nebulised solution, 2500 units (2.5 mg) once daily. Some patients over the age of 21 years may benefit from twice daily dosage.

### 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. Eligibility for mucolytics is as per national policy. [http://www.england.nhs.uk/wp-content/uploads/2013/04/a01-ps-a.pdf](http://www.england.nhs.uk/wp-content/uploads/2013/04/a01-ps-a.pdf)
- 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 dornase alpha and the associated nebuliser system.
- 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.
- 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 dornase alfa where shared care is already established
- 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 patients – this should already have been done as 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 dornase alpha for existing patients as recommended by specialist.
  - Ensure continued prescribing of dornase alpha remains clinically appropriate at dose advised by initiating team
  - Notify Consultant if treatment with dornase alpha is discontinued.
  - Ensure there are no drug interactions or contraindications with any other medications initiated in primary care
- **New patients**
  - New patients 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 with dornase alpha 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).

### Responsibilities of the Patient / Carer:

#### General:
- To inhale dornase alfa as prescribed.
- Report any possible side effects to their GP or specialist.
- To report any queries or problems with nebulised dornase alpha 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.
• Avoid breast feeding unless discussed with specialist
• Inform GP 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 dornase alpha and will advise 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 dornase alpha 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>
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</table>
| Tracey Daniels   | Specialist physiotherapist for CF  | 01904 725601/5528
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| Dr Murray Wheeler| Consultant Paediatrician           | 01904 725510
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References:
• British National Formulary 66 (Sept 2013)
• Pulmozyme® SPC . http://emc.medicines.org.uk/ date of last text revision: September 2010)

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\DORNASE ALPHA Shared Care Guideline V1
Shared Care Guidelines are also available electronically via http://www.yorkandscarboroughformulary.nhs.uk/

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