Patient Group Direction

Supply of oseltamivir for pre and post exposure prophylaxis of avian influenza as a public health measure in adults and children aged one year or older.

This specimen Patient Group Direction template has been produced by Health Protection Scotland to assist NHS boards

NHS boards must ensure that the Patient Group Direction is considered and approved in line with local clinical governance arrangements for Patient Group Directions

PGD for supply of oseltamivir pre and post exposure prophylaxis of avian influenza as a public health measure in adults and children aged one year or older.

Authorisation

This specimen Patient Group Direction (PGD) template has been produced by Health Protection Scotland to assist NHS boards. NHS boards should ensure that the final PGD is considered and approved in line with local clinical governance arrangements for PGDs.

The qualified health professionals who may supply oseltamivir under this PGD can only do so as named individuals. It is the responsibility of each professional to practice within the bounds of their own competence and in accordance with their own Code of Professional Conduct and to ensure familiarity with the marketing authorisation holder's summary of product characteristics (SmPC) for all vaccines administered in accordance with this PGD.

NHS board governance arrangements will indicate how records of staff authorised to operate this PGD will be maintained. Under PGD legislation there can be no delegation. Supply of oseltamivir has to be by the same practitioner who has assessed the patient under the PGD.

This PGD has been produced for NHS ..... by

Doctor		Signature	
Pharmacist		Signature	
Nurse		Signature	

Approved on behalf of NHS .....by

Medical Director		Signature	
Director of Pharmacy/Senior Pharmacist		Signature	
Clinical Governance Lead		Signature	

Date Approved

Effective from 11/03/2016 Review Date 31/03/2017

Clinical Situation

Indication	Pre and post exposure prophylaxis of avian influenza.
Inclusion Criteria	Adults and children (one year of age or older): **Pre-exposure:** individuals who will be handling or in close contact with live, sick, dying or dead birds infected or potentially infected with avian influenza (other than H7N9), or their bedding. **Post-exposure:** individuals who have handled or who have been in close contact with live, sick, dying or dead birds infected or potentially infected with avian influenza (other than H7N9), or their bedding, unless 7 days or more have elapsed since the last exposure.
Exclusion Criteria	• Suspected or confirmed H7N9 influenza is not covered by this PGD as different doses are required • Last exposure was more than 7 days previously • Children aged under one year • Children of bodyweight <10kg • Individuals with a known allergy or hypersensitivity to oseltamivir or any of the excipients • Individuals with moderate to severe renal disease (creatinine clearance ≤60mL/min) because a dose adjustment is required • Immunocompromised individuals[1] due to disease or treatment eg adults taking steroids at a dose equivalent to prednisolone ≥ 40 mg daily for more than one week; children receiving steroids equivalent to prednisolone orally or rectally of ≥ 2mg/kg/day for at least one week • Individuals taking drugs with potentially clinically significant drug interactions eg chlorpropamide, methotrexate, phenylbutazone, probenecid[2]
Cautions /Need for further advice/ Circumstances when further advice should be sought from a doctor	Refer individuals to a medical practitioner if: • They exhibit sudden onset of symptoms of confusion, chest pain, breathing difficulties or any other symptoms giving cause for concern • They have long term conditions such as chronic respiratory or cardiovascular disease exhibiting rapidly worsening symptoms
Action if Excluded	Some individuals excluded under this PGD may be suitable for post exposure prophylaxis if prescribed under a patient specific direction. Refer to a medical practitioner without delay.
Action if Patient Declines	• Advise the individual or carer of the possible consequences of refusing treatment and of alternative sources of treatment • Advise about the protective effects of the treatment, risks of infection, risk of spreading the disease to others and disease complications. • Document refusal and advice given in patient's record • Refer to a medical practitioner without delay.

[1] HPS guidance on use of antiviral agents for the treatment and prophylaxis of influenza (2015-16)
[2] Refer to the Summary of Product Characteristics

Description of Treatment

<table>
<tr><td>Name of Medicine</td><td>Oseltamivir</td></tr>
<tr><td>Form/Strength</td><td>75mg, 45mg and 30mg capsules</td></tr>
<tr><td>Route of administration</td><td>Oral
Capsules should be swallowed whole with water.
For individuals with swallowing difficulties, the capsules can be opened and the contents mixed with a small amount of sweetened food, such as honey, flavoured syrup or sugared water, just before administration (see Patient Information Leaflet).</td></tr>
<tr><td>Dosage and Frequency</td><td>Adults and children aged 13 years and older: One 75mg capsule once a day, preferably in the morning with breakfast, for duration of treatment. Taking with food can reduce nausea or vomiting.
For adults with a body weight less than 40 kg and children aged from 1 year to 12 years of age: refer to the table below[3].
<table>
<tr><th>Body Weight</th><th>Dose, preferably in the morning with breakfast</th></tr>
<tr><td>10 kg to 15 kg</td><td>30 mg once daily</td></tr>
<tr><td>> 15 kg to 23 kg</td><td>45 mg once daily</td></tr>
<tr><td>> 23 kg to 40 kg</td><td>60 mg once daily</td></tr>
<tr><td>> 40 kg</td><td>75 mg once daily</td></tr>
</table>
If the child has a body weight less than 10 kg, refer to a medical practitioner.
If the body weight cannot be determined and the child appears to be of average weight for their age use the following table[4]:
<table>
<tr><th>Age</th><th>Dose, preferably in the morning with breakfast, for 10 days</th></tr>
<tr><td>1 to 3 years</td><td>30 mg once daily</td></tr>
<tr><td>3 to 6 years</td><td>45 mg once daily</td></tr>
<tr><td>7 to 12 years</td><td>60 mg once daily</td></tr>
<tr><td>Over 12 years</td><td>75 mg once daily</td></tr>
</table>
Start the medication as soon as possible</td></tr>
<tr><td>Duration of treatment</td><td>Minimum of 10 days
All patients should receive treatment for 10 days following last known exposure.
Individuals handling or in close contact with live, sick, dying or dead birds or their bedding need to receive treatment to cover the total exposure period and for 10 days following the last known exposure.
Pre-exposure: if the individual is likely to have close contact in the</td></tr>
</table>

[3] Doses taken from the SPC
[4] Taken from the BNFc

<table>
<tr><td></td><td>future with live, sick, dying or dead birds or their bedding (eg as a responder to an avian influenza incident) they will need to receive treatment to start prior to the exposure, to cover the whole exposure period and for 10 days following the last known exposure.

In these instances, the initial course will be 10 days. Once a worker has ended their exposure to the birds or their bedding, any remaining doses from the initial course should be properly disposed of. A new 10 day course should be issued to cover the 10 days after exposure ends.

The maximum period of treatment that an individual can receive for a single incident through this PGD is 42 days. Health Protection Scotland should be contacted if an individual has already received 42 days of prophylaxis for a single incident but is being considered for further prophylaxis.</td></tr>
<tr><td>Quantity to supply/administer</td><td>As above.

Adults: Up to 10 x 75mg capsules per single issue

Children:

<table><tr><th>Body Weight</th><th>Age</th><th>Quantity of capsules to be supplied for 10 days treatment</th></tr><tr><td>10 kg to 15 kg</td><td>1 to 3 years</td><td>10 x 30 mg</td></tr><tr><td>> 15 kg to 23 kg</td><td>3 to 6 years</td><td>10 x 45 mg</td></tr><tr><td>> 23 kg to 40 kg</td><td>7 to 12 years</td><td>20 x 30 mg</td></tr><tr><td>> 40 kg</td><td>Over 12 years</td><td>10 x 75 mg</td></tr></table></td></tr>
<tr><td>▼ black triangle medicines</td><td>No</td></tr>
<tr><td>Legal Category</td><td>Prescription Only Medicine</td></tr>
<tr><td>Is the use outwith the SmPC</td><td>Yes

Guidance from Public Health England[5] recommends chemoprophylaxis with oseltamivir as per the inclusion criteria</td></tr>
<tr><td>Storage requirements</td><td>Do not store above 25^{o}C</td></tr>
<tr><td>Disposal</td><td>Any unused product or waste material should be disposed of in accordance with local requirements.</td></tr>
</table>

Warnings including possible adverse reactions and management of these	Frequently reported adverse reactions include nausea, vomiting, abdominal pain and dyspepsia These reactions may only occur on a single occasion, on either the first or second treatment day, and resolve spontaneously within 1-2 days. However, if symptoms persist patients should consult a healthcare professional. Patients should be advised not to discontinue treatment without consulting a doctor or pharmacist

[5] www.gov.uk/government/uploads/system/uploads/attachment_data/file/360265/occupationalguidanceforresponding20090101b.pdf

	Other commonly reported adverse reactions include bronchitis, dizziness (including vertigo), fatigue, headache, insomnia, herpes simplex, nasopharyngitis, upper respiratory tract infections, sinusitis, cough, sore throat, pyrexia, rhinorrhoea, pain including limb pain. A detailed list of adverse reactions is available in the Summary of Product Characteristics, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
Reporting procedure for adverse reactions	Any adverse reaction to the product should be documented in the medical records Alert a doctor in the event of serious adverse reaction Report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: http://yellowcard.mhra.gov.uk
Advice to Patient/carer including written information	Supply the marketing authorisation holder's patient information leaflet (PIL) Each individual should be given a copy of the PHE information for contact of avian influenza Advise the individual or their carer: • that taking the medication with a small amount of food can reduce nausea or vomiting • that the capsules can be opened and taken with a small amount of sweetened food as explained in the PIL • of any possible side effects and their management • to seek medical advice in the event of a severe adverse reaction • to seek advice if common side effects do not spontaneously resolve 48 hours after they first appear • that the patient should complete the course • to read the PIL leaflet before taking the medication • explain that the PIL does not mention avian influenza because the manufacturers have not sought a product license for this indication, but Health Protection Scotland recommends the use of this medicine in these circumstances and it is deemed best practice • to seek medical advice if they experience influenza symptoms within 7 days

Characteristics of staff authorised under the PGD

Professional qualifications	Those registered health care professionals that are listed and approved in legislation as able to operate under patient group directions.
Additional requirements	• Must be authorised by name as an approved practitioner under

	the current terms of this Patient Group Direction before working to it • Must be deemed competent to assess the person's capacity to understand the nature and purpose of the treatment in order to give or refuse consent • Must be competent in the use of PGDs for supply of medicines • Must be familiar with the product and alert to changes in the Summary of Product Characteristics • Have access to the Patient Group Direction and associated online resources.

Audit Trail

Record/Audit Trail	Record: • Whether valid informed consent was given • Name of patient, address, date of birth and GP with whom the patient is registered • Name of practitioner who supplied the product • Name and brand of product • Date of supply • Dose, form and route of administration of product • Quantity supplied • Batch number and expiry date • Advice given; including advice given if excluded or declines treatment • Details of any adverse drug reactions and actions taken • Record supplied via Patient Group Direction (PGD) • Records should be signed and dated All records should be clear, legible and contemporaneous. A record of all individuals receiving treatment under this Patient Group Direction should also be kept for audit purposes in accordance with local policy
Additional references	• Summary of Product Characteristics www.medicines.org.uk • PHE Avian influenza: guidance, data and analysis August 2014 www.gov.uk/government/collections/avian-influenza-guidance-data-and-analysis • Occupational guidance for those responding to a suspected or confirmed avian influenza incident www.gov.uk/government/uploads/system/uploads/attachment_data/file/360265/occupationalguidanceforresponding20090101b.pdf • HPS guidance on use of antiviral agents for the treatment and prophylaxis of influenza (2015/16) http://www.hps.scot.nhs.uk/resp/seasonalInfluenza.aspx • British National Formulary (BNF) https://www.medicinescomplete.com/mc/bnf/current/ • British National Formulary for children (BNFc) www.medicinescomplete.com/mc/bnfc/2011/

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This PGD does not remove professional obligations and accountability. It is the responsibility of each professional to practice with the bounds of their own competence and in accordance with their Code of Professional Conduct and to ensure familiarity with the manufacturer's summary of product characteristics for all medicines supplied in accordance with this PGD.

Note to Authorising Managers

Authorised staff should be provided with an individual copy of the clinical content of the PGD and a photocopy of the document showing their authorisation.

I have read and understood the Patient Group Direction. I agree to supply oseltamivir only in accordance with this PGD.

Name of Professional	**Signature**	**Date**

I agree that the professionals listed above are authorised to supply/administer medicines in accordance with this PGD to patients cared for in this service area.

Lead Clinician for the service area		
Name:	Signature:	Date: