Public Health England

NHS England

PHE publications gateway number: 2016666

PATIENT GROUP DIRECTION (PGD)

Supply of oseltamivir for post exposure prophylaxis of avian influenza H5N8 as a public health measure for adults and children aged one year or older

For the supply of oseltamivir for post exposure prophylaxis of avian influenza H5N8 for adults and children aged one year and older by registered healthcare practitioners identified in Section 3, subject to any limitations to authorisation detailed in Section 2

Reference:	20180123 Oseltamivir avian influenza H5N8 prophylaxis PGD
Version no:	02.00
Valid from:	01 February 2018
Review date:	01 August 2020
Expiry date:	01 February 2021

Public Health England has developed this PGD Template for local authorisation

Those using this PGD must ensure that it is formally authorised and signed by a clinical governance or patient safety lead, who has designated responsibility for signing PGDs, so this document meets legal requirements for a PGD. **THE PGD IS NOT LEGAL OR VALID WITHOUT THIS LOCAL, FORMAL AUTHORISATION.**

Authorising organisations must not alter or amend the *clinical* content of this document (sections 4, 5 and 6); such action will invalidate the *clinical sign-off* with which it is provided.

As operation of this PGD is the responsibility of commissioners and service providers, the authorising organisation can decide which staff groups, in keeping with relevant legislation, can work to the PGD. Therefore sections 2, 3 and 7 must be completed and can be amended.

THE PRACTITIONER MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT.

Practitioners and organisations must check that they are using the current version of the PGD. Amendments may become necessary prior to the published expiry date.

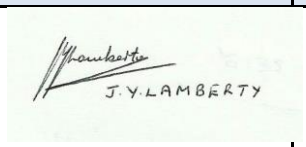
Any queries regarding the content of this PGD should be addressed to: jackie.lamberty@phe.gov.uk

Change history

Version number	Change details	Date
01.00	Original PGD template	24 February 2017
02.00	• update to off-label use • update to information for individuals with swallowing difficulties • amendment to age range for doses for children • addition of maximum duration of treatment • additional supply and labelling requirements • additional patient information • updates to references • minor typographical changes	22 January 2018

1. PGD template development

This PGD template has been developed by the following on behalf of Public Health England:

Developed by:	Name	Signature	Date
Pharmacist (Lead author)	Jacqueline Lamberty Lead Pharmacist Medicines Management Services Public Health England		23 January 2018
Doctor	Dr John Astbury Consultant in Health Protection. Head of Health Protection, Cumbria and Lancashire Health Protection Team Public Health England North West (Cumbria and Lancashire)		23 January 2018
Registered nurse	Grainne Nixon Consultant Nurse Health Protection Health Protection Team Public Health England North West (Cumbria and Lancashire)		23 January 2018

This PGD template has been peer reviewed by an Expert panel in accordance with the PHE PGD Policy. It has been agreed by the PHE Medicines Management Group and the PHE Quality and Clinical Governance Delivery Board.

Expert panel

Name	Designation
Dr Richard Pebody (Chair)	Consultant Epidemiologist – PHE National Infection Service
Dr Gavin Dabrera	Interim Head, Legionella and Influenza Preparedness and Response Section, PHE National Infection Service
Adam John Grainger	Senior Medicines Performance Pharmacist, NHS Midlands and Lancashire CSU
Mark McGivern	Consultant in Health Protection - Cumbria and Lancashire Health Protection Team, PHE North West
Dr Sally Millership	Consultant in Communicable Disease Control, Public Health England, East of England Health Protection Team
Dr Matthieu Pegorie	Consultant in Health Protection –Greater Manchester, PHE North West
Shelagh Snape	Senior Health Protection Practitioner, Cumbria and Lancashire Health Protection Team, PHE North West (Cumbria and Lancashire)

2. Organisational authorisations

The PGD is not legally valid until it has had the relevant organisational authorisation.

It is the responsibility of the organisation that has legal authority to authorise the PGD, to ensure that all legal and governance requirements are met. The authorising body accepts governance responsibility for the appropriate use of the PGD.

NHS England South (South West) authorise this PGD for use by the services or providers listed below:

Authorised for use by the following organisations and/or services
All NHS England South, (South West) commissioned services. This patient group direction (PGD) must only be used by the registered healthcare practitioners identified in Section 3 who have been named by their organisation to practice under it. The most recent in-date final version signed off by NHS England South (South West) must be used.
Limitations to authorisation
This PGD is only authorised for pre and post exposure prophylaxis of avian influenza as advised by Public Health England. PHE must give their own authorisation for its use to the organisation employing those individuals that will use it.

Organisational approval (legal requirement)			
Role	**Name**	**Sign**	**Date**
Medical Director NHS England South (South West) tor	Dr Caroline Gamlin		22 February 2018

Additional signatories according to locally agreed policy			
Role	**Name**	**Sign**	**Date**
Head of Pharmacy NHS England South (South West)	Jon Hayhurst		22 February 2018

Organisations must add an individual practitioner authorisation sheet or list of authorised practitioners. This varies according to local policy but this should be a signature list or an individual agreement as included at the end of this PGD.

3. Characteristics of staff

Qualifications and professional registration	To be completed by the organisation authorising the PGD eg: Registered professional with one of the following bodies: • nurses currently registered with the Nursing and Midwifery Council (NMC) • pharmacists currently registered with the General Pharmaceutical Council (GPhC).
Additional requirements	• must be authorised by name as an approved practitioner under the current terms of this PGD before working to it • must have undertaken appropriate training for working under PGDs for supply or administration of medicines • must be competent in the use of PGDs (see NICE Competency framework for health professionals using PGDs) • must be familiar with the product and alert to changes in the Summary of Product Characteristics • must have access to the PGD and associated online resources • should fulfil any additional requirements defined by local policy **THE PRACTITIONER MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT.**
Continued training requirements	Practitioners should be constantly alert to any subsequent recommendations from Public Health England and/or NHS England and other sources of medicines information. Note: The most current national recommendations should be followed but a Patient Specific Direction (PSD) may be required to supply medication with updated recommendations that are outside the criteria specified in this PGD.

4. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	Post exposure prophylaxis of avian influenza as advised by Public Health England.
Criteria for inclusion[1]	**Post-exposure:** adults and children (one year of age or older) who have: • handled or who have been in close contact with live, sick, dying or dead birds infected or potentially infected with avian influenza H5N8 (between 48 hours before onset of symptoms in birds and culling) **or** • handled faecal matter or contaminated litter or swabbing, culling or removal of carcasses related to birds infected or potentially infected with avian influenza H5N8 **or** • had a significant exposure as advised by the local PHE Centre Health Protection Team **unless:** • full PPE was worn as per HSE guidance throughout exposure without breaches as monitored by the lead agency[2] **or** • 7 days or more have elapsed since the last exposure
Criteria for exclusion[3]	• suspected or confirmed exposure to non-H5N8 avian flu • full PPE was worn as per HSE guidance throughout all exposures without breaches as monitored by the lead agency • last exposure was more than 7 days previously • children aged under one year • children with a body weight less than 10 kg • 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) or individuals who state they have a current diagnosis by a healthcare professional of chronic kidney disease or impaired renal function diagnosed, because a dose

[1] Criteria for post exposure antiviral prophylaxis can be discussed with the local Health Protection Team.
[2] HSE guidance: Avoiding the risk of infection when working with poultry that is suspected of having H5 or H7 notifiable avian influenza. A breach would constitute omission of any item of PPE or use inconsistent with this guidance.
[3] Exclusion under this Patient Group Direction does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation will be required.

(continued overleaf) **Criteria for exclusion** (continued)	adjustment is required • immunocompromised individuals[4] due to disease or treatment eg adults taking steroids at a dose equivalent to prednisolone ≥ 40mg 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 other drugs with clinically significant drug interactions eg chlorpropamide, methotrexate, phenylbutazone[5]
Action to be taken if the patient is excluded	Some individuals excluded under this PGD may be suitable for post exposure prophylaxis if prescribed. Refer to a medical practitioner without delay. Suspected or confirmed exposure to non-H5N8 influenza: use the PGD for the 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 alternative PGD does not cover exposure to suspected or confirmed H7N9 influenza as different doses are required.
Action to be taken if the patient or carer declines prophylaxis	• 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
Cautions	Refer individuals to a medical practitioner if: • they are exhibiting 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

[4] PHE guidance on use of antiviral agents for the treatment and prophylaxis of seasonal influenza (September 2017)
[5] Refer to the Summary of Product Characteristics

5. Description of treatment

<table>
<tr><td>Name, strength & formulation of drug</td><td>Oseltamivir 75mg, 45mg and 30mg capsules</td></tr>
<tr><td>Legal category</td><td>POM - Prescription only medicine</td></tr>
<tr><td>Black triangle▼</td><td>No</td></tr>
<tr><td>Off-label use</td><td>Yes

Guidance from Public Health England recommends chemoprophylaxis with oseltamivir as per the inclusion criteria. Where a product is recommended off-label consider, as part of the consent process, informing the individual/carer that the product is being offered in accordance with national guidance but that this is outside the product licence.</td></tr>
<tr><td>Route / method of administration</td><td>Oral. The individual should start the medication as soon as possible.

The 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 chocolate or cherry syrup, and dessert toppings such as caramel or fudge sauce or sugared water, just before administration (see Patient Information Leaflet)</td></tr>
<tr><td>Dose and frequency of administration</td><td>Adults and children aged 13 years and older: One 75mg capsule once a day, preferably in the morning with breakfast, for the 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[6]

<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, they are excluded from this PGD. Refer them 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 table overleaf[7]

<table>
<tr><th>Age</th><th>Dose, preferably in the morning with breakfast</th></tr>
<tr><td>1 to 3 years</td><td>30 mg once daily</td></tr>
<tr><td>4 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>
</td></tr>
</table>

[6] Doses taken from the SPC
[7] Taken from the BNFc

<table>
<tr><td>Duration of prophylaxis</td><td>Individuals need to receive prophylaxis for 10 days following the last known exposure.

The maximum period of treatment that an individual can receive for a single incident through this PGD is 42 days.</td></tr>
<tr><td>Quantity to be supplied</td><td>Adults: Sufficient to provide prophylaxis for 10 days following the last known exposure.
<table>
<tr><th>Body Weight</th><th>Age</th><th>Quantity of capsules to be supplied for 10 days prophylaxis</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>
When supplying under PGD, this should be from the manufacturer's original pack or over-labelled pre-packs so that the patient details, date and additional instructions can be written on the label at the time of supply. As split packs cannot be supplied, an over-supply might be required. Individuals must be advised to take any remaining capsules to a community pharmacy for destruction.</td></tr>
<tr><td>Storage</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>
<tr><td>Drug interactions</td><td>Individuals taking the following medicines are excluded from this PGD:
• chlorpropamide
• methotrexate
• phenylbutazone
The Green Book states that administration of influenza antiviral agents within two weeks of administration of a live attenuated influenza vaccine may adversely affect the effectiveness of the vaccine.</td></tr>
<tr><td>Identification & management of adverse reactions</td><td>Frequently reported adverse reactions include nausea, vomiting, headache, 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.
Individuals should be advised not to discontinue treatment without consulting a doctor or pharmacist.
Other commonly reported adverse reactions include bronchitis, dizziness (including vertigo), fatigue, 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</td></tr>
</table>

Reporting procedure of 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.
Written information to be given to patient or carer	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
Patient advice /follow up treatment	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 individual 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 PHE 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 10 days • if an over-supply has been required, individuals must be advised to take any remaining capsules to a community pharmacy for destruction
Records (continued overleaf)	Record: • whether valid informed consent was given • name of individual, address, date of birth and GP with whom the individual is registered • name of the member of staff who supplied the product • name and brand of the product • date of supply • dose, form and route of administration of the product • quantity supplied • batch number and expiry date • advice given; including advice given if the individual is excluded or declines treatment • details of any adverse drug reactions and actions taken • record the product was supplied via Patient Group Direction • records should be signed and dated

Records (continued)	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.

6. Key references

Key references	• Summary of Product Characteristics www.medicines.org.uk • Patient Information Leaflet www.medicines.org.uk • HSE guidance: Avoiding the risk of infection when working with poultry that is suspected of having H5 or H7 notifiable avian influenza http://www.hse.gov.uk/biosafety/diseases/aisuspected.pdf • Interim AI H5N8 management algorithm https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/629692/Interim_recommendations_Avian_flu_H5N8_Algorithm.pdf • Avian influenza A (H5N8) in the UK: risk assessment https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/603115/H5N8_avian_influenza_risk_assessment.pdf • Managing the human health implications of avian influenza in poultry and wild birds. Guidance for health protection teams Version 3.0 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/629690/Managing_Avian_influenza_in_poultry_guidance_for_HPTs.pdf • Investigation & management of possible human cases of avian influenza amongst contacts associated with avian influenza incidents, v2 July 2017 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/629691/Investigation_and_management_of_possible_human_cases_avian_flu_algorithm.pdf • The Green Book Chapter 19 Influenza December 2017 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/456568/2904394_Green_Book_Chapter_19_v10_0.pdf • British National Formulary (BNF) and British National Formulary for children (BNFc) https://bnf.nice.org.uk/ • NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions https://www.nice.org.uk/guidance/mpg2 • NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions https://www.nice.org.uk/guidance/mpg2/resources/mpg2-patient-group-directions7 • Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20th March 2013 https://www.gov.uk/government/publications/guidance-on-the-safe-management-of-healthcare-waste

7. Individual practitioner authorisation sheet

BY SIGNING THIS PATIENT GROUP DIRECTION YOU ARE INDICATING THAT YOU AGREE TO ITS CONTENTS AND THAT YOU WILL WORK WITHIN IT

PATIENT GROUP DIRECTIONS DO NOT REMOVE INHERENT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY

IT IS THE RESPONSIBILITY OF EACH PROFESSIONAL TO PRACTISE ONLY WITHIN THE BOUNDS OF THEIR OWN COMPETENCE

Practitioner

I confirm that I have read and understood the content of this Patient Group Direction and

that I am willing and competent to work to it within my professional code of conduct

Signed……..……..…..Date…….…….....

Name (Print)…….……..…….…….…….…….....

Designation……..…….....

Authorising manager

Manager to give authorisation on behalf of **INSERT NAME OF ORGANISATION** for the named healthcare professional who has signed the PGD

Signed…….…… Date…….....

Name (Print)……..……..…….…….....

Designation……..…….…….....

Note to authorising manager

By signing above you are confirming that you have assessed the staff member as competent to work under this PGD and that they have the organisational approval to do so

You must give this signed PGD to each authorised practitioner as it shows their authorisation to use the PGD