UK Health Security Agency

NHS

Publications gateway number: GOV-10641

Patient Group Direction (PGD) for the supply of oseltamivir for pre and post exposure H7N9 avian influenza

For the supply of oseltamivir for pre and post exposure prophylaxis of H7N9 avian influenza 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:	20211217 Oseltamivir H7N9 avian influenza PGD
Version no:	03.00
Valid from:	17 December 2021
Review date:	17 December 2023
Expiry date:	16 December 2024

The UK Health Security Agency (UKHSA) has developed this PGD for local authorisation

Those using this PGD must ensure it is organisationally authorised and signed in Section 2 by an appropriate authorising person, relating to the class of person by whom the product is to be supplied, in accordance with Human Medicines Regulations 2012 (HMR2012)[1]. **The PGD is not legal or valid without signed authorisation in accordance with HMR2012 Schedule 16 Part 2.**

Authorising organisations must not alter, amend or add to 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. Sections 2, 3 and 7 must be completed and amended within the designated editable fields provided.

The final authorised copy of this PGD should be kept by the authorising organisation completing Section 2 for 25 years after the PGD expires. Provider organisations adopting authorised versions of this PGD should also retain copies for 25 years after the PGD expires.

Individual practitioners must be authorised by name, under the current version of this PGD before working according to it.

Practitioners and organisations must check they are using the current version of the PGD. Amendments may become necessary prior to the published expiry date. Current versions of UKHSA avian influenza PGDs for authorisation can be found from: https://www.gov.uk/government/publications/avian-influenza-pre-and-post-exposure-prophylaxis-pgd-template

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

Enquiries relating to the availability of organisationally authorised PGDs and subsequent versions of this PGD should be directed to: nwicb.medsqueries@nhs.net

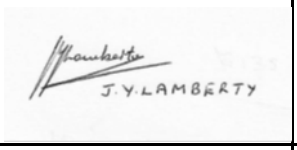
[1] This includes any relevant amendments to legislation (such as 2013 No.235, 2015 No.178, 2015 No.323 and the Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020

Change history

Version number	Change details	Date
01.00	Original PGD template	28 September 2018
02.00	1. References to PHE changed to UKHSA 2. Minor rewording of standard text for consistency with other UKHSA PGDs; updated references 3. Chronic kidney disease or impaired renal function exclusion criterion amended to severe renal disease requiring haemodialysis 4. Criteria for inclusion and exclusion amended from 7 days or more to 8 days or more 5. Criteria for exclusion: expansion of definition of immunosuppression 6. Expansion of actions to be taken if the patient is excluded 7. Addition of doses in renal failure 8. Addition of quantity to be supplied for patients with renal failure 9. Addition to storage requirements 10. Expansion of drug interactions with live attenuated influenza vaccine 11. Addition of advice to patient when an oversupply is made 12. Additional information section added 13. Addition to recording requirements to cover Mental Capacity Act 2005	3 December 2021
03.00	Dose and frequency: reference to taking in the morning with breakfast deleted, as adult dose is twice a day	17 December 2021

1. PGD development

This PGD has been developed by the following on behalf of the UKHSA:

Developed by:	Name	Signature	Date
Pharmacist (Lead author)	Jacqueline Lamberty Lead Pharmacist Medicines Governance, UKHSA		17 December 2021
Doctor	Dr John Astbury Consultant in Health Protection Head of Health Protection, North West (Cumbria and Lancashire) Health Protection Team, UKHSA		17 December 2021
Registered nurse	Shelagh Snape Senior Health Protection Practitioner North West (Cumbria and Lancashire) Health Protection Team, UKHSA		17 December 2021

This PGD has been peer reviewed by the Avian Influenza PGD Expert panel in accordance with the UKHSA PGD Policy. It has been agreed by the UKHSA Medicines Governance Group and ratified by the UKHSA Clinical Quality and Oversight Board.

Expert panel

Name	Designation
Dr Meera Chand (Chair)	Co-director of Clinical and Emerging Infections (Interim), Clinical & Public Health Group, UKHSA
Dr Nicholas Aigbogun	Consultant in Communicable Disease Control, Yorkshire and Humber Health Protection Team, UKHSA
Dr Colin Brown	Director (Interim): Clinical and Emerging Infections & Deputy Director (Interim): HCAI, Fungal, AMR, AMU, & Sepsis Division Clinical & Public Health Group, UKHSA
Dr Gavin Dabrera	Consultant in Acute Respiratory infections, Clinical and Public Health, UKHSA
Dr Emily Dobell	Consultant Epidemiologist, UKHSA
Adam John Grainger	Senior Medicines Performance Pharmacist, NHSEI Midlands and Lancashire CSU
Mark McGivern	Consultant in Health Protection, North West Health Protection Team, UKHSA
Dr Conall Watson	Consultant Epidemiologist – influenza and seasonal respiratory viruses, Immunisation & Vaccine-Preventable Diseases Division, UKHSA

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 all legal and governance requirements are met. The authorising body accepts governance responsibility for the appropriate use of the PGD.

Norfolk and Waveney ICB authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisations and/or services
East Coast Community Healthcare CIC Norfolk Community Health and Care NHS Trust
Limitations to authorisation

Organisational approval (legal requirement)			
Role	**Name**	**Sign**	**Date**
Executive Director of Nursing	**Patricia D'Orsi**		**23/1/2024**

Additional signatories according to locally agreed policy			
Role	**Name**	**Sign**	**Date**
Associate Director of Pharmacy and Medicines Optimisation (Chief Pharmacist)	**Michael Dennis**		**16/1/2024**

Section 7 provides a practitioner authorisation sheet. Individual practitioners must be authorised by name to work to this PGD. Alternative practitioner authorisation sheets may be used where appropriate in accordance with local policy, but this should be an individual agreement, or a multiple practitioner authorisation sheet 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 for instance, 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). The practitioners above must also fulfil the Additional requirements detailed below. Check Section 2 Limitations to authorisation to confirm whether all practitioners listed above have organisational authorisation to work under this PGD.
Additional requirements	Additionally, practitioners: • 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 have undertaken training appropriate to this PGD • 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 (SPC) • must be competent to assess the individual and discuss treatment options • must have access to the PGD and associated online resources. • should fulfil any additional requirements defined by local policy • insert any additional requirements **The individual practitioner must be authorised by name, under the current version of this PGD before working according to it.**
Continued training requirements	• Insert any continued training requirements

4. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	Pre and post exposure prophylaxis of H7N9 avian influenza as advised by the UKHSA.
Criteria for inclusion[2]	Adults and children (one year of age or older) who have or will have: • handled or been in close contact with live, sick, dying or dead birds infected or potentially infected with H7N9 avian influenza or • handled or been in close contact with faecal matter or contaminated litter/other materials from birds infected or potentially infected with H7N9 avian influenza • swabbed, culled or removed carcasses of birds infected or potentially infected with H7N9 avian influenza or • had a significant exposure as advised by the local UKHSA Health Protection Team **unless** 8 days or more have elapsed since the last exposure
Criteria for exclusion Continued overleaf	Individuals: • with exposure to suspected or confirmed avian influenza other than H7N9 • whose last exposure was 8 days or more previously • who are aged under one year • with a body weight less than 10 kg • who have a known allergy or hypersensitivity to oseltamivir or to any of the excipients • with severe renal disease requiring haemodialysis • who are immunocompromised[3] due to disease or treatment for instance: ❖ severe primary immunodeficiency ❖ current or recent (within 6 months) chemotherapy or radiotherapy for malignancy ❖ solid organ transplant recipients on immunosuppressive therapy ❖ bone marrow transplant recipients currently receiving immunosuppressive treatment, or within 12 months of receiving immunosuppression ❖ individuals with current graft-versus-host disease ❖ individuals currently receiving high dose systemic corticosteroids (equivalent to ≥40 mg prednisolone per day for >1 week in an adult, or ≥ 2mg/kg/day for ≥1 week in a child) and for at least 3 months after treatment has stopped ❖ HIV infected individuals with severe immunosuppression (CD4<200/µl or <15% of total

[2] Criteria for post exposure antiviral prophylaxis can be discussed with the local Health Protection Team.
[3] UKHSA Guidance on use of antiviral agents for the treatment and prophylaxis of seasonal influenza Version 11, November 2021

Criteria for exclusion (continued)	lymphocytes in an adult or child over 5; CD4< 500/µl or <15% of total lymphocytes in a child aged 1 to 5; expert clinical opinion in a child aged under 1) ❖ individuals currently or recently (within 6 months) on other types of highly immunosuppressive therapy or where the individual's specialist regards them as severely immunosuppressed. • who are taking medicines with clinically significant drug interactions for instance chlorpropamide, methotrexate, phenylbutazone
Action to be taken if the patient is excluded	For suspected or confirmed exposure to non-H7N9 influenza: use Oseltamivir non-H7N9 influenza PGD. Where exposure was 8 days or more previously: inform the individual prophylaxis is not indicated beyond 7 days following exposure. For individuals aged under one year, or with a body weight of less than 10kg, or with a known allergy or hypersensitivity to oseltamivir or to any of the excipients, or those who require haemodialysis: refer to a medical practitioner. A Patient Specific Direction (PSD) would be required for any alternative dosage or treatment recommended. For individuals who specify a history of immunosuppression due to disease or treatment, discuss with a Consultant in Health Protection or a Consultant Virologist or Microbiologist for advice. Depending on the nature of the immunosuppression, discussion may be needed on a case by case basis between the Health Protection Team and specialists such as Consultant Virologists, Microbiologists or Epidemiologists. Some individuals might need a different dose, some might need an alternative medicine or, for some, complete cessation of all exposures, if possible, may be advised. A PSD would be required for any alternative dosage or treatment recommended as a result of this discussion. Some individuals excluded under this PGD may be suitable for pre or post exposure prophylaxis if prescribed. Refer to a medical practitioner without delay.
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. Inform the relevant local Health Protection team and, if appropriate, refer to a medical practitioner for an alternative treatment.
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

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

Oseltamivir is not licensed for avian influenza. National UK guidance recommends chemoprophylaxis with oseltamivir twice daily for 5 days (see Dose and frequency of administration). This is based on virological evidence of oseltamivir resistance in cases of avian influenza A(H7N9), and is in line with advice from the World Health Organization (WHO) and the Centres for Disease Control and Prevention (CDC).

Consider, as part of the consent process, informing the individual/carer the product is being offered in accordance with national guidance but 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 or dessert toppings such as caramel, fudge sauce or sugared water just before administration (see Patient Information Leaflet).</td></tr>
<tr><td>Dose and frequency of administration

Continued overleaf</td><td>Adults and children aged 13 years and older: see table below

The capsules should preferably be taken with food to reduce nausea or vomiting.

<table>
<tr><th>Renal function[4]</th><th>Dose</th></tr>
<tr><td>No known chronic renal impairment</td><td>One 75mg capsule twice a day</td></tr>
<tr><td>Moderate impairment
(CrCl 31-60 ml/min)</td><td>One 30mg capsule twice a day</td></tr>
<tr><td>Severe impairment
(CrCl 11-30ml/min)</td><td>One 30mg capsule once a day</td></tr>
<tr><td>Established renal failure
(CrCl ≤10ml/min)</td><td>One 30mg capsule once</td></tr>
<tr><td>Haemodialysis</td><td>Refer to a medical practitioner; do not supply under this PGD</td></tr>
<tr><td>Peritoneal dialysis</td><td>One 30mg capsule once</td></tr>
</table>

The doses given above are for individuals with stable chronic kidney disease. If there is a history of renal failure, supply as per the latest documented creatinine clearance (CrCl) results.</td></tr>
</table>

[4] UKHSA Guidance on use of antiviral agents for the treatment and prophylaxis of seasonal influenza Version 11, November 2021

Dose and frequency of administration (continued)

Estimated glomerular filtration rate (eGFR) may be more readily available. If eGFR is the only value available, do not delay chemoprophylaxis and supply a dose according to eGFR (substituting eGFR for the CrCL figure in the table above). Some individuals may receive a larger oseltamivir dose as a result, but this is unlikely to be harmful as clinical experience reveals a wide margin of safety.

For children with renal dysfunction aged less than 13 years, adjust the oseltamivir dose as per the Oseltamivir chapter in the British National Formulary (BNF) for children.

If CrCl or eGFR results are not known, refer to a medical practitioner. If a decision is made to supply oseltamivir, a PSD will be required.

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.

Body Weight	**Dose, preferably in the morning with breakfast**
10 kg to 15 kg	30 mg twice daily for 5 days
> 15 kg to 23 kg	45 mg twice daily for 5 days
> 23 kg to 40 kg	60 mg twice daily for 5 days
> 40 kg	75 mg twice daily for 5 days

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 below:

Age	**Dose, preferably in the morning with breakfast**
1 to 3 years	30 mg twice daily for 5 days
4 to 6 years	45 mg twice daily for 5 days
7 to 12 years	60 mg twice daily for 5 days
Over 12 years	75 mg twice daily for 5 days

No dose adjustment is needed in obese individuals

Duration of prophylaxis

Five (5) days, unless the individual has established renal failure or is undergoing peritoneal dialysis (see Dose and frequency of administration above)

Quantity to be supplied

Sufficient to cover five days' supply

Body Weight	**Age**	**Quantity of capsules to be supplied**
10 kg to 15 kg	1 to 3 years	10 x 30 mg
> 15 kg to 23 kg	3 to 6 years	10 x 45 mg
> 23 kg to 40 kg	7 to 12 years	20 x 30 mg
> 40 kg	Over 12 years	10 x 75 mg

Renal impairment:

Quantity of capsules to be supplied	**Quantity of capsules to be supplied**
Moderate impairment	10 x 30mg
Severe impairment	5 x 30mg
Established renal failure	1 x 30mg
Peritoneal dialysis	1 x 30mg

Continued overleaf

Quantity to be supplied (continued)	When supplying under PGD, this must be a complete manufacturer's original pack or over-labelled pre-packs. The individual's name, the date and additional instructions must be written on the label at the time of supply. As split packs cannot be supplied, if an over-supply is required, individuals must be advised to take any remaining medicine to a community pharmacy for destruction.
Storage	Medicines must be stored securely according to national guidelines and in accordance with the product's SPC. Do not store above 25^{o}C
Disposal	Any unused product or waste material should be disposed of in accordance with local r.
Drug interactions	Individuals taking the following medicines are excluded from this PGD (see exclusion criteria): • chlorpropamide • methotrexate • phenylbutazone The Green Book states that administration of influenza antiviral agents within two weeks of administration of a live attenuated influenza vaccine (LAIV) may adversely affect the effectiveness of the vaccine. Therefore, oseltamivir and LAIV should not be administered concomitantly. LAIV should be delayed until 48 hours following the cessation of treatment with oseltamivir. If LAIV has been given in the past two weeks, the individual may need to be revaccinated with another appropriate influenza vaccine and medical advice should be obtained.
Identification & management of adverse reactions	Very common (≥ 1/10) and common (≥ 1/100 to < 1/10) adverse reactions include nausea, vomiting, abdominal pain and dyspepsia. These reactions may only occur on a single occasion on either the first or second day of treatment and resolve spontaneously within 1-2 days. However, if symptoms persist individuals 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, 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 SPC.
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. Healthcare professionals and individuals/parents/carers are encouraged to report all suspected adverse reactions in children and severe adverse reactions in adults to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme or search for MHRA Yellow Card in the Google Play or Apple App Store.

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 information for contact of avian influenza, available from Managing the human health implications of avian influenza - guidance for health protection teams (publishing.service.gov.uk)
Patient advice /follow up treatment	Advise the individual or their carer: • taking the medication with a small amount of food can reduce nausea or vomiting • 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, but to continue taking the medicine • to complete the course • to read the PIL leaflet before taking the medication • consider explaining the PIL does not mention avian influenza because the manufacturer has not sought a product license for this indication, but national guidance 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 of last exposure to source of H7N9 infection • if an over-supply has been required, to take any remaining capsules to a community pharmacy for destruction
Additional information	Pregnancy: oseltamivir is considered safe for use in pregnancy. Recent studies suggest there is no evidence of harm in pregnant women treated with oseltamivir, however published data is limited. Breastfeeding: oseltamivir is considered acceptable for use in breastfeeding mothers. The benefits of breastfeeding are considered to outweigh any, albeit unidentified, risks. Use of oseltamivir is not a reason to discontinue or put limitations on breastfeeding. Oseltamivir and its active metabolite are excreted into human breast milk in very small amounts. Limited data suggest clinical sequelae from maternal use would not be expected in a breastfed infant. The UK Drugs in Lactation Advisory Service (UKDILAS) advises, as a precaution, infants should be monitored for vomiting or diarrhoea. This guidance applies to infants born full term and healthy. If an infant is unwell, premature, or the mother is taking multiple medicines, then an individual risk assessment will need to be made.
Records Continued overleaf	Record: • whether valid informed consent was given or a decision to supply was made in the individual's best interests in accordance with the Mental Capacity Act 2005

Records (continued)	• name of individual, address, date of birth and GP with whom the individual is registered (or record where an individual is not registered with a GP) • name of the healthcare professional who supplied the product • name and brand/manufacturer 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 PGD Records should be signed and dated (or password-controlled record on e-records). All records should be clear, legible and contemporaneous. A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.

6. Key references

Key references	• Summary of Product Characteristics accessed 1 December 2021 • Patient Information Leaflet accessed 1 December 2021 • Managing the human health implications of avian influenza in poultry and wild birds. Guidance for health protection teams Version 5.0 March 2021 • Guidance: Investigation and initial clinical management of possible human cases of avian influenza with potential to cause severe human disease Updated 17 November 2021 • HSE guidance: Avoiding the risk of infection when working with poultry that is suspected of having H5 or H7 notifiable avian influenza accessed 1 December 2021 • Influenza: treatment and prophylaxis using anti-viral agents updated November 2021 • Influenza: the green book, chapter 19 updated 29 October 2020 • Influenza (Avian and other zoonotic) World Health Organization 13 November 2018 • Treatment and Prophylaxis Influenza (Flu) Centres for Disease Control and Prevention updated 6 April 2017 • Oseltamivir or zanamivir - can they be used in breastfeeding mothers for the treatment or prophylaxis of influenza. 7 August 2020 • British National Formulary (BNF) and British National Formulary for children (BNFc) accessed 1 December 2021 • NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions updated 27 March 2017 • NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions updated 27 March 2017 • Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20 March 2013

7. Individual practitioner authorisation sheet

By signing this PGD you are indicating you agree to the contents and you will work within it

PGDs do not remove inherent professional obligations or accountability

It is the responsibility of each professional to practice 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