



Publications gateway number: GOV-17655

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

This PGD is for the supply of oseltamivir for pre and post exposure prophylaxis of avian influenza for adults and children aged one year and older, by registered healthcare practitioners identified in <u>Section 3</u>, subject to any <u>limitations to authorisation</u> detailed in <u>Section 2</u>.

Reference: 20241201 Oseltamivir avian influenza PGD

Version no: 1.0

Valid from: 1 December 2024
Review date: 1 December 2026
Expiry date: 30 November 2027

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, but only for the purposes for which these sections are provided, that is the responsibilities and governance arrangements of the NHS organisation using the PGD. The fields in Section 2 and 7 cannot be used to alter, amend or add to the clinical content. Such action will invalidate the UKHSA clinical content authorisation which is provided in accordance with the regulations.

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 Avian influenza: PGD templates

For general enquires about the clinical content of the PGD contact: acute.respiratory@ukhsa.gov.uk
Enquiries relating to the availability of organisationally authorised PGDs and subsequent versions of this PGD should be directed to: insert local contact details

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¹ This includes any relevant amendments to legislation.

Change history

Version number	Change details	Date
1.0	Original PGD template compiled from previous UKHSA PGDs covering supply of oseltamivir for pre and post exposure prophylaxis to H7N9 and non-H7N9 avian influenza, to bring dosing instructions in line with WHO guidance and with expert consensus at UKHSA.	01 December 2024

1. PGD development

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

Developed by:	Name	Signature	Date
Pharmacist (Lead author)	Shilan Ghafoor Medicines Governance Pharmacist, UKHSA	88	1 December 2024
Doctor	Dr John Astbury Consultant in Health Protection Head of Environmental Public Health North West Health Protection Team, UKHSA	100	1 December 2024
Registered nurse	Nicola Middleton Lead HPP South East (TVHIOW) Health Protection Team, UKHSA	le	1 December 2024

This PGD has been peer reviewed by the Avian Influenza PGD Expert panel and ratified by the UKHSA Medicines Governance Committee in accordance with the UKHSA PGD and Protocol Policy.

Expert panel

Name	Designation
Dr Sophia Makki (Chair)	Consultant Medical Epidemiologist, Acute Respiratory Infections Team, 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 and Deputy Director (Interim): HCAI, Fungal, AMR, AMU, & Sepsis Division, UKHSA
Rosie Furner	Advanced Specialist Pharmacist - Medicines Governance, Patient Group Directions and Medicines Mechanisms, NHS Specialist Pharmacist Services (SPS)
Gemma Hudspeth	Senior Health Protection Practitioner, North East Health Protection Team Regions Directorate, UKHSA
Jackie Lamberty	Medicines Governance Consultant Lead Pharmacist, UKHSA
Mr Mark McGivern	Consultant in Health Protection, Head of Health Protection, UKHSA North West (Cumbria and Lancashire)
Dr Sakib Rokadiya	Consultant Infectious Diseases Physician, UKHSA
Dr Richard Puleston	Consultant Epidemiologist and Head of Acute Respiratory Infections, TARZET, UKHSA
Kevin Shaw	Deputy Director of Nursing and Quality, NHS Lincolnshire Integrated Care Board

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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.

NHS Cheshire and Merseyside authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisations and/or services		
Any service providing avian flu prophylaxis within the NHS Cheshire and Merseyside footprint		
Limitations to authorisation		
Only for services commissioned by NHS Cheshire and Merseyside or agreed by exception with the UKHSA		

Organisational approval (legal requirement)			
Role	Name	Sign	Date
Executive Medical Director, NHS Cheshire and Merseyside	Professor Rowan Pritchard Jones	R. Ponad Sons.	11/02/2025

Additional signatories according to locally agreed policy			
Role	Name	Sign	Date

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

<u> </u>		
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) Allied health care professionals currently registered with the Health and Care Professions Council (HCPC) but must be one of the registered professionals who can legally supply and administer under a PGD Pharmacists and pharmacy technicians 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 for example Patient Group Directions - elearning for healthcare 	
	must have undertaken training appropriate for working under this PGD	
	must be competent in the use of PGDs (see <u>NICE Competency framework</u> 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	

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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 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 ³ :		
	handled or been in close contact with live, sick, dying or dead birds infected or potentially infected with any strain of avian influenza or		
	handled or been in close contact with faecal matter or contaminated litter/other materials from birds infected or potentially infected with any strain of avian influenza		
	swabbed, culled or removed carcasses of birds infected or potentially infected with any strain of 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	Individuals:		
	 with confirmed avian influenza who will require treatment which is outside of this PGD 		
	 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 established renal failure (CrCl ≤10ml/min) 		
	with severe renal disease requiring haemodialysis		
	 who are immunocompromised⁴ 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 		
Continued overleaf			

² Criteria for post exposure antiviral prophylaxis can be discussed with the local Health Protection Team.

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³ <u>UKHSA Guidance for Health Protection Teams: Managing the human health risk of avian influenza in poultry and wild birds. Version 6.0, January 2023</u>

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

Criteria for exclusion (continued)

- 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 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 individual is excluded

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 individual or carer declines prophylaxis

Advise the individual or their carer of the possible consequences of declining chemoprophylaxis and of alternative options.

Advise about the protective effects of chemoprophylaxis, 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.

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

Name, strength and formulation of drug	Oseltamivir 75mg, 45mg and 30mg capsules		
Legal category	POM - Prescription only medicine		
Black triangle▼	No		
Off-label use	Yes		
	Oseltamivir is not licensed for avian influenza. The World Health Organisation (WHO) recommends chemoprophylaxis with oseltamivir following exposure to a zoonotic influenza virus associated with high mortality in humans or unknown risk of severe disease. Expert consensus at UKHSA recommends a dose of twice daily for 5 days (see Dose and frequency of administration). This is based on virological evidence of oseltamivir resistance occurring with a single-amino acid change.		
	Consider, as part of the consent protection the product is being offered in account this is outside the product licence.	ocess, informing the individual/carer rdance with national guidance but	
Route / method of Oral.			
administration	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).		
	The capsules should preferably be taken with food to reduce the risk of nausea or vomiting.		
Dose and frequency of administration	Adults with body weight greater than 40kg and children aged 13 years and older: see table below		
	Renal function ⁵	Dose	
	No known chronic renal impairment	One 75mg capsule twice a day*	
	Moderate impairment (CrCl 31-60 ml/min)	One 30mg capsule twice a day	
	Severe impairment (CrCl 11-30ml/min)	One 30mg capsule once a day	
	Established renal failure (CrCl ≤10ml/min)	Refer to a medical practitioner; do not supply under this PGD	
	Haemodialysis Refer to a medical practitioner; do not supply under this PGD		
	Peritoneal dialysis One 30mg capsule once as a single dose		
Continued overleaf			

⁵ World Health Organization Clinical practice guidelines for influenza published 12 September 2024

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Dose and frequency of administration (continued)

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.

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 <u>Oseltamivir chapter in the British National</u> 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.

*In the event the 75mg capsules are not available due to supply issues, the dose can be made up of the 30mg and 45mg presentation. The individual should be counselled on using the two strengths to make up the required dose.

Duration of prophylaxis

5 (five) days, unless the individual 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

Continued overleaf

Quantity to be supplied		If the 75mg capsules are not available		
(continued)		due to supply disruptions, give 10 x30mg and 10x45mg capsules		
	Renal impairment:			
	Quantity of capsules to be supplied	Quantity of capsules to be supplied		
	Moderate impairment	10 x 30mg		
	Severe impairment	5 x 30mg		
	Peritoneal dialysis	1 x 30mg		
	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°C			
Disposal	Any unused product or waste material should be disposed of in accordance with local arrangements.			
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 agent 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 and 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

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

Healthcare professionals should explain to individuals that the leaflets provided have a different dosing schedule to what has been advised as the product is being offered outside of product license but in line with national guidance (see Off-label use).

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 avian influenza 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.

Continued overleaf

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.

Additional information (continued)

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

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
- 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 12 November 2024
- Patient Information Leaflet accessed 12 November 2024
- World Health Organization Clinical practice guidelines for influenza published 12 September 2024
- Avian influenza: guidance and algorithms for managing incidents in birds - Managing the human health implications of avian influenza in poultry and wild birds. Guidance for health protection teams Version 6.0 March 2023
- Guidance: Investigation and initial clinical management of possible human cases of avian influenza with potential to cause severe human disease Updated 28 February 2024
- HSE guidance: Avoiding the risk of infection when working with poultry that is suspected of having H5 or H7 notifiable avian influenza accessed 12 November 2024
- Influenza: treatment and prophylaxis using anti-viral agents -Guidance on use of antiviral agents for the treatment and prophylaxis of seasonal influenza updated December 2021
- <u>Influenza: the green book, chapter 19</u> updated 10 November 2023
- <u>Using oseltamivir and zanamivir during breastfeeding</u> 12 October 2023
- British National Formulary (BNF) and British National Formulary for children (BNFc) accessed 12 Nov 2024
- 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 and sustainable management of healthcare waste 26 January 2024

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7. Practitioner authorisation sheet

Name PGD vXX.XX Valid from: XX/XX/20XX Expiry: XX/XX/20XX

Before signing this PGD, check that the document has had the necessary authorisations in section two. Without these, this PGD is not lawfully valid.

Practitioner

By signing this PGD you are indicating that you agree to its contents and that you will work within it.

PGDs 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 and professional code of conduct.

I confirm that I have read and understood the content of this PGD and that I am willing and competent to work to it within my professional code of conduct.				
Name	Designation	Signature	Date	

Authorising manager

I confirm that the practitioners named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of **insert name of organisation** for the abovenamed health care professionals who have signed the PGD to work under it.

Name	Designation	Signature	Date

Note to authorising manager

Score through unused rows in the list of practitioners to prevent practitioner additions post managerial authorisation.

This authorisation sheet should be retained to serve as a record of those practitioners authorised to work under this PGD.