NHS Grampian NHS Highland NHS Orkney NHS Shetland NHS Tayside NHS Eileanan Siar Western Isles

Patient Group Direction For The Supply Of Oseltamivir For Pre And Post Exposure Prophylaxis Of Avian Influenza In Adults And Children Aged One Year Or Older by Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles

Lead Author: Adapted from Public Health Scotland Supply Of Oseltamivir For Pre And Post Exposure Prophylaxis Of Avian Influenza In Adults And Children Aged One Year Or Older Patient group direction (PGD) template Version 1.1 – PHS Publication date 1st of July 2025		**Approver:** NoS PGD Group **Authorisation:** NHS Grampian

Signature:		**Signature:**

NoS Identifier: NoS/PGD/AvianFlu/1640	**Review Date:** 30 June 2028 **Expiry Date:** 30 June 2028	**Date Approved by NoS:** 6th August 2025

NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles have authorised this Patient Group Direction to help individuals by providing them with more convenient access to an efficient and clearly defined service within the NHS Boards. This Patient Group Direction cannot be used until Appendix 1 and 2 are completed.

Uncontrolled when printed

Version 1.1

Revision History for NoS:

NoS PGD that has been superseded	NoS/PGD/PGD/AvianFlu/1640 Version 1.0 (Unpublished by NoS due to required update from PHS)

Most recent changes NoS

Version	Date of change	Summary of Changes	Section heading
1.0	Unpublished by NoS due to required update from PHS		
1.1	July 2025	Reference to NoS Appendix 1 and 2	Authorisation
		Training requirements for NoS	Continuing education and training
		Additional information added	Dosage
		Duration added into table	Frequency
		Dose adjustment statement removed for children with renal dysfunction	Frequency
		Title added above table for clarity	Quantity to supply/administer
		Aged less than 13 years with known renal impairment added	Exclusions, Action if Excluded

PHS recent changes

Version	Date	Summary of changes
1.1	01 July 2025	The following changes from V1.0 are: Table headers in Frequency and Quantity to supply/administer updated

Review date: The review date for a PGD needs to be decided on a case-by-case basis in the interest of safety. The expiry date should not be more than 3 years, unless a change in national policy or update is required.

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Authorisation

This specimen Patient Group Direction (PGD) template has been produced by Public Health Scotland and adapted by North of Scotland PGD Group (NoS) 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 medicine 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 manufacturer's product information/Summary of Product Characteristics (SmPC) for all medicines supplied 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 the medicine has to be by the same practitioner who has assessed the patient under the PGD.

All authorised staff are required to read the PGD and sign the Agreement to Supply Medicines Under PGD (Appendix 1).

A Certificate of Authorisation (Appendix 2) signed by the authorising professional/manager should be supplied. This should be held in the individual health professional's records, or as agreed within the individual Health Board.

This PGD has been produced for NoS by:					
Doctor	Clare-Louise Walker	Signature	Clare Walker	Date Signed	29/07/2025
Pharmacist	Gayle Macdonald	Signature	GMacd	Date Signed	09/07/2025
Nurse	Lynda Davidson	Signature	Lynda Davidson	Date Signed	29/07/2025

Approved for use within NoS by:

NoS Group Chair	**Signature**	**Date Signed**
Lesley Coyle		05/08/2025

Authorised and executively signed for use within NoS by:

NHS Grampian Chief Executive	**Signature**	**Date Signed**
Adam Coldwells – Interim Chief Executive		06/08/2025

Version 1.1 – Approved for NoS from 6th August 2025

1. Clinical situation

1.1. Indication

Pre and post exposure prophylaxis of avian influenza.

1.2. Inclusion criteria[1]

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 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 Health Protection Team/Incident Management Team

unless:

- 8 days or more have elapsed since the last exposure

1.3. Exclusion criteria

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 10kg
- with a known allergy or hypersensitivity to oseltamivir or any of the excipients
- with established renal failure (CrCl ≤10ml/min)
- with severe renal disease requiring haemodialysis
- with renal impairment, who are aged less than 13 years (PSD required due to dose adjustment)

[1] Criteria for post exposure antiviral prophylaxis can be discussed with the local Health Protection Team

- who are immunocompromised[2] 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 lymphocytes in an adult or child over 5; CD4< 500/µl or <15% of total lymphocytes in a child aged 1 to 5)
  - 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 potentially clinically significant drug interactions e.g. chlorpropamide, methotrexate, phenylbutazone.

1.4. 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

1.5. Action if 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, or those under 13 years with renal impairment: 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/

[2] Guidance on use of antiviral agents for the treatment and prophylaxis of seasonal influenza

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.

1.6. 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.

Inform or refer to the clinician in charge.

2. Description of treatment

2.1. Name of medicine/form/strength

Oseltamivir

75mg, 45mg and 30mg capsules.

2.2. Route of administration

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 chocolate or cherry syrup, and dessert toppings such as caramel or 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.

2.3. Dosage

Adults and children aged 13 years and older (>40kg in weight), no known renal impairment

75mg twice daily for 5 days

Refer to Frequency section for dose and frequency in those <13 years, <40kg and those with renal impairment.

2.4 Frequency

The doses given below 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 below). 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.

Adults and children aged 13 years and older (>40kg in weight).

Renal Function[3]	Dose
No known chronic renal impairment	One 75mg capsule twice a day* for 5 days
Moderate impairment (CrCl 31-60ml/min)	One 30mg capsule twice a day for 5 days
Severe impairment (CrCl 11-30ml/min)	One 30mg capsule once a day for 5 days
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.

For children aged less than 13 years with renal dysfunction doses require to be adjusted, refer to a medical practitioner. This is not covered under this PGD and requires a Patient Specific Direction (PSD).
Oseltamivir chapter in the British National Formulary (BNF) for children.

For adults with a body weight less than 40 kg and children aged from 1 year to 12 years of age.

Body Weight	Dose
10kg to 15kg	30mg twice daily for 5 days
>15kg to 23kg	45mg twice daily for 5 days
>23kg to 40kg	60mg twice daily for 5 days
>40kg	75mg twice daily for 5 days*

If the child has a body weight less than 10kg, 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
1 to 3 years	30mg twice daily for 5 days
4 to 6 years	45mg twice daily for 5 days
7 to 12 years	60mg twice daily for 5 days
Over 12 years	75mg 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.

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[3] **UKHSA Guidance on use of antiviral agents for the treatment and prophylaxis of seasonal influenza**

2.5. Duration of prophylaxis

5 (five) days, unless the individual is undergoing peritoneal dialysis

2.6. Quantity to supply/administer

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	Age	Quantity of capsules to be supplied
10kg to 15kg	1 to 3 years	10 x 30mg
>15kg to 23kg	3 to 6 years	10 x 45mg
>23kg to 40kg	7 to 12 years	20 x 30mg
>40kg	Over 12 years	10 x 75mg *If the 75mg capsules are not available due to supply disruptions, give 10 x30mg and 10x45mg capsules*

Renal Impairment Adults and children aged 13 years and older (>40kg in weight).

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 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.

2.7. ▼ black triangle medicines

No

2.8. Legal category

Prescription only medicine (POM).

2.9. Is the use outwith the SMPC?

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 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 process, informing the individual/carer the product is being offered in accordance with national guidance but this is outside the product licence.

2.10. Storage requirements

Medicines must be stored securely according to national guidelines and in accordance with the product's SmPC. Do not store above 25ºC.

2.11. 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.

The Green Book, Chapter 19 states 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.

3. Adverse reactions

3.1. 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 to 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.

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 SmPC, which is available from the electronic Medicines Compendium website.

3.2. Reporting procedure for adverse reactions

Healthcare professionals and individuals/carers should report all suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on http://www.mhra.gov.uk/yellowcard

Any adverse reaction should be documented in accordance with locally agreed procedures in the individual's record and the individual's GP should be informed.

3.3. Advice to patient or carer including written information

Written information to be given to individual:

- provide manufacturer's consumer information leaflet/patient information leaflet (PIL) provided.

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

Individual advice/follow up treatment:

- 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
- the individual should be advised to seek medical advice in the event of a severe adverse reaction
- inform the individual/carer of 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
- that the patient should 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, individuals must be advised to take any remaining capsules to a community pharmacy for destruction.

3.4. Observation following vaccination

Not applicable.

3.5. Follow up

In line with local NHS Board policy.

3.6. Additional facilities

Not applicable.

4. Characteristics of staff authorised under the PGD

4.1. Professional qualifications

The following classes of registered healthcare practitioners are permitted to operate patient group directions:

- nurses and midwives currently registered with the Nursing and Midwifery Council (NMC)
- pharmacists currently registered with the General Pharmaceutical Council (GPhC)
- pharmacy technicians currently registered with the General Pharmaceutical Council (GPhC)
- chiropodists/podiatrists, dieticians, occupational therapists, orthoptists, orthotists/prosthetists, paramedics, physiotherapists, radiographers and speech and language therapists currently registered with the Health and Care Professions Council (HCPC)
- dental hygienists and dental therapists registered with the General Dental Council
- optometrists registered with the General Optical Council.

4.2. Specialist competencies or qualifications

Persons must only work under this PGD where they are competent to do so.

All persons operating this PGD:

- must be authorised by name by their employer as an approved person under the current terms of this PGD before working to it
- must be familiar with the vaccine product and alert to changes in the manufacturer's product information/SmPC
- 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 have access to the PGD and associated online resources
- should fulfil any additional requirements defined by local policy.

Employer

The employer is responsible for ensuring that persons have the required knowledge and skills to safely deliver the activity they are employed to provide under this PGD.

As a minimum, competence requirements stipulated in the PGD must be adhered to.

4.3. Continuing education and training

All practitioners operating under the PGD are responsible for ensuring they remain up to date with the use of medicines included. If any training needs are identified these should be discussed with the individuals in the organisation responsible for authorising individuals to act under this PGD.

- Have undertaken NoS PGD module training on TURAS Learn
- Have attended basic life support training either face to face or online and updated in-line with individual Board requirements
- Have undertaken immunisation training where available
- Have undertaken NHS e-anaphylaxis training or equivalent which covers all aspects of the identification and management of anaphylaxis updated in-line with individual Board requirements
- Maintain their skills, knowledge and their own professional level of competence in this area according to their individual Code of Professional Conduct.

5. Audit trail

Record the following information:

- valid informed consent was given
- name of individual, address, date of birth and GP with whom the individual is registered if possible
- name of person who supplied the product
- name and brand of product
- date of supply
- dose, form and route of administration
- quantity supplied
- batch number and expiry date
- advice given, including advice given if excluded or declines
- details of any adverse drug reactions and actions taken
- supplied under PGD

Records should be kept in line with local procedures

Local policy should be followed to encourage information sharing with the individual's General Practice

All records should be clear, legible and contemporaneous and in an easily retrievable format.

6. Additional references

Practitioners operating the PGD must be familiar with:

- Summary of Product Characteristics
- Patient Information Leaflet
- Managing the human health risk of avian influenza in poultry and wild birds: Guidance for health protection teams
- Investigation and initial clinical management of possible human cases of avian influenza with potential to cause severe human disease
- Guidance on use of antiviral agents for the treatment and prophylaxis of seasonal influenza
- British National Formulary (BNF)
- British National Formulary for children (BNFc)
- Clinical practice guidelines for influenza

7. PHS Version history

Version	Date	Summary of changes
1.0	10 January 2025	New PGD compiled from previous 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.
1.1	01 July 2025	The following changes from V1.0 are: Table headers in Frequency and Quantity to supply/administer updated

NoS Version History

Version	Date of change	Summary of Changes	Section heading
1.0	Unpublished by NoS due to required update from PHS		
	January 2025	Reference to NoS Appendix 1 and 2	Authorisation
		Training requirements for NoS	Continuing education and training
	May 2025	Quantity of capsules to be supplied changed to 5 days in both tables	Quantity to supply/administer

	May 2025	Statement removed from tables stating to be taken with breakfast.	Frequency
1.1	July 2025	Reference to NoS Appendix 1 and 2	Authorisation
		Training requirements for NoS	Continuing education and training
		Additional information added	Dosage
		Duration added into table	Frequency
		Dose adjustment statement removed for children with renal dysfunction	Frequency
		Title added above table for clarity	Quantity to supply/administer
		Aged less than 13 years with known renal impairment added	Exclusions, Action if Excluded

Appendix 1 - Healthcare Professional Agreement to Supply Medicine(s) Under Patient Group Direction

I: _____ (Insert name)

Working within: _____ e.g. Area, Practice

Agree to supply the medicine(s) contained within the following Patient Group Direction:

Patient Group Direction For The Supply Of Oseltamivir For Pre And Post Exposure Prophylaxis Of Avian Influenza In Adults And Children Aged One Year Or Older by Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles, Version 1.1

I have completed the appropriate training to my professional standards enabling me to supply the medicine(s) under the above direction. I agree not to act beyond my professional competence, nor out with the recommendations of the direction.

Signed: _____

Print Name: _____

Date: _____

Profession: _____

Professional Registration number/PIN: _____

NHS Grampian NHS Highland NHS Orkney NHS Shetland NHS Tayside NHS Eileanan Siar Western Isles

Appendix 2 - Healthcare Professionals Authorisation to Supply Medicine(s) Under Patient Group Direction

The Lead manager/Professional of each clinical area is responsible for maintaining records of all clinical areas where this PGD is in use, and to whom it has been disseminated.
The Senior Nurse/Professional who approves a healthcare professional to supply the medicine(s) under this PGD is responsible for ensuring that they are competent, qualified and trained to do so, and for maintaining an up-to-date record of such approved persons.
The Healthcare Professional that is approved to supply the medicine(s) under this PGD is responsible for ensuring that they understand and are qualified, trained and competent to undertake the duties required. The approved person is also responsible for ensuring that supply is carried out within the terms of the direction, and according to their individual code of professional practice and conduct.
Patient Group Direction For The Supply Of Oseltamivir For Pre And Post Exposure Prophylaxis Of Avian Influenza In Adults And Children Aged One Year Or Older by Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles, Version 1.1
Local clinical area(s) where the listed healthcare professionals will operate under this PGD:

Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date

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Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date