This patient group direction (PGD) must only be used by registered health professionals who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used.

Patient Group Direction (PGD)

For the administration or supply of

Oseltamivir

By registered health care professionals for

pre and post exposure of avian influenza

PLEASE NOTE: Patients may be consulted for this PGD on the phone and should send another person to collect their medication to reduce any contact with the patient and the public.

PGD NUMBER 156

Change history: this PGD is version 0.1v for Manx Care but incorporates all the versions and changes listed below from the UK PGD

Version number	Change details FOR THE UK PGD	Date
01.00	Original PGD template	24/02/2017
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	22/01/2018
03.00	• addition of doses in renal failure • expansion of definition of immunosuppression • expansion of action to be taken if the patient is excluded • expansion of drug interaction with LAIV	07/01/2021
04.00	• removal of H5N8 as an exclusion • addition of 'other materials' to inclusion criteria	04/03/2021
05.00	• amendment of inclusion and exclusion criteria from 7 days or more to 8 days or more • additional information for doses in chronic kidney disease • references to PHE changed to UKHSA • minor rewording of standard text for consistency with other UKHSA PGDs; updated references	03/12/2021

1. Medicines practice guideline 2: *Patient group directions*

Refer to the relevant sections of NICE medicines practice guideline 2: *Patient group directions* as stated in the blank template notes. For further information about PGD signatories, see the NHS and Manx Care PGD website FAQs

2. PGD development

Refer to the NICE PGD competency framework for people developing PGDs

Job Title & organisation	Name	Signature	Date
Author of the PGD			
Member of the PGD working group			

3. PGD authorisation

Refer to the NICE PGD competency framework for people authorising PGDs

Job Title	Name	Signature	Date
Medical Director			
Chief Pharmacist/ Pharmaceutical Adviser			
Senior Paramedic			
Director of Nursing			
GP Adviser			
Senior Microbiologist (if PGD contains antimicrobials)			

4. PGD adoption by the provider

Refer to the NICE PGD competency framework for people authorising PGDs

Job title and organisation	Signature	Date	Applicable or not applicable to area
Dr Sree Andole Medical Director			

5. Training and competency of registered healthcare professionals, employed or contracted by the Manx Care, GP practice or Hospice

Refer to the NICE PGD competency framework for health professionals using PGDs

	Requirements of registered Healthcare professionals working under the PGD
Qualifications and professional registration	• Registered healthcare professionals, working within or contracted by the Manx Care, GP practice or Hospice who are permitted staff groups outlined within the current PGD policy • Pharmacists must be practising in Manx Care authorised premises i.e. contracted pharmacy premises
Initial training	• Knowledge of current guidelines and the administration of the drug specified in this PGD/BNF and of the inclusion and exclusion criteria • Training which enables the practitioner to make a clinical assessment to establish the need for the medication covered by this PGD • Local training in the use of PGD's
Competency assessment	Staff will be assessed on their knowledge of drugs and clinical assessment as part the competency framework for registered health professionals using PGD's
Ongoing training and competency	The registered health care professionals should make sure they are aware of any changes to the recommendations for this medication; it is the responsibility of the registered health care professionals to keep up to date with continuing professional development. PGD updates will be held every two years

6. Clinical Conditions

Clinical condition or situation to which this PGD applies	Pre and post exposure prophylaxis of avian influenza as advised by the IOM Government DEFA officers ** *PLEASE NOTE: Patients may be consulted for this PGD on the phone and should send another person to collect their medication to reduce any contact with affected patients*
Inclusion criteria[1] *(continued)*	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 avian influenza or • handled or been in close contact with faecal matter or contaminated litter/other materials from birds infected or potentially infected with avian influenza • swabbed, culled or removed carcasses of birds infected or potentially infected with avian influenza or

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

Inclusion criteria *(continued)*	• had a significant exposure as advised by the IOM Government DEFA officers **unless**: • 8 days or more have elapsed since the last exposure
Exclusion criteria	Individuals: • with exposure to suspected or confirmed H7N9 avian influenza 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[2] due to disease or treatment for instance: o severe primary immunodeficiency o current or recent (within 6 months) chemotherapy or radiotherapy for malignancy o solid organ transplant recipients on immunosuppressive therapy o bone marrow transplant recipients currently receiving immunosuppressive treatment, or within 12 months of receiving immunosuppression o 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 o 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) o 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 other drugs with clinically significant drug interactions for instance, chlorpropamide, methotrexate, phenylbutazone

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

Cautions (including any relevant action to be taken)	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
Arrangements for referral for medical advice	Patient should be referred to a more experienced clinical practitioner for further assessment
Action to be taken if patient 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 involved in their care will be required. 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 (GP or MEDS) without delay
Action to be taken if patient declines treatment	• A verbal explanation should be given to the patient on: the need for the medication and any possible effects or potential risks which may occur as a result of refusing treatment • This information must be documented in the patients' health records • Any patient who declines care must have demonstrated capacity to do so • Where appropriate care should be escalated 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

7. Details of the medicine

<table>
<tr><td>Name, form and strength of medicine</td><td>Oseltamivir 75mg, 45mg and 30mg capsules</td></tr>
<tr><td>Legal category</td><td>POM - Prescription only medicine</td></tr>
<tr><td>Indicate any <u>off-label use</u> (if relevant)</td><td>Yes

• Oseltamivir is not licensed for avian influenza. <u>National UK guidance</u> recommends chemoprophylaxis with oseltamivir as per the inclusion criteria
• Consider, as part of the consent process, informing the individual or their carer the product is 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, and dessert toppings such as caramel or fudge sauce or sugared water, just before administration (see <u>Patient Information Leaflet</u>)</td></tr>
<tr><td>Dose and frequency
(continued)</td><td>Adults and children aged 13 years and older: see table below
The capsules should preferably be taken in the morning with breakfast, for the duration of treatment. Taking with food can reduce nausea or vomiting.

<table>
<tr><th>Renal function[3]</th><th>Dose</th></tr>
<tr><td>No known chronic renal impairment</td><td>One 75mg capsule once a day</td></tr>
<tr><td>Moderate impairment
(CrCl 31-60 mL/min)</td><td>One 30mg capsule once a day</td></tr>
<tr><td>Severe impairment
(CrCl 11-30mL/min)</td><td>One 30mg capsule every 48 hours</td></tr>
<tr><td>Established renal failure
(CrCl ≤10mL/min)</td><td>One 30mg capsule once, repeated every 7 days</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, repeated every 7 days</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>

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

Dose and frequency *(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 to supply is made, a Patient Specific Direction (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 once daily
> 15 kg to 23 kg	45 mg once daily
> 23 kg to 40 kg	60 mg once daily
> 40 kg	75 mg once daily

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 once daily
4 to 6 years	45 mg once daily
7 to 12 years	60 mg once daily
Over 12 years	75 mg once daily

No dose adjustment is needed in obese individuals

<table>
<tr><td>Quantity to be supplied</td><td>Adults: sufficient to cover the duration of prophylaxis as above. 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 overleaf.

<table>
<tr><th>Body Weight</th><th>Age</th><th>Quantity of capsules to be supplied for each 10 days of 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>

Renal impairment:

<table>
<tr><th>Quantity of capsules to be supplied</th><th>Quantity of capsules to be supplied for each 10 days of prophylaxis</th></tr>
<tr><td>Moderate impairment</td><td>10 x 30mg</td></tr>
<tr><td>Severe impairment</td><td>5 x 30mg</td></tr>
<tr><td>Established renal failure</td><td>2 x 30mg</td></tr>
<tr><td>Peritoneal dialysis</td><td>2 x 30mg</td></tr>
</table>

When supplying under PGD, this should be from the manufacturer’s original pack or over-labelled pre-packs so that the individual’s name, 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.</td></tr>
<tr><td>Maximum or minimum treatment period</td><td>• Individuals need to receive prophylaxis to cover the total exposure period and for 10 days following the last known exposure.
• Once a worker has ended their exposure, any remaining doses should be properly disposed of by returning them to a community pharmacy for destruction.
• The maximum period of treatment that an individual can receive for a single incident through this PGD is 42 days.</td></tr>
<tr><td>Storage</td><td>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 arrangements.</td></tr>
</table>

Adverse effects	**Very common**: • Nausea • Vomiting • Headache • abdominal pain • 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 healthcare professional. **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 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

Records to be kept	Record: • whether valid informed consent was given or a decision to supply was made in the individual's best interests in accordance with local legislation • 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 practitioner 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.

8. Patient information

Verbal/Written information to be given to patient or carer	• Where medication is being supplied under a PGD, written patient information leaflet must also be supplied • A patient information leaflet is available on request
Follow-up advice to be given to patient or carer *(continued)*	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 take the medication for the specified number of days • 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

Follow-up advice to be given to patient or carer *(continued)*	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 non-H7N9 infection • if an over-supply has been required, to take any remaining capsules to a community pharmacy for destruction

9. Appendix A

References

1. British National Formulary (BNF) available online: https://bnf.nice.org.uk
2. Nursing and Midwifery "The code" available online: https://www.nmc.org.uk
3. Current Health Care Professions Council standards of practice
4. General Pharmaceutical Council standards
5. The General Optical Council
6. Electronic medicines compendium available online: https://www.medicines.org.uk
7. Summary of Product Characteristics accessed 1 December 2021
8. Patient Information Leaflet accessed 1 December 2021
9. Managing the human health implications of avian influenza in poultry and wild birds Guidance for health protection teams Version 53.0 March 2021
10. Guidance: Investigation and initial clinical management of possible human cases of avian influenza with potential to cause severe human disease Updated 17 November 2021
11. 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
12. Influenza: treatment and prophylaxis using anti-viral agents updated November 2021
13. Influenza: the green book, chapter 19 last updated 29 October 2020
14. Oseltamivir or zanamivir - can they be used in breastfeeding mothers for the treatment or prophylaxis of influenza. 7 August 2020
15. British National Formulary (BNF) and British National Formulary for children (BNFc) accessed 1 December 2021
16. NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions last updated 27 March 2017
17. NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions last updated 27 March 2017
18. Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20 March 2013

10. Appendix B

Health professionals agreed to practice
• Each registered healthcare professional will hold their own Competency framework which will be signed and agreed by their mentor • A mentor is defined within the Manx Care policy as any ward/area managers, sisters, senior nurses, GPs, pharmacists or senior paramedics who has completed the PGD training themselves

11. Appendix C

Additional Information	
Drug interactions	Individuals taking the following medicines are excluded from this PGD (see exclusion criteria): • chlorpropamide • methotrexate • phenylbutazone The Green Book 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.
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.

12. Appendix D

Frequently Asked Questions
Why have I been given this medicine? You have been given a course of antiviral medicine called Oseltamivir (Tamiflu®) because you have come into close contact with poultry/contaminated materials from poultry suspected or confirmed (delete as appropriate) to be infected with bird flu virus type [insert virus type]. This means that you might have been exposed to the bird flu virus. The risk to your health is low but taking antiviral medicine reduces this risk even further. It will also reduce the risk of you becoming unwell with an ordinary human flu virus, while you are taking the antivirals. **How much should I take?** To work effectively you must take one capsule every day until the course you have been given finishes or until your GP or other health professional tells you to stop. **Can I take this medicine if I am pregnant?** If you are pregnant or are currently breast feeding, please bring this to the attention of the health professional who gave you the medicines, before you start taking them and they will advise you. **What if I have another medical condition?** Please tell the health professional who is providing the antiviral medicines about any medical condition or allergies to medicines. **Does this medicine have side effects?** Not usually and side effects will generally be mild. Side effects have been rarely reported and include nausea and mild stomach ache/upset. Nausea is less likely if the medicine is taken with food. **When should I start taking this medicine?** As soon as you get it. **Does my family need this medicine?** No, only people who are believed to have come into close contact with a bird infected with bird flu need to take the medicine. This is because only people who have handled or have been in very close contact with infected birds are at risk of getting bird flu. **What if I develop symptoms?** If you suddenly develop any of the following symptoms up to 10 days after your last contact with the affected birds or affected [farm/premises] it is important that you contact either your GP or other health professional by telephone as soon as possible. You should refer to this information sheet so they understand why you are taking these medicines