UK Health Security Agency

NHS

Publications number: GOV-12936

Patient Group Direction (PGD) for the supply of oseltamivir for treatment of seasonal influenza

For the supply of oseltamivir for treatment of seasonal influenza for residents, users and staff of care facilities (with or without nursing), by registered healthcare practitioners identified in Section 3, subject to any limitations to authorisation detailed in Section 2.

Reference:	20220805OseltamivirTreatment_PGD
Version number:	05.00
Valid from:	8 August 2022
Review date:	8 August 2024
Expiry date:	7 August 2025

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 seasonal influenza PGDs for authorisation can be found from: Influenza post exposure prophylaxis and treatment: PGD templates

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

Enquiries relating to the availability of organisationally authorised PGDs and subsequent versions of this PGD should be directed to: pgd@cheshireandmerseyside.nhs.uk

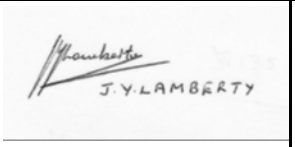
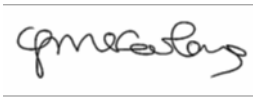
[1] This includes any relevant amendments to legislation

Change history

Version number	Change details	Date
01.00	Original PGD template developed	11 December 2014
02.00	Template reviewed; put into new PHE format and changes to clinical and organisational content made	7 January 2016
03.00	Review: • updates to title and criteria for inclusion: wording changed to 'residents/users and staff of care facilities' • amendments to inclusion and exclusion criteria • additions to actions to be taken if the patient is excluded • renal impairment definitions added • information regarding not splitting packs • additions to patient advice • updated references • minor typographical changes for consistency with other PGDs	5 June 2018
04.00	• amendment to No. 5 criteria for inclusion • addition of haemodialysis to criteria for exclusion • additions to off label use • addition of quantity and duration of treatment of 10 days in immunocompromised individuals • updated references	7 February 2019
05.00	• criteria for inclusion: risk groups updated to align with the Green Book Chapter 19 • criteria for exclusion: removed unstable medical conditions, severely unwell, new or worsening breathing difficulties or chest pain and added note under additional information • criterial for exclusion: removed clinically significant drug interactions and added note under drug interactions • criteria for exclusion: added individuals who are immunocompromised and have chronic kidney disease (CKD) with creatinine clearance CrCl ≤10mL/min or who are on peritoneal dialysis; those taking zanamivir • additional information: added information for oseltamivir resistance and information for CKD • route and method of administration: additional information regarding taking with food • dose and frequency of administration: additional information for renal doses, CrCl and eGFR levels, immunocompromised individuals and obesity; updated dose and frequency table • quantity: amended for immunocompromised individuals • drug interactions: information regarding clinically significant drug interactions; information on influenza vaccinations • minor wording changes in line with standard UKHSA PGD text; change from PHE to UKHSA, updated references	8 August 2022

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, Health Equity and Clinical Governance Directorate, Clinical and Public Health Group, UKHSA		8 August 2022
Doctor	Dr Matthew Donati Consultant Medical Virologist/ Head of Virology, Specialised Microbiology and Laboratories, SW Regional Laboratory and Severn Infection Sciences, UKHSA		8 August 2022
Registered nurse	Lesley McFarlane Lead Immunisation Nurse Specialist, Immunisation and Vaccine Preventable Diseases Division, UKHSA		8 August 2022

This PGD has been peer reviewed by the Seasonal 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 Conall Watson	Chair, Consultant Epidemiologist – influenza and seasonal respiratory viruses, Immunisation and Vaccine-Preventable Diseases Division, UKHSA. Registered pharmacist
Dr Nicholas Aigbogun	Consultant in Communicable Disease Control, Yorkshire and Humber Health Protection Team, UKHSA
Mark Borthwick	Consultant Pharmacist, Oxford University Hospitals NHS Foundation Trust
Rosie Furner	Community Services Pharmacist, East Sussex Healthcare NHS Hospital Trust
Gemma Hudspeth	Health Protection Practitioner, North East and Yorkshire Region, UKHSA. Registered nurse
Jo Jenkins	Specialist Pharmacist (Patient Group Directions), Medicines Use and Safety Division, NHS England (NHSE)
Michelle Jones	Principal Medicines Optimisation Pharmacist, NHS Bristol North Somerset and South Gloucestershire Integrated Care Board
Kevin Shaw	Deputy Director of Nursing and Quality, NHS Lincolnshire Clinical Commissioning Group. Registered nurse
Kelly Stoker	Head of Infection Prevention Control, Safer Care Team, Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust. Registered nurse

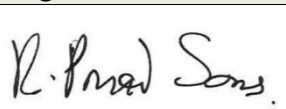
2. Organisational authorisations

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 influenza treatment 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, Cheshire and Merseyside ICB NHS	Prof Rowan Pritchard Jones		29.04.25

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

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) Additional registered healthcare professionals to be added by organisation authorising the 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/administration of medicines for example Patient Group Directions - elearning for healthcare • 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 have access to the PGD and associated online resources • should fulfil any additional requirements defined by local policy • authorising organisation to insert any additional requirements **The practitioner must be authorised by name, under the current version of the PGD, before working according to it.**
Continued training requirements	Authorising organisation to insert any continued training requirements

Note: The authorising organisation should ensure staff working with this PGD are trained in addressing issues of consent, including those individuals with dementia. The healthcare professional working under this PGD should follow their existing organisational procedures in relation to consent.

4. Clinical condition or situation to which this PGD applies.

Clinical condition or situation to which this PGD applies	Treatment of influenza A and B: 1. When **all** of the following circumstances apply: • national surveillance schemes have indicated that influenza virus is circulating in the community[2] as advised by the Chief Medical Officer (CMO) **and** • the person is in an 'at-risk' group, including being aged 65 years and over (see inclusion criteria) **and** • the person has an 'influenza-like illness' (ILI) and can start treatment within 48 hours of the onset of symptoms 2. Outside the periods when surveillance indicates that influenza virus is circulating in the community, if there is an outbreak of an ILI in a long-term residential or nursing home (care homes), oseltamivir may be offered to 'at risk' residents and 'at risk' staff as part of treatment for those who have symptoms of influenza. This is regardless of vaccination status. However, this should only be done if there is a high level of certainty that the causative agent in a localised outbreak is influenza, usually based on virological evidence of infection with influenza in the index case or cases. UKHSA Health Protection Teams (HPTs) will advise on whether influenza is the likely causative agent.
Criteria for inclusion Continued overleaf	This PGD will come into force only when either national surveillance schemes have indicated influenza virus is circulating or when, in a localised outbreak, there is a high level of certainty the causative agent is influenza, as advised by the local HPT. Individuals must: **1.** Be a resident or user of a care facility or staff working in a care facility[3] **and** **2.** Be exhibiting signs or symptoms of an influenza-like illness (ILI)[4] **and** 3. Either be aged 65 years and over (regardless of risk group) **or,** if aged 13 – 64 years, must be in one of the defined risk groups below: • chronic (long-term) respiratory disease such as asthma that requires continuous or repeated use of inhaled or systemic steroids or with previous exacerbations requiring hospital admission, chronic obstructive pulmonary disease (COPD) or bronchitis

[2] The UKHSA uses information from a range of clinical, virological and epidemiological influenza surveillance schemes to identify periods when there is a substantial likelihood that people presenting with an influenza-like illness are infected with influenza virus

[3] Care workers who are in an 'at risk' group are at risk of complicated influenza and require treatment

[4] Influenza is characterised in its early stages by sudden onset of pyrexia (fever) associated with aches, pains, loss of appetite. Sore throat, nausea, vomiting and harsh unproductive coughs are also common. Heavy colds are commonly confused with influenza. In older individuals these symptoms may be mild or absent initially

Criteria for inclusion (continued)	• chronic heart disease or vascular disease, such as heart failure • chronic liver disease • chronic kidney disease (CKD) at stage three, four or five[5] (see Additional information) with some exceptions (see criteria for exclusion) • chronic neurological disease, such as Parkinson's disease or motor neurone disease, or learning disability • diabetes or adrenal insufficiency • immunosuppression due to disease or treatment (refer to the Green Book Chapter 19) • asplenia or dysfunction of the spleen • morbid obesity (defined as a BMI of 40 and above) • any other clinical risk group, as listed in the Green Book chapter 19, that puts the individual at risk of complications of influenza • pregnant women at any stage of pregnancy (first, second or third trimesters) and up to 2 weeks post-partum (see Additional information) 4. Be able to begin therapy within 48 hours of the onset of symptoms. Alternatively supply can be considered after 48 hours of the onset of symptoms, when the local HPT or a specialist in infectious disease, such as a medical microbiologist or virologist, advises this could be considered[6]. Note such supplies are not being directed (see footnote 6 below). This is a clinical decision which rests with the practitioner working under this PGD and this is off-label use.
Criteria for exclusion[7] Continued overleaf	Individuals will not be considered for treatment with oseltamivir under this PGD if the following criteria apply: • they are not a resident or user of or working in a care facility • they are less than 13 years of age • they are receiving haemodialysis • they are immunocompromised and have CKD with creatinine clearance CrCl ≤10mL/min • they are immunocompromised and on peritoneal dialysis • they have a known allergy to oseltamivir or to any of the excipients in the capsules • they have been symptomatic with this episode of ILI for more than 48 hours, unless initiation is advised by the local HPT (see footnote 6 below)

[5] Chronic kidney disease: assessment and management NICE Guidance (NG203)

[6] The practitioner making the supply under this PGD remains professionally accountable and clinically responsible for ensuring a supply is appropriate for an individual as assessed under this PGD. Where the HPT advise a course of treatment can be considered, they are not directing the supply must be made – this is a clinical decision which rests with the practitioner working under this PGD

[7] Exclusion under this PGD does not necessarily mean the medication is contraindicated, but it would be outside the remit of the PGD and another form of authorisation will be required

Criteria for exclusion (continued)	• they have disturbance of consciousness, delirium or excessive drowsiness • they have significant vomiting or are unable to drink fluids • they are receiving zanamivir
Action to be taken if the individual or carer declines treatment	Advise the individual or their carer of the possible consequences of refusing the treatment, the protective effects of the treatment, the risks of infection, the risks of spreading the disease to others in the care facility, disease complications and alternative sources of treatment. Consider if the individual is suitable for treatment with zanamivir or refer to the local HPT or a specialist in infectious disease such as a medical microbiologist or virologist for further guidance. Document the refusal and the advice given in the individual's patient record. Inform the care home manager and the GP or care home doctor without delay. These individuals should be managed with bed rest, fluids and symptomatic remedies such as analgesics or referred to NHS services if necessary. All individuals and their carers should be advised to seek medical advice if symptoms worsen or do not improve within a week.
Action to be taken if the individual is excluded	Some individuals excluded under this PGD may be suitable for treatment with oseltamivir if clinically assessed and prescribed. Consider if the individual is suitable for treatment with zanamivir (see PGD for treatment with zanamivir in care facilities). Any individual excluded under this PGD who is clinically assessed as requiring treatment and who is not suitable for treatment with zanamivir should be referred to local NHS services for advice without delay. If more than 48 hours from symptom onset and there is no advice in place from the local HPT or a specialist in infectious disease such as a medical microbiologist or virologist, the HPT should be consulted or advice sought from a medical or non-medical prescriber. Note that primary care prescribing is restricted to when the CMO has indicated influenza is circulating in the community.
Additional information Continued overleaf	If an individual is severely unwell, has new or worsening breathing difficulties, chest pain or is otherwise medically unstable and may be at risk of hospitalisation, initiate the antiviral but ensure the individual is referred for assessment by an appropriate clinician, typically a doctor. It is normal practice to administer only one neuraminidase inhibitor to an individual at a time. Therefore supply either oseltamivir or zanamivir but not both (see PGD for treatment with zanamivir in care facilities) and confirm another neuraminidase inhibitor has not been prescribed.

Additional information (continued)	Zanamivir inhaler is recommended as first line therapy (see PGD for treatment with zanamivir in care facilities) in the following circumstances: • if the HPT has advised the confirmed or dominant circulating influenza strain is higher risk for oseltamivir resistance and the individual is immunocompromised[8] or • the individual is known to have oseltamivir resistant influenza whether immunocompromised or not or • the individual is strongly suspected to have oseltamivir resistant influenza whether immunocompromised or not, for example they have been in contact with known oseltamivir resistant influenza If the individual is unable to use inhalers, seek advice from a specialist in infectious disease such as a medical microbiologist or virologist. **Chronic kidney disease:** the SPC dose recommendations for renal impairment are based on creatinine clearance (CrCl) which is no longer routinely reported by laboratories; the estimated Glomerular Filtration Rate (eGFR) is usually reported. There may therefore be a misalignment between the laboratory result reported for renal impairment and the result required to ensure the correct dosage and frequency. Where not reported, do not delay treatment but substitute the CrCl value with the eGFR result in the dosage table and supply a dose according to eGFR. 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. Further information on CKD classifications can be found at Chronic kidney disease: assessment and management NICE guidance (NG203). **Breastfeeding**: the UK Drugs in Lactation Advisory Service (UK DILAS) advises oseltamivir is acceptable for use in breastfeeding mothers and 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 (see NHS/ UKMI Medicines Q and As: Oseltamivir or zanamivir—can mothers breastfeed after treatment for influenza?).

[8] For definition of immunocompromised see Green Book Chapter 19

5. Description of treatment

Name, strength and formulation of drug	Oseltamivir 75mg capsules Oseltamivir 30mg capsules
Legal category	POM - Prescription only medicine
Black triangle▼	No
Off-label use	Yes • when used outside the periods when national surveillance indicates that influenza virus is circulating generally in the community - see footnote below[9] • when supplied after 48 hours of the onset of symptoms • in renal impairment with CrCl ≤10mL/min, the SPC states 'not recommended'. The UKHSA guidance on use of antiviral agents for the treatment and prophylaxis of seasonal influenza gives the dose in the table overleaf • the duration of treatment given for individuals who are severely immunocompromised with renal impairment is outside the SPC but is recommended in The UKHSA guidance on use of antiviral agents for the treatment and prophylaxis of seasonal influenza Where a product is recommended off-label, consider, as part of the consent process, informing the individual/carer the product is being offered in accordance with national guidance but that this is outside the product licence.
Route / method of administration	Oral The capsules should be taken preferably in the morning with breakfast because taking with food can reduce nausea or vomiting. 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 syrup, dessert toppings or sugared water, just before administration (see Patient Information Leaflet).
Dose and frequency of administration Continued overleaf	See table overleaf Initiate treatment as soon as possible, ideally within 12 hours of onset of symptoms, but certainly within the first two days (48 hours) of onset of symptoms, unless otherwise advised by the local HPT. Supply individuals with no known renal impairment with a full dose. The doses given in the table overleaf are for individuals with stable CKD. If there is a history of renal impairment 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 treatment

[9] The product licence covers treatment of influenza *when influenza virus is circulating in the community.* However NICE guidelines recommend oseltamivir can be used during localised outbreaks of ILI *outside the periods when national surveillance indicates that influenza virus is circulating generally in the community,* in 'at-risk' people living in long-term residential or nursing homes (care homes).

Dose and frequency of administration (continued)

and supply a dose according to eGFR, substituting eGFR for the CrCl figure in the table below. Some individuals may receive a larger dose of oseltamivir as a result, but this is unlikely to be harmful as clinical experience reveals a wide margin of safety.

If the individual is definitely known to have chronic renal impairment and CrCl or eGFR results are not available, consider if they are suitable for treatment with zanamivir (see PGD for treatment with zanamivir in care homes) or refer to a medical practitioner. If a decision to supply oseltamivir is made, a Patient Specific Direction (PSD) will be required.

No dose adjustment is needed in obese individuals.

For severely immunocompromised individuals[10], supply a course for **10** days rather than 5 days, except those with CrCl ≤10mL/min or those on peritoneal dialysis, who are excluded from this PGD (see dosage table below).

<table>
<tr><th>Renal Impairment</th><th>Daily dose</th><th>Duration for normal immune function</th><th>Duration for severely immunocompromised individuals[10]</th></tr>
<tr><td>Normal renal function;
weight 40kg+</td><td>One 75mg capsule twice daily</td><td rowspan="4">5 days</td><td rowspan="4">10 days</td></tr>
<tr><td>Normal renal function;
weight >23kg to 40kg</td><td>Two 30mg capsules twice a day</td></tr>
<tr><td>CrCl >30 to 60 mL/min</td><td>One 30mg capsule twice a day</td></tr>
<tr><td>CrCl >10 to 30mL/min</td><td>One 30mg capsule once a day</td></tr>
<tr><td>CrCl ≤10mL/min</td><td>One 30mg capsule</td><td>One dose only</td><td>Refer to a medical practitioner; do not supply under this PGD</td></tr>
<tr><td>Haemodialysis</td><td colspan="3">Refer to a medical practitioner; do not supply under this PGD</td></tr>
<tr><td>Peritoneal dialysis</td><td>One 30mg capsule</td><td>One dose only</td><td>Refer to a medical practitioner; do not supply under this PGD</td></tr>
</table>

Duration of treatment

See dosage schedule above

Quantity to be supplied

Not severely immunocompromised

- no known chronic renal impairment and weight above 40kg: 10 x 75mg capsules
- no known chronic renal impairment and weighing >23kg to 40kg: 20 x 30mg capsules
- CrCl >30 to 60 mL/min: 10 x 30 mg capsules
- CrCl >10 to 30mL/min: 5 x 30mg capsules
- CrCl ≤10mL/min: 1 x 30mg capsule
- peritoneal dialysis: 1 x 30mg capsule

Continued overleaf

[10] For definition of severely immunocompromised refer to UKHSA guidance on use of antiviral agents for the treatment and prophylaxis of seasonal influenza

Quantity to be supplied (continued)	**Severely immunocompromised individuals** • no known renal impairment 20 x 75mg capsules • no known chronic renal impairment and weighing >23kg to 40kg: 40 x 30mg capsules • CrCl >30 to 60 mL/min: 20 x 30 mg capsules • CrCl >10 to 30mL/min: 10 x 30mg capsules • CrCl ≤10mL/min, on haemodialysis or peritoneal dialysis: excluded from the PGD When supplying under PGD, this should be from the manufacturer's original pack or over-labelled pre-packs so the individual's name, the 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.
Storage	Do not store above 25^{o}C
Disposal	Any unused stock should be disposed of in accordance with local arrangements. Individuals receiving an over-supply should be advised to return any remaining capsules to a community pharmacy for destruction.
Drug interactions	Clinically important drug interactions such as chlorpropamide, methotrexate, phenylbutazone, leflunomide, nitisinone or teriflunomide are unlikely, due to the known safety margin for most of these products, the elimination characteristics of the active metabolite (glomerular filtration and anionic tubular secretion) and the excretion capacity of these pathways. The Green Book states administration of influenza antiviral agents within two weeks of administration of a live attenuated influenza nasal spray vaccine, as used in the school-age vaccination programme, may adversely affect the effectiveness of the vaccine. Adult influenza vaccinations are inactivated and are not affected by antiviral administration. A detailed list of drug interactions is available in the SPC
Identification and management of adverse reactions	Frequently reported adverse reactions include nausea and vomiting. These reactions may only occur on a single occasion, on either the first or second treatment day, and resolve spontaneously within one to two 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, abdominal pain and dyspepsia. A detailed list of adverse reactions is available in the SPC
Reporting procedure of adverse reactions	Document any reported adverse reaction to the product in the individual's medical records.

Reporting procedure of adverse reactions (continued)	Alert an appropriate clinician in the event of a serious adverse reaction. Report any suspected severe adverse reactions 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)[11].
Advice /follow up	Inform the individual or their carer: • to read the PIL before taking the medication • taking the medication with food can reduce nausea or vomiting • if they have difficulty swallowing, the capsules can be opened and taken with a small amount of sweetened food (see PIL) • of any possible side effects and their management • to seek advice if common side effects do not spontaneously resolve 48 hours after presentation • to seek medical advice in the event of a severe adverse reaction, if breathing difficulties develop or if general health rapidly worsens • to complete the course • if an over-supply has been, individuals must be advised to take any remaining capsules to a community pharmacy for destruction Promote bed rest, fluids and symptomatic remedies such as analgesics Advise to isolate or stay away from work to prevent transmission
Special considerations	Use of oseltamivir is not a substitute for influenza vaccination. The protection against influenza lasts only as long as oseltamivir is taken.
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 the individual, address, date of birth and their GP • name of the member of staff who supplied the product • name and brand of product • date of supply • dose, form and route of administration of 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 • the medicine was supplied via PGD • if an over-supply is required and advice to return the remaining product to a community pharmacy for destruction has been given All records should be signed and dated, contemporaneous, clear and legible A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy Inform the individual's GP that oseltamivir has been supplied under this PGD

[11] Pre-packs will contain a copy of the PIL

6. Key references

Key references	• Summary of Product Characteristics accessed July 2022 • British National Formulary accessed July 2022 • NICE guidelines on the use of amantadine, oseltamivir and zanamivir for the treatment of influenza TA168 reviewed November 2014 • Guidance on the management of outbreaks of influenza-like illnesses in care homes V5.0 updated November 2020 • NHS Specialist Pharmacy Service page re NHS PGDs accessed July 2022 • NHS/ UKMI Medicines Q and As: Oseltamivir or zanamivir—can mothers breastfeed after treatment for influenza? updated July 2020 • UKHSA guidance on use of antiviral agents for the treatment and prophylaxis of seasonal influenza updated November 2021 • Green Book Chapter 19 Influenza updated 29 October 2020 • Chronic kidney disease: assessment and management NICE guidance NG203) updated 24 November 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 and Social Care 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 I have read and understood the content of this PGD and 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 you have assessed the staff member as competent to work under this PGD and 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