UK Health Security Agency

NHS

Publications number: GOV-12936

Patient Group Direction (PGD) for the supply of inhaled zanamivir (Relenza®) for the treatment of seasonal influenza

For the supply of zanamivir inhalation powder (Relenza®) for the 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:	20220808 Zanamivir Treatment PGD
Version number:	04.00
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 avian influenza PGDs for authorisation can be found from: Influenza post exposure prophylaxis and treatment: PGD templates - GOV.UK (www.gov.uk)

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

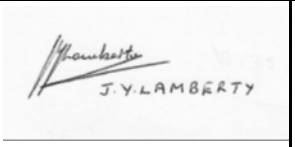
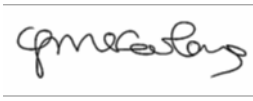
[1] This includes any relevant amendments to legislation

Change history

Version number	Change details	Date
01.00	Original PGD template developed	January 2016
02.00	• inclusion criteria expanded to include care facilities, those with chronic kidney disease at stage three, four or five, morbid obesity (defined as a BMI of 40 and above), pregnant women at any stage of pregnancy (first, second or third trimesters) and use after 48 hours of onset of symptoms if advised by the local PHE Centre HPT. • additional information on pregnancy and breastfeeding • additional information on bronchospasm • no dose modification is required for individuals with impaired renal or hepatic function or in older individuals • updated references • updated standard wording for consistency with PHE PGD templates	June 2018
03.00	• removal of pregnant women at any stage of pregnancy (first, second or third trimesters) and up to 2 weeks post-partum from inclusion criteria • addition of milk protein allergy, pregnancy and breastfeeding to exclusion criteria following update to SPC	December 2018
04.00	• criteria for inclusion: risk groups updated to align with the Green Book Chapter 19. Pregnancy and breastfeeding added • criteria for exclusion: removed pregnancy and breastfeeding, unstable medical conditions, severely unwell, new or worsening breathing difficulties or chest pain and added note under additional information • criteria for exclusion: added those taking oseltamivir • 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 & 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 & 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 & 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

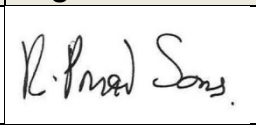
2. Organisational authorisations

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 that 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 (e-lfh.org.uk) • 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 that 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/or 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), zanamivir 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 that 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. However, those with asthma or COPD requiring regular inhaled or systemic steroids are excluded; see criteria for exclusion • chronic heart disease or vascular disease such as heart failure • chronic liver disease

[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 kidney disease (CKD) at stage three, four or five[5] • 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 the 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 zanamivir 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 have a known allergy to zanamivir or any of the excipients in the preparation, including lactose. Individuals with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not use Relenza® • they have milk protein allergy • 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) • they have disturbance of consciousness, delirium or excessive drowsiness • they have asthma or COPD requiring regular oral or inhaled corticosteroids, due to the increased risk of bronchospasm • they are unable to use the inhaler device

[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 that the supply must be made – this is a clinical decision that rests with the practitioner working under this PGD

[7] Exclusion under this Patient Group Direction 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 are taking oseltamivir
Action to be taken if the individual or their 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 oseltamivir 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 zanamivir if clinically assessed and prescribed. Consider if the individual is suitable for treatment with oseltamivir (see PGD for treatment with oseltamivir in care facilities). Any individual excluded under this PGD who is clinically assessed as requiring treatment and who is not suitable for treatment with oseltamivir 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 zanamivir or oseltamivir but not both and confirm another neuraminidase inhibitor has not been prescribed. Relenza® is recommended as first line therapy (unless the individual is unable to use inhalers) when the confirmed or dominant circulating influenza strain is higher risk for oseltamivir resistance and the individual is immunocompromised, or the individual is known to or is strongly suspected to have oseltamivir resistant influenza whether immunocompromised or not.

Additional information (continued)	Although the SPC states the efficacy and safety of Relenza® has not been established in immunocompromised individuals due to limited data, and the efficacy of zanamivir for the treatment of individuals aged 65 years and over has not been established, nevertheless, when treatment with oseltamivir is contraindicated or there is a high risk of oseltamivir resistant influenza, treatment with zanamivir should be considered in these cohorts. **Pregnancy and breastfeeding:** the SPC states that, as a precautionary measure, it is preferable to avoid the use of Relenza® during pregnancy, unless the clinical condition of the woman is such that the potential benefit to the mother significantly outweighs the possible risk to the fetus. However, studies suggest there is no evidence of harm in pregnant women treated with inhaled zanamivir[8]. The SPC states a decision must be made whether to discontinue breastfeeding or to discontinue or abstain from Relenza® therapy, taking into account the benefit of breastfeeding for the child and the benefit of therapy for the woman. However, NHS/ UKMI Medicines Q and As: Oseltamivir or zanamivir—can mothers breastfeed after treatment for influenza? states zanamivir is considered acceptable for use in breastfeeding mothers. There are no data on zanamivir use during lactation, but based on limited oral bioavailability, the systemic exposure of a breastfed infant from maternal treatment is expected to be insignificant. Therefore, the benefits of breastfeeding are considered to outweigh any, albeit unidentified, risks and use of Relenza® is not a reason to discontinue, or put limitations on breastfeeding.

[8] Guidance on use of antiviral agents for the treatment and prophylaxis of seasonal influenza (publishing.service.gov.uk)

5. Description of treatment

Name, strength and formulation of drug	Zanamivir inhalation powder 5mg / dose (Relenza®)
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 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	Inhalation of powder via *Diskhaler*® (provided with the pack). See patient information leaflet (PIL) for instructions on how to use the *Diskhaler®.*
Dose and frequency of administration	Two inhalations (2 x 5 mg blisters) twice a day Treatment should be initiated as soon as possible within 48 hours of onset of symptoms No dose modification is required for individuals with impaired renal or hepatic function or in older individuals
Duration of treatment	5 (five) days
Quantity to be supplied	One pack: contains 5 disks each containing 4 blisters of zanamivir 5 mg/blister, with *Diskhaler*® device.
Storage	Do not store above 30°C.
Disposal	Any unused product or waste material should be disposed of in accordance with local arrangements
Drug interactions	None reported.
Identification & management of adverse reactions Continued overleaf	Adverse effects associated with zanamivir are rare. They include rash, urticaria, bronchospasm, dyspnoea and throat tightness/constriction. There have been very rare reports of individuals being treated with zanamivir who have experienced bronchospasm and/or decline in respiratory function which may be acute and/or serious. Some of these individuals did not have any previous history of respiratory

[9] The product licence covers treatment of influenza *when influenza virus is circulating in the community.* However NICE guidelines recommend zanamivir 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).

Identification & management of adverse reactions (continued)	disease. Any individuals experiencing such reactions should discontinue zanamivir and seek medical evaluation immediately. Individuals with asthma or COPD requiring regular oral or inhaled corticosteroids are excluded from this PGD due to the increased risk of bronchospasm with zanamivir. 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 Alert an appropriate clinician in the event of a serious adverse reaction Report suspected 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).
Advice /follow up	Inform the individual or their carer: • to read the PIL before using the medication • 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 Promote bed rest, fluids and symptomatic remedies such as analgesics Advise to isolate or stay away from work to prevent transmission
Special considerations / additional information	Use of zanamivir is not a substitute for influenza vaccination. The protection against influenza lasts only as long as zanamivir is administered. Zanamivir may be supplied to individuals as an alternative to oseltamivir when the likely influenza strain is higher risk for oseltamivir resistance or an exclusion to oseltamivir applies.
Records Continued overleaf	Record: • whether valid informed consent was given or a decision to supply was made in the individual's best interests in accordance with the Mental Capacity Act 2005 • 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

Records (continued)	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 zanamivir has been supplied under this PGD

6. Key references

Key references	• Summary of Product Characteristics accessed July 2022 • NICE guidelines on the use of amantadine, oseltamivir and zanamivir for the treatment of influenza TA168 last reviewed November 2014 • PHE 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? August 2020 • UKHSA guidance on use of antiviral agents for the treatment and prophylaxis of seasonal influenza Version 11, November 2021 • Green Book Chapter 19 Influenza Updated 29 October 2020 • NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions updated 27 March 2017 • NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions updated 27 March 2017 • Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20 March 2013

7. Individual practitioner authorisation sheet

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

PGDs do not remove inherent professional obligations or accountability

It is the responsibility of each professional to practice only within the bounds of their own competence

Practitioner

I confirm 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