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

Patient Group Direction for the Administration of Shingles (Herpes Zoster) Live Vaccine Zostavax® by Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles

Lead Author: Adapted from PHS National PGD by the Medicines Management Specialist Nurse NHSG	**Consultation Group:** See relevant page in the PGD	**Approver:** NoS PGD Group **Authorisation:** NHS Grampian
Signature:		**Signature:**
NoS Identifier: NoS/PGD/Zostavax/ MGPG1288	**Review Date:** August 2023 **Expiry Date:** August 2024	**Date Approved:** August 2022

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 4

Revision History:

Reference and approval date of PGD that has been adapted and/or superseded	PGD adapted from PHS national PGD and supersedes NoS/PGD/Zostavax/MGPG1212 Version 3.	
Date of change	**Summary of Changes**	**Section heading**
August 2022	PGD adapted from new PHS PGD template and new NoS PGD template.	
August 2022	Dates updated for 2022/23 programme.	Inclusion criteria
August 2022	Section updated to highlight that those who decline vaccination remain eligible until they reach 80 years of age.	Action if treatment is declined
August 2022	Exclusion where COVID vaccine has been received within the past 7 days removed as this isn't an absolute contraindication.	Exclusion criteria

NoS Identifier: NoS/PGD/Zostavax/MGPG1288
Keyword(s): PGD Patient Group Direction shingles herpes zoster vaccine live zostavax

Policy Statement:
It is the responsibility of the individual healthcare professional and their line managers to ensure that they work within the terms laid down in this PGD and to ensure that staff are working to the most up to date PGD. By doing so, the quality of the services offered will be maintained, and the chances of staff making erroneous decisions which may affect individual, staff or visitor safety and comfort will be reduced. Supervisory staff at all levels must ensure that staff using this PGD act within their own level of competence.

The lead author is responsible for the review of this PGD and for ensuring the PGD is updated in line with any changes in clinical practice, relevant guidelines, or new research evidence.

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.

Document:	Drafted:	August 2022
	Completed:	August 2022
	Approved:	August 2022 (published – August 2022)
	Amended & reauthorised:	

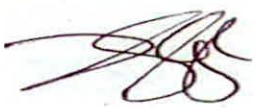
Organisational Authorisations

This PGD is not legally valid until it has had the relevant organisational authorisation.

PGD Developed/Reviewed by;

Medical practitioner	**Name:** Dr Maggie Watts **Health Board:** NHSWI **Title:** Director of Public Health **Contact email:** maggie.watts@nhs.scot **Signature** ..... **Date:** 18/08/2022
Senior representative of the professional group who will provide care under the direction	**Name:** Jackie Donachie **Health Board:** NHST **Title:** Vaccine Programme Manager **Contact email:** jacqueline.donachie2@nhs.scot **Signature** ..... **Date**: 23/08/2022
Lead author	**Name:** Frances Adamson **Health Board:** NHSG **Title :** Medicines Management Specialist Nurse **Contact email:** frances.adamson@nhs.scot **Signature** ..... **Date:** 17/08/2022
Pharmacist	**Name:** Mary McFarlane **Health Board:** NHSS **Title :** Principal Pharmacist **Contact email:** mary.mcfarlane@nhs.scot **Signature** ..... **Date:** 22/08/2022

Approved for use within NoS Boards by;

North of Scotland (NoS) PGD Group Chair	Signature	Date Signed
Lesley Coyle		17/08/2022

Authorised and executively signed for use within NoS Boards by;

NHS Grampian Chief Executive	Signature	Date Signed
Professor Caroline Hiscox		23/08/2022

Management and Monitoring of Patient Group Direction

PGD Consultative Group

The consultative group is legally required to include a medical practitioner, a pharmacist and a representative of the professional group who will provide care under the direction.

Name:	Title:
Frances Adamson	**Lead Author:** Medicines Management Specialist Nurse NHSG
Mary McFarlane	**Pharmacist:** Principal Pharmacist NHSS
Dr Maggie Watts	**Medical Practitioner:** Director of Public Health NHSWI
Jackie Donachie	**Senior Representative:** Vaccination Programme Manager NHST
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Clinical indication to which this PGD applies

Definition of situation/Condition	This Patient Group Direction (PGD) will authorise approved healthcare professionals as detailed in the characteristics of staff authorised to work under this PGD to administer shingles (herpes zoster) vaccine (Live) Zostavax® to individuals for the prevention of shingles (herpes zoster) and herpes zoster-related post-herpetic neuralgia (PHN) in line with Scottish Government immunisation programme included in age cohorts as described by the most current CMO Letter. This PGD should be used in conjunction with the recommendations in the current British National Formulary (BNF), British National Formulary for Children (BNFC), The Green Book and the individual Summary of Product Characteristics (SmPC).
Inclusion criteria	Individuals not previously vaccinated with Zostavax® included in age cohorts described by most current CMO Letter. From September 2022 eligible individuals are: • Routine vaccination of 70 year olds (defined by age at 1st September 2022) • Opportunistic vaccination of 71-79 year olds who have not previously been vaccinated (defined by age at 1st September 2022) Prior to the administration of the vaccine, valid consent to receiving treatment under this PGD must be obtained. Consent must be in line with current individual NHS Boards consent policy.
Exclusion criteria	Individuals who: • Have severe immunosuppression as defined in chapter 28a: shingles (herpes zoster) of the Green Book • have had a confirmed anaphylactic reaction to a previous dose of varicella vaccine • Are less than 70 years of age • Are over 80 years of age (even if they have previously been eligible) • Have had a confirmed anaphylactic reaction to any component of the vaccine, including neomycin or gelatin. Practitioners must check the marketing authorisation

	holder's summary of product characteristics (SmPC) for details of vaccine components • Have a history of severe (i.e. anaphylactic reaction) to latex where the vaccine is not latex free • Have active untreated tuberculosis • Are acutely unwell - postpone until patient has fully recovered • Have had two or more episodes of shingles in one year. Unless immunological investigation has been undertaken and discussion with local specialist teams • Have received high dose intravenous immunoglobulin (IVIG) or varicella zoster immunoglobulin (VZIG) in the previous 6 weeks • Are currently being treated or are within 48 hours of cessation of treatment with oral or intravenous antivirals (such as aciclovir) • Have received yellow fever vaccination within the last 4 weeks (postpone vaccination). Individuals for whom no valid consent has been received.
Precautions and special warnings	**Zostavax® is a live attenuated vaccine. If there is any doubt of the individual's suitability for vaccine do not vaccinate and seek further advice.** Minor illness without fever or systemic upset is not a valid reason to postpone immunisation. If an individual is acutely unwell, immunisation may be postponed until they have fully recovered. If healthcare professionals administering the vaccine have concerns about the nature of therapies (including biologicals) or the degree of immunosuppression they should contact the relevant specialist for advice. Specialist advice should also be sought for individuals on combination therapy. The use of topical aciclovir is not an exclusion. Humoral deficiencies affecting IgG or IgA antibodies are not of themselves a contra-indication unless associated with T cell deficiencies. If there is any doubt (e.g. common variable immune deficiency), immunological advice should be sought prior to administration. The use of the vaccine is not excluded in individuals who are receiving topical/inhaled corticosteroids and in people who are receiving corticosteroids as replacement therapy (e.g. for adrenal insufficiency).

	Individuals who received high dose short term immunosuppression at doses equivalent to ≤40mg prednisolone per day for an acute episode of illness such as asthma / chronic obstructive pulmonary disease (COPD) or COVID-19 are not considered severely immunosuppressed and may be vaccinated with Zostavax® when they have recovered. Individuals who have shingles should wait until symptoms have ceased before being considered for shingles immunisation. The natural boosting that occurs following an episode of shingles, however, makes the benefit of offering zoster vaccine immediately following recovery unclear. The presence of a neurological condition is not a contraindication to immunisation but if there is evidence of current neurological deterioration, deferral of vaccination may be considered, to avoid incorrect attribution of any change in the underlying condition. The risk of such deferral should be balanced against the risk of the preventable infection, and vaccination should be promptly given once the diagnosis and/or the expected course of the condition becomes clear.
Action if excluded from treatment	Medical advice must be sought – refer to relevant medical practitioner for advice on the vaccine and circumstances under which it could be given using a patient specific direction. The risk to the individual of not being immunised must be taken into account. Discussion of the risk and benefits of vaccination should take place. Discussions and decisions taken should be documented in clinical records. In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated at a later date and ensure another appointment is arranged. In case of postponement due to current/recent shingles, PHN or current/recent treatment with antivirals arrange a future date for immunisation. Document the reason for exclusion under the PGD and any action taken in the individual's appropriate clinical records.

Action if treatment is declined	Advise about the protective effects of the vaccine and the risk of infection and disease complications. Ensure they have additional reading material e.g. the Patient Information Leaflet (PIL) available to print here. Document advice given and decision reached. Advise how future immunisation may be accessed if they subsequently decide to receive the vaccine but noting that those aged 80 years and over are not eligible for this vaccine. Inform/refer to the relevant medical practitioner if individual declines treatment. Document that the administration of the vaccine was declined, the reason and advice given in appropriate clinical records.

Description of vaccine available under the PGD

Name form and strength of vaccine	Shingles (herpes zoster) vaccine (live) Zostavax® powder and pre-filled solvent for suspension for injection.
Legal status	Zostavax® is a Prescription-only Medicine (POM).
Is the use out with the SmPC?	The SmPC states that Zostavax® and 23-valent pneumococcal polysaccharide vaccine (PPV) should not be given concomitantly. This is superseded by the Green Book Chapter 28a recommendation that the two vaccines may be given at the same time. The individual should be informed prior to the administration that the use is off-label, however the vaccine is being offered in accordance with national guidance. Vaccine should be stored according to the conditions detailed below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to NHS Board guidance on storage and handling of vaccines guidance. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use, administration under this PGD is allowed.
Dosage/Maximum total dose	0.65mL
Frequency of dose/Duration of treatment	Single dose/administration

Maximum or minimum treatment period	N/A
Route/Method of administration	Administer by intramuscular injection. The preferred site is the deltoid region of the upper arm. Intramuscular injection is the preferred route of administration as injection-site adverse reactions were significantly less frequent in those who received the vaccine via this route. For individuals with a bleeding disorder, Zostavax® should be given by deep subcutaneous injection to reduce the risk of bleeding. Zostavax® is available as a vial containing an off-white compact crystalline plug of powder and a prefilled syringe of clear and colourless diluent. To reconstitute the vaccine, use the solvent provided. Inject the entire content of the pre-filled syringe into the vial containing the powder. Gently agitate to dissolve completely. Withdraw the entire content of the reconstituted vaccine vial into a syringe for injection. When reconstituted, Zostavax® is a semi-hazy to translucent, off-white to pale yellow liquid. The vaccine should be visually inspected for particulate matter and discoloration prior to administration. In the event of any foreign particulate matter and/or variation of physical aspect being observed, do not administer the vaccine. It is recommended that the vaccine be administered immediately after reconstitution to minimise loss of potency. When vaccine has been reconstituted and inspected, it should be administered immediately or at least within 30 minutes. When administering at the same time as other vaccines care should be taken to ensure that the appropriate route of injection is used for each of the vaccinations. The vaccines should be given when possible in different limbs to allow monitoring of local reactions to Zostavax®. If given in the same limb they should be given at different sites at least 2.5cm apart (American Academy of Paediatrics 2003). The site at which each vaccine was administered should be noted in the individual's records.

Quantity to be administered	0.65mL
Storage requirements	Vaccine will be stored in a temperature controlled refrigerator between +2°C and +8°C. Refrigerators should have maximum and minimum temperatures recorded daily. Do not freeze. Store in original packaging in order to protect from light. Individual NHS Board guidance on the storage, handling and cold chain in relation to vaccines must be observed. Likewise, individual NHS Board guidance in relation to waste management and the disposal of all spent, partially spent or unused vaccines must also be observed. In the event of an inadvertent or unavoidable deviation of these conditions, vaccine that has been stored outside the conditions stated above should be quarantined and risk assessed for suitability of continued off-label use or appropriate disposal.
Additional Information	Immunisation with Zostavax® should ideally be delayed for seven days after COVID-19 vaccination and vice versa. The vaccine has not been tested for routine co-administration and there may be a reduced response to Zostavax®. Where individuals attend requiring both vaccines, however, and require rapid protection or are considered likely to be lost to follow up, co-administration may still be considered under a PSD. Zostavax® can be given at the same time as inactivated influenza vaccinations. Zostavax® can be given at the same time as the 23-valent pneumococcal polysaccharide vaccine (PPV). Zostavax® and MMR vaccine if not administered on the same day, then a four week minimum interval period should be observed. Travel vaccines containing live attenuated virus e.g. yellow fever, may be given to the age group recommended for shingles vaccination. There is limited evidence on the timing of administration of Zostavax® and Yellow Fever vaccine, with a single case report demonstrating good response to Yellow Fever vaccine 21 days after receiving Zostavax®. Given the lack of data it would be appropriate to leave a four-week interval between administration of Yellow Fever vaccine and Zostavax®. Apart from the above combinations Zostavax® can be administered at any time before or after other live vaccines.

Follow-up (if applicable)	Following immunisation individuals should remain under observation in line with individual NHS Board policy. Individuals should not leave if they are feeling unwell without speaking to the healthcare professional who administered the vaccine first. If necessary a doctor or the individuals GP should be contacted for advice.
Advice (Verbal)	• Advise individual what to expect and of the possible side effects and their management • Advise individual that if they develop a varicella-like rash after vaccination, they should avoid direct contact with a susceptible (chickenpox naïve) person until the rash is dry and crusted • The individual should be advised to seek medical advice in the event of a severe adverse reaction • Individuals should be advised to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme. When administration is postponed advise the individual when to return for vaccination.
Advice (Written)	The PIL contained in the medicine(s) should be made available to the individual. Where this is unavailable, or unsuitable, sufficient information should be given in a language that they can understand. Supply immunisation promotional material as appropriate. More information regarding this vaccine can be found at: https://www.nhsinform.scot/healthy-living/immunisation
Identifying and managing possible adverse reactions	Syncope (fainting) can occur following, or even before, any vaccination especially in adolescents as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from faints. The most commonly reported side effects for Zostavax®, occurring in at least one in ten people were injection site reactions including erythema (redness), pain, swelling, and pruritus (itching). Other common reactions reported in at least one in 100 people were haematoma, induration and warmth at the injection site, pain in arm or leg and headache.

	As with all vaccines there is a very small possibility of anaphylaxis and facilities for its management must be available. **This list is not exhaustive. Please also refer to current BNF and manufacturers SmPC for details of all potential adverse reactions.** **BNF**: BNF British National Formulary - NICE **SmPC/PIL/Risk Minimisation Material:** Home - electronic medicines compendium (emc) MHRA Products | Home RMM Directory - (emc) If an adverse reaction does occur give immediate treatment and inform relevant medical practitioner as soon as possible. Document in accordance with locally agreed procedures in the individual's record. Report any suspected adverse reactions using the Yellow Card System. Yellow Card Scheme - MHRA
Facilities and supplies required	The following are to be available at sites where the vaccine is to be administered: • Pharmaceutical refrigerator (or a validated cool box for storing vaccine if mobile unit) • An acceptable level of privacy to respect individual's right to confidentiality and safety • Basic airway resuscitation equipment (e.g. bag valve mask) • Immediate access to Epinephrine (Adrenaline) 1 in 1000 injection • Access to a working telephone • Another competent adult, who can summon urgent emergency support if required should ideally be present • Access to medical support (this may be via the telephone) • Approved equipment for the disposal of used materials • Clean and tidy work areas, including access to hand washing facilities or alcohol hand gel • A copy of this PGD in print or electronically

Characteristics of staff authorised to administer vaccine under PGD

Professional qualifications	The following classes of registered healthcare professionals are permitted to administer vaccines as identified and included in individual Board immunisation delivery plans: • Nurses and midwives currently registered with the Nursing and Midwifery Council (NMC) • Pharmacists 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.
Specialist competencies	**Approved by the organisation as:** • Competent to assess the individual's capacity to understand the nature and purpose of vaccination in order to give or refuse consent • Familiar with the vaccine product and alert to changes in the product information. • Competent to undertake administration of the vaccine and discuss issues related to vaccination • Competent in the recognition and management of anaphylax or under the supervision of persons able to respond appropriately to immediate adverse reactions • Competent in the handling and storage of vaccines, and management of the "cold chain" • Competent to work under this PGD and authorised by name as an approved person to work under the terms of the PGD.
Ongoing training and competency	**All professionals working under this PGD must:** • 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 • 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. **Note:** All practitioners operating under the PGD are responsible for ensuring they remain up to date with the use of the vaccine. If any training needs are identified these should be discussed with those responsible for authorisation to act under the PGD. • Have knowledge and familiarity of the following; o Current edition of the Green Book o SmPC for the vaccine to be administered in accordance with this PGD o Relevant policy relating to vaccine storage and immunisation procedures for use within their Health Board o Relevant Scottish Government Health Directorate advice including the relevant CMO letter(s).
Responsibilities of professional manager(s)	**Professional manager(s) will be responsible for;** Ensuring that the current PGD is available to all staff providing care under this direction. Ensuring that staff have received adequate training in all areas relevant to this PGD and meet the requirements above. Maintain up to date record of all staff authorised to administer the vaccine specified in this direction.

Documentation

Authorisation of administration	Qualified registered healthcare professionals working within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles listed and approved in legislation as able to operate under PGD can be authorised to administer the vaccine specified in this PGD in accordance with local delivery plans and by agreement at individual Board level as per the following: Nurses, midwives and health visitors can be authorised by their line manager. Pharmacists working within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles can be authorised to administer the medicine(s) specified in this PGD when they have completed local Board requirements for service registration.

	The following list of healthcare professionals can be authorised by their Line Manager, Head of Service or Vaccine Coordinator: Chiropodists, dental hygienists, dental therapists, dieticians, occupational therapists, optometrists, orthoptists, orthotist/prosthetists, paramedics, physiotherapists, podiatrists, radiographers and speech and language therapists. All authorised staff are required to read the PGD and sign the Agreement to Administer 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.
Record of administration	An electronic or paper record must be completed to allow audit of practice. An electronic/Hospital Electronic Prescribing and Medicines Administration (HEPMA) record of the screening and subsequent administration, or not of the medicine(s) specified in this PGD should be made in accordance with individual Health Board electronic/HEPMA recording processes. If a paper record is used for recording the screening of individuals and the subsequent administration, or not of the medicine(s) specified in this PGD, it should include as a minimum: • Date and time of vaccine administration • Individuals name, address and CHI • GP with whom the individual is registered • Exclusion criteria, record why the vaccine was not administered (if applicable) • Record that valid consent to treatment under this PGD was obtained • The name, brand, dose, form, batch number, expiry date, route/and anatomical site of the vaccination administered • Advice given, including advice given if excluded or declined vaccination under this PGD • Signature and name in capital letters of the healthcare professional who administered the vaccine, and who undertook the assessment of the individual's clinical suitability for the vaccine • Record of any adverse effects and the actions taken (advise individuals' GP/relevant medical practitioner). Depending on the clinical setting where administration is undertaken, the information should be recorded manually or electronically on the individual service specific system, as appropriate.

	• Individual's GP records if appropriate • Secondary Care Medical Notes • HEPMA • Individual service specific systems. Local policy should be followed with respect to sharing information with the individual's General Practitioner. All records should be clear, legible and contemporaneous and in an easily retrievable format.
Audit	All records of the vaccine specified in this PGD will be filed with the normal records of medicines in each practice/service. A designated person within each practice/service where the PGD will be used will be responsible for annual audit to ensure a system of recording medicines administered under a PGD.
References	Electronic Medicines Compendium http://www.medicines.org.uk Zostavax®– Date of revision of text 08/09/2021, accessed 02/08/22. British National Formulary accessed 02/08/22. Department of Health (2006): Immunisation against Infectious Disease [Green Book] Shingles (herpes zoster): the green book, chapter 28a - GOV.UK (www.gov.uk) American Academy of Pediatrics (2003) Active immunisation. In: Pickering LK (ed.) Red Book: 2003 Report of the Committee on Infectious Diseases, 26th edition. Elk Grove Village, IL: American Academy of Pediatrics, p 33.

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

Appendix 1

Healthcare Professional Agreement to Administer Vaccine Under Patient Group Direction

I: _____ (Insert name)

Working within: _____ e.g. Area, Practice

Agree to administer the vaccine contained within the following Patient Group Direction:

Patient Group Direction for the Administration of Shingles (Herpes Zoster) Live Vaccine Zostavax® by Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles

I have completed the appropriate training to my professional standards enabling me to administer the vaccine 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 Administer Vaccine 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 administer the vaccine 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 administer the vaccine 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 administration 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 Administration of Shingles (Herpes Zoster) Live Vaccine Zostavax® by Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles
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

Patient Group Direction for the Administration of Shingles (Herpes Zoster) Live Vaccine Zostavax® by Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles					
Name of Healthcare Professional	**Signature**	**Date**	**Name of Manager**	**Signature**	**Date**