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

Patient Group Direction (PGD)

For the administration or supply of

Zostavax®, Shingles (Herpes Zoster, live) vaccine

By registered health care professionals for

individuals who are eligible for the national shingles immunisation programme for the prevention of herpes zoster ('zoster' or shingles) and herpes zoster-related post-herpetic neuralgia (PHN)

Throughout the Manx Care and those contracted by the Manx Care where appropriate within practice

PGD NUMBER 137

1. Change History

Version number	Change Details	Date
Final – revised 27 Aug 2013	New PHE PGD	Valid from 1 Sept 2013
V 02.00	See earlier version of this PGD for change details	04/06/2015
V 03.00	See earlier version of this PGD for change details	16/11/2015
V 04.00	See earlier version of this PGD for change details	03/02/2016
V 05.00	See earlier version of this PGD for change details	02/08/2016
V 06.00	See earlier version of this PGD for change details	07/04/2017
V 07.00	See earlier version of this PGD for change details	12/07/2017
V 08.00	PHE Shingles PGD amended to: • include additional healthcare practitioners in Section 3 • refer to PHE Vaccine Incident Guidance in the off-label and storage sections • move the exclusion following natural infection to the cautions section and refer to the 'Shingles vaccination: Guidance for healthcare professionals' • include additional information in relation to the possible future availability of inactivated shingles vaccine • update off-label status section • include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates	31/01/2019
V 09.00	PHE Shingles PGD amended to: • reword inclusion criteria to remove catch-up cohort and define eligibility at 70 years and retention of eligibility until individuals 80th birthday • identify examples of biological therapy that are immunosuppressive monocloncal antibodies • include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates	18/02/2021
V 10.00	PHE Shingles PGD amended to: • rename as the Zostavax PGD and replace 'shingles (herpes zoster, live) vaccine' with 'Zostavax®' • reflect recommendations in the revised Green Book Chapter 28a and changes to the national shingles programme following the introduction of Shingrix® vaccine (see PHE Shingrix PGD) with amendment to the criteria for exclusion, cautions, actions if excluded, drug interaction and additional information sections • include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates and the Green Book Chapter 28a	22/08/2021

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

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

3. PGD development

Refer to the NICE PGD competency framework for people developing PGDs

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

4. PGD authorisation

Refer to the NICE PGD competency framework for people authorising PGDs

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

5. PGD adoption by the provider

Refer to the NICE PGD competency framework for people authorising PGDs

Job title and organisation	Signature	Date	Applicable or not applicable to area

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

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

	Requirements of registered Healthcare professionals working under the PGD
Qualifications and professional registration	Registered healthcare professionals, working within or contracted by the Manx Care, GP practice or Hospice who are permitted staff groups outlined within the current PGD policy Additionally practitioners: • must be familiar with the vaccine product and alert to changes in the Summary of Product Characteristics (SPC), Immunisation Against Infectious Disease ('The Green Book'), and national and local immunisation programmes • must have undertaken training appropriate to this PGD as required by local policy and in line with the National Minimum Standards and Core Curriculum for Immunisation Training • must be competent to undertake immunisation and to discuss issues related to immunisation • must be competent in the handling and storage of vaccines, and management of the 'cold chain' • must be competent in the recognition and management of anaphylaxis Practitioners must ensure they are up to date with relevant issues and clinical skills relating to immunisation and management of anaphylaxis, with evidence of appropriate Continued Professional Development (CPD).
Initial training	• Knowledge of current guidelines and the administration of the drug specified in this PGD/BNF and of the inclusion and exclusion criteria • Training which enables the practitioner to make a clinical assessment to establish the need for the medication covered by this PGD • Local training in the use of PGD's

Competency assessment	Staff will be assessed on their knowledge of drugs and clinical assessment as part the competency framework for registered health professionals using PGD's
Ongoing training and competency	The registered health care professionals should make sure they are aware of any changes to the recommendations for this medication; it is the responsibility of the registered health care professionals to keep up to date with continuing professional development. PGD updates will be held every two years

7. Clinical Conditions

Clinical condition or situation to which this PGD applies	Zostavax® is indicated for vaccination of adults who are eligible for the national shingles immunisation programme for the prevention of herpes zoster ('zoster' or shingles) and herpes zoster-related post-herpetic neuralgia (PHN) in accordance with the recommendations given in Chapter 28a of Immunisation Against Infectious Disease: 'The Green Book'
Inclusion criteria	Individuals who: • are aged 70 years (routine cohort) • have existing eligibility for Zostavax® under the national immunisation programme but remain unimmunised. Individuals from 70 years of age remain eligible for shingles immunisation until their 80th birthday.
Exclusion criteria[1] *(continued)*	Individuals for whom no valid consent has been received Individuals who: • are under 70 years of age • are 80 years of age or over, even if they were previously in an eligible cohort • have had a confirmed anaphylactic reaction to a previous dose of varicella vaccine or to any component of Zostavax®, including neomycin or gelatin • are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation) • have active untreated tuberculosis • have shingles infection with active lesions • have received systemic therapy in the last 48 hours with anti-viral medicines known to be effective against varicella zoster virus, such as aciclovir, • have received MMR vaccine in the preceding 4 weeks • are within 14 days of commencement of immunosuppressive therapy • have a primary or acquired immunodeficiency state as defined in Chapter 28a as a contraindication to Zostavax® administration • are on immunosuppressive or immunomodulating therapy as defined in Chapter 28a as a contraindication to Zostavax®

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

Exclusion criteria[2] *(continued)*	administration Note: Zostavax® is not contraindicated for use in individuals who are receiving topical or inhaled corticosteroids or corticosteroid replacement therapy. Individuals with low levels of immunosuppression can receive Zostavax®. If primary healthcare professionals administering the vaccine have concerns about the nature of therapies or the degree of immunosuppression, they should contact the relevant specialist for advice. Specialist advice should also be considered for individuals on combination immunosuppressive therapy.
Cautions (including any relevant action to be taken)	• The decision to administer shingles vaccine to immunosuppressed individuals should be based on a clinical risk assessment. If the individual is under specialist care, and it is not possible to obtain full information on that individual's treatment history, then vaccination should not proceed until the advice of the specialist or a local immunologist has been sought. • Individuals who have previously received immunosuppressive therapy should be carefully evaluated for the reconstitution of the immune system prior to receiving Zostavax®. **Transmission** • There is a theoretical risk, in those who develop a rash following Zostavax® vaccination, of transmitting the attenuated vaccine virus to a susceptible individual. This risk should be weighed against the reduced risk of developing natural shingles and much higher risk of transmission from the circulating wild type varicella zoster virus in the community. • As a precautionary measure, individuals who develop a vesicular rash after receiving Zostavax® should ensure the rash area is kept covered when in contact with a susceptible (chicken pox naïve) person until the rash is dry and crusted. If the individual with the vesicular rash are themselves immunosuppressed, they should avoid contact with susceptible people until the rash is dry and crusted, due to the higher risk of virus shedding. Prophylactic aciclovir can be considered in vulnerable patients exposed to a varicella like rash in a recent vaccinee. • In the event of a person developing a varicella (widespread) or shingles-like (dermatomal) rash post-Zostavax®, a vesicle fluid sample should be sent for analysis, to confirm the diagnosis and determine whether the rash is vaccine-associated or wild-type. See Chapter 28a for more details.
Arrangements for referral for medical advice	Patient should be referred to a more experienced clinical practitioner for further assessment

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

Action to be taken if patient excluded *(continued)*	• Individuals who are not of eligible age for the national shingles immunisation programme should be advised when they will become eligible or why they are not eligible for immunisation • For individuals who have had a confirmed anaphylactic reaction to a previous dose of varicella vaccine or to any component of Zostavax® there is as an alternative inactivated vaccine Shingrix®. However, supply of Shingrix® is currently, at the time of writing, limited such that under the national shingles vaccination programme it is only recommended to be offered to immunosuppressed individuals (see Chapter 28a for current recommendations) • Individuals suffering acute severe febrile illness should postpone immunisation until they have recovered • Individuals with untreated tuberculosis should postpone immunisation until their tuberculosis has been treated • Zostavax® is not recommended for the treatment of shingles 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 Zostavax® immediately following recovery unclear • Individuals who have received systemic anti-viral medicines known to be effective against varicella zoster virus, such as aciclovir, should postpone Zostavax® vaccination until at least 48 hours after cessation of treatment, as these medicines may reduce the response to the vaccine. The use of topical aciclovir is not a contraindication to vaccination • Individuals who have received MMR vaccine should postpone Zostavax® administration until a four-week minimum interval period has been observed • Individuals within 14 days of commencement of immunosuppressive therapy are not currently, at the time of writing, eligible for pre-treatment vaccination with Shingrix®. Supply of Shingrix® is currently, at the time of writing, limited and so vaccine supplied via the national programme should not be used for this indication. Eligible individuals who have not received Zostavax® are recommended to receive a single dose of vaccine at the earliest opportunity and at least 14 days before starting immunosuppressive therapy, although leaving one month would be preferable if a delay is possible (see Chapter 28a for current recommendations) • Immunosuppressed individuals who are eligible for shingles vaccination but who are contraindicated to the receipt of the live vaccine Zostavax®, in accordance with Chapter 28a should be offered Shingrix® instead (see PHE Shingrix PGD). If there is any doubt, individual patients should be discussed with their specialist

Action to be taken if patient excluded *(continued)*	• The risk to the individual of not being vaccinated must be taken into account • When administration is postponed arrange a future date for vaccination as appropriate, with due consideration of the individual's age to ensure they will meet the inclusion criteria for immunisation. If vaccination cannot be given before the individual is 80 years old explain why vaccination will no longer be indicated • Document the reason for exclusion and any action taken in individual's clinical records • Inform or refer to the GP or a prescriber as appropriate
Action to be taken if patient declines treatment	• A verbal explanation should be given to the patient on: the need for the medication and any possible effects or potential risks which may occur as a result of refusing treatment • This information must be documented in the patients' health records • Any patient who declines care must have demonstrated capacity to do so • Where appropriate care should be escalated • Informed consent, from the individual or a person legally able to act on the person's behalf, must be obtained for each administration

8. Details of the medicine

Name, form and strength of medicine	Zostavax®, shingles (herpes zoster, live) vaccine, powder and solvent for suspension for injection. After reconstitution, Zostavax® lyophilised suspension (0.65ml) contains shingles (herpes zoster) vaccine, consisting of live attenuated virus derived from varicella zoster virus.
Legal category	Prescription only medicine (POM)
Black triangle▼	Yes
Indicate any <u>off-label use</u> (if relevant)	• Vaccine should be stored according to the conditions detailed in the <u>Storage section</u> below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to <u>PHE Vaccine Incident Guidance</u>. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use this would constitute off-label administration under this PGD • Where a vaccine is recommended off-label consider, as part of the consent process, informing the individual/carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence
Route/method of administration *(continued)*	• Following reconstitution, Zostavax® is given as a single dose by intramuscular or subcutaneous injection, preferably in the deltoid region of the upper arm. Intramuscular administration is preferred 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® should NOT be injected intravascularly. • When administering at the same time as other vaccines care should be taken to ensure that the appropriate route of injection is used for all

Route/method of administration *(continued)*	the vaccinations. • The vaccines should be given at separate sites, preferably in different limbs. If given in the same limb, they should be given at least 2.5cm apart. The site at which each vaccine was given should be noted in the individual's records. • It is recommended that the vaccine be administered immediately after reconstitution, to minimise loss of potency. Discard reconstituted vaccine if it is not used within 30 minutes. • Avoid contact with disinfectants. • When reconstituted, Zostavax® is a semi-hazy to translucent, off-white to pale yellow liquid. Discard the vaccine if there is any foreign particulate matter present or the appearance of the reconstituted vaccine differs from this description. • The SPC for the vaccine provides further guidance on reconstitution and administration.
Dose and frequency	Single dose of 0.65ml of reconstituted Zostavax®
Quantity to be administered	Single 0.65ml dose of reconstituted Zostavax®
Maximum or minimum treatment period	Single dose
Storage	• Store between +2°C to +8°C. • Store in original packaging in order to protect from light. • Do not freeze. • Avoid contact with disinfectants. • After reconstitution the vaccine should be used immediately. However, the in-use stability has been demonstrated for 30 minutes when stored at +20°C to +25°C. • 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. Refer to PHE Vaccine Incident Guidance.
Adverse effects *(continued)*	The most common adverse reactions observed after administration of Zostavax® are: • injection site reactions including: • redness • swelling • pain • itching Other relatively common reactions include: • Bruising • hardening (induration) • warmth at the injection site • headache • pain in the relevant limb Very rarely a varicella (chickenpox) - like illness has been. In the event of a person developing a varicella (widespread) or shingles-

Adverse effects *(continued)*	like (dermatomal) rash post-Zostavax® vaccination, a vesicle fluid sample should be sent for analysis, to confirm the diagnosis and determine whether the rash is vaccine-associated or wild-type (see Chapter 28a). A detailed list of adverse reactions is available in the SPC As with all vaccines, healthcare professionals and individuals/carers are encouraged to 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. Any adverse reaction to the vaccine should be documented in the individual's record and the individual's GP should be informed
Records to be kept	• The administration of any medication given under a PGD must be recorded within the patients' medical records • Please see Appendix C for more details.

9. Patient information

Verbal/Written information to be given to patient or carer	• Verbal information must be given to patients and or carers for all medication being administered under a PGD • Where medication is being supplied under a PGD, written patient information leaflet must also be supplied • A patient information leaflet is available on request
Follow-up advice to be given to patient or carer	• Inform the individual/carer of possible side effects and their management. • Give advice regarding normal reaction to the injection, for example redness and pain at the injection site. • The individual/carer should be advised to seek medical advice in the event of a severe adverse reaction. • Individuals should be advised to seek medical attention if they develop a varicella (widespread) or shingles-like (dermatomal) rash post-Zostavax® vaccination.

10. Appendix A

References

1. British National Formulary (BNF) available online: https://bnf.nice.org.uk
2. Nursing and Midwifery (2018) "The code" available online: https://www.nmc.org.uk
3. Current Health Care Professions Council standards of practice
4. General Pharmaceutical Council standards
5. The General Optical Council
6. Electronic medicines compendium available online: https://www.medicines.org.uk

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- Zostavax® Summary of Product Characteristics. MSD Ltd. Updated 8 May 2021. https://www.medicines.org.uk/emc/product/6101
- Immunisation Against Infectious Disease: The Green Book, Chapter 28a. Updated 23 August 2021. https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book
- Shingles: Guidance and Vaccination Programme. Updated 18 August 2021. https://www.gov.uk/government/collections/shingles-vaccination-programme
- Shingles vaccination: Guidance for healthcare professionals. Public Health England. Published March 2018. https://www.gov.uk/government/publications/shingles-vaccination-guidance-for-healthcare-professionals

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- Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health. 20 March 2013. https://www.gov.uk/government/publications/guidance-on-the-safe-management-of-healthcare-waste
- National Minimum Standards and Core Curriculum for Immunisation Training. Published February 2018. https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners
- NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published March 2017. https://www.nice.org.uk/guidance/mpg2
- NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. Updated March 2017. https://www.nice.org.uk/guidance/mpg2/resources
- PHE Immunisation Collection. https://www.gov.uk/government/collections/immunisation
- PHE Vaccine Incident Guidance. https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors

11. Appendix B

Health professionals agreed to practice

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

12. Appendix C

Special considerations/ additional information	• Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and easy access to a telephone at the time of vaccination. • The risk and severity of shingles is much higher in immunosuppressed individuals so ideally those eligible should receive Zostavax® preferably one month and at least 14 days before commencing immunosuppressive therapy. • An inactivated shingles vaccine, Shingrix®, is now available. However, supply of Shingrix® is currently, at the time of writing, limited such that under the national shingles vaccination programme it is only recommended to be offered to immunosuppressed individuals contraindicated to the live vaccine. Inactivated shingles vaccine cannot be administered under this PGD (see PHE Shingrix PGD) and current national guidance should be referred to (see Chapter 28a for current recommendations). • All immunosuppressed individuals who are inadvertently administered Zostavax® require urgent assessment and may need to receive prophylactic aciclovir. Immunosuppressed individuals who develop a varicella rash following inadvertent vaccination should be urgently assessed and offered prompt treatment with IV high-dose aciclovir, give the risks and severity of disseminated zoster. • Zostavax® can be given at the same time as inactivated influenza vaccine. • Zostavax® vaccine can also be given at the same time as 23-valent pneumococcal polysaccharide vaccine for those who are eligible for both vaccines. • In the rare event that MMR vaccine is indicated in this age group it should be administered on the same day, or a four-week minimum interval period should be observed. Other live vaccines can be administered at any time before or after Zostavax®. • Immunisation with Zostavax® should ideally be delayed for seven days after COVID-19 vaccination and vice versa. Neither vaccine has been tested for routine co-administration; 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 • There is no data on concomitant use with anti-viral medications known to be effective against varicella zoster virus but it is likely that these will reduce the response to Zostavax® - see Criteria for exclusion. • See Chapter 28a for more details.

Disposal	Equipment used for immunisation, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of safely in a UN-approved puncture-resistant 'sharps' box, according to local authority arrangements and guidance in the technical memorandum 07-01 (Department of Health, 2013).
Drug interactions	• None reported. • See the Additional information section and SPC for information on co-administration with anti-virals and other vaccines.
Supplies	• Centrally purchased vaccines for the national immunisation programme can only be ordered via ImmForm and are provided free of charge. • Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see Green Book Chapter 3).
Records	Record: • that valid informed consent was given • name of individual, address, date of birth and GP with whom the individual is registered • name of immuniser • name and brand of vaccine • date of administration • dose, form and route of administration of vaccine • quantity administered • batch number and expiry date • anatomical site of vaccination • advice given, including advice given if excluded or declines immunisation • details of any adverse drug reactions and actions taken • supplied via PGD Records should be signed and dated (or a password controlled immuniser's record on e-records). All records should be clear, legible and contemporaneous. This information should be recorded in the individual's GP record and any other appropriate medical records, such as care or nursing records. A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.