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

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 73

Change History (next page)

1. Change history

Version number	Change details	Date
Final – revised 27/08/13	New PHE PGD	Valid from 01/09/13
Version 02.00	See earlier version of this PGD for change details	04/06/15
Version 03.00	See earlier version of this PGD for change details	16/11/15
Version 04.00	See earlier version of this PGD for change details	03/03/16
Version 05.00	See earlier version of this PGD for change details	02/08/16
Version 06.00	PHE Shingles PGD amended to: • define eligible cohorts by age rather than age on 1 Sept, in the inclusion and exclusion criteria, as per service specification from April 2017 • update transmission paragraph	07/04/17
Version 07.00	PHE Shingles PGD amended to: • correct date in inclusion criteria to '2012' and add DOB note	12/07/17
Version 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	31/01/19
Version 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 monoclonal antibodies • include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates	18/02/2021

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	Shingles (Herpes Zoster, live) vaccine 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 shingles (herpes zoster, live) vaccine under the national immunisation programme but remained unimmunised. Individuals from 70 years of age remain eligible for shingles immunisation until their 80th birthday
Exclusion criteria *(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 the vaccine, 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 active infection with shingles or post-herpetic neuralgia • have received systemic therapy with anti-viral medicines, such as aciclovir, in the last 48 hours • have received MMR vaccine in the preceding 4 weeks • are pregnant

Exclusion criteria *(continued)*	• are within 14 days of commencement of immunosuppressive therapy (Note: individual may be able to receive the vaccine under PSD following specialist advice) • have a primary or acquired immunodeficiency state (see overleaf) are on immunosuppressive or immunomodulating therapy (see overleaf) Primary or acquired immunodeficiency states may be due to conditions such as: • acute and chronic leukaemias, lymphoma (including Hodgkin's lymphoma) • immunosuppression due to HIV/AIDS • cellular immune deficiencies • remaining under follow up for a lymphoproliferative disorder including haematological malignancies such as indolent lymphoma, chronic lymphoid leukaemia, myeloma and other plasma cell dyscrasias (Note: this list is not exhaustive) • solid organ or stem cell transplant (see Chapter 28a for information on when vaccination may be indicated for these individuals under PSD) Immunosuppressive or immunomodulating therapy that would contraindicate shingles (herpes zoster, live) vaccination under this PGD includes: • those with renal failure, stage 4 or 5 CKD, who are receiving or have received in the past 3 months any immunosuppressive therapy (due to potential reduced clearance of immunosuppressive therapies) • those who are receiving or have received in the past 6 months immunosuppressive chemotherapy or radiotherapy for malignant disease or non-malignant disorders or who are not demonstrated to be in remission • those who are receiving or have received in the past 12 months biological therapy, such as anti-TNF therapy (for example etanercept) or immunosuppressive monoclonal antibodies (for example infliximab, alemtuzumab, ofatumumab or rituximab) • those who are receiving or have received in the past 3 months immunosuppressive therapy (regardless of renal function) including: i. high-dose corticosteroids (>40mg prednisolone per day for more than 1 week); ii. lower dose corticosteroids (>20mg to ≤40mg prednisolone per day for more than 14 days) iii. non-biological oral immune modulating drugs eg methotrexate >25mg per week, azathioprine >3.0mg/kg/day or 6-mercaptopurine >1.5mg/kg/day

Exclusion criteria *(continued)*	(see Chapter 28a for information on when vaccination may be indicated for these individuals under PSD) Note: Shingles (herpes zoster, live) vaccine is not contraindicated for use in individuals who are receiving topical/inhaled corticosteroids or corticosteroid replacement therapy. Long term stable low dose corticosteroid therapy (defined as ≤20mg prednisolone per day for more than 14 days) either alone or in combination with low dose non- biological oral immune modulating drugs (eg methotrexate ≤25mg per week, azathioprine ≤3.0mg/kg/day or 6-mercaptopurine ≤1.5mg/kg/day) are not considered sufficiently immunosuppressive and these individuals can receive the vaccine under this PGD unless they also have impaired renal function (see above)
Cautions (including any relevant action to be taken) *(continued)*	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 previously received immunosuppressive therapy should be carefully evaluated for the reconstitution of the immune system prior to receiving shingles (herpes zoster, live) vaccine. Immunocompetent individuals who present with a history of a recent shingles episode should ideally have their vaccination delayed for one year as boosting from natural infection is likely to offer protection at least until this time. For those aged between 79 and 80 years at the time of natural shingles infection, it is acceptable to reduce the interval from recovery to vaccination from one year to enable shingles (herpes zoster, live) vaccine to be administered as part of the national programme before the 80th birthday (see Shingles vaccination: Guidance for healthcare professionals) **Transmission** There is a theoretical risk, in those who develop a rash following shingles (herpes zoster, live) vaccination, of transmitting the attenuated vaccine virus to a susceptible individual. However, vaccination will reduce the risk of developing natural shingles which is associated with a much higher risk of transmission, from the circulating wild type varicella zoster virus in the community. As a precautionary measure, individuals who develop a varicella-like rash after shingles (herpes zoster, live) vaccination should ensure

Cautions (including any relevant action to be taken) *(continued)*	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 person with the vesicular rash is 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 vaccine. In the event of a person developing a varicella (widespread) or shingles-like (dermatomal) rash post shingles (herpes zoster, live) vaccination, a vesicle fluid sample should be sent for analysis, to confirm the diagnosis and determine whether the rash is vaccine-associated. 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
Action to be taken if patient excluded	• 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 • If in the eligible age group, but excluded on medical grounds as above, seek appropriate advice from the local Screening and Immunisation Team, local Health Protection Team or the individual's clinician, as immunisation under a PSD may be indicated or an alternative inactivated vaccine may be available (see Additional Information) • Individuals suffering acute severe febrile illness should postpone immunisation until they have recovered • Individuals who have received systemic anti-viral medicines should postpone shingles (herpes zoster, live) vaccination until at least 48 hours after any antiviral treatment is completed, as these medicines may reduce the response to the vaccine. The use of topical aciclovir is not a contraindication to vaccination • 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 • The risk to the individual of not being vaccinated must be taken into account • 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 • Advise the individual/carer about the protective effects of the vaccine, the risks of infection and potential complications • Document advice given and the decision reached • Inform or refer to the GP or a prescriber as appropriate

8. Details of the medicine

Name, form and strength of medicine	Shingles (herpes zoster, live) vaccine eg: • 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).
Indicate any off-label use (if relevant)	Vaccine should be stored according to the conditions detailed in the Storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to PHE Vaccine Incident Guidance. 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	• Following reconstitution, shingles (herpes zoster, live) is given as a single dose by intramuscular or subcutaneous injection, preferably in the deltoid region of the upper arm. Intramuscular administration is preferred due to comparable immune response and less frequent injection site adverse reactions than subcutaneous administration. • For individuals with a bleeding disorder, vaccines normally given by an intramuscular route should be given by deep subcutaneous injection to reduce the risk of bleeding (see Green Book Chapter 4) • Shingles (herpes zoster, live) vaccine should NOT be injected intravascularly • See Appendix C for more information
Dose and frequency	A single dose of 0.65ml of reconstituted shingles (Herpes Zoster, live) vaccine

Quantity to be administered and/or supplied	Single 0.65ml dose of reconstituted shingles (herpes zoster, live) vaccine
Maximum or minimum treatment period	A 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 - 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	• The most common adverse reactions observed after administration of shingles (herpes zoster, live) vaccine are injection site reactions, including redness, swelling, pain and itching. Other relatively common reactions include bruising, hardening (induration) and warmth at the injection site, headache and pain in the relevant limb. Very rarely a varicella (chickenpox) - like illness has been reported • In the event of a person developing a varicella (widespread) or shingles-like (dermatomal) rash post shingles (herpes zoster, live) vaccination, a vesicle fluid sample should be sent for analysis, to confirm the diagnosis and determine whether the rash is vaccine- associated • A detailed list of adverse reactions is available in the SPC, which is available from electronic Medicines Compendium website: www.medicines.org.uk
Records to be kept	The administration of any medication given under a PGD must be recorded within the patient's medical records

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	• If symptoms do not improve or worsen or you become unwell, seek medical advice immediately • 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 shingles (herpes zoster, live) vaccination so that their clinician may test vesicle fluid form the rash to confirm the diagnosis and determine whether the rash is vaccine-associated • When administration is postponed advise the individual when to return for vaccination 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

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 13 October 2020. http://www.medicines.org.uk/emc/medicine/25927
- Immunisation Against Infectious Disease: The Green Book, Chapter 28a. Updated 26 February 2016. https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book
- Shingles: Guidance and Vaccination Programme. Updated 23 March 2020. 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

Route/method of administration	• 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 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, shingles (herpes zoster, live) vaccine is a semihazy 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 and is available from the electronic Medicines Compendium website: http://www.medicines.org.uk

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 regulations and guidance in the technical memorandum 07-01 (Department of Health, 2013)
Drug interactions	• None reported • Shingles (herpes zoster, live) vaccine can be given at the same time as inactivated influenza vaccine • Shingles (herpes zoster, live) vaccine can also be given at the same time as 23-valent pneumococcal vaccine. Such administration is recommended in Chapter 28a of 'The Green Book' following assessment of the evidence, concluding that there is no reduction in the effectiveness of Zostavax® • 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 shingles (herpes zoster, live) vaccine • There is no data on concomitant use with anti-viral medications but it is likely that these will reduce the response to shingles (herpes zoster, live) vaccine – see Exclusion criteria • A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
Records to be kept	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
Special considerations/ additional information	• Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and 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 shingles vaccine preferably one month and at least 14 days before commencing immunosuppressive therapy • An inactivated shingles vaccine has now been developed. This vaccine was not available to the UK market at the time this PGD was written but may become available in the future as an option for the immunisation of immunosuppressed individuals. Inactivated shingles vaccine cannot be administered under this PGD and current national guidance should be referred to • All immunosuppressed individuals who are inadvertently administered shingles (herpes zoster, live) vaccine require urgent assessment and may need to receive prophylactic aciclovir. Immunosuppressed individuals who develop a varicella rash following inadvertent vaccination can be offered prompt treatment with IV high-dose acyclovir • See Chapter 28a for more details