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

Shingrix® Herpes Zoster vaccine (recombinant, adjuvanted)

By registered health care professionals for

prevention of herpes zoster ('zoster' or shingles) and herpes zoster-related post-herpetic neuralgia (PHN), to individuals who are eligible for the national shingles immunisation programme but for whom Zostavax®, shingles (herpes zoster, live) vaccine, is clinically contraindicated

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

PGD NUMBER 158

1. Change History

Version number	Change Details	Date
V01.00	New Shingrix® Herpes Zoster Vaccine PGD	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	Shingrix® Herpes Zoster Vaccine (recombinant, adjuvanted) is indicated for the prevention of herpes zoster ('zoster' or shingles) and herpes zoster-related post-herpetic neuralgia (PHN) and this PGD applies to its administration to adults who are eligible for the national shingles immunisation programme but for whom Zostavax®, shingles (herpes zoster, live) vaccine is clinically contraindicated because of immunosuppression, in accordance with the recommendations given in Chapter 28a of Immunisation Against Infectious Disease: 'The Green Book'.
Inclusion criteria	Individuals should first be assessed for eligibility for vaccination with Zostavax® in accordance with the national shingles immunisation programme (see PHE Zostavax PGD) Individuals for whom Zostavax®, shingles (herpes zoster, live) vaccine is clinically contraindicated because of immunosuppression and who: • are aged 70 years (routine cohort) • have existing eligibility for shingles vaccination under the national immunisation programme but remain unimmunised. Individuals from 70 years of age remain eligible to commence shingles immunisation until their 80th birthday
Exclusion criteria	Individuals for whom no valid consent has been received Individuals who: • are under 70 years of age • are 80 years of age or over, except those who have received a partial course of Shingrix® • do not have clinical contraindications to receiving Zostavax®, shingles (herpes zoster, live) vaccine4 • have had a confirmed anaphylactic reaction to a previous dose of varicella vaccine or to any component of the vaccine • are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation) • have shingles infection with active lesions

Cautions (including any relevant action to be taken)	The immunogenicity of the vaccine could be reduced in immunosuppressed subjects. Vaccination should proceed in accordance with the national recommendations. Shingrix® should be given with caution to individuals with thrombocytopenia or any coagulation disorder since bleeding may occur following intramuscular administration to these subjects (see Route and method of administration).
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 • Individuals who are in an eligible age group but do not have a clinical contraindication to receiving Zostavax®, shingles (herpes zoster, live), vaccine should be assessed to receive Zostavax®. This PGD does not cover the administration of Zostavax® • Individuals who have had a confirmed anaphylactic reaction to a previous dose of varicella vaccine or to any component of the vaccine should not be vaccinated unless approved following the specialist advice of an allergist. A Patient Specific Direction would be required • Individuals suffering acute severe febrile illness should postpone immunisation until they have recovered • Individuals who present with a shingles infection with active lesions should postpone immunisation. As individuals eligible for Shingrix® are immunocompromised, and therefore at increased risk of recurrent zoster, there is no need to defer Shingrix® for a particular pre-determined time frame. Shingrix® can be give once any active shingles lesions have resolved • 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 commenced 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 • 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	Herpes zoster vaccine (recombinant, adjuvanted): • Shingrix®, powder and suspension for suspension for injection. After reconstitution, one dose (0.5ml) of Shingrix® contains varicella zoster virus glycoprotein E antigen 50 micrograms, adjuvanted with AS01B
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 license
Route/method of administration *(continued)*	• Shingrix® must be reconstituted in accordance with the manufacturer's instructions prior to administration. • Following reconstitution, Shingrix® vaccine is given by intramuscular injection, preferably in the deltoid region of the upper arm. • Subcutaneous administration is not recommended. Maladministration via the subcutaneous route may lead to an increase in transient local reactions. • Individuals with bleeding disorders may be vaccinated intramuscularly if, in the opinion of a doctor familiar with the individual's bleeding risk, vaccines or similar small volume intramuscular injections can be administered with reasonable safety by this route. If the individual receives medication/treatment to reduce bleeding, for example treatment for haemophilia, intramuscular vaccination can be scheduled shortly after such medication/treatment is administered. Individuals on stable anticoagulation therapy,

Route/method of administration *(continued)*	including individuals on warfarin who are up to date with their scheduled INR testing and whose latest INR was below the upper threshold of their therapeutic range, can receive intramuscular vaccination. A fine needle (equal to 23 gauge or finer calibre such as 25 gauge) should be used for the vaccination, followed by firm pressure applied to the site (without rubbing) for at least 2 minutes. The individual/carer should be informed about the risk of haematoma from the injection • 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 • The vaccine should be inspected visually for any foreign particulate matter or variation in appearance prior to reconstitution. If either is observed, do not reconstitute the vaccine • The reconstituted vaccine is an opalescent, colourless to pale brownish liquid. Discard the vaccine if there is any foreign particulate matter and/or variation in appearance • After reconstitution, the vaccine should be used promptly • The SPC for the vaccine provides further guidance on reconstitution and administration
Dose and frequency	• Single 0.5ml dose per administration. • Administer a course of two doses with an 8-week interval between doses • If flexibility in the vaccination schedule is necessary, the second dose can be administered between 2 and 6 months after the first dose • If the course is interrupted it should be resumed but not repeated, even if more than 6 months have elapsed since the first dose
Quantity to be administered	two dose course (see Dose and frequency of administration)
Maximum or minimum treatment period	Single 0.5ml dose per administration (two dose course)
Storage	• Store between +2°C to +8°C • Store in original packaging in order to protect from light • Do not freeze • 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 Shingrix® are: • pain at the injection site • myalgia • fatigue and headache • Most of these reactions were not long-lasting (median duration of 2 to 3 days) Other relatively common reactions include injection site reactions, including: • Pain • Redness • swelling and/or pruritis gastrointestinal symptoms, including: • nausea • vomiting • diarrhoea • and/or abdominal pain), chills and fever 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 *(continued)*	• 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 pain at the injection site. • The individual/carer should be advised to seek medical advice in the event of a severe adverse reaction.

Follow-up advice to be given to patient or carer *(continued)*	• 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 commenced 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

Shingles

- Shingrix® Summary of Product Characteristics. GlaxoSmithKline UK. Updated 26 March 2021. https://www.medicines.org.uk/emc/product/12054/smpc
- 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 27 August 2021. 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. • Shingrix® can be given at the same time as unadjuvanted inactivated influenza vaccine, 23-valent pneumococcal vaccine (PPV23) or reduced antigen diphtheria-tetanus-acellular pertussis (dTaP). The vaccines should be administered at different injection sites. The adverse reactions of fever and shivering were more frequent when PPV23 vaccine is co-administered with Shingrix®. • Because of the absence of data on co-administration of Shingrix® vaccine with adjuvanted influenza vaccine, it should not be routine to offer appointments to give this vaccine at the same time as the adjuvanted influenza vaccine. Based on current information, scheduling should ideally be separated by an interval of at least 7 days to avoid incorrect attribution of potential adverse events. 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. • Immunisation with Shingrix® should ideally be delayed for seven days after COVID-19 vaccination and vice versa. Neither vaccine has been tested for routine co-administration; there is potential for the side effects of Shingrix® to be confused with those of COVID-19 vaccines. 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. • As Shingrix® is an inactivated vaccine, where individuals in an eligible cohort present having received another inactivated or live vaccine, Shingrix® vaccination should still be considered. In most cases, vaccination should proceed to avoid any further delay in protection and to avoid the risk of the patient not returning for a later appointment. In such circumstances, patients should be informed about the likely timing of potential adverse events relating to each vaccine.

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	• See the Additional information section for information on co-administration with other vaccines. • A detailed list of drug interactions is available in the SPC
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.