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) Vaccine (Recombinant, Adjuvanted) Shingrix® By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles

Lead Author: Adapted from Public Health Scotland Administration of shingles (herpes zoster) vaccine (recombinant, adjuvanted) Shingrix® Patient group direction (PGD) template - Version 4.0 – PHS Publication date 15th January 2024		**Approver:** NoS PGD Group **Authorisation:** NHS Grampian
Signature:		**Signature:**
NoS Identifier: NoS/PGD/Shingrix/1441	**Review Date:** 14th January 2026 **Expiry Date:** 14th January 2026	**Date Approved by NoS:** 30th January 2024

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 4.0

Revision History for NoS:

NoS PGD that has been adapted and/or superseded	New PGD adapted from Public Health Scotland/ supersedes NoS PGD 1404, Version 3

Most recent changes NoS

Version	Date of change	Summary of Changes	Section heading
4.0	January 2024	Reference to NoS Appendix 1 and 2	Authorisation
		Training requirements for NoS	Continuing education and training

PHS recent changes

Version	Date	Summary of changes
4.0	15 January 2024	The following changes to version 3.0 of the PGD have been made: • The inclusion criteria have been updated to provide date of birth age ranges.

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.

Contents

Authorisation

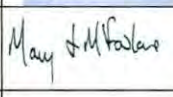
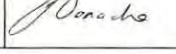
This specimen Patient Group Direction (PGD) template has been produced by Public Health Scotland and adapted by North of Scotland PGD Group (NoS) to assist NHS Boards. NHS Boards should ensure that the final PGD is considered and approved in line with local clinical governance arrangements for PGDs.

The qualified health professionals who may administer vaccine under this PGD can only do so as named individuals. It is the responsibility of each professional to practice within the bounds of their own competence and in accordance with their own Code of Professional Conduct and to ensure familiarity with the manufacturer's product information/Summary of Product Characteristics (SmPC) for all vaccines administered in accordance with this PGD.

NHS Board governance arrangements will indicate how records of staff authorised to operate this PGD will be maintained. Under PGD legislation there can be no delegation. Administration of the vaccine has to be by the same practitioner who has assessed the patient under the PGD.

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.

This PGD has been produced for NoS by:					
Doctor	Dr Paul Treon	Signature		Date Signed	30/01/204
Pharmacist	Mary McFarlane	Signature		Date Signed	25/01/2024
Nurse	Jackie Donachie	Signature		Date Signed	25/01/2024

Approved for use within NoS by:

NoS Group Chair	**Signature**	**Date Signed**
Lesley Coyle		25/01/2024

Authorised and executively signed for use within NoS by:

NHS Grampian Chief Executive	**Signature**	**Date Signed**
Adam Coldwells – Interim Chief Executive		30/01/2024

Version 4.0 – Approved for NoS from 30th January 2024

1. Clinical situation

1.1. Indication

Shingles (herpes zoster) vaccine (recombinant, adjuvanted) (Shingrix®) is indicated for prevention of shingles (herpes zoster) and herpes zoster-related post-herpetic neuralgia (PHN) in line with JCVI advice/recommendations as set out in Green Book **Chapter 28a** and subsequent correspondence/publications from Scottish Government.

1.2. Inclusion criteria

Shingles (herpes zoster) vaccine (recombinant, adjuvanted) (Shingrix®) vaccine should be offered in accordance with the recommendations in Green Book **Chapter 28a**

National policy must be followed in relation to the priority groups eligible for vaccination at a particular point in time.

- Severely immunosuppressed individuals aged 50 years and over as defined in Green Book **Chapter 28a**
- Individuals aged 50 years and older anticipating immunosuppressive therapy in accordance with the recommendations in Green Book **Chapter 28a**
- Individuals aged 18 to 49 years receiving stem cell transplantation or a CAR-T and similar therapies as set out in Green Book **Chapter 28a**

From September 2023 eligible individuals for the national programme for adult shingles vaccination programme, as defined in Green Book **Chapter 28a** are:

- Routine vaccination of those individuals in the date of birth range 31st August 1952 to 01st September 1953.
- Routine vaccination of those individuals in the date of birth range 31st August 1957 to 01st September 1958.

- Vaccination of 71-79 year olds (defined by age at 1st September 2023), who have not previously received shingles vaccination. Where an individual has turned 80 years of age following their first dose of Shingrix®, a second dose should be provided before the individual's 81st birthday to complete the course.

Valid consent has been given to receive the vaccine.

1.3. Exclusion criteria

Individuals who:

- Are aged under 18 years
- Have had a confirmed anaphylactic reaction to a previous dose of varicella or zoster vaccine or to any component of the vaccine. Practitioners must check the marketing authorisation holder's Summary of Product Characteristics (SmPC) for details of vaccine components.
- Have had two or more episodes of shingles in one year unless immunological investigation has been undertaken and discussed with local specialist teams.
- Are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation).

1.4. Cautions/need for further advice/ circumstances when further advice should be sought from a doctor

The Green Book advises that there are very few individuals who cannot receive Shingrix® vaccine. Where there is doubt, rather than withholding vaccination, appropriate advice should be sought from the relevant specialist, or from the local immunisation or health protection team.

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.

Shingrix® should be given with caution to individuals with thrombocytopenia or any coagulation disorder since bleeding may occur following intramuscular administration to these subjects.

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.

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.

1.5 Action if excluded

Specialist advice must be sought on the vaccine and circumstances under which it could be given. Immunisation using a patient specific direction may be indicated. The risk to the individual of not being immunised must be taken into account.

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.

Document the reason for exclusion and any action taken in accordance with local procedures.

Inform or refer to the clinician in charge.

In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated and ensure another appointment is arranged.

In case of postponement due to current/recent shingles arrange a future date for immunisation.

1.6. Action if patient declines

Advise the individual about the protective effects of the vaccine, the risks of infection and potential complications of disease.

Advise how future immunisation may be accessed if they subsequently decide to receive the vaccine but noting that for most individuals, they remain eligible until their 80th birthday, as defined by age at 1st September 2023 (with no upper age limit for those immunocompromised).

Document advice given and decision reached.

Inform or refer to the clinician in charge.

2. Description of treatment

2.1. Name of medicine/form/strength

Shingles (herpes zoster) vaccine (recombinant, adjuvanted) (Shingrix®).

Powder and diluent for suspension for injection presented as a vial of powder plus a vial of suspension.

2.2. Route of administration

Shingrix® should be given by intramuscular injection, preferably in the deltoid region of the upper arm.

Subcutaneous administration is not recommended. Shingrix® must not be given intravascularly.

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, 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.

The vaccine must be reconstituted in accordance with the manufacturer’s instructions prior to administration.

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.

After reconstitution, the vaccine should be used promptly; if this is not possible, the vaccine should be stored in a refrigerator (2°C – 8°C). If not used within 6 hours it should be discarded.

2.3. Dosage

0.5mL

2.4. Frequency

Two doses, a minimum 8 weeks apart.

In immunocompetent individuals the second dose should be administered from two months up to twelve months after the first dose.

In those who are severely immunosuppressed the second dose should be administered eight weeks to six months after their first.

If the course is interrupted it should be resumed but not repeated, even if more than 12 months have elapsed since the first dose.

2.5. Duration of treatment

See frequency section.

2.6. Maximum or minimum treatment period

See frequency section.

2.7. Quantity to supply/administer

See frequency section.

2.8. ▼ black triangle medicines

No

2.9. Legal category

Prescription only medicine (POM).

2.10. Is the use out with the SmPC?

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 or vaccine incident guidance. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use, administration under this PGD is allowed.

Where a vaccine is recommended off-label consider, as part of the consent process, informing the individual/parent/carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence.

2.11. Storage requirements

Vaccine should be stored at a temperature of +2° to +8°C.

Store in the original packaging to protect from light.

Do not freeze.

NHS Board guidance on Storage and Handling of vaccines should 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.

2.12. Additional information

Minor illnesses without fever or systemic upset are not valid reasons to postpone immunisation. If an individual is acutely unwell, immunisation may be postponed until they have fully recovered.

In line with general advice about co-administration of inactivated or non-live vaccines, Shingrix® can be given concomitantly with inactivated influenza vaccine and/or 23 valent pneumococcal vaccine (PPV23).

As Shingrix® is non-live 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.

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.

3. Adverse reactions

3.1. Warnings including possible adverse reactions and management of these

The safety of Shingrix® has been evaluated in clinical trials; in those aged 50 years and above the most frequently reported side effects were pain at the injection site (68%), myalgia (33%), and fatigue (32%). Most of these reactions were not long-lasting (median duration 2-3 days).

For full details/information on possible side effects, refer to the marketing authorisation holder's SmPC.

As with all vaccines there is a very small possibility of anaphylaxis and facilities for its management must be available.

In the event of severe adverse reaction individuals should be advised to seek medical advice.

3.2. Reporting procedure for adverse reactions

Healthcare professionals and individuals/carers should report all suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on http://www.mhra.gov.uk/yellowcard

Any adverse reaction to a vaccine should be documented in accordance with locally agreed procedures in the individual's record and the individual's GP should be informed.

3.3. Advice to patient or carer including written information

Written information to be given to individuals:

- Provide manufacturer's consumer information leaflet/patient information leaflet (PIL) provided with the vaccine.

- Immunisation promotional material may be provided as appropriate.

Individual advice / follow up treatment:

- Inform the individual/carer of possible side effects and their management.
- The individual should be advised to seek medical advice in the event of a severe adverse reaction.
- Inform the individual that they can report suspected adverse reactions to the MHRA using the Yellow Card reporting scheme on: www.mhra.gov.uk/yellowcard

When applicable, advise individual/parent/carer when the subsequent dose is due.

3.4. Observation following vaccination

Following immunisation, patients remain under observation in line with NHS Board policy.

3.5. Follow up

As above.

3.6. Additional facilities

A protocol for the management of anaphylaxis and an anaphylaxis pack must always be available whenever vaccines are given. Immediate treatment should include early treatment with intramuscular adrenaline, with an early call for help and further IM adrenaline every 5 minutes.

The health professionals overseeing the immunisation service must be trained to recognise an anaphylactic reaction and be familiar with techniques for resuscitation of a patient with anaphylaxis.

4. Characteristics of staff authorised under the PGD

4.1. Professional qualifications

The following classes of registered healthcare practitioners are permitted to administer this vaccine:

- 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.

4.2. Specialist competencies or qualifications

Persons must only work under this PGD where they are competent to do so.

All persons operating this PGD:

- must be authorised by name by their employer as an approved person under the current terms of this PGD before working to it.
- must be familiar with the vaccine product and alert to changes in the manufacturer's product information/Summary of Product Characteristics information.
- must be competent to undertake immunisation and to discuss issues related to immunisation to assess patients for vaccination and obtain consent.

- must be competent in the correct storage of vaccines and management of the cold chain if receiving, responsible for, or handling the vaccine.
- must be competent in the recognition and management of anaphylaxis or under the supervision of persons able to respond appropriately to immediate adverse reactions.
- must have access to the PGD and associated online resources.
- should fulfil any additional requirements defined by local policy.

Employer:

The employer is responsible for ensuring that persons have the required knowledge and skills to safely deliver the activity they are employed to provide under this PGD.

As a minimum, competence requirements stipulated in the PGD must be adhered to.

4.3. Continuing education and training

All practitioners operating under the PGD are responsible for ensuring they remain up to date with the use of vaccines included. If any training needs are identified these should be discussed with the individuals in the organisation responsible for authorising individuals to act under this PGD.

- 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 where available
- 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.

5. Audit trail

Record the following information:

- valid informed consent was given
- name of individual, address, date of birth and GP with whom the individual is registered if possible
- name of person that undertook assessment of individual's clinical suitability and subsequently administered the vaccine
- name and brand of vaccine
- date of administration
- dose, form and route of administration of vaccine
- batch number
- where possible 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
- administered under PGD

Records should be kept in line with local procedures.

Local policy should be followed to encourage information sharing with the individual's General Practice.

All records should be clear, legible and contemporaneous and in an easily retrievable format.

6. Additional references

Practitioners operating the PGD must be familiar with:

- Immunisation against Infectious Disease [Green Book]
- Immunisation against Infectious Disease [Green Book] chapter 28a
- Current edition of British National Formulary (BNF) and BNF for children
- Marketing authorisation holder's Summary of Product Characteristics
- All relevant Scottish Government advice including the relevant CMO letter(s)
- Professional Guidance on the Administration of Medicines in Healthcare Settings 2019
- Professional Guidance on the Safe and Secure Handling of Medicines

7. Version history

Version	Date	Summary of changes
1.0	1 September 2022	New National Specimen PGD produced.
2.0	1 August 2022	The following changes to version 1.0 of the PGD have been made: • Inclusion sections dates updated for 2022/23 programme and to show where an individual has turned 80 years of age following their first dose of Shingrix®, a second dose should be provided to complete the two-dose schedule. • Action if declines section updated to highlight that those who decline vaccination remain eligible until they reach 80 years of age.
3.0	1 September 2023	The following changes to version 2.0 of the PGD have been made: • This PGD has undergone minor rewording, layout, formatting changes for clarity and consistency with other PHS national specimen PGDs. • This PGD reflects the move to universal use of Shingrix® for the prevention of herpes zoster and herpes zoster-post herpetic neuralgia. • Inclusion criteria section updated to reflect revised Green Book Chapter. • Exclusion criteria updated as per revised Green Book Chapter. • Action if excluded section updated to remove reference to Zostavax®. • Action of patient declines updated as per revised Green Book Chapter. • Dosage and frequency section updated as per revised Green Book Chapter. • Additional information section updated to remove recommendation for a seven day interval between Shingrix® and COVID-19 and to align with Green Book chapter advice on co-administration with influenza vaccine.

Version	Date	Summary of changes
		• Black Triangle section updated as no longer applicable
4.0	15 January 2024	The following changes to version 3.0 of the PGD have been made: • The inclusion criteria have been updated to provide date of birth age ranges

Version history NoS

Version	Date of change	Summary of Changes	Section heading
3.0	August 2023	Reference to NoS Appendix 1 and 2	Authorisation
		Training requirements for NoS	Continuing education and training

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

Appendix 1 - Healthcare Professional Agreement to Administer Medicine(s) Under Patient Group Direction

I: _____ (Insert name)

Working within: _____ e.g. Area, Practice

Agree to administer the medicine(s) contained within the following Patient Group Direction:

Patient Group Direction For The Administration Of Shingles (Herpes Zoster) Vaccine (Recombinant, Adjuvanted) Shingrix® By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles – Version 4.0

I have completed the appropriate training to my professional standards enabling me to administer the medicine(s) 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 Medicine(s) 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 medicine(s) 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 medicine(s) 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) Vaccine (Recombinant, Adjuvanted) Shingrix® By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles – Version 4.0
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

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Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date