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National reference:
CYM-25009
Local reference:
PGD 0181 D

Patient Group Direction

for the administration of

Shingrix[®] (herpes zoster) vaccine to adults for the prevention of herpes zoster and herpes zoster-related post-herpetic neuralgia

by registered healthcare professionals in accordance with the

National Shingles Immunisation Programme

in Powys Teaching Health Board (PTHB)

Operational from: 19 August 2025

Review Date: 01 March 2028

Expiry Date: 31 August 2028

Version number: v1.0



PGD for the administration of Shingrix® (herpes zoster) vaccine to adults in accordance with the National Shingles Immunisation Programme

Reference: Shingrix® vaccine PGD
 Version no: 1.0
 Valid from: 19 August 2025
 Review date: 01 March 2028
 Expiry date: 31 August 2028

Welsh Medicines Advice Service has developed this PGD for local authorisation

This PGD is not relevant to privately provided community pharmacy services. Those using this PGD must ensure that it is authorised by the organisation in which they are operating and signed in section 2 by an appropriate authorising person, relating to the class of person by whom the product is to be supplied, in accordance with the Human Medicines Regulations 2012 (HMR2012)¹. **THE PGD IS NOT LEGAL OR VALID WITHOUT SIGNED AUTHORISATION IN ACCORDANCE WITH HMR2012 SCHEDULE 16 Part 2.**

Authorising organisations must not *alter*, *amend* or *add* to the *clinical* content of this document such action will invalidate the *clinical sign-off* with which it is provided.

As operation of this PGD is the responsibility of service providers, the authorising organisation can decide which staff groups, in keeping with relevant legislation, can work to the PGD.

INDIVIDUAL PRACTITIONERS MUST BE LISTED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT.

Practitioners and organisations must check that they are using the current version of the PGD. Amendments may become necessary prior to the published expiry date.

Any queries regarding the clinical content of this PGD should be addressed to: welshmedicines.information@wales.nhs.uk

Change history

Version number	Change details	Date
v1.0	New PGD template for use in NHS Wales	19 August 2025


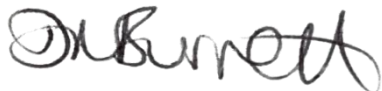

¹ This includes any relevant amendments to legislation (e.g. [2013 No.235](#), [2015 No.178](#), [2015 No.323](#) and [2024 No.729](#)).

1. PGD Development

This PGD has been developed by the following health care professionals on behalf of NHS Wales.

This section MUST REMAIN when a PGD is adopted by an organisation.

PGD Development

Name	Designation	Signature
Expert reviewer – Liam Taylor	Deputy Medical Director. Aneurin Bevan University Health Board. Member of the Vaccine Clinical Advisory Group.	
Main author – Dianne Burnett	National Lead Pharmacist Medicines Advice. Welsh Medicines Advice Service, Cardiff and Vale UHB. Member of the Vaccine Clinical Advisory Group.	
Expert reviewer – Hawys Youlden	Lead Nurse/Practitioner VPDP, Health Protection Team, Public Health Wales	

This PGD has been peer reviewed by the Vaccine Clinical Advisory Group in accordance with the WMAS PGD Policy and ratified by the All-Wales PGD Advisory Board.

Expert Panel – Vaccine Clinical Advisory Group

Name	Designation
Andrew Evans	Chief Pharmaceutical Officer
Dianne Burnett	National Lead Pharmacist Medicines Advice. Welsh Medicines Advice Service, Cardiff and Vale UHB
Christopher Johnson	Head of VPDP, Public Health Wales
Beverley Griggs	Consultant in Health Protection/Communicable Disease Control, Public Health Wales
Liam Taylor	Medical Director representative, Primary Care
Siân Owen	Lead Doctor Immunisation, Associate Specialist in Community Paediatrics, Betsi Cadwaladr UHB
Heather Payne	Senior Medical Officer Welsh Government
Paul Labourne	Senior Nursing Officer, Office of the CNO, Welsh Government
Nicola Bevan	Nurse Consultant, Deputy Head Vaccine Preventable Disease Program Public Health Wales
Hawys Youlden	Lead Nurse/Practitioner VPDP, Health Protection Team, Public Health Wales

Date VCAG approval of PGD: 25 July 2025

Date All Wales PGD Advisory Board ratification: 04 August 2025



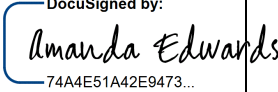
2. Organisational authorisation

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

It is the responsibility of the organisation that has legal authority to authorise this PGD, to ensure that all legal and governance requirements are met. The authorising body accepts governance responsibility for the appropriate use of the PGD.

Powys Teaching Health Board authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisations and/or services
<p>Powys Teaching Health Board</p> <p>Powys Teaching Health Board GP Practices: role, organisation, name, signature and date must be added (in the Additional signatories according to locally agreed policy) to indicate adoption</p>
Limitations to authorisation

Organisational approval (legal requirement)			
Role	Name	Sign	Date
Lead Doctor for PTHB	Dr Kate Wright	<p>DocuSigned by:</p>  <p>1F267952823F473...</p>	9/3/2025
Chief Pharmacist for PTHB	Jonathan Boyd	<p>Signed by:</p>  <p>6D8ECFE8C9EB423...</p>	8/26/2025
Clinical Governance Lead for PTHB: Assistant Director for Innovation and Improvement	Amanda Edwards	<p>DocuSigned by:</p>  <p>74A4E51A42E9473...</p>	9/3/2025



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Additional signatories according to locally agreed policy			
Role	Name	Sign	Date
Executive Director of Nursing and Midwifery for PTHB	Claire Roche	DocuSigned by: <i>Claire Roche</i> F07413E114E04B1...	8/27/2025

Local enquiries regarding the use of this PGD may be directed to: Medicines Management on 01874 712641

Assembly, final preparation and administration of vaccines supplied and administered under this PGD must be subject to NHS governance arrangements and standard operating procedures that ensure that the safety, quality or efficacy of the product is not compromised. The assembly, final preparation and administration of the vaccines should also be in accordance with the manufacturer’s instructions in the product’s UK [Summary of Product Characteristics](#) and/or in accordance with official national recommendations.

[Appendix B](#) provides a practitioner authorisation sheet. Individual practitioners must be authorised by name to work to this PGD. Alternative practitioner authorisation sheets may be used where appropriate in accordance with local policy, but this should be an individual agreement, or a multiple practitioner authorisation sheet as included at the end of this PGD.

Details of local policy or guidance that should be read in conjunction with this PGD
PTHB Additional local appendix (attached to the end of this PGD)

Retention statement

The final authorised copy of this PGD should be kept by the authorising organisation completing section 2 for 8 years after the PGD expires as the PGD relates to adults only. Provider organisations adopting authorised versions of this PGD should also retain copies for the periods specified above.



3. Characteristics of Staff

<p>Qualifications and professional registration</p>	<p>Practitioners must only work under this PGD where they are competent to do so.</p> <p>Practitioners working to this PGD must also be one of the following registered professionals who can legally supply and administer under a PGD (see Patient Group Directions: who can use them):</p> <ul style="list-style-type: none"> ➤ nurses and midwives currently registered with the Nursing and Midwifery Council (NMC). ➤ pharmacy professionals (pharmacists and pharmacy technicians) 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 (GDC). ➤ optometrists registered with the General Optical Council (GOC). <p>Practitioners must also fulfill all the additional requirements.</p> <p>Check section 2 limitations to authorisation to confirm whether all the registered practitioners listed above have organisational authorisation to work under this PGD.</p>
<p>Additional requirements</p> <p>(continued over page)</p>	<p>Additionally:</p> <ul style="list-style-type: none"> ➤ practitioners must be employed by or providing services on behalf of PTHB or a PTHB GP Practice. ➤ practitioners must be authorised by name as an approved practitioner under the current terms of this PGD before working to it. ➤ practitioners must be competent in the use of PGDs (see NICE competency framework for health professionals using PGDs). ➤ practitioners must be familiar with the vaccine product and alert to changes in the Summary of Product Characteristics (SmPC), Immunisation Against Infectious Disease (the 'Green Book'), and national and local immunisation programmes (the Welsh Health Circulars and Public Health Wales). ➤ practitioners must have undertaken appropriate training for working under PGDs for supply / administration of medicines. ➤ if practitioners are new to immunisation the national minimum standards and core curriculum for vaccination training apply. Practitioners delivering training should adapt the curriculum (the topics covered, and the level of detail required) to the specific needs of the workforce depending on the nature of their role in terms of delivering the shingles vaccine programme.



<p>Additional requirements (continued)</p>	<ul style="list-style-type: none"> ➤ all new immunisers should complete a competency assessment, for formal assessment and sign-off of their clinical competency. The competencies required will depend on the individual service area and the role of the immuniser. A competency assessment tool is available in the national minimum standards and core curriculum for vaccination training. ➤ the competency assessment tool is also useful for more experienced immunisers to self-assess and identify if there are any areas where they need to update or further their knowledge and skills. ➤ if a practitioner has not received any vaccine update training in the past year, it is recommended that they also undertake the administration, storage and legal aspects e-learning modules available in the Immunisation programme - Public Health Wales (nhs.wales). This page offers support on how to access these resources via ESR, or for staff outside of NHS Wales via the learning@Wales platform. Training resources and guidance documents are also available to view here: Immunisation training resources and events - Public Health Wales ➤ practitioners must be competent to undertake immunisation and to discuss issues related to immunisation. ➤ practitioners must be competent in the injection technique appropriate for the vaccine. See route/method of administration section. ➤ practitioners must be competent in the handling and storage of vaccines, and management of the cold chain. ➤ practitioners must be competent in the recognition and management of anaphylaxis. ➤ practitioners must have access to the PGD and associated online resources. ➤ practitioners should fulfil any additional requirements defined by local policy. ➤ practitioners must understand the process of consent and how this applies when giving vaccines. <p>The individual practitioner must be authorised by name, under the current version of this PGD before working according to it.</p>
<p>Ongoing training and competency (continued over page)</p>	<p>Practitioners must:</p> <ul style="list-style-type: none"> ➤ ensure they are up to date with relevant issues and clinical skills relating to immunisation and management of anaphylaxis, with evidence of appropriate Continuing Professional Development (CPD). ➤ be aware of any updates to relevant national guidelines from Public Health Wales, NHS Wales, Welsh Government Welsh Health Circulars (WHC) and other sources of medicines information. ➤ be aware of any updates made to the product in its SmPC or BNF entries or the relevant chapter(s) of the Green Book.



<p>Ongoing training and competency (continued)</p>	<ul style="list-style-type: none"> ➤ as registered professionals, be professionally accountable and must work within their competence. A record of training and competence must be maintained. ➤ have demonstrated competence in Basic Life Support skills including resuscitation skills and the management of anaphylaxis. <p>Note: The most current national recommendations should be followed, but a Patient Specific Direction (PSD) may be required to administer the vaccine in line with updated recommendations that are outside the criteria specified in this PGD.</p>
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4. Clinical Condition

<p>Clinical condition or situation to which this PGD applies</p>	<p>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) for adults who are eligible for the National Shingles Vaccination Programme in accordance with the Welsh Health Circulars: WHC/2023/024, WHC/2025/028 and the recommendations given in Shingles (herpes zoster): the green book, chapter 28a.</p>
<p>Inclusion Criteria</p>	<p>Shingrix® Herpes zoster vaccine can be given to:</p> <ul style="list-style-type: none"> ➤ immunocompetent individuals who: <ul style="list-style-type: none"> ○ reach the age of 65 or 70 years of age during the period 1 September 2023 and 31 August 2028. These individuals should be vaccinated on or after (but not before) their 65th or 70th birthday. ○ are between 65 and 69 years of age who present opportunistically in accordance with WHC/2023/024. ○ are aged between 70 years and 79 years old and have never received a shingles vaccine or immunisation course is incomplete. ○ are currently aged 80 years or over but received a first dose of Shingrix® before turning 80 years old and require a second Shingrix® dose to complete the course before their 81st birthday. ➤ all severely immunosuppressed individuals from 01 August 2025, who: <ul style="list-style-type: none"> ○ are aged 18 years and above (with no upper age limit) and meet the definition of severe immunosuppression in the Green book chapter 28a (Box 1: Definition of severe immunosuppression for the Shingrix vaccine programme). <p>See WHC/2023/024 and WHC/2025/028 for further information on cohort eligibility.</p>
<p>Exclusion Criteria²</p> <p>(continued over page)</p>	<p>Shingrix® Herpes zoster vaccine should not be given to:</p> <ul style="list-style-type: none"> ➤ individuals for whom no valid consent has been received or a 'best-interests' decision, in accordance with the Mental Capacity Act 2005, has not been obtained (for further information on consent see chapter 2 of the Green Book). ➤ immunocompetent individuals who: <ul style="list-style-type: none"> ○ are 80 years of age or over, EXCEPT those who have received a partial course of Shingrix® (who are no longer eligible to have a second dose of the vaccine from their 81st birthday). ➤ all individuals who: <ul style="list-style-type: none"> ○ have had a confirmed anaphylactic reaction to a previous dose of varicella-containing vaccine or to any component of the vaccine.

² Exclusion under this PGD does not necessarily mean the vaccine described in Section 5 are contraindicated, but it would be outside the remit of this PGD. Another form of authorisation for administration of the vaccine would be required.



<p>Exclusion Criteria (continued)</p>	<ul style="list-style-type: none"> ○ 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. ○ are pregnant. ○ have already received one dose of Zostavax[®] or two doses of Shingrix[®] prior to assessment. ○ have received a dose of Shingrix[®] in the last 8 weeks. <p>Where there is doubt, rather than withholding vaccination, seek appropriate advice or refer. See cautions section below.</p>
<p>Cautions</p>	<p>Please refer to the SmPC for full details of special warnings and precautions for use.</p> <p>Facilities for management of anaphylaxis should be available at all vaccination premises (see chapter 8 of the Green Book and advice issued by the Resuscitation Council UK).</p> <p>Syncope (fainting) can occur following, or even before, any vaccination 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.</p> <p>Individuals with immunosuppression or taking immunosuppressant medication may have a reduced response to vaccination. However, vaccination should proceed in accordance with national recommendations.</p> <p>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).</p>
<p>Action to be taken if the individual is excluded or the individual or carer declines</p> <p>(continued over page)</p>	<ul style="list-style-type: none"> ➤ Seek advice from the individual's clinician, Immunisation Coordinator, or local immunisation team. ➤ 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. ➤ In case of postponement due to acute illness, advise when the individual can be vaccinated and ensure another appointment is arranged. ➤ Individuals who present with a shingles infection with active lesions should postpone immunisation until recovered. As severely immunosuppressed individuals are at increased risk of recurrent zoster, Shingrix[®] can be given once any active shingles lesions have resolved. ➤ If clinically indicated, Shingrix[®] may be considered in pregnancy, following a discussion of the risks and benefits with the individual. In such cases, if the individual wishes to proceed with vaccination, Shingrix[®] may be given under a PSD.
<p>Action to be taken if the individual is</p>	<ul style="list-style-type: none"> ➤ When administration is postponed, arrange a future date for vaccination as appropriate, with due consideration of the individual's age to ensure



<p>excluded or the individual or carer declines (continued)</p>	<p>they will meet the inclusion criteria for immunisation.</p> <ul style="list-style-type: none"> ➤ If vaccination cannot be commenced before an immunocompetent 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. ➤ Explain the reasons for exclusion and any action taken and document in the individual's patient record. ➤ Inform or refer to the individual's GP or a prescriber as appropriate. ➤ Informed consent, from the individual or a person legally able to act on the person's behalf, must be obtained for prior to administration. Where a person lacks the capacity, in accordance with the Mental Capacity Act 2005, a decision to vaccinate may be made in the individual's best interests. For further information on consent see chapter 2 of the Green Book. ➤ If the individual declines, advise about the protective effects of the vaccine and the consequences of not receiving it. The risk to the individual of not being immunised should be considered. ➤ Document all advice given and the decision reached in the individual's patient record.
<p>Arrangements for referral for medical advice</p>	<p>If there is any doubt about the administration of the vaccine or an individual's fitness or suitability to receive the vaccine, an appropriate medical professional should be consulted.</p>

5. Description of treatment

Name, strength & formulation of drug	<p>Herpes zoster vaccine (recombinant, adjuvanted):</p> <ul style="list-style-type: none"> ➤ Shingrix[®], powder and suspension for suspension for injection. <p>After reconstitution, one dose (0.5 mL) of Shingrix[®] contains varicella zoster virus glycoprotein E antigen 50 micrograms, adjuvanted with AS01_B.</p>
Legal category	<p>POM - Prescription Only Medicine.</p>
Black triangle ▼	<p>No.</p>
Off-label use	<p>Yes.</p> <p>The Shingrix[®] SmPC advises an interval of 2 months between doses, which may be extended to between 2 and 6 months if flexibility is required. For individuals who are or about to become severely immunosuppressed and who might benefit from a shorter vaccination schedule, a 1-to-2-month interval between doses may be observed.</p> <p>The dose intervals advised in the Green Book and subsequently in this PGD are different to that outlined above; between 6 and 12 months for immunocompetent individuals and 8 weeks to 6 months for severely immunosuppressed individuals.</p> <p>Where a vaccine is recommended off-label, as part of the consent process, consider informing the individual or their carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence (off-label).</p> <p>Vaccines should be stored according to the conditions detailed in the storage section in this document. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to section 5 (storage) and section 11 (incident) of advisory document on ordering storage and handling of vaccines. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use this would constitute off-label administration under this PGD.</p>
Preparation	<p>Shingrix[®] must be reconstituted in accordance with the manufacturer's instructions prior to administration. See SmPC.</p>
Route / Method of Administration (continued over page)	<ul style="list-style-type: none"> ➤ The vaccine should be inspected visually for particles and discolouration before preparation and administration. Should either occur, discard the vial in accordance with local procedures. ➤ The reconstituted vaccine is an opalescent, colourless to pale brownish liquid. Discard the vaccine if there is any foreign particulate matter or variation in appearance. ➤ After reconstitution, the vaccine should be used promptly (see storage section). ➤ Following reconstitution, Shingrix[®] vaccine is given by intramuscular injection, preferably into the deltoid muscle of the upper arm.

<p>Route / Method of Administration (continued)</p>	<ul style="list-style-type: none"> ➤ 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 or other treatment to reduce bleeding, for example treatment for haemophilia, intramuscular vaccination can be scheduled shortly after such medication or 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 or carer should be informed about the risk of haematoma from the injection. If in any doubt, consult with the clinician responsible for prescribing or monitoring the individual's anticoagulant therapy. <p>Co-administration:</p> <ul style="list-style-type: none"> ➤ 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 vaccinations. See special considerations / additional information section. ➤ The vaccines should be given at separate sites, preferably in different limbs. If given in the same limb, they should be given at least 2.5 cm apart. ➤ The site at which each vaccine was given should be noted in the individual's records.
<p>Dose and frequency of administration</p>	<p>Single 0.5 mL dose per administration. If the course is interrupted or delayed, it should be resumed as soon as possible but the first dose should not be repeated.</p> <p>Eligible immunocompetent individuals</p> <ul style="list-style-type: none"> ➤ 2 doses of Shingrix[®], with the second dose given 6 to 12 months after the first dose. <p>Severely immunosuppressed individuals (includes stem cell transplant recipients):</p> <ul style="list-style-type: none"> ➤ 2 doses of Shingrix[®], with the second dose given 8 weeks to 6 months after the first dose. <p>Severely immunosuppressed individuals who have already received 2 doses of Shingrix[®] do not require revaccination.</p>

Duration of treatment	A two-dose course. See dosage schedule above.
Supplies	<ul style="list-style-type: none"> ➤ Vaccines for use for the national immunisation programme are provided free of charge. ➤ NHS standard operating procedures should be followed for appropriate ordering, storage, handling, recording, preparation, administration and waste minimisation. ➤ Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see storage section below).
Storage	<p>Store between +2°C to +8°C.</p> <p>Store in original packaging in order to protect from light.</p> <p>Do not freeze.</p> <p>Once reconstituted, any unused vaccine should be stored in a refrigerator at +2°C to +8°C if not immediately required.</p> <p>Though chemical and physical in-use stability has been demonstrated for 24 hours at +30°C, from a microbiological viewpoint, the reconstituted vaccine should be used as soon as possible. Any remaining vaccine should be discarded 6 hours following reconstitution.</p> <p>In the event of an inadvertent or unavoidable deviation of these conditions, a vaccine that has been stored outside the conditions stated above (fridge failure / breaches in cold chain) should be quarantined and risk assessed for suitability of continued off-label use or appropriate disposal.</p> <p>Refer to:</p> <ul style="list-style-type: none"> ➤ advisory document on ordering storage and handling of vaccines section 5 (storage). ➤ Green Book chapter 3, and relevant local vaccine policy or guidance. ➤ vaccine incident guidance: responding to vaccine errors. ➤ local Medicines Advice Service for advice. <p>Any loss of vaccines due to expiry date, wastage or fridge failure/breaches in cold chain must be reported following local procedure and documented on ImmForm and via DatixCymru incident reporting system.</p>



<p>Disposal</p>	<ul style="list-style-type: none"> ➤ Any unused product or waste material should be disposed of in accordance with local requirements. ➤ Equipment used for immunisation, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of at the end of a session by sealing in a UN-approved puncture-resistant 'sharps' box, according to local authority regulations and guidance in the Welsh Health Technical Memorandum 07-01 Safer management of healthcare waste.
<p>Drug Interactions</p>	<ul style="list-style-type: none"> ➤ Immunological response may be diminished in those receiving immunosuppressive treatment, but it is important to still immunise this group. Vaccination is recommended even if the antibody response may be limited. ➤ See the special considerations / additional information section for information on co-administration with other vaccines. ➤ If co-administered with other vaccines, refer to their relevant PGDs. ➤ A detailed list of drug interactions is available in the SmPC.
<p>Identification and management of adverse effects</p>	<p>If the individual or carer is concerned about their health at any time, they should seek advice from their GP or NHS 111 Wales.</p> <p>Hypersensitivity reactions and anaphylaxis can occur after vaccination but are very rare. Signs include swelling of the face, lips, tongue or throat, hives, difficulty breathing or swallowing and dizziness.</p> <p>A detailed list of adverse reactions is available in the Summary of Product Characteristics.</p> <p>Very common adverse reactions observed after administration of Shingrix® are injection-site reactions (such as pain, redness and swelling) myalgia and headache. Most of these reactions are not long-lasting (median duration of 2 to 3 days). Other very common side-effects include gastrointestinal symptoms (including nausea, vomiting, diarrhoea and abdominal pain), fatigue, chills and fever.</p> <p>As Shingrix® vaccine is a non-live vaccine, it should not cause the development of a vesicular rash. If a vesicular rash does develop after the Shingrix® vaccine, the patient should be referred for assessment and management as it is likely that they have developed shingles naturally (not due to the vaccine).</p>
<p>Reporting procedure for suspected adverse reactions</p>	<p>Any adverse reaction to the product should be documented in the individual's medical records and their GP should be informed.</p> <p>Report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) by using the Yellow Card reporting scheme or search for MHRA Yellow Card in the Google Play or Apple App store.</p> <p>All serious adverse reactions and those considered avoidable should also be reported on the DatixCymru incident reporting system.</p>



<p>Written information to be given to the individual or their carer</p>	<p>Provide the individual or their carer with the holder's patient information leaflet (PIL).</p> <ul style="list-style-type: none"> ➤ Immunisation promotional material may be provided as appropriate. <ul style="list-style-type: none"> ○ Get vaccinated against shingles. ○ Resources are available to order from Health Information Resources. ➤ If applicable, inform the individual or carer that large print, Braille or audio CD PILs may be available from https://www.medicines.org.uk/emc/xpil (freephone 0800 198 5000) by providing the medicine name and product code number, as listed on the product SmPC.
<p>Individual or carer advice / follow up</p>	<p>Inform the individual or their carer:</p> <ul style="list-style-type: none"> ➤ a full explanation of risks and benefits to the individual or their carer in order to obtain informed consent. ➤ to talk to a doctor or pharmacist if they get any side effects, including side effects not listed in the leaflet. ➤ of normal reactions to the injection, for example redness and pain at the injection site. ➤ to seek medical attention in the event of a severe adverse reaction or if common side effects do not spontaneously resolve after 3 days vaccination. ➤ to seek medical attention if they develop a varicella (widespread) or shingles-like (dermatomal) rash post-Shingrix[®] vaccination. ➤ that they can report side effects directly to the Yellow Card reporting scheme. ➤ not to drive for 15 minutes after vaccination as fainting can occur following vaccination. ➤ when subsequent doses are due if appropriate. ➤ when administration is postponed, 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 an immunocompetent individual is 80 years old, explain why vaccination will no longer be indicated (there is no upper age limit for severely immunocompromised individuals). ➤ if they have a weakened immune system that they may not make a full immune response to the vaccine.
<p>Special considerations / additional information (continued over page)</p>	<p>The practitioner should have immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a telephone at the time of vaccination.</p> <p>See chapter 8 of the Green Book and advice issued by the Resuscitation Council.</p>



<p>Special considerations / additional information</p> <p>(continued)</p>	<p>An age-appropriate protocol for the management of anaphylaxis and an anaphylaxis pack must always be available. Immediate treatment should include early treatment with:</p> <ul style="list-style-type: none"> ➤ 12 years and above: 500 micrograms IM (0.5 mL of 1:1000 or 1 mg/mL adrenaline). ➤ an early call for help and further IM adrenaline every 5 minutes. See chapter 8 of the Green Book and advice issued by the Resuscitation Council. <p>Individuals anticipated to commence immunosuppressive treatment should, where feasible, complete the course of Shingrix® before treatment is scheduled to begin, with a dose interval of 8 weeks. Under no circumstances should there be a delay in commencing immunosuppressive treatment in order to complete the vaccine schedule. The first dose of Shingrix® should be given at least 14 days before treatment starts, though 1 month prior is preferred. If immunosuppressive treatment is subsequently commenced after the first dose of Shingrix® is given, the second dose may be given 8 weeks to 6 months later.</p> <p>Where individuals in an eligible cohort present having recently received another inactivated or live vaccine, Shingrix® vaccination should still be offered. In such circumstances, patients should be informed about the likely timing of potential adverse events relating to each vaccine. Shingrix® can be given at the same time as inactivated influenza vaccine or 23-valent pneumococcal vaccine (PPV23). The vaccines should be administered at different injection sites. The adverse reactions of fever and shivering are more frequent when PPV23 vaccine is co-administered with Shingrix®.</p> <p>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. This is to avoid confusing the differential diagnosis of any acute illness by wrongly attributing signs or symptoms to adverse effects of the vaccine.</p>
<p>Records</p> <p>(continued over page)</p>	<p>Record:</p> <ul style="list-style-type: none"> ➤ that valid informed consent was given or a decision to vaccinate was made in the individual’s best interests in accordance with the Mental Capacity Act 2005. ➤ how the individual met or did not meet the inclusion/exclusion criteria of the PGD. ➤ name of individual, address, date of birth and the GP with whom the individual is registered. ➤ allergies and previous adverse events. ➤ name and signature of the health professional administering the vaccine (if recording on paper). If recording in a digital record, name only, signature will be replaced by electronic logging of the user). ➤ name and brand of vaccine.



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Records

(continued)

- date of administration.
- dose, form and route administration.
- quantity administered.
- anatomical site of vaccination.
- batch number and expiry date of vaccine.
- relevant information provided to the individual or their carer including side effects and advice given if excluded or declines.
- details of any adverse drug reaction and actions taken.
- referral arrangements (if any).

Records should be signed and dated (or password-controlled immunisers record on e-records).

All records should be clear, legible and contemporaneous.

All records electronically or otherwise must be kept in accordance with NHS Wales record keeping. See: [records management code of practice for health and social care 2022](#).

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.

Appendices

Appendix A: References

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- UK Health Security Agency (UKHSA). Vaccination against shingles: information for healthcare practitioners. Last updated 25 November 2024. Available from: <https://www.gov.uk/government/publications/shingles-vaccination-guidance-for-healthcare-professionals> [accessed 01 July 2025]
- UK Health Security Agency (UKHSA). Vaccination of individuals with uncertain or incomplete immunisation status. Published September 2013. Last updated 09 July 2025. Available from: <https://www.gov.uk/government/publications/vaccination-of-individuals-with-uncertain-or-incomplete-immunisation-status> [accessed 25 July 2025]
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Appendix B: Practitioner authorisation sheet

Patient Group Direction for the administration of Shingrix® (herpes zoster) vaccine to adults in accordance with the National Shingles Vaccination Programme v1.0

Valid from: 19 August 2025 Expiry: 31 July 2028

Before signing this PGD, check that the document has had the necessary authorisations in [section 2](#). Without these, this PGD is not lawfully valid. Signed copies of these sheets should be kept in accordance with the retention statement in [section 2](#).

Practitioner

By signing this PGD you are indicating that you agree to its contents and that you will work within it. PGDs do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

I confirm that I have read and understood the content of this PGD and that I am willing and competent to work to it within my professional code of conduct.

Name	Designation	Signature	Date

Authorising manager

I confirm that the practitioners named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of PTHB or a PTHB GP Practice for the above-named health care professionals who have signed the PGD to work under it.

Name	Designation	Signature	Date

Note to authorising manager

Score through unused rows in the list of practitioners to prevent practitioner additions post managerial authorisation.

This authorisation sheet should be retained to serve as a record of those practitioners authorised to work under this PGD in accordance with the retention statement in the [organisational authorisation section](#).



Additional appendix for vaccination PGDs, detailing Powys Teaching Health Board (PTHB) PGD requirements

Section of PGD	Additional requirements
<p>Characteristics of staff</p>	<p>Practitioner must have completed eLfh PGD eLearning Patient Group Directions training (available via learning@wales, PTHB staff to access via ESR). Evidence of ongoing PGD training to be submitted to Line Manager annually– this should include an annual completion certificate of PGD e-learning or a dated screenshot of the PGD e-learning assessment results as proof of completion.</p> <p>The practitioner must update at least every 2 years on the administration/use, contra-indications and adverse effects of the vaccination.</p> <p>Practitioners must make a self-declaration of competency on PADR (if relevant). The personal development plan (yellow) section of the PADR booklet should be used to record completion of Statutory and Mandatory training, including annual PGD e-learning.</p> <p>Individuals operating under this PGD must be assessed as competent -refer to the practitioner authorisation sheet and the PTHB competency checklist.</p> <p>Must be competent in the recognition, management and reporting of recognised adverse reactions, including anaphylaxis. Must be competent in the administration of adrenaline and have up to date Basic Life Support skills.</p> <p>Compliance with all mandatory NHS training (if relevant), including safeguarding at the level relevant to the role.</p> <p>Must be familiar with All Wales Advisory document on Ordering Storage and Handling of Vaccines, and must have completed:</p> <ul style="list-style-type: none"> • immunisation training (also see National Minimum Standards and Core Curriculum for Immunisation). Please contact PTHB Immunisation coordinator for further information. • cold chain training (also available via ESR). <p>It is the responsibility of the healthcare professional to maintain their own competency to practice within this PGD.</p>
<p>Clinical Condition: Situation</p>	<p>It is the responsibility of the administering healthcare professional to ensure that the individual is within the inclusion criteria, and that there are no reasons for exclusion before proceeding. If there is any reason for concern, seek medical advice.</p>
<p>Clinical Condition: Inclusion criteria</p>	<p>Medical and drug history taken, no reason for exclusion.</p> <p>PTHB Consent to Treatment and Examination Policy</p>
<p>Clinical Condition: Exclusion criteria</p>	<p>If relevant, other PTHB PGDs may be found using this link Patient Group Directions (PGDs) - Powys Teaching Health Board (nhs.wales).</p>



<p>Cautions</p>	<p>Check for any other medications that the individual is taking, including topical or inhaled products, food supplements and herbal or homeopathic products. (Refer to BNF/SPC for full list).</p> <p>Under Section 128 and 130 of the Social Services and Wellbeing (Wales) Act 2014, staff have a duty to inform the Local Authority if they have reasonable cause to suspect that an adult or child is at risk. Any vulnerable adult or child protection concerns should be referred to Safeguarding and the PTHB safeguarding policies followed. Consider discussing with GP. Any safeguarding concerns need to be directed to Safeguarding Hub:</p> <ul style="list-style-type: none"> • to generic email address: PowysTHB.Safeguarding@wales.nhs.uk and • Central Safeguarding number: 01686 252806 • Out of hours: 0345 0544847 <p>Advice can also be sought from local Safeguarding leads</p>
<p>Action to be taken if the individual or carer declines treatment</p>	<p>The patient information leaflet should be available to inform consent.</p>
<p>Description of treatment: Route and method of administration</p>	<p>See Green book chapter 4.</p>
<p>Description of treatment: Supplies</p>	<p>Refer to All Wales Advisory document on Ordering Storage and Handling of Vaccines.</p>
<p>Description of treatment: Storage</p>	<p>Refer to:</p> <ul style="list-style-type: none"> • MMP 427 Safe and Secure Management of Refrigerated Medicines and Vaccines SOP <p>Any loss of vaccines due to expiry date, wastage or fridge failure/breaches in cold chain must be reported on ImmForm, to PTHB Immunisation Coordinator (Powys.Immunisations@wales.nhs.uk), and via PTHB Datix reporting system Once for Wales Reporting System.</p>
<p>Description of treatment: Adverse reactions</p>	<p>Report any suspected adverse reactions to a doctor.</p> <p>In case of an acute anaphylactic reaction occurring, adequate treatment provision must be available for immediate use: Anaphylaxis and resuscitation equipment including adrenaline (1 in 1000) injection and a working telephone. In case of anaphylaxis:</p> <ul style="list-style-type: none"> • Refer to adrenaline (epinephrine) PGD0017 and anaphylaxis procedure • Request medical assistance urgently. If the GP is not immediately available dial 999 to transfer to A&E • Ensure reaction is fully documented in patient notes • Ensure all patient records are marked ALLERGIC TO Shingrix® Herpes zoster vaccine (recombinant, adjuvanted)



	<ul style="list-style-type: none"> • The individual may be advised to wear a MedicAlert or similar device to alert other healthcare providers • Report via Datix Once for Wales Reporting system
<p>Description of treatment: Written information</p>	<p>Further information for printing and website links suitable for individuals can be found on the Public Health Wales intranet site Public Health Wales Immunisation and Vaccine Preventable Disease Programme, NHS 111 Wales and Health Information Resources.</p>
<p>Description of treatment: Records</p>	<p>Record consultation details as required by local procedures, to include:</p> <ul style="list-style-type: none"> • Name of representative who gave consent if appropriate. • Medical and drug history taken, including any allergies and previous adverse events • PGD title and version number



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Competency check list for manager or senior team lead to use as part of the authorising process for health professionals to work to a Patient Group Direction (PGD). Review of authorisation will take place on each PGD update and at the individual's annual PADR.

	Name: Role:	Sign / Initial	Further training identified (Y/N) Specify in "comment"	Comments
1	The PGD sign off is for the following PGD:(document the exact title and PGD number) _____			
2	We have discussed the expiry of the PGD and are using a version accessed electronically			
3	The member of staff has the appropriate qualifications and professional registration as outlined in the PGD			
4	The Patient Group Direction has been read in full by the staff member			
5	The identified training has been completed as specified in the PGD and is in date			
6	We have discussed some examples of inclusion criteria and exclusion criteria			
7	The staff member is confident in the administration method and doses			

Staff member print & sign name		Date
Manager or senior team lead to print & sign name		Date

Please send a copy of this completed form to the individual's line manager and to the staff member, in conjunction with the Practitioner authorisation sheet. A copy of this form should also be kept by service lead in the training file.