Public Health England

NHS

PHE publications gateway number: GOV-9179

Shingrix® Herpes Zoster Vaccine Patient Group Direction (PGD)

This PGD is for the administration of Shingrix® Herpes Zoster Vaccine (recombinant, adjuvanted), for the 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.

This PGD is for the administration of Shingrix® Herpes Zoster Vaccine (recombinant, adjuvanted) by registered healthcare practitioners identified in Section 3, subject to any limitations to authorisation detailed in Section 2.

Reference no:	Shingrix PGD
Version no:	v01.00
Valid from:	1 September 2021
Review date:	1 March 2023
Expiry date:	31 August 2023

Public Health England has developed this PGD to facilitate the delivery of publicly funded immunisation in line with national recommendations.

Those using this PGD must ensure that it is organisationally authorised 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 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 (sections 4, 5 and 6); such action will invalidate the clinical sign-off with which it is provided. In addition, authorising organisations must not alter section 3 'Characteristics of staff'. Only sections 2 and 7 can be amended within the designated editable fields provided.

Operation of this PGD is the responsibility of commissioners and service providers. 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 8 years.

Individual practitioners must be authorised 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. Current versions of PHE PGD templates for authorisation can be found from: Immunisation patient group direction (PGD) templates

Any concerns regarding the content of this PGD should be addressed to: immunisation@phe.gov.uk
Enquiries relating to the availability of organisationally authorised PGDs and subsequent versions of this PGD should be directed to: For East Anglia email: England.eaimms@nhs.net
For Essex email: England.essexatimms@nhs.net
For Bedfordshire, Hertfordshire, Luton and Milton Keynes email: England.immsqa@nhs.net

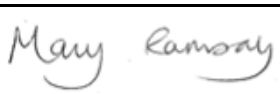
[1] This includes any relevant amendments to legislation (such as 2013 No.235, 2015 No.178 and 2015 No.323).

Change history

Version number	Change details	Date
V01.00	New Shingrix® Herpes Zoster Vaccine PGD	22 August 2021

1. PGD development

This PGD has been developed by the following health professionals on behalf of Public Health England:

Developed by:	Name	Signature	Date
Pharmacist (Lead Author)	Elizabeth Graham Lead Pharmacist, Immunisation and Countermeasures, PHE		25/08/2021
Doctor	Mary Ramsay Consultant Epidemiologist and Head of Immunisation and Countermeasures, PHE		25/08/2021
Registered Nurse (Chair of Expert Panel)	David Green Nurse Consultant, Immunisations and Countermeasures, PHE		25/08/2021

This PGD has been peer reviewed by the PHE Immunisations PGD Expert Panel in accordance with PHE PGD Policy. It has been ratified by the PHE Medicines Governance Group and the PHE Quality and Clinical Governance Delivery Board.

Expert Panel

Name	Designation
Nicholas Aigbogun	Consultant in Communicable Disease Control, Yorkshire and Humber Health Protection Team, Public Health England
Gayatri Amirthalingam	Consultant Epidemiologist, Immunisation and Countermeasures, Public Health England
Sarah Dermont	Clinical Project Coordinator and Registered Midwife, NHS Infectious Diseases in Pregnancy Screening Programme, Public Health England
Ed Gardner	Advanced Paramedic Practitioner / Emergency Care Practitioner, Medicines Manager, Proactive Care Lead
Michelle Jones	Senior Medicines Optimisation Pharmacist, NHS Bristol North Somerset and South Gloucestershire CCG
Jacqueline Lamberty	Lead Pharmacist Medicines Management Services, Public Health England
Vanessa MacGregor	Consultant in Communicable Disease Control, Public Health England, East Midlands Health Protection Team
Alison Mackenzie	Consultant in Public Health Medicine / Screening and Immunisation Lead, Public Health England (South West) / NHS England and NHS Improvement South (South West)
Gill Marsh	Principal Screening and Immunisation Manager, Public Health England / NHS England and NHS Improvement (North West)
Lesley McFarlane	Screening and Immunisation Manager: Clinical (COVID-19 and Influenza), Public Health England / NHS England and NHS Improvement (Midlands)
Tushar Shah	Lead Pharmacy Advisor, NHS England and NHS Improvement (London Region)

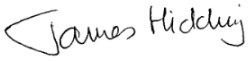
2. Organisational authorisations

This 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 the PGD, to ensure that all legal and governance requirements are met. The authorising body accepts governance responsibility for the appropriate use of the PGD.

NHS England and NHS Improvement East of England authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisations and/or services
All NHS England and NHS Improvement East of England commissioned immunisation services or NHS Trust providing immunisation services covering Norfolk, Suffolk, Cambridgeshire, Peterborough, Essex, Southend-on-Sea, Thurrock, Bedfordshire, Hertfordshire, Luton and Milton Keynes local authorities, and Health and Justice facilities where NHS England and NHS Improvement East of England is the commissioner.
Limitations to authorisation
None

Organisational approval (legal requirement)			
Role	**Name**	**Sign**	**Date**
Associate Medical Director	**Dr. James Hickling**		**02/09/2021**

Additional signatories according to locally agreed policy			
Role	**Name**	**Sign**	**Date**
Screening and Immunisation Lead	**Dr. Pam Hall**		**01/09/2021**
Pharmacist	**Dr. Paul Duell**		**01/09/2021**
Screening and Immunisation Coordinator	**Alex Burghelea**		**01/09/2021**

For East Anglia email: England.eaimms@nhs.net
For Essex email: England.essexatimms@nhs.net
For Bedfordshire, Hertfordshire, Luton and Milton Keynes email: England.immsqa@nhs.net

Section 7 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.

3. Characteristics of staff

Qualifications and professional registration	Registered professional with one of the following bodies: • nurses and midwives currently registered with the Nursing and Midwifery Council (NMC) • pharmacists currently registered with the General Pharmaceutical Council (GPhC) (Note: This PGD is not relevant to privately provided community pharmacy services) • paramedics and physiotherapists currently registered with Health and Care Professions Council (HCPC) The practitioners above must also fulfil the Additional requirements detailed below. Check Section 2 Limitations to authorisation to confirm whether all practitioners listed above have organisational authorisation to work under this PGD.
Additional requirements	Additionally, practitioners: • must be authorised by name as an approved practitioner under the current terms of this PGD before working to it • must have undertaken appropriate training for working under PGDs for supply/administration of medicines • must be competent in the use of PGDs (see NICE Competency framework for health professionals using PGDs) • 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 • must have access to the PGD and associated online resources • should fulfil any additional requirements defined by local policy **The individual practitioner must be authorised by name, under the current version of this PGD before working according to it.**
Continued training requirements	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). Practitioners should be constantly alert to any subsequent recommendations from Public Health England and/or NHS England and NHS Improvement and other sources of medicines information. 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.

4. Clinical condition or situation to which this PGD applies

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'.
Criteria for inclusion	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.[2]
Criteria for exclusion[3]	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®[2] • do not have clinical contraindications to receiving Zostavax®, shingles (herpes zoster, live) vaccine[4] • 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 • are pregnant
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).

[2] 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.
[3] Exclusion under this PGD does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation will be required.
[4] Refer to Chapter 28a and PHE Zostavax PGD for further detail of those with clinical contraindications to Zostavax® shingles (herpes zoster, live) vaccine, primarily those with primary or acquired immunodeficiency states or on significant immunosuppressive or immunomodulating therapy.

Action to be taken if the patient is 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 the patient or carer declines treatment	Informed consent, from the individual or a person legally able to act on the individual's behalf, must be obtained prior to administration. Advise the individual/carer about the protective effects of the vaccine, the risks of infection and potential complications. Document advice given and the decision reached. Inform or refer to the GP or a prescriber as appropriate.
Arrangements for referral for medical advice	As per local policy

5. Description of treatment

Name, strength and formulation of drug	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.
Off-label use	Vaccine should be stored according to the conditions detailed in the Storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to PHE Vaccine Incident Guidance. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use this would constitute off-label administration under this PGD. Where a vaccine is recommended off-label consider, as part of the consent process, informing the individual/carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence.
Route / method of administration Continued over page	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, 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

Route / method of administration (continued)	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 of administration	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.
Duration of treatment	A two dose course (see Dose and frequency of administration)
Quantity to be supplied / administered	Single 0.5ml dose per administration.
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).
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.
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.

Identification and management of adverse reactions	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.
Reporting procedure of adverse reactions	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.
Written information to be given to patient or carer	Offer marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine.
Patient advice / follow up treatment	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. 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.
Special considerations / additional information Continued over page	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

Special considerations / additional information (continued)	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.
Record	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.

6. Key references

Key references	**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 **General** • 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

7. Practitioner authorisation sheet

Shingrix PGD PGD v01.00 Valid from: 01/09/2021 Expiry: 31/08/2023

Before signing this patient group direction (PGD), check that the document has had the necessary authorisations in section two. Without these, this PGD is not lawfully valid.

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 **INSERT NAME OF ORGANISATION:** 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.