Public Health England

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PATIENT GROUP DIRECTION (PGD)

Administration of Zostavax® reconstituted lyophilised suspension.
Shingles (*herpes zoster*) vaccine, live

Adults who are eligible for the national shingles immunisation programme

For the administration of Zostavax® reconstituted lyophilised suspension (shingles vaccine, live) by nurses currently registered with the Nursing and Midwifery Council (NMC), to adults who are eligible for the national shingles immunisation programme, for the prevention of herpes zoster ("zoster" or shingles) and herpes zoster-related post-herpetic neuralgia (PHN).

Reference no:	*Shingles PGD*
Version no:	*v02.00*
Valid from:	*1 September 2015*
Review date:	*1 May 2016*
Expiry date:	*31 August 2016*

Public Health England has developed this PGD for local authorisation by NHS England to facilitate delivery of the National Immunisation Programme.

Those using this PGD must ensure that it is formally authorised and signed by a clinical governance or patient safety lead, who has designated responsibility for signing PGDs on behalf of NHS England for their geographical area, so that this document meets legal requirements for a PGD. **THE PGD IS NOT LEGAL OR VALID WITHOUT THIS LOCAL, FORMAL AUTHORISATION.**

Authorising organisations must not alter or amend the body of this document; such action will invalidate the clinical sign-off with which it is provided.

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

THE PRACTITIONER 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 local authorisation can be found from:
https://www.gov.uk/government/collections/immunisation
Any concerns regarding the content of this PGD template should be addressed to:
Immunisation@phe.gov.uk

Change history

Version number	Change details	Date
Final Version – revised 27 Aug 2013	New PHE PGD	Valid from 1 Sept 2013
Version 02.00	• PHE Shingles PGD transferred to new PHE PGD Template • Complete document review with multiple changes to text	4 June 2015

1. PGD Template Development

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

Developed by:	Name	Signature	Date
Pharmacist (Lead Author)	Elizabeth Graham Lead Pharmacist Immunisation Services, PHE		04/06/2015
Doctor	Mary Ramsay Consultant Epidemiologist and Head Immunisation, Hepatitis & Blood Safety Department, PHE		04/06/2015
Registered Nurse	David Green Nurse Consultant – Immunisations, PHE		04/06/2015

This PGD template has been peer reviewed by the PHE Immunisations PGD Expert Panel in accordance with PHE Policy for PGD Templates. It has been ratified by PHE Medicines Management Group and PHE Clinical Governance Group.

Acknowledgements

Name	Designation
Gayatri Amirthalingam	Consultant Epidemiologist, Public Health England
Dr Max Kammerling	Screening and Immunisations Lead (SIL) – Surrey and Sussex
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Lesley McFarlane	Screening and Immunisation Co-ordinator (SIC) NHS England Leicestershire and Lincolnshire
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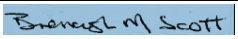
2. Organisational Authorisations

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 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 London Region authorise this PGD for use by the services or providers listed below:

Authorised for use by the following organisations and/or services
This PGD must only be used by nurses working for providers that are directly commissioned by NHS England (London Region), who have been named and authorised to practice under it.
Limitations to authorisation

Organisational Approval (legal requirement)			
Role	**Name**	**Sign**	**Date**
Deputy Chief Nurse, NHS England London Region	**Bronagh Scott**		**31/07/15**

Additional signatories according to locally agreed policy			
Role	**Name**	**Sign**	**Date**
Assistant Head of Quality (Out of Hospital Care), , NHS England London Region	**Eileen Bryant**		28/07/2015
Pharmacy Advisor, NHS England London Region	**Tony Carson**		27/07/2015

Organisations must add an Individual Practitioner Authorisation sheet or List of Authorised Practitioners. This varies according to local policy but this should be a signature list or an individual agreement as included at the end of this PGD.

3. Characteristics of Staff

Qualifications and professional registration	Nurses currently registered with the Nursing and Midwifery Council (NMC).
Additional requirements	• Must be authorised by name as an approved practitioner under the current terms of this Patient Group Direction 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 patient group directions). • Must be familiar with the vaccine product and alert to changes in Summary Product Characteristics, 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 for Immunisation Training (2005). • 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. • Have access to the Patient Group Direction and associated online resources. • Should fulfil any additional requirements defined by local policy. **THE 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 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	Zostavax® is indicated for vaccination of adults who are eligible for the national shingles immunisation programme for the prevention of herpes zoster ("zoster" or shingles) and herpes zoster-related post-herpetic neuralgia (PHN) in accordance with the recommendations given in Chapter 28a of *Immunisation Against Infectious Disease: The Green Book.*
Criteria for inclusion	**Routine Cohort (2015/16)** • Adults aged 70 years on 1st September 2015 **Catch-up cohort (2015/16)** • Patients aged 78 years old on 1st September 2015 who have not previously had a dose of shingles vaccine. • Patients who were previously eligible for shingles vaccine under this programme, who have not been immunised with shingles vaccine, until their 80th birthday (ie patients aged 71, 72 and 79 years on 1st September 2015).

Criteria for exclusion[1]
 	
Criteria for exclusion (continued over page)
	• Patients for whom no valid consent has been received
	Patients who:
	• Are under 70 years of age on 1st September 2015
	• Are 80 years of age or over, even if they were previously in an eligible cohort
	• Are between 73 and 77 years of age inclusive on 1st September 2015
	• Have had a confirmed anaphylactic reaction to a previous dose of varicella vaccine;
	• Have had a confirmed anaphylactic reaction to any component of the vaccine, including neomycin or gelatin;
	• Have active untreated tuberculosis
	• Have active infection with shingles or post-herpetic neuralgia
	• Are pregnant
	• Have primary or acquired immunodeficiency state due to conditions such as:
	  ○ acute and chronic leukaemias;
	  ○ lymphoma;
	  ○ current or recent treatment of malignant disease;
	  ○ immunosuppression due to HIV/AIDS;
	  ○ cellular immune deficiencies;
	• Remain under follow up for lymphoproliferative disorders including haematological malignancies such as indolent lymphoma, leukaemia or plasma cell myeloma. Although not exhaustive, examples of these malignancies may include acute and chronic lymphocytic leukaemia, follicular lymphoma or multiple myelomas.
	• Are receiving or have received immunosuppressive therapy including high-dose corticosteroids (40 mg prednisolone per day

[1] Exclusion under this Patient Group Direction does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation will be required

Criteria for exclusion (continued)	for more than one week), biological therapies or combination therapies in the last 6 months (see "The Green Book" for information on when vaccination may be indicated for these individuals under PSD). **Zostavax® is not contraindicated** for use in individuals who are receiving topical/inhaled corticosteroids, low-dose systemic corticosteroids (<40mg per day of prednisolone), corticosteroid replacement therapy or other low-dose immunosuppressive therapy (methotrexate <0.4 mg/Kg/week, azathioprine <3.0 mg/Kg/day, or 6mercaptopurine <1.5 mg/Kg/day). **Exclusions from PGD** There are limited data on the safety and efficacy of Zostavax® in patients with the following conditions. In such cases, the patient's General Practitioner (GP) and/or specialist clinician should assess the patient and can issue a **Patient Specific Direction (PSD)** or administer the vaccine themselves where the benefits of vaccination outweigh any potential risk. • HIV infection • Patients who have undergone immunosuppressive chemotherapy or radiotherapy for malignant disease • Past history of lymphoproliferative disorder • Therapy with a single, low-dose, non-biological oral immune modulating drug, either alone or with low dose steroids, for treatment of rheumatoid arthritis, psoriasis, polymyositis, sarcoidosis, inflammatory bowel disease, and other conditions. Examples of such therapies include methotrexate (<0.4mg/kg/week), azathioprine (<3.0mg/kg/day), or 6-mercaptopurine (<1.5mg/kg/day). In these individuals, the degree of immunosuppression should be assessed on a case by case basis. **Temporary Exclusion** • Acute severe febrile illness – postpone administration until completely recovered. • Immunocompetent individuals who have developed shingles in the last 12 months – defer vaccination. • S**ystemic** therapy with anti-viral medicines, such as aciclovir, - administration of Zostavax® should be delayed until at least 48 hours after treatment is completed, as these medicines may reduce the response to the vaccine. The use of topical aciclovir is not a contraindication to vaccination. • MMR vaccine administered less than 4 weeks ago – defer vaccination until 4 weeks or more post MMR vaccination

Cautions including any relevant action to be taken	**Transmission** Transmission of vaccine virus may occur rarely between those vaccinated and susceptible contacts, even in the absence of a varicella-like rash. Individuals who do develop a varicella-like rash after vaccination with Zostavax® should avoid direct contact with a susceptible (chicken pox naïve) person until the rash is dry and crusted. In the event of a person developing a varicella (widespread) or shingles-like (dermatomal) rash post-Zostavax®, a vesicle fluid sample should be sent for analysis, to confirm the diagnosis and determine whether the rash is vaccine-associated. Please see Chapter 28a of *Immunisation Against Infectious Disease: The Green Book* for more details.
Action to be taken if the patient is excluded	If in the eligible age group, but excluded on medical grounds as above, seek appropriate advice from the local Screening and Immunisation Team, a Consultant in Health Protection or the patient's clinician, as a PSD may be indicated. The risk to the individual of not being vaccinated must be taken into account. Document reason for exclusion and any action taken in patient's clinical records. In a GP practice setting, inform or refer to the GP. **Temporary exclusion** When administration is postponed arrange a future date for vaccination as appropriate, with due consideration of the patients age to ensure they will meet the inclusion criteria for immunisation. If vaccination cannot be given before the patient is 80 years old explain why vaccination will no longer be indicated.
Action to be taken if the patient or carer declines treatment	Informed consent, from the patient or a person legally able to act on the patient's behalf, must be obtained prior to administration. Advise patient/carer about the protective effects of the vaccine, the risks of infection and potential complications. Document advice given and decision reached. In a GP practice setting, inform or refer to the GP.
Arrangements for referral for medical advice	As per local policy

5. Description of Treatment

Name, strength & formulation of drug	Zostavax®, Shingles (herpes zoster) vaccine (live), powder and solvent for suspension for injection in a pre-filled syringe. After reconstitution, Zostavax® lyophilised suspension (0.65mL) contains **Shingles (herpes zoster) vaccine**, consisting of live attenuated virus derived from **varicella zoster** virus.
Legal category	Prescription Only Medicine (POM).
Black Triangle▼	No.
Off-label use	Yes, only with respect to concomitant use of pneumococcal vaccine, see section on drug interactions below.
Route / method of administration	Following reconstitution, Zostavax® vaccine is given as a single dose by **subcutaneous injection**, preferably in the deltoid region of the upper arm. Zostavax® should **NOT** be injected intramuscularly or intravascularly. When administering at the same time as other vaccines care should be taken to ensure that the appropriate route of injection is used for all the vaccinations. The vaccines should be given at separate sites, preferably in different limbs. If given in the same limb, they should be given at least 2.5cm apart. The site at which each vaccine was given should be noted in the individual's records. It is recommended that the vaccine be administered immediately after reconstitution, to minimize loss of potency. Discard reconstituted vaccine if it is not used within 30 minutes. Note: • The product must not be mixed with other medicinal products in the same syringe • Avoid contact with disinfectants • When reconstituted, Zostavax® is a semi-hazy to translucent, off-white to pale yellow liquid. Discard the vaccine if there is any particulate matter present or the appearance of solvent or reconstituted vaccine differs from this description. The Summary of Product Characteristics for Zostavax® provides further guidance on administration and is available from the electronic Medicines Compendium website: http://www.medicines.org.uk/EMC/medicine/25927/SPC/Zostavax/
Dose and frequency of administration	Single dose of 0.65mL of reconstituted Zostavax® vaccine.
Duration of treatment	Single Dose
Quantity to be supplied / administered	Single 0.65mL dose of reconstituted Zostavax® vaccine

Supply	Centrally purchased vaccines for the national immunisation programme for the NHS can only be ordered via ImmForm and are provided free of charge to NHS organisations.
Storage	Store in a refrigerator at +2°C to +8°C. Store in original packaging in order to protect from light. Do not freeze Avoid contact with disinfectants. Shelf life is 18 months After reconstitution the vaccine should be used immediately. However, the in-use stability has been demonstrated for 30 minutes when stored at 20°C - 25°C.
Disposal	Equipment used for immunisation, including used vials, ampoules, or partially discharged vaccines in an oral applicator, should be disposed of at the end of a session by sealing in a proper, puncture-resistant 'sharps' box, according to local authority regulations and guidance in the technical memorandum 07-01 (Department of Health, 2013).
Drug Interactions[2]	None reported. Zostavax® can be given at the same time as inactivated influenza vaccine. Zostavax® can also be given at the same time as 23-valent pneumococcal vaccine**;** Such administration is off-label but recommended in the "Green Book" following assessment of the evidence concluding that there is no reduction in the effectiveness of Zostavax®. In the rare event that MMR vaccine is indicated in this age group it should be administered on the same day, or a four week minimum interval period should be observed. Other live vaccines can be administered at any time before or after Zostavax®. There is no data on concomitant use with anti-viral medications but it is likely that these will reduce the response to Zostavax® - see exclusions.
Identification & Management of Adverse Reactions[3]	The most common adverse reactions observed after administration of Zostavax® vaccine are injection site reactions, including redness, swelling, pain and itching. Other relatively common reactions include bruising, hardening (induration) and warmth at the injection site, headache and pain in the relevant limb. Very rarely a varicella (chickenpox) - like illness has been reported. In the event of a person developing a varicella (widespread) or shingles-like (dermatomal) rash post-Zostavax®, a vesicle fluid sample should be sent for analysis, to confirm the diagnosis and determine whether the rash is vaccine-associated. A detailed list of adverse reactions associated with Zostavax® is available in the Summary of Product Characteristics for this vaccine, which is available from electronic Medicines Compendium website: www.medicines.org.uk

[2] Refer to British National Formulary (BNF) and Summary of Product Characteristics (SPC) for complete list

Reporting procedure of Adverse Reactions	As with all vaccines, healthcare professionals and patients/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: http://yellowcard.mhra.gov.uk Any adverse reaction to the vaccine should be documented in the patient's record. The patient's GP should also be informed.
Written information to be given to patient or carer	Supply marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine.
Patient advice /Follow up treatment	Inform patient/carer of possible side effects and their management. Give advice regarding normal reaction to the injection, for example redness and pain at the injection site. The patient/carer should be advised to seek medical advice in the event of a severe adverse reaction. Patients should be advised to seek medical attention if they develop a varicella (widespread) or shingles-like (dermatomal) rash post-Zostavax® so that their clinician may test vesicle fluid from the rash to confirm the diagnosis and determine whether the rash is vaccine-associated. When administration is postponed advise the patient when to return for vaccination with due consideration of the patients age to ensure they will meet the inclusion criteria for immunisation. If vaccination cannot be given before the patient is 80 years old explain why vaccination will no longer be indicated.
Special Considerations / Additional Information	Immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a telephone. Minor illnesses without fever or systemic upset are NOT valid reasons to postpone immunisation. In cases of acute severe febrile illness, postpone administration until completely recovered. Please note: • The risk and severity of shingles is much higher in immunosuppressed individuals so ideally those eligible should receive Zostavax® preferably one month and at least 14 days before commencing immunosuppressive therapy; • All immunosuppressed individuals who are inadvertently vaccinated with Zostavax® require urgent assessment and may need to receive prophylactic aciclovir. Immunosuppressed individuals who develop a varicella rash following inadvertent vaccination can be offered prompt treatment with aciclovir. Please see Chapter 28a of *Immunisation Against Infectious Disease: The Green Book* for more details.

Records	Record: • That valid informed consent was given • Name of patient, address, date of birth and GP with whom the patient is registered • Name of member of staff who administered the vaccine • 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 • Record administered via Patient Group Direction (PGD) • Records should be signed and dated (or password controlled immunisers record on e-records) All records should be clear, legible and contemporaneous. This information should be recorded in the patients GP record and any other appropriate medical records eg care or nursing records. A record of all individuals receiving treatment under this Patient Group Direction should also be kept for audit purposes in accordance with local policy.

6. Key References

Key references	**Shingles** • Zostavax® Summary of Product Characteristics. Sanofi Pasteur MSD. Updated 7 May 2015 http://www.medicines.org.uk/emc/medicine/25927 • Immunisation Against Infectious Disease: The Green Book, Chapter 28a Updated May 2015 (pending publication) • Enhanced Service Specification: Shingles (catch-up) vaccination programme 2015/16. Published 9 March 2015 http://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2015/03/shingles-catch-up-spec-fin.pdf • Shingles: Guidance and Vaccination Programme. Updated 4 December 2014 https://www.gov.uk/government/collections/shingles-vaccination-programme • Revised recommendations for the administration of more than one live vaccine. Public Health England. 24 April 2015 https://www.gov.uk/government/publications/revised-recommendations-for-administering-more-than-1-live-vaccine **General** • PHE Immunisation Collection. Updated 9 December 2014 https://www.gov.uk/government/collections/immunisation • British National Formulary (BNF) May 2015 www.BNF.org https://www.medicinescomplete.com/mc/bnf/current/PHP8418-varicellazoster-vaccines.htm • National Minimum Standards for Immunisation Training (2005) https://www.gov.uk/government/publications/immunisation-training-national-minimum-standards • NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions Published August 2013 https://www.nice.org.uk/guidance/mpg2 • NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. 11 February 2014 https://www.nice.org.uk/guidance/mpg2/resources/mpg2-patient-group-directions7 • Competency Framework – assessment tool (Appendix). Supporting the delivery of immunisation education. Royal College of Nursing (RCN) 2013. http://www.rcn.org.uk/__data/assets/pdf_file/0005/553748/004479.pdf • 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

7. Individual Practitioner Authorisation sheet

BY SIGNING THIS PATIENT GROUP DIRECTION YOU ARE INDICATING THAT YOU AGREE TO ITS CONTENTS AND THAT YOU WILL WORK WITHIN IT

PATIENT GROUP DIRECTIONS 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

Practitioner

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

Signed……..……..Date…….…….....

Name (Print)……..……..…….…….…….....

Designation……..…….....

Authorising Manager

Manager to give authorisation on behalf of **INSERT NAME OF ORGANISATION** for the named Health Care Professional who has signed the PGD

Signed…….……. Date…….....

Name (Print)……..……..……..…….....

Designation……..…….…….....

Note to Authorising Manager

By signing above you are confirming that you have assessed the staff member as competent to work under this PGD and that they have the organisational approval to do so

You must give this signed PGD to each Authorised Practitioner as it shows their authorisation to use the PGD