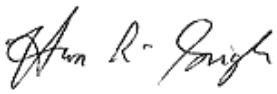
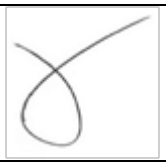
Patient Group Direction (PGD) for the Administration of

SHINGLES (Herpes Zoster) VACCINE

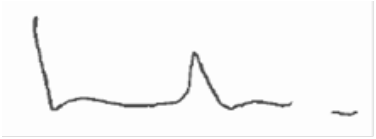
by Registered Professionals to Individuals Accessing NHS Services in
Durham, Darlington, Tees, North Cumbria, Northumberland and Tyne & Wear

YOU MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE YOU ATTEMPT TO WORK ACCORDING TO IT.

Direction Number: - **NECSAT 2018/016**
Valid from: 1st September 2018
Review date: 1st May 2020
Expiry date: 31st August 2020

This patient group direction has been developed & produced by: -			
Title	Name	Signature	Date
Medicines Optimisation Pharmacist (Lead Author) (North of England Commissioning Support)	**Hira Singh** *(Senior Pharmacist)*		21/08/2018
Medicines Optimisation Pharmacist (North of England Commissioning Support)	**Sue White** *(Senior Pharmacist)*		21/08/2018
Immunisation and Screening Manager (NHS England, Cumbria and North East)	**Veronica Latham** *(Senior Nurse)*		20/08/2018
Assistant Medical Director (NHS England, Cumbria and North East)	**Dr James Gossow** *(Senior Doctor)*		24/08/2018

Development supported by Nykola Goodwill (Immunisation and screening coordinator, Cumbria & North East))

This PGD has been approved for use in Cumbria and North East Sub Region (NHS England) by:			
Title	Name	Signature	Date
Deputy Medical Director (NHS England Cumbria and North East)	**Dr Jonathan Slade** *(Governance Authorisation)*		25/08/2018

1. Clinical Condition or Situation to Which the Direction Applies

Indication (defines situation or condition)

Immunisation of adults against shingles as part of the current national immunisation programme

Objectives of care

- To lower the incidence and severity of herpes zoster (shingles) disease in adults aged 70 years and above, in whom the risk and severity of disease and of subsequent post herpetic neuralgia (PHN) is higher

Inclusion criteria (as per Public Health England (PHE) Green Book Guidance

Only use those criteria that are specific to your authorised role & competence.
Ensure appropriate consent /best interest decision is in place before commencing any vaccination.

Current PHE immunisation schedule recommends the vaccine should be offered to : -

- patients aged 70 years, on or after their 70th birthday
- patients aged 78 years, on or after their 78th birthday
- patients who were eligible for immunisation in the previous programme years but have not yet been vaccinated against shingles. These are:
    - anyone in their 70s who was born on or after 02/09/1942
    - 79 year olds (until their 80th birthday).

Please note the following important inclusion points

- are must be taken not to miss the patients who have already turned 70 or 78 years of age since 2nd Sept. 2017.
- Patients remain eligible until their 80th birthday. The programme does not offer patients the vaccine after they become 80 due to the reducing efficacy of the vaccine as age increases.
- The shingles vaccine can now be offered opportunistically to patients throughout the year as they become of eligible age, i.e. 70 or 78 years of age at any point in the year following their 70th or 78th birthday.

Exclusion criteria

General exclusions *(Refer to current Summary of Product Characteristics (SPC) &/or BNF for full list of details)*: -

- No valid consent; /best interest decision in place
- Has an active untreated TB infection;
- Are pregnant;
- Are under 70 years of age;
- Are 80 years old and over (even if they were previously in an eligible cohort)
- Are not and have not previously been in an eligible cohort for the national immunisation programme
- Patient is acutely unwell (postpone vaccination until recovered. Minor infections without fever or systemic upset are not reasons to postpone immunisation).
- Have had a confirmed anaphylactic reaction to a previous dose of varicella containing vaccine; to any component of the vaccine; or to any substance carried over from manufacture including neomycin or gelatin. Practitioners must check the manufacturers SPC.
- Severe hypersensitivity to any ingredient or component of the vaccine(s) – (please also refer to precautions section).
- Immunocompetent individuals who have developed shingles in the last 12 months – defer vaccination.
- Have active infection with shingles or post-herpetic neuralgia within the last 12 months (see also precautions section).

Exclusion criteria continued

- Have primary or acquired immunodeficiency state due to conditions such as: acute and chronic leukaemias; lymphoma (including Hodgkin's lymphoma); immunosuppression due to HIV/AIDS; cellular immune deficiencies; those remaining under follow up for a lymphoproliferative disorder including haematological malignancies such as indolent lymphoma, chronic lymphoid leukaemia, myeloma and other plasma cell dyscrasias (Note: this list is not exhaustive); solid organ or stem cell transplant (see "The Green Book" chapter 28a for information on when vaccination may be indicated for these individuals under PSD).
- Are currently receiving immunosuppressive or immunomodulating therapy including:
  - those with renal failure, stage 4 or 5 CKD, who are receiving or have received in the past 3 months any immunosuppressive therapy (due to potential reduced clearance of immunosuppressive therapies)
  - those who are receiving or have received in the past 6 months immunosuppressive chemotherapy or radiotherapy for malignant disease or non-malignant disorders,
  - those who are receiving or have received in the past 12 months biological therapy (e.g. anti-TNF therapy such as alemtuzumab, ofatumumab, rituximab, etanercept or infliximab), unless otherwise directed by a specialist
  - those who are receiving or have received in the past 3 months immunosuppressive therapy including:
    i) short term high-dose corticosteroids (>40mg prednisolone per day for more than 1 week);
    ii) long term lower dose corticosteroids (>20mg to ≤40mg prednisolone per day for more than 14 days)
    iii)non-biological oral immune modulating drugs e.g. methotrexate >25mg per week, azathioprine >3.0mg/kg/day or 6-mercaptopurine >1.5mg/kg/day

  (see below** and "The Green Book" chapters 6 & 28a for further guidance and more 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 or corticosteroid replacement therapy. Long term stable low dose corticosteroid therapy (defined as ≤20mg prednisolone per day for more than 14 days) either alone or in combination with low dose non-biological oral immune modulating drugs (e.g. methotrexate ≤25mg per week, azathioprine ≤3.0mg/kg/day or 6-mercaptopurine ≤1.5mg/kg/day) are not considered sufficiently immunosuppressive and these individuals can receive the vaccine under this PGD unless they also have impaired renal function (see above). Specialist advice should be sought for other treatment regimes.
- Are within 14 days of commencement of immunosuppressive therapy (Note: individual may be able to receive the vaccine under PSD following specialist advice).
- Those currently receiving systemic therapy with anti-viral medicines, such as aciclovir. NB. Administration of Zostavax® should be delayed until 48 hours after treatment is completed, as these medicines may reduce the response to the vaccine.
- Have had MMR vaccine administered within the last 4 weeks– defer vaccination for at least 4 weeks after MMR vaccination

Refer to current SPC/ Green Book (current on-line version)/ BNF for full list of details

Precautions

- Zostavax® is not recommended for the treatment of shingles or post herpetic neuralgia (PHN). Individuals who have shingles or PHN should wait until symptoms have ceased before being considered for shingles immunisation. The natural boosting that occurs following an episode of shingles, however, makes the benefit of offering zoster vaccine immediately following recovery, limited. Ideally, shingles vaccine should be delayed until therapy with anti-viral drugs, such as aciclovir is completed as they may reduce response to the vaccine. The use of topical aciclovir is not a contraindication to vaccination.
- As a precautionary measure, any person who develops a vesicular rash after receiving Zostavax® should avoid direct contact with a susceptible (chickenpox naïve) person until the rash is dry and crusted.

Precautions - continued

- The decision to administer Zostavax to an individual should be based on obtaining complete clinical information to undertake the assessment. If the individual is under highly specialist care, and it may not be possible to obtain full information on that individual's treatment history, then vaccination should not proceed until the advice of the specialist or a local immunologist has been sought.
- Immunosuppressed individuals who are inadvertently vaccinated with Zostavax should be urgently assessed to establish the degree of immunosuppression.
- Immunosuppressed individuals who develop a varicella rash following inadvertent vaccination should be urgently assessed and offered prompt treatment with aciclovir, given the risks and severity of disseminated zoster. Please refer to PHE Information for Healthcare professionals for further information on action to take in the event of development of a vesicular rash following Zostavax administration).
- As a precautionary measure, any person who develops a vesicular rash after receiving Zostavax should ensure the rash area is kept covered when in contact with a susceptible (chickenpox naïve) person until the rash is dry and crusted. If the person who received the vaccine is themselves immunosuppressed, they should avoid contact with susceptible people until the rash is dry and crusted, due to the higher risk of virus shedding.
- Hypersensitivity reactions to previous dose of vaccine or component of vaccine:
  - NB. "Local adverse reactions that generally start within a few hours of the injection are usually mild and self-limiting. Although these are often referred to as 'hypersensitivity reactions', they are not allergic in origin, but may be either due to high titres of antibody or a direct effect of the vaccine product, e.g. endotoxin in whole-cell bacterial vaccines. The occurrence or severity of such local reactions does not contraindicate further doses of immunisation with the same vaccine or vaccines containing the same antigens."

Action if excluded

- Discuss with or refer to clinician/doctor. Ensure all actions/decisions are documented.
- The risk to the individual of not being immunised must be taken into account.
- If postponement due to acute illness, arrange a future date for immunisation.

Circumstances in which further advice should be sought from a doctor and/or specialist

- Patient meeting the exclusion criteria
- Patient requires additional information in order to decide whether or not to have the vaccination
- A Best Interest decision is required for an individual who lacks mental capacity to consent. Seek support from lead clinician responsible for individuals care.
- The safety and efficacy of Zostavax® have not been established in adults who are known to be infected with HIV with or without evidence of immunosuppression (see contraindications). Immunosuppressed patients who require protection against shingles should seek advice from a specialist.

Action if vaccination refused

- Ensure patient/guardian/carer fully understands the risks of declining vaccination.
- Advise about protective effects of vaccine & the risks of infection and disease complications If postponement due to acute illness, arrange a future date for immunisation
- Document refusal, advice given, actions/decisions in notes (written or electronic). Inform or refer to doctor as appropriate

Special Considerations / Additional Information

- Discard reconstituted vaccine if it is not used within 30 minutes
- Zostavax® should be administered with caution to individuals with immuno-deficient close contacts, such as individuals with malignancies, or who are otherwise immuno-compromised or individuals receiving immunosuppressive therapy. (See precautions section).

Concomitant administration with other vaccines

- Zostavax® can be given at the same time as inactivated influenza vaccine. Care should be taken to ensure that the appropriate route and site of injection is used for all the vaccinations and to check there are no contra-indications in administering a live vaccine to individuals presenting for seasonal influenza vaccination.
- Zostavax® can be administered at the same time as the PPV-23 or four weeks apart from PPV-23. (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 then they should be administered on the same day, or if this is not possible then a four week minimum interval should be observed. In line with PHE advice (April 2015), there are no other restrictions for timing between Zostavax and other live vaccines currently used.
- Zostavax® can be administered concomitantly with other live vaccines. Where more than one vaccine is administered at the same time, the vaccines should be given at a separate site, preferably at different body sites or at least 2.5cm apart (See also Green Book chapter 28a).

Other information

- 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 acyclovir, particularly if they develop a varicella rash. (See Precautions section).

2. Description of treatment

Name, strength & formulation of drug

- Zostavax® (Herpes Zoster or shingles) vaccine is available as a vial and a pre-filled syringe, Zostavax® (Herpes Zoster) vaccine (live), powder & solvent for suspension for injection
- Zostavax® (Herpes Zoster) vaccine (live), powder & solvent for suspension for injection (in a pre-filled syringe)
  - The powder is a white to off white powder compact crystalline plug. The solvent is a clear colourless fluid.

Once reconstituted:
1 dose (0.65ml) contains Varicella-zoster virus (live, attenuated) as a semi-hazy to translucent, off white to pale yellow liquid.

Legal Status:

POM –Prescription Only Medicines

Dosage / Dose range

0.65ml (1 single dose)

Route / Method (Please refer to the manufacturer's SPCs and on line version of the Green Book for detailed information).

- To be administered by INTRAMUSCULAR (IM) or subcutaneous (SC) injection, preferably in the deltoid region of the upper arm.
- IM injection is the preferred route of administration, as injection-site adverse reactions were significantly less frequent in those who received the vaccine via this route of administration.
- Zostavax® should not be administered by intra-vascular injection.
- For individuals with a bleeding disorder Zostavax® should be given by deep subcutaneous injection
- After reconstitution of the lyophilised suspension, the vaccine should be used immediately, but may be used up to 30 minutes following reconstitution.

Frequency of Administration

One dose (0.65ml) only

Maximum dose

One dose (0.65ml)

Follow up treatment

Follow current Green Book recommendations as applicable

3. Further Aspects of Treatment

Relevant Warnings & Potential Adverse Effects

Relevant Warnings: - See manufacturers SPC for full details / current Green Book online Chapter 28a

Potential Adverse Effects/ Reactions: - Usually transient and only last a few days after vaccination.

Please be aware of Resuscitation Council Guidelines

Very common & common reactions	• Injection site reactions (erythema, pain, swelling, pruritus, haematoma, induration and warmth); rash. • Headache, Pain in arm or leg
Uncommon effects & rare reactions	• Varicella (chicken pox) like illness; Nausea, pyrexia. • Anaphylaxis

This list is not exhaustive. Please also refer to current manufacturers SPC for details of all potential adverse reactions.

Identification and Management of Adverse Reactions

- Patient/ Carer / Guardian requested to report side effects
- Individuals 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.
- Advice on management including anaphylaxis: - Chapter 8 of the Green Book provides detailed advice on managing adverse drug reactions (ADRs) following immunisation, e.g. Analgesia for pain &/or fever; prevention of dehydration; drinking plenty of clear fluids).
- Refer to doctor/specialist as appropriate

Reporting Procedure of Adverse Effects

- Report to doctor if appropriate & document in patient's medical records.
- All adverse reactions due to ▼ vaccines should be reported to the MHRA using the yellow card system.
- For established vaccines only report serious adverse reaction. Please refer to www.mhra.gov.uk/yellowcard and the online Green Book - Chapter 9.

Advice to Patient / Carer (verbal or written)

- Explain protection level expected from vaccine.
- Provide a patient information leaflet and discuss as required.
- Provide advice on & explain potential warnings & side effects and request to report them if they occur.
- Provide advice on management of adverse reactions (see above and manufacturers SPC).
- Explain procedure for dealing with anaphylaxis /severe allergic reactions.
- Explain the "Out of Hours" procedure. Give date of next vaccine if applicable.
- Provide patient with vaccination record card (to include date of next vaccination, completion of course or blood test) if applicable.
- Complete patient-held vaccination record (where applicable)

Arrangements for Referral to Medical Advice

- Doctor/specialist appointment as and when appropriate

Records

In all cases manual records, computerised records and data collection should include: -

- Patient's name and date of birth;
- Reason vaccination required;
- Date of administration;
- Confirmation that consent has been obtained;
- Dose, site and route of injection;
- Brand name, batch number and expiry date of vaccine;
- Whom administered by and signature of vaccinator (if not recorded on computer).
- Confirmation that there are no contraindications; That side effects have been discussed;
- Support literature given (where applicable);
- Signature and printed name and designation (in black ink) for paper records. For computer records, ensure data authentication of practitioner delivering care.

Additional Facilities

- Access to updated online Green Book information; the latest SPC and BNF.
- Store in a refrigerator (+2°C to +8°C). Have access to a telephone.
- Stock control & storage of vaccines in accordance with national and local policies / protocols/ guidelines.
- Emergency equipment available including immediate access to Epinephrine (Adrenaline) 1in 1000 injection (as a minimum). (Please refer to PGD for adrenaline as applicable)

References

- NICE Good Practice Guidance 02 : Patient Group Directions Aug 2013
- Public Health England: Shingles immunisation programme from 1 September 2015 – letter 3rd Aug 2015 NHS England Gateway Number: 03842; PHE Gateway Number: 2015-204
- Public Health England (PHE): Vaccination against Shingles: Information for healthcare professionals (March 2018)Public Health England *(2013):* Immunisation Against Infectious Disease - The "Green Book" Chapter 28a: Shingles (herpes zoster) (Feb 2016). Accessed at https://www.gov.uk/government/publications/shingles-herpes-zoster-the-green-book-chapter-28a on 20th April 2017
- Current British National Formulary (BNF),
- Nursing and Midwifery Council (NMC), 2007: Standards for Medicines Management.
- Nursing and Midwifery Council (NMC), 2007: Record Keeping Advice Sheet.
- Nursing and Midwifery Council (NMC), 2008: Code of Professional Conduct: standards of conduct, performance & ethics for nurses and midwives.
- Resuscitation Council (UK), October 2015: Emergency Medical Treatment of anaphylactic reaction by first medical responders and community nurses. www.resus.org.uk/siteindx.htm
- MSD Ltd; Zostavax vaccine - Summary of Product Characteristics (SPC), 15/01/2018 (accessed from Electronic Medicines Compendium on 20/08/2018).

4. Characteristics of Healthcare Professional Staff

Only those healthcare professionals that have been specifically authorised by their clinical lead/supervisor/manager may use this PGD for the indications defined within it.

Under current legislation, only the following currently registered healthcare professionals may work under Patient Group Directions (PGDs). These professionals may only supply or administer medicines under a PGD as named individuals. These professionals include -

Pharmacists	Nurses	Chiropodists/Podiatrists
Health Visitors	Physiotherapists	Midwives
Dieticians	Optometrists	Registered Orthoptists
Prosthetists and Orthotists	Radiographers	Occupational Therapists
Speech and Language Therapists	Dental Hygienists	Dental Therapists
State registered paramedics or individuals who hold a certificate of proficiency in ambulance paramedic skills issued by the Secretary of State, or issued with his approval.		

Qualifications required (professional registration applies to specific professions)

Professionals using this PGD must be currently registered with their relevant professional body, e.g.

- For Nurses: - Nursing & Midwifery Council (NMC)
- For Pharmacists: - General Pharmaceutical Council (GPhC)
- For Allied Health Professionals: - Health Professions Council

Additional requirements (applies to all staff)

- Maintain knowledge of vaccinations; either through a recognised course or through in-house training supported by attendance at vaccination study day(s).
- Meet the National minimum standards & competencies in immunisation training as defined in the PHE & RCN publication, "National Minimum Standards and Core Curriculum for Immunisation Training for Registered Healthcare Practitioners (February 2018)," either through training or professional competence ensuring that annual training is offered to all staff
- Have up to date resuscitation skills and anaphylaxis training (and competent to recognise & manage anaphylaxis).
- Competent to undertake immunisations and have a current authorised Adrenaline PGD.
- Will have undertaken training in the role, care and administration of the medicine specified in the PGD.
- Have access to a current BNF and *Immunisation Against Infectious Disease* (Green Book online version).
- Any additional training requirements as deemed necessary by your organisation or authorising body.

Continued training requirements (applies to all staff)

- Annual attendance at an update on resuscitation skills and the management of anaphylaxis within the community/primary care (mandatory).
- Maintenance of own level of updating and competence with evidence of continued professional development.
- Annual updates in immunisation (recommended).
- Any continued training requirements as deemed necessary by your organisation or the authorising body.

Individual Healthcare Professional Authorisation

This form can be used for the purpose of managing, monitoring and authorising the use of this Patient Group Direction by the named healthcare professional.

- **This page is to be retained by the individual healthcare professional/practitioner.**
- This PGD is to be read, agreed to and signed by all registered Healthcare Professionals it applies to. Healthcare Professionals must be authorised by the person(s) named below before using the PGD.
- By signing this document, the healthcare professional confirms that they understand the PGD, that they are competent to work under this PGD, that they will practice in accordance with the parameters of the PGD and accept full clinical responsibility for any decisions made with using this PGD).
- Patient Group Directions should be used in conjunction with reference to national or local policies, guidelines or standard text (e.g. manufacturers Summary of Product Characteristics) and DO NOT replace the need to refer to such sources.

Name of Healthcare Professional:-_____

I have read and understood the Patient Group Direction.

SHINGLES (Herpes Zoster) VACCINE

I agree to administer Shingles vaccine only in accordance with this Patient Group Direction (NECSAT 2018/016)

Signature of Healthcare Professional: - _____

Date signed: - _____

State profession: - _____

Authorisation to use this PGD by: -

I agree that the above named healthcare professional is authorised to administer medicines in accordance with this PGD by:

Name of Manager/Clinical Lead: - _____

Signature of Manager/Clinical Lead: - _____

Date signed: - _____

PGD Valid from: 1st Sept. 2018	Review Date: - May 2020	**Expiry Date: - 31st August 2020**

Management & Monitoring of Patient Group Direction NECSAT 2018/016

SHINGLES (Herpes Zoster) VACCINE

Healthcare Professional Authorisation (service/practice list)

This form can be used for the purpose of managing, monitoring and authorising the use of this Patient Group Direction by the named healthcare professionals.

- This page should be signed by all healthcare professionals authorised to use this PGD and retained and kept on file by the service/practice manager as a record of all practitioners authorised to use this PGD

The following healthcare professionals are authorised to administer

Shingles vaccine (Zostavax) under the Patient Group Direction (NECSAT 2018/016)

PGD Valid from date: 1st September 2018 **PGD Expiry Date:** 31st August 2020

Healthcare Professional			**Authorised by:**		
Name	**Signature**	**Date**	**Name**	**Signature**	**Date**

PGD Valid from:- 1st Sept. 2018	Review Date: - May 2020	**Expiry Date: - 31st August 2020**