



Bronllys Hospital, Bronllys, Brecon, Powys, LD3 0LU

This Patient Group Direction (PGD) must only be used by registered healthcare professionals who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used. Healthcare professionals should always access the PGD via the PTHB internet to ensure that they are always working to the most up to date version

Patient Group Direction

for the administration of

23-valent pneumococcal polysaccharide vaccine (PPV23)

by

registered Healthcare Professionals

to

individuals from 65 years of age and individuals from 2 years of age in a clinical risk group in accordance with the national immunisation programme for active immunisation against pneumococcal disease and UK [guidelines](#) for the public health management of clusters of severe pneumococcal disease in closed settings

in

Powys Teaching Health Board

Version number: PGD 0043E

| Change History | | |
|-----------------------|--|-------------|
| Version number | Change details | Date |
| PGD0043 | Initial issue | 1/10/16 |
| PGD0043-A | Review issue in line with PHE template | 01/07/2020 |
| PGD0043-B | Review issue in line with current PHE template | 26/08/2020 |
| PGD0043-C | Review issue in line with Public Health Link from the Chief Medical Officer for Wales CEM/CMO/2021/23, 6 May 2021; new incident reporting system - Once for Wales Reporting System. | 01/07/2021 |
| PGD0043-D | <p>Review issue in line with UKHSA template to:</p> <ul style="list-style-type: none"> include minor rewording of standard text, layout and formatting changes for clarity and consistency with organisation change and other UKHSA PGDs amend NHS England and NHS Improvement (NHSEI) to NHSE following completion of merger on 1st July 2022 remove NHS England DES (2020/21) cohort 64 years turning 65 years old by 31 March statement and related footnote from criteria for inclusion as PPV is now part of General Medical Services Statement of Financial Entitlements Directions 2022/23 (GMS SFE) remove the generic pneumococcal polysaccharide vial from name, dose and strength section as it has been discontinued by manufacturer update supplies section following the change to supply route on 1 July 2021 remove from special considerations section the generic statement from Green Book Chapter 7 regarding the timing of the vaccination in immunosuppressive treatments and aligned it to the specific guidance in Chapter 25 update references <p>Remove the 'order of prioritisation' from the inclusion criteria and appendix D 'priority groups', as this is not included in the UKHSA template.</p> <p>Removal of specific interaction information with COVID 19 vaccines.</p> <p>Addition of safeguarding information.</p> | 01/08/22 |

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| <p>PGD0043E</p> | <p>Review issue in line with UKHSA PGD template v5.00 to:</p> <ul style="list-style-type: none"> • include minor rewording of standard text, layout and formatting changes for clarity and consistency with other UKHSA PGDs • confirm that PPV administration for occupational exposure should be under a Patient Specific Direction (PSD) • include an updated list of known adverse reactions • remove details of specific supply information for PPV (the supply route is now well embedded) • reflect clinical exceptions to the recommended 8 week interval between PCV and PPV vaccination in special considerations and additional information section <p>Reviewed to include minor rewording of standard text, layout and formatting changes for clarity and consistency with other PTHB PGDs</p> | <p>01/09/2024</p> |
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This Powys Teaching Health Board (PTHB) PGD is based on the UKHSA PGD template v5.00 developed by the following on behalf of the UKHSA and peer reviewed by the UKHSA Immunisations PGD Expert Panel in accordance with the UKHSA PGD and Protocol Policy (also ratified by the UKHSA Medicines Governance Committee).

The UKHSA template has been adapted for use in PTHB.


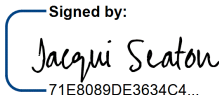

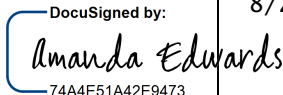
Developed by the following health professionals on behalf of the UKHSA:

| Developed By: | Name |
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| Pharmacist (Lead Author) | Christina Wilson Lead Pharmacist Immunisation Services, Immunisation and Vaccine Preventable Diseases Division, UKHSA |
| Doctor | Professor Shamez Ladhani Paediatric Infectious Diseases Consultant, St George's Hospital London, Professor of Paediatric Infections and Vaccinology, St George's University London and Consultant Epidemiologist, Immunisation and Vaccine Preventable Diseases Division, UKHSA |
| Registered Nurse (Chair of Expert Panel) | David Green Nurse Consultant, Immunisation and Vaccine Preventable Diseases Division, UKHSA |

Expert panel

| Name | Designation |
|---------------------|---|
| Nicholas Aigbogun | Consultant in Communicable Disease Control, Yorkshire and Humber Health Protection Team, UKHSA |
| Alison Campbell | Screening and Immunisation Coordinator, Clinical, NHSE Midlands |
| Jane Freeguard | Deputy Director of Vaccination – Medicines and Pharmacy, NHSE |
| Rosie Furner | Specialist Pharmacist - Medicines Governance, Patient Group Directions and Medicines Mechanisms, NHS Specialist Pharmacist Services (SPS) |
| Ed Gardner | Advanced Paramedic Practitioner / Emergency Care Practitioner, Medicines Manager, Primary Care based, Southbourne Surgery |
| Gemma Hudspeth | Senior Health Protection Practitioner, North East Health Protection Team Regions Directorate, UKHSA |
| Jacqueline Lamberty | Medicines Governance Consultant Lead Pharmacist, UKHSA |
| Michelle Jones | Principal Medicines Optimisation Pharmacist, NHS Bristol North Somerset and South Gloucestershire Integrated Care Board (ICB) |
| Elizabeth Lockett | Senior Screening and Immunisation Manager, NHSE South West |
| Vanessa MacGregor | Consultant in Communicable Disease Control, East Midlands Health Protection Team, UKHSA |
| Lesley McFarlane | Lead Immunisation Nurse Specialist, Immunisation and Vaccine Preventable Diseases Division, UKHSA |
| Nikki Philbin | Screening and Immunisation Manager, Vaccination and Screening Programmes, NHSE Midlands |
| Tushar Shah | Lead Pharmacy Adviser, NHSE London |

PGD Authorisation

| Name | Job title and organisation | Signature | Date |
|---|---|--|-----------|
| Senior doctor Dr Kate Wright | Lead doctor for PTHB |  DocuSigned by: <i>Kate Wright</i> 1F267952823F473... | 8/16/2024 |
| Chief Pharmacist Jacqui Seaton | Chief Pharmacist for PTHB |  Signed by: <i>Jacqui Seaton</i> 71E8089DE3634C4... | 8/14/2024 |
| Senior representative of professional group using the PGD Claire Roche | Executive Director of Nursing and Midwifery for PTHB |  DocuSigned by: <i>Claire Roche</i> F07413E114E04B1... | 8/21/2024 |
| Clinical Governance Lead Amanda Edwards | Clinical Governance Lead for PTHB – Assistant Director for Innovation and Improvement |  DocuSigned by: <i>Amanda Edwards</i> 74A4E51A42E9473... | 8/22/2024 |

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.

[Appendix A](#) provides a staff accreditation sheet. Individual practitioners must be authorised by name, under the current version of this PGD before working according to it.

Those using this PGD must ensure that it is organisationally authorised and signed 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](#).**

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 for 25 years after the PGD expires. Provider organisations adopting authorised versions of this PGD should also retain copies for 25 years after the PGD expires.

¹ This includes any relevant amendments to legislation

Reference Number: PGD 0043E

Valid from: 01/09/24

Review date: 01/09/26

Expiry date: 01/03/27

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. Enquiries relating to the use of this PGD, availability of organisationally authorised PGDs and subsequent versions of this PGD should be directed to Medicines Management: 01874 712641.

PGD adoption by the provider

| Name | Job title and organisation | Signature | Date |
|--|----------------------------|-----------|------|
| Signatures to be determined locally, if relevant | | | |

Characteristics of staff

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| <p>Qualifications and professional registration</p> | <p>All practitioners should only administer vaccinations where it is within their scope of clinical practice to do so. Practitioners must also fulfil the additional requirements and continued training requirements to ensure their competency is up to date, as outlined in the sections below.</p> <p>Practitioners working to this PGD must also be a registered professional with one of the following bodies:</p> <ul style="list-style-type: none"> • 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 the Health and Care Professions Council (HCPC) <p>Check Appendix A – Staff Accredited to use Patient Group Direction to confirm whether all practitioners listed above have organisational authorisation to work under this PGD.</p> |
| <p>Additional requirements</p> | <p>Additionally, practitioners:</p> <ul style="list-style-type: none"> • 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 have completed Patient Group Directions training (available via eLfh PGD eLearning programme. 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. • must be competent in the use of PGDs (see NICE Competency framework for health professionals using PGDs). Individuals operating under this PGD must be assessed as competent (see Appendix A) • 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 |

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| | <ul style="list-style-type: none"> • 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 and online training. Please contact PTHB Immunisation coordinator for further information. • 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. Completion of cold chain training (also available via ESR) • must be familiar with All Wales Advisory document on Ordering Storage and Handling of Vaccines • 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 • must have access to the PGD and associated online resources • should fulfil any additional requirements defined by local policy <p>THE INDIVIDUAL PRACTITIONER MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT.</p> |
| <p>Continued training requirements</p> | <p>Updating at least every 2 years on the administration of 23-valent pneumococcal polysaccharide vaccine. 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 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>Compliance with all mandatory NHS training (if relevant).</p> <p>Practitioners should be constantly alert to any subsequent recommendations from Welsh Government and/or Public Health Wales and/or NHS Wales and the</p> |

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| | <p>UKHSA, NHS England (NHSE) and other sources of medicines information.</p> <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> <p>It is the responsibility of the healthcare professional to maintain their own competency to practice within this PGD.</p> |
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Clinical condition or situation to which this PGD applies

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| Clinical condition or situation to which this PGD applies | <p>Indicated for the active immunisation of individuals from 65 years of age and individuals from 2 years of age in a clinical risk group, for the prevention of pneumococcal disease in accordance with the national immunisation programme and UK guidelines for the public health management of clusters of severe pneumococcal disease in closed settings. For reference, see Managing clusters of pneumococcal disease in closed settings and recommendations given in Chapter 25 of Immunisation Against Infectious Disease: the Green Book.</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 with the vaccination. If there is any reason for concern, seek medical advice.</p> |
| Criteria for inclusion | <p>Individuals who:</p> <ul style="list-style-type: none"> • are aged 65 years and over • are aged 2 years and over and have a medical condition included in the clinical risk groups defined in the Green Book Chapter 25, Table 25.2. • have asplenia, splenic dysfunction or chronic kidney disease (see Green Book Chapter 25 Table 25.2) and require a pneumococcal polysaccharide vaccine (PPV23) booster • are identified as requiring vaccination by the local Health Protection Team for the public health management of pneumococcal disease in accordance with Managing pneumococcal disease in closed settings |

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| | <ul style="list-style-type: none"> • Medical and drug history taken, no reason for exclusion • Informed consent, from the individual or a person legally able to act on the individual’s behalf, must be obtained prior to administration. NB Refer to PTHB Consent to Treatment and Examination Policy <p>Note: individuals at risk of frequent or continuous occupational exposure to metal fumes (such as welders) should be considered for immunisation taking into account exposure control measures in place. This indication is outside the remit of this PGD and should therefore be administered under either a written instruction or a PSD.</p> <p>Any vulnerable adult or child protection concerns should be referred to Safeguarding and PTHB safeguarding policies followed. Where there are safeguarding concerns (Child Protection or Protection of Vulnerable Adults, POVA) advice from the local Safeguarding team should be sought (see below).</p> |
| <p>Criteria for exclusion²</p> | <p>Individuals who have not given valid consent (or for whom 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. Several resources are available to inform consent (see written information to be given to individual, parent or carer section).</p> <p>If consent is not given, please refer to sections “Action to be taken if the individual is excluded” and “Action to be taken if the individual, parent or carer declines treatment”.</p> <p>Individuals who:</p> <ul style="list-style-type: none"> • are less than 2 years of age • have previously received PPV23 over the age of 2 years, except individuals with asplenia, splenic dysfunction and chronic kidney disease (see Green Book Chapter 25) and those recommended for vaccination in the public health management of clusters of severe pneumococcal disease in closed settings • have had a confirmed anaphylactic reaction to a previous dose of PPV23 or to any component of the vaccine |

¹ 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

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| | <ul style="list-style-type: none"> • have received pneumococcal conjugate vaccine (PCV) in the preceding 8 weeks • are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation) • Conditions outside of the clinical situations criteria |
| <p>Cautions including any relevant action to be taken</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>Individuals with a bleeding disorder may develop a haematoma at the injection site (see route and method of administration).</p> <p>Antibody response may be impaired in those with immunological impairment and those with an absent or dysfunctional spleen (see Special considerations and additional information section regarding appropriate timing of vaccination).</p> <p>Syncope (fainting) can occur following, or even before any vaccination, especially in adolescents as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from faints.</p> <p>Check for any other medications that the patient 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> |

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| <p>Action to be taken if the individual is excluded</p> | <p>If the individual is under the age of 2 years, PPV23 is not indicated. Ensure PCV immunisation is up to date instead (see PCV PGD or PCV Risk Groups PGD as applicable).</p> <p>If PPV23 has previously been given to an individual over the age of 2 years and the individual does not have asplenia, splenic dysfunction or chronic kidney disease (see Green Book Chapter 25) and immunisation is not indicated for the individual in line with public health management of severe pneumococcal disease in closed settings, further PPV23 is not indicated.</p> <p>Individuals who have recently received PCV should postpone PPV immunisation until 8 weeks has elapsed. In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated and ensure another appointment is arranged at the earliest opportunity.</p> <p>Seek appropriate advice from the local Screening and Immunisation Team, local Health Protection Team or the individual’s clinician as required.</p> <p>The risk to the individual of not being immunised must be taken into account.</p> <p>Document the reason for exclusion and any action taken in the individual’s clinical records. Explain reason to individual/carer.</p> <p>Inform or refer to the GP or a prescriber as appropriate.</p> |
| <p>Action to be taken if the individual, parent or carer declines treatment</p> | <p>Informed consent, from the individual or a person legally able to act on the person’s behalf, must be obtained for each administration and recorded appropriately. 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.</p> <p>The patient information leaflet should be available to inform consent.</p> <p>Advise the individual, parent or carer about the protective effects of the vaccine, the risks of infection and potential complications of disease.</p> |

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| | <p>Document advice given and the decision reached. Inform or refer to the GP as appropriate.</p> <p>Inform the Child Health department if appropriate – if any vaccination is declined for a child under 19 years, Child Health must be informed and appropriate form completed. Where appropriate, inform the GP using the local agreed system.</p> |
| Arrangements for referral for medical advice | <p>Refer to GP, paediatrician or consultant in communicable disease control (CCDC) for clinical advice as necessary.</p> <p>Document any advice given.</p> |

Description of treatment

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| Name, strength and formulation of drug | <p>Pneumovax® 23 solution for injection in a pre-filled syringe.</p> <p>Each 0.5ml dose contains 25 micrograms of each of the following 23 pneumococcal polysaccharide serotypes: 1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19F, 19A, 20, 22F, 23F, 33F.</p> |
| Legal category | Prescription only medicine (POM) |
| Black triangle▼ | No. |
| Off-label use | <p>Administration of a further dose of PPV23 to high-risk individuals who have already received a dose of PPV23 more than 12 months previously is off-label but may be recommended in accordance with Managing pneumococcal disease in closed settings.</p> <p>Vaccines 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 the All Wales Advisory document on Ordering Storage and Handling of Vaccines and Vaccine Incident Guidance. Where vaccines are assessed in accordance with these guidelines as appropriate for continued use, this would constitute off-label administration under this PGD.</p> <p>Where a vaccine is recommended off-label consider, as part of the consent process, informing the individual, parent or carer that the vaccine is being offered outside of product licence but in accordance with national guidance.</p> |

Route and method of administration

Administer by intramuscular or subcutaneous injection, preferably into the deltoid muscle of the upper arm. See Green book [chapter 4](#). The intramuscular route is routinely used because localised reactions are more common when vaccines are given subcutaneously.

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 into 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.

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. 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 be vaccinated via the intramuscular 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 other treatment is administered. 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, parent or carer should be informed about the risk of haematoma from the injection.

For individuals with an unstable bleeding disorder (or where intramuscular injection is otherwise not considered suitable), vaccines normally given by an intramuscular route should be given by deep subcutaneous injection, in accordance with [Chapter 4](#) of the Green Book.

The vaccine's normal appearance is a clear colourless solution.

The vaccine should be visually inspected for foreign particulate matter and other variation of expected appearance prior to preparation and administration. Should either occur, do not administer the dose and

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| | <p>discard the vaccine in accordance with local procedures.</p> <p>The vaccine SPC provides further guidance on preparation and administration.</p> |
| Dose and frequency of administration | <p>Single 0.5ml dose.</p> <p>Individuals with asplenia, splenic dysfunction or chronic kidney disease (see Chapter 25) should be revaccinated at 5 year intervals.</p> <p>PPV23 should be offered to high-risk individuals recommended to receive vaccination by the local Health Protection Team for the public health management of pneumococcal disease in accordance with Managing pneumococcal disease in closed settings, unless they have received PPV23 in the previous 12 months.</p> <p>Revaccination is not routinely indicated for other individuals.</p> |
| Duration of treatment | <p>Single 0.5ml dose (see Dose and frequency of administration regarding indications for revaccination).</p> |
| Quantity to be supplied and administered | <p>Single 0.5ml dose.</p> |
| Supplies | <p>Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see Green Book Chapter 3).</p> <p>Also refer to All Wales Advisory document on Ordering Storage and Handling of Vaccines.</p> <p>Centrally purchased vaccines for the national immunisation programme for the NHS can only be ordered via ImmForm. Vaccines used for the national immunisation programme are provided free of charge.</p> |
| Storage | <p>Store at +2°C to +8°C.</p> <p>Store in original packaging in order to protect from light.</p> <p>Do not freeze.</p> <p>Protocols for the storage and handling of vaccines should be followed to prevent vaccine wastage.</p> |

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| | <p>In the event of an inadvertent or unavoidable deviation of these conditions, vaccines that have been stored outside the conditions stated above should be quarantined and risk assessed on a case-by-case basis for suitability of continued off-label use or appropriate disposal. Refer to All Wales Advisory document on Ordering Storage and Handling of Vaccines and Vaccine Incident Guidance. See 'MMP 427 Safe and Secure Management of Refrigerated Medicines and Vaccines SOP' for details of actions required in the event of a fridge temperature excursion.</p> <p>Contact the vaccine manufacturer where more specific advice is required about managing a temperature excursion.</p> <p>Any loss of vaccines due to expiry date 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>Disposal</p> | <p>Follow local clinical waste policy and NHS standard operating procedures to ensure safe and secure waste disposal.</p> <p>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 NHSE guidance (HTM 07-01): safe and sustainable management of healthcare waste and guidance in the Welsh Health Technical Memorandum 07-01 Safer management of healthcare waste.</p> |
| <p>Drug interactions</p> | <p>The 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.</p> <p>PPV23 may be given at the same time as other vaccines.</p> <p>A list of drug interactions associated with Pneumovax[®]23 is available from the SPC.</p> |

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| <p>Identification and management of adverse reactions</p> | <p>Local reactions following vaccination are very common including pain, swelling, soreness, warmth, induration and/or redness at the injection site. These reactions occur within 3 days of vaccination and resolve by day 5.</p> <p>A low-grade fever may occur.</p> <p>The most common systemic adverse events reported are asthenia/fatigue, myalgia and headache. Rarely, injection-site cellulitis (with a short onset time from vaccine administration) has been reported. Other adverse events have been reported in clinical trials and post-marketing surveillance but the frequency of these is not known.</p> <p>This list is not exhaustive- a detailed list of adverse reactions is available in the vaccine SPC.</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) PGD 0017 and anaphylaxis policy • 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 PNEUMOCOCCAL POLYSACCHARIDE VACCINE PPV23 (Pneumovax® 23) and specify type of reaction. • The patient may be advised to wear a MedicAlert or similar device to alert other healthcare providers <p>Report via Datix Once for Wales Reporting system.</p> <p>Report any suspected adverse reactions to a doctor.</p> |
| <p>Reporting procedure of adverse reactions</p> | <p>Healthcare professionals and individuals, parents and carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme or by searching for MHRA Yellow Card in the Google Play or Apple App Store.</p> <p>Any adverse reaction to a vaccine should be documented in the individual's record and the individual's GP should be informed.</p> |

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| | <p>All significant adverse drug reactions and any administration errors must be recorded via PTHB Once for Wales Reporting System.</p> |
| <p>Written information to be given to individual, parent or carer</p> | <p>Offer the marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine.</p> <p>Immunisation promotional material may be provided as appropriate:</p> <ul style="list-style-type: none"> • Splenectomy leaflet <p>For resources in accessible formats and alternative languages, please visit Home- Health Publications. Where applicable, inform the individual, parent or carer that large print, Braille or audio CD PILs may be available from emc accessibility (freephone 0800 198 5000) by providing the medicine name and product code number, as listed on the product SPC.</p> <p>Further information for printing and website links suitable for patients 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>Advice and follow up treatment</p> | <p>Inform the individual, parent or carer of possible side effects and their management.</p> <p>Vaccination may not result in complete protection in all recipients.</p> <p>Individuals at especially increased risk of serious pneumococcal infection (such as individuals with asplenia, splenic dysfunction and those who have received immunosuppressive therapy for any reason), should be advised regarding the possible need for early antimicrobial treatment in the event of severe, sudden febrile illness.</p> <p>The individual, parent or carer should be advised to seek medical advice in the event of an adverse reaction and report this via the Yellow Card reporting scheme.</p> <p>When applicable, advise the individual, parent or carer when to return for vaccination or when a subsequent vaccine dose is due.</p> |
| <p>Special considerations and additional information</p> | <p>Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a working telephone at the time of vaccination.</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.

Individuals who are a contact of pneumococcal disease do not usually require PPV23. Immunisation may be indicated where there is a confirmed cluster of severe pneumococcal disease in a closed setting and should be on the advice of your local Health Protection Team. Pneumococcal vaccines may be given to pregnant women when the need for protection is required without delay. There is no evidence of risk from vaccinating pregnant women or those who are breast-feeding with inactivated viral or bacterial vaccines or toxoids.

Timing of vaccination

Individuals with immunosuppression and HIV infection (regardless of CD4 count) should be given pneumococcal vaccines according to the recommendations.

Wherever possible, immunisation or boosting of immunosuppressed or HIV-positive individuals should be either carried out before immunosuppression occurs or deferred until an improvement in immunity has been seen. The optimal timing for any vaccination should be based upon a judgement about the relative need for rapid protection and the likely response. For individuals due to commence immunosuppressive treatments, inactivated vaccines should ideally be administered at least 2 weeks before treatment begins. In some cases, this will not be possible and therefore vaccination may be carried out at any time and re-immunisation considered after treatment is finished and recovery has occurred. Ideally, PPV23 should be given 4 to 6 weeks before elective splenectomy or initiation of treatment such as chemotherapy or radiotherapy. Where this is not possible, it can be given up to 2 weeks before treatment (see [Green Book Chapter 25](#)).

If it is not practical to vaccinate 2 weeks or more before splenectomy, immunisation should be delayed until at least 2 weeks after the operation.

If it is not practicable to vaccinate 2 weeks or more before initiation of either chemotherapy or radiotherapy (or both), immunisation should be

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| | <p>delayed until at least 3 months after completion of therapy in order to maximise the response to the vaccine. Immunisation of these individuals should not be delayed if this is likely to result in failure to vaccinate.</p> <p>Splenectomy, chemotherapy or radiotherapy should never be delayed to allow time for vaccination.</p> <p>Co-administration with PCV</p> <p>An 8 week interval between administration of PCV 13 or PCV15 and PPV23 vaccination is advised, to ensure optimum immunogenicity for the common vaccine serotypes covered by both vaccines.</p> <p>The clinical exceptions to the requirement for an 8 week interval are:</p> <ul style="list-style-type: none"> (i) when PPV23 is given in error of PCV13 or PCV15. In such cases, PCV13 or PCV15 can be given at the same visit or as soon as possible after the PPV23 dose with no limit to the interval between doses. This contrasts with previous recommendations to leave a longer interval between doses, because of a small risk of hyporesponsiveness and (ii) an individual recently immunised with PCV13 or PCV15 is recommended for immunisation as part of a pneumococcal outbreak where the responsible pneumococcal serotype is in PPV23 (but not in PCV13 or PCV15). In such cases, the benefits of early protection from the additional PPV23 serotypes outweighs the improved immunogenicity offered from maintaining an 8 week interval between the 2 vaccines. <p>Local procedures for medicines error reporting should be followed. A PSD should be used to co-administer both vaccines. Refer to Vaccine Incident Guidance.</p> <p>Note: although this specific advice above is not presently advocated in Chapter 25, it is anticipated the updated Chapter will do so in due course.</p> |
| <p>Records</p> | <p>Record consultation details as required by local procedures. The practitioner should ensure the following is recorded:</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. Record name of representative who gave consent if appropriate. |

- name of individual, address, date of birth and GP with whom the individual is registered
- medical and drug history taken, including any allergies and previous adverse events
- printed name and signature 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
- any reasons for exclusion or referral, including actions taken
- advice given, including advice given if excluded or declines immunisation
- details of any adverse drug reactions and actions taken
- administered via PGD, record PGD title and version number

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

All records should be clear, legible and contemporaneous.

This information should be recorded in the individual's GP record. Where vaccine is administered outside the GP setting appropriate health records should be kept and the individual's GP informed.

The local Child Health Information Services team must be notified using the appropriate documentation or pathway as required by any local or contractual arrangement. If a vaccine is administered to a child up to 19 years of age, forward a notification of vaccination given to Child Health Department using the appropriate documentation/pathway as required by any local or contractual arrangement (based in Brecon Hospital for under 5 years and Llandrindod Hospital for school age).

A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.

Key references

| Key references | Pneumococcal polysaccharide vaccine |
|----------------|---|
| | <ul style="list-style-type: none"> • Immunisation Against Infectious Disease: the Green Book Chapter 25, last updated 14 August 2023. https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book • Summary of Product Characteristics for Pneumovax® 23 vaccine, Merck Sharp & Dohme Limited. Last updated 16 December 2022. https://www.medicines.org.uk/emc/product/9692/smpc • Guidelines for the public health management of clusters of severe pneumococcal disease in closed settings. Updated 21 February 2020. https://www.gov.uk/government/publications/managing-clusters-of-pneumococcal-disease-in-closed-settings <p>General</p> <ul style="list-style-type: none"> • All Wales Advisory document on Ordering Storage and Handling of Vaccines 7th Edition September 2017 • Welsh Health Technical Memorandum 07-01 Safer management of healthcare waste • NHSE Health Technical Memorandum 07-01: safe and sustainable management of healthcare waste, last updated 7 March 2023 Error! Bookmark not defined. https://www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-hm-07-01/ • National Minimum Standards and Core Curriculum for Immunisation Training, published 7 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, updated 27 March 2017. https://www.nice.org.uk/guidance/mpg2 • NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions, updated 4 January 2018. https://www.nice.org.uk/guidance/mpg2/resources • Immunisation Collection https://www.gov.uk/government/collections/immunisation • Vaccine Incident Guidance https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors |

Appendix A – Staff Accredited to use the Patient Group Direction

Authorising Manager: I confirm that the practitioners named below have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of Powys Teaching Health Board or a Powys GP practice for the named healthcare professionals below who have signed the PGD to work under it. *The authorising manager must use the competency checklist (below).*

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 Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct.

| Printed name of health professional | Signature of health professional | Printed name of senior representative authorising health professional | Signature of senior representative authorising health professional | Date |
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The authorising manager should retain a copy of the list, which will be requested for audit purposes. This list should be kept by PTHB (or the provider organisation adopting an authorised version of the PGD) for 25 years after the PGD expires.

The healthcare professional should retain a copy of the document after signing.

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 " comments | 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 | | | |

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|--|--|------|
| 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 individual’s line manager and to the staff member, in conjunction with the PGD Appendix A authorisation sheet. A copy of this form should also be kept by service lead in the training file.