Bwrdd Iechyd Addysgu Powys
Powys Teaching Health Board

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. Health 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

Pneumococcal polysaccharide conjugate vaccine (13-valent or 15-valent, adsorbed) (PCV13 or PCV15)

by

registered healthcare practitioners

to

individuals from 6 weeks of age with an underlying medical condition which puts them at increased risk from pneumococcal disease

in

Powys Teaching Health Board

Version number: PGD 0166C

Reference Number: PGD0166C
Valid from: 28/02/2025
Review date: 30/11/2026
Expiry date: 31/05/2027

Change History		
Version number	**Change details**	**Date**
PGD0166	Initial issue	01/09/2020
PGD0166-A	Review issue to: • include minor rewording of standard text, layout and formatting changes for clarity and consistency with organisation change and other UKHSA PGD and updated references • add a note in criteria for management of clusters and outbreaks of pneumococcal disease • add to cautions section information for premature infants and occurrence of apnoea following vaccination. • include in the off-label the administration of an additional booster as per 'Green Book, Chapter 25' • update the patient advice section in line with the Green Book Chapter 25, 13 January 2020 • add to special considerations information for splenectomy immunisation post bone marrow transplant and timing of vaccination for leukemia. • Updated safeguarding details	11/03/2022
PGD 0166B	Review in line with UKHSA Notice of extension of the validity of the PCV Risk groups PGD template v5.00, which was extended pending anticipated revisions to Chapter 25 of the Green Book Reviewed to: • include minor rewording of standard text, layout and formatting changes for clarity and consistency with organisation change and other PTHB PGDs	22/02/2024

PGD 0166C	Review issue in line with UKHSA PGD template v6.0 to include: • minor rewording, layout and formatting changes for clarity and consistency with other UKHSA and PTHB PGD templates • details of a newly approved PCV15-valent vaccine (Vaxneuvance®) • recommendation for PCV15 in addition to PCV13, in line with Chapter 25 updates in the Green Book • updated considerations for individuals anticipated to receive a cochlear implant • clarification of exclusion criteria for at-risk individuals aged 2 years and above • clarification of the immunisation offer to at-risk individuals aged 10 years and over • interval between PPV23 and PCV doses for at-risk patients clarified as 8 weeks, not 2 months, in line with Table 25.3 of the Green Book • update of adverse reactions in common to both PCV vaccines	28/02/2025

This Powys Teaching Health Board (PTHB) PGD is based on the UKHSA PGD template v6.0 developed by the following health professionals 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
Pharmacist (Lead Author)	Christina Wilson Lead Pharmacist- Immunisation Programmes, 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 for Immunisation Programmes, UKHSA

Expert Panel

Name	Designation
Dr Nicholas Aigbogun	Consultant in Communicable Disease Control, Yorkshire and Humber Health Protection Team, UKHSA
Jess Baldasera	Health Protection Practitioner, North East Health Protection Team, Regions Directorate, UKHSA
Helen Beynon	Clinical Advisor, Immunisation Clinical Advice Response Service (CARS), NHSE London
Alison Campbell	Screening and Immunisation Coordinator, Clinical, NHSE Midlands
Jane Freeguard	Deputy Director of Vaccination – Medicines and Pharmacy, NHSE
Rosie Furner	Advanced Specialist Pharmacist, Medicines Governance (Patient Group Directions and Medicines Mechanisms) NHS Specialist Pharmacy Service
Ed Gardner	Advanced Paramedic Practitioner, Emergency Care Practitioner, Primary Care Based, Southbourne Surgery
Shilan Ghafoor	Medicines Governance Pharmacist, Medicines Governance, UKHSA
Greta Hayward	Consultant Midwife – Immunisation Programmes – UKHSA
Michelle Jones	Principal Medicines Optimisation Pharmacist, NHS Bristol North Somerset and South Gloucestershire Integrated Care Board
Elizabeth Luckett	Senior Screening and Immunisation Manager, NHSE South West
Dr Vanessa MacGregor	Consultant in Communicable Disease Control, East Midlands Health Protection Team, UKHSA
Lesley McFarlane	Lead Immunisation Nurse Specialist, Immunisation Programmes, UKHSA
Briony Mason	Screening and Immunisation Coordinator NHSE West Midlands
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PGD Authorisation

Name	Job Title and Organisation	Signature	Date
Senior Doctor Dr Kate Wright	Lead Doctor for PTHB	DocuSigned by: Kate Wright 1F267952823F473...	2/4/2025
Chief Pharmacist Jacqui Seaton	Chief Pharmacist for PTHB	Signed by: Jacqueline Seaton 71E8089DE3634C4...	2/4/2025
Senior Representative of Professional Group using the PGD Claire Roche	Executive Director of Nursing and Midwifery for PTHB	DocuSigned by: Claire Roche F07413E114E04B1...	2/17/2025
Clinical Governance Lead Amanda Edwards	Clinical Governance Lead for PTHB –Assistant Director for Innovation and Improvement	DocuSigned by: Amanda Edwards 74A4E51A42E9473...	2/25/2025

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 PTHB 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.

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 availability of organisationally authorised PGDs and subsequent versions of this PGD should be directed to: Info.MedicinesManagement.Powys@wales.nhs.uk

[1] This includes any relevant amendments to legislation

PGD adoption by the provider

Name	Job title and organisation	Signature	Date

1. Characteristics of staff

Qualifications and professional registration	All practitioners should only administer vaccination where it is within their clinical scope of 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. Practitioners working to this PGD must also be one of the following registered professionals who can legally supply and administer under a PGD: • nurses and midwives currently registered with the Nursing and Midwifery Council (NMC) • pharmacists and pharmacy technicians 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) Check Appendix A – Staff Accredited to use the Patient Group Direction to confirm whether all practitioners listed above have organisational authorisation to work under this PGD.
Additional requirements	Additionally, practitioners: • must be authorised by name as an approved practitioner under the current terms of this PGD before working to it • must have undertaken appropriate training for working under PGDs for supply and 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 • 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 1 in 1000 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 **The individual practitioner must be authorised by name, under the current version of this PGD before working according to it.**
Continued training requirements	Updating at least every 2 years on the administration of pneumococcal polysaccharide conjugate vaccine (13-valent or 15-valent, adsorbed) (PCV13 or PCV15) 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. Compliance with all mandatory NHS training (if relevant). Practitioners should be constantly alert to any subsequent recommendations from Welsh Government and/or Public Health Wales and/or NHS Wales and the UKHSA 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 outside of criteria specified in this PGD.

	It is the responsibility of the healthcare professional to maintain their own competency to practice within this PGD.

2. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	Indicated for the active immunisation of individuals with an underlying medical condition which puts them at increased risk from pneumococcal disease in accordance with the national immunisation programme and recommendations given in Chapter 7 and Chapter 25 of Immunisation Against Infectious Disease: the Green Book. This PGD does not cover the routine childhood PCV immunisation programme which is covered by the PTHB PCV PGD 0140. **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 immunisation. If there is any reason for concern, seek medical advice.**
Criteria for inclusion	Individuals who are: • under 2 years who have, or are anticipated to have asplenia, splenic dysfunction, complement disorder or severe immunocompromise[2] (see Special considerations and additional information) • from 2 years to under 10 years of age who are previously unvaccinated or partially vaccinated (such that they did not complete the routine PCV course as part of the national schedule) and who have a medical condition included in Appendix B • over 2 years of age and have, or are anticipated to have severe immunocompromise**Error! Bookmark not defined.** (see Special considerations and additional information) Note: for the management of clusters and outbreaks of pneumococcal disease, see the PTHB PCV PGD 0140 or PPV23 PGD 0043 (as appropriate). • Informed consent, from the individual or a person legally

[2] Examples of severe immunocompromise include individuals with bone marrow transplant, acute and chronic leukaemia, multiple myeloma or genetic disorders affecting the immune system (such as IRAK-4, NEMO)

	able to act on the individual's behalf, must be obtained prior to administration. NB Refer to PTHB Consent to Treatment and Examination Policy • Medical and drug history taken, no reason for exclusion 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).
Criteria for exclusion (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)	Individuals for whom valid consent or a best-interests decision in accordance with the Mental Capacity Act 2005, has not been obtained (for further information on consent, see Chapter 2 of the Green Book). Several resources are available to inform consent (see written information to be given to individual or carer section). Individuals who: • are less than 6 weeks of age • have received a dose of PCV (irrespective of valency) within the last 4 weeks (Note: national schedule recommends an 8 week interval, see Dose and frequency of administration section) • are aged 10 years or over and do not have (or are not anticipated to have) severe immunocompromise • are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation) • have had a confirmed anaphylactic reaction to a previous dose of pneumococcal vaccine or to any component of the vaccine including diphtheria toxoid Refer to sections "Action to be taken if the individual is excluded" and "Action to be taken if the individual or carer declines treatment".
Cautions including any relevant action to be taken	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). Whilst immunogenicity of the vaccine could be reduced in immunosuppressed individuals, vaccination is still recommended. Premature infants with asplenia, splenic dysfunction, complement disorder or severe immunocompromise**Error!**

	Bookmark not defined. should be vaccinated in accordance with the Green Book Chapter 25 immunisation schedule and according to their chronological age. For premature infants without asplenia, splenic dysfunction, complement disorder or severe immunocompromise**Error! Bookmark not defined.**, the PCV PGD 0140 should be used. The occurrence of apnoea following vaccination is especially increased in infants who are born very prematurely. Very premature infants (born ≤28 weeks of gestation) who are in hospital should have respiratory monitoring for 48 to 72 hrs when given their first immunisation, particularly those with a previous history of respiratory immaturity. If the child has apnoea, bradycardia or desaturations after the first immunisation, the second immunisation should also be given in hospital, with respiratory monitoring for 48 to 72 hrs. 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. Check for any other medications that the individual is taking, including topical or inhaled products, food supplements and herbal or homeopathic products. (Refer to BNF/SPC for full list) 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: • to generic email address: PowysTHB.Safeguarding@wales.nhs.uk and • Central Safeguarding number: 01686 252806 • Out of hours: 0345 0544847 Advice can also be sought from local Safeguarding leads

Action to be taken if the individual is excluded	Explain reason to individual / carer. If aged less than 6 weeks, defer immunisation and provide an appointment as appropriate. If a dose of PCV (irrespective of valency) was received within the last 4 weeks, defer immunisation for an appropriate interval (see Dose and frequency of administration). Individuals aged 2 years and above with a clinical condition outlined in Appendix B, should be prioritised for PPV vaccination over vaccination with PCV13 or PCV15. Refer to the PTHB PPV23 PGD 0043 and ensure the individual's vaccination history is up to date in line with this PGD and recommendations as outlined in the Green Book, Chapter 25. In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated and ensure another appointment is arranged. Seek appropriate advice from the local Screening and Immunisation Team, local Health Protection Team or the individual's clinician as required. The risk to the individual of not being immunised must be taken into account. Document the reason for exclusion and any action taken in the individual's clinical records. Inform or refer to the individual's GP or a prescriber as appropriate.
Action to be taken if the individual or carer declines treatment	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. Advise the individual, parent or carer about the protective effects of the vaccine, the risks of infection and the potential complications. The patient information leaflet should be available to inform consent. Document the advice given and the decision reached.

	Inform or refer to the individual's GP as appropriate. 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.
Arrangements for referral for medical advice	Refer to GP, paediatrician or consultant in communicable disease control (CCDC) for clinical advice as necessary. Document any advice given.

3. Description of treatment

Name, strength and formulation of drug	Pneumococcal polysaccharide conjugate vaccine (adsorbed), either: • **Prevenar® 13** (13-valent) suspension for injection in a pre-filled syringe • **Vaxneuvance®** (15-valent) suspension for injection in a pre-filled syringe
Legal category	Prescription only medicine (POM)
Black triangle▼	Vaxneuvance®. As a new vaccine product, the Medicines and Healthcare products Regulatory Agency (MHRA) has a specific interest in the reporting of adverse drug reactions for this product. All suspected adverse drug reactions should be reported using the MHRA Yellow Card reporting scheme.
Off-label use	**Infants <37 weeks gestation** Administration of a 2-dose primary series of Prevenar®13 or Vaxneuvance® to pre-term infants <37 weeks gestation, with asplenia, splenic dysfunction, complement disorder or severe immunocompromise[2], is contrary to the 3 dose primary schedule detailed in the SPCs but is in accordance with the the recommendations for individuals with asplenia, splenic dysfunction, complement disorder or severe immunocompromise[2] in the Green Book, Chapter 7 and Chapter 25. **Individuals under 2 years** Administration of an additional booster following a 2+1 schedule is off-label as the additional booster is not included

	in the SPC but is in accordance with the recommendations and Chapter 25 of the Green Book. 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 vaccine is assessed in accordance with these guidelines as appropriate for continued use, this would constitute off-label administration under this PGD. Where a vaccine is recommended off-label consider, as part of the consent process, informing the individual, parent or carer that the vaccine is being offered outside of product licence but in accordance with national guidance.
Route and method of administration	Administer by intramuscular injection, preferably into the anterolateral aspect of the thigh in infants under one year of age. The deltoid muscle of the upper arm may be used in individuals over one year of age. See Green Book Chapter 4. When administering at the same time as other vaccines, care should be taken to ensure that the appropriate route of injection is used for all vaccinations. 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. Individuals with bleeding disorders may be vaccinated intramuscularly if, in the opinion of a doctor familiar with the individual's bleeding risk, vaccines or similar small volume intramuscular injections can be administered with reasonable safety by this route. If the individual receives medication or other treatment to reduce bleeding, for example treatment for haemophilia, intramuscular vaccination can be scheduled shortly after such medication or treatment is administered. Individuals on stable anticoagulation therapy, including individuals on warfarin who are up to date with their scheduled INR testing and whose latest INR was below the upper threshold of their therapeutic range, can receive intramuscular vaccination. A fine needle (equal to 23 gauge or finer calibre such as 25 gauge) should be used for the vaccination, followed by firm pressure applied to the site (without rubbing) for at least 2 minutes. The individual or carer should be informed about the risk of haematoma from the injection.

	Prevenar®13 is a uniform white suspension which may sediment during storage. The vaccine should be well shaken. Vaxneuvance® is an opalescent suspension. Holding the prefilled syringe horizontally, shake vigorously to uniformly distribute the suspension before administering the vaccine. 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 vaccine and discard the syringe in accordance with local procedures. The vaccine SPC provides further guidance on preparation and administration.
Dose and frequency of administration	Single 0.5ml dose per administration. **Individuals aged under 1 year of age** Individuals at increased risk of pneumococcal disease due to asplenia, splenic dysfunction, complement disorder or severe immunocompromise**Error! Bookmark not defined.** should receive: • a 2-dose priming schedule of PCV13 or PCV15 vaccine with an 8 week interval[3] between priming doses administered in the first year of life (commencing no earlier than 6 weeks of age), then • a booster dose to be administered at one year of age (on or after the first birthday), then • a further booster dose, 8 weeks after the first booster All other individuals under 1 year of age should be fully vaccinated in accordance with the routine PCV immunisation programme (see PTHB PGD0140 and the Vaccination of individuals with uncertain or incomplete immunisation status guidance). **Individuals from 1 year to under 2 years of age** Individuals with asplenia, splenic dysfunction (see Appendix B), complement disorder or severe immunocompromise**Error! Bookmark not defined.**, aged between their first and second birthday should receive: • their routine PCV13 or PCV15 booster scheduled on or shortly after their first birthday followed by • an additional booster dose of PCV13 or PCV15 with an interval of 8 weeks between the PCV13 or PCV15 booster doses.

[3] The immunisation interval may be reduced to 4 weeks if necessary, to ensure the immunisation schedule is completed.

	Note: This is the schedule to follow regardless of whether the child had none, one or 2 routine primary doses of PCV13 or PCV15 in infancy. The intervals may be reduced to 4 weeks if necessary, to ensure that the immunisation schedule is completed. **Individuals from 2 years to under 10 years of age** Excluding the severe immunocompromised[2], no further doses are needed for individuals from 2 years to under 10 years of age with a medical condition included in Appendix B, who have completed the routine PCV immunisation schedule (with PCV13 or PCV15). Priority should be given to vaccinating such individuals with PPV23 from the age of 2 years (see the PTHB PPV23 PGD0043). Individuals who are unvaccinated or partially unvaccinated should be offered a single dose of PCV13 or PCV15. Severely immunocompromised**Error! Bookmark not defined.** individuals, who have not received an additional booster of PCV13 or PCV15 recommended between one and 2 years of age, should be offered a single dose of PCV13 or PCV15, **irrespective** of any routine childhood vaccinations they have already received. **Individuals from 10 years of age** Excluding the severely immunocompromised**Error! Bookmark not defined.**, no further doses are needed for individuals from 10 years of age, with a medical condition included in Appendix B. See special considerations and additional information section (Individuals aged over 10 years of age). Severely immunocompromised**Error! Bookmark not defined.** individuals who have not received an additional booster of PCV13 or PCV15, should be offered a single dose of PCV13 or PCV 15**, irrespective** of any routine childhood vaccinations they have already received. PCV13, PCV15 or additional PPV23 doses are not needed if the individual received PPV23 in the previous 2 years. **Pneumococcal polysaccharide vaccine (PPV23)** Additionally, all individuals with a medical condition included in Appendix B should receive a dose of PPV23 on or after their second birthday (see PTHB PPV PGD0043). Individuals eligible for both PCV13 (or PCV15) and PPV23 should have the PCV13 (or PCV15) dose first followed by PPV23 at least 8 weeks later.

Duration of treatment	Single 0.5ml dose, repeated at recommended intervals as outlined above in dose and frequency of administration.
Quantity to be administered	Single 0.5ml dose per administration.
Supplies	PCV vaccine for additional doses from one year of age for at risk groups is not centrally procured and these should be ordered from the manufacturer or their wholesalers. Details are given in the Green Book Chapter 25. Centrally purchased vaccines for the national routine childhood immunisation programme for the NHS can only be ordered via ImmForm, that is vaccines for use for primary immunisation and the booster at one year of age. Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see the Green Book Chapter 3). Also refer to All Wales Advisory document on Ordering Storage and Handling of Vaccines.
Storage	Store at +2°C to +8°C. Store in original packaging in order to protect from light. Do not freeze. Following a single temperature excursion, Prevenar®13 is stable at temperatures up to 25°C for a maximum of 4 days. At the end of this period, Prevenar®13 should be used within this timeframe or discarded in accordance with local procedures. Stability data indicates Vaxneuvance® is stable at temperatures up to 25°C for 48 hours. This information is only intended to guide health care professionals in case of temporary temperature excursions. Protocols for the storage and handling of vaccines should be followed to prevent vaccine wastage. In the event of an inadvertent or unavoidable deviation of these conditions, vaccine that has been stored outside the conditions stated above should be quarantined and risk assessed 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 and contact the manufacturer if specific advice on management of the temperature excursion is required.

	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. 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.
Disposal	Equipment used for immunisation, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of safely in a UN-approved puncture-resistant sharps box, according to local waste disposal 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.
Drug interactions	Immunological response may be diminished in those receiving immunosuppressive treatment. Vaccination is recommended even if the antibody response may be limited. PCV13 or PCV15 may be given at the same time as other vaccines, with the exception of PPV23. Individuals eligible for both PCV13 (or PCV15) and PPV23 should have the PCV13 or PCV15 dose first, followed by PPV23 at least 8 weeks later. A detailed list of interactions is available from the product SPC.
Identification and management of adverse reactions	Local reactions following vaccination are very common such as pain, swelling or redness at the injection site and decreased appetite. Other commonly reported adverse reactions include fever, irritability, fatigue, myalgia, rash and headache. Diarrhoea is a commonly reported reaction specific to Prevenar®13. Hypersensitivity reactions, such as bronchospasm, angioedema and anaphylaxis can occur but are rare. A detailed list of adverse reactions is available from the product SPC. Report any suspected adverse reactions to a doctor.

	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:
	• Refer to adrenaline (epinephrine) PGD0017 and anaphylaxis procedure
	  • Request medical assistance urgently. If the GP is not immediately available dial 999 to transfer to A&E
	  • Ensure reaction is fully documented in individual's notes
	  • Ensure all individual's records are marked **ALLERGIC TO pneumococcal polysaccharide conjugate vaccine (adsorbed) (specify 13-valent or 15-valent and brand).**
	  • The individual may be advised to wear a MedicAlert or similar device to alert other healthcare providers
	  • Report via Once for Wales Reporting System.

Reporting procedure of adverse reactions	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. Any adverse reaction to a vaccine should be documented in the individual's record and the individual's GP should be informed. All significant adverse drug reactions and any administration errors must be recorded via the Once for Wales Reporting System.
Written information to be given to the individual (or parent or carer)	Offer the marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine. Immunisation promotional material may be provided as appropriate: • Splenectomy leaflet For resources in accessible formats and alternative languages, please visit Home - Health Publications. Where applicable, inform the individual 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 in the product's SPC. Further information for printing and website links suitable for individuals can be found on the Public Health Wales intranet site Public Health Wales Immunisation and Vaccine Preventable Disease Programme, NHS 111 Wales and Health Information Resources.
Advice and follow up treatment	Inform the individual, parent or carer of possible side effects and their management. Vaccination may not result in complete protection in all recipients. Individuals at especially increased risk of serious pneumococcal infection (such as individuals with asplenia 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. 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. Give appropriate advice if medication is used off-label. Advise the individual, parent or carer when any subsequent immunisations are due. When administration is postponed advise the individual, parent or carer when to return for vaccination.
Special considerations and additional information	Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a working telephone at the time of vaccination. 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. Neonates diagnosed at increased risk of pneumococcal disease due to asplenia, splenic dysfunction, complement disorder or severe immunocompromise**Error! Bookmark not defined.** should be offered immunisation as soon as appropriate (such as with their first primary immunisations) and do not need to wait until the routine offer of PCV13 or PCV15 at 12 weeks of age.

	Individuals on eculizumab (Soliris®) or other complement inhibitor therapy aged 2 years and above are not at increased risk of pneumococcal disease and do not require PPV23 or additional doses of PCV13 or PCV15. Wherever possible, immunisation or boosting of immunosuppressed individuals should be either carried out before immunosuppression occurs or deferred until an improvement in immunity has been seen (see the Green Book Chapter 25). Immunisation of these individuals should not be delayed if this is likely to result in failure to vaccinate. Those requiring splenectomy, where possible, should be vaccinated before elective splenectomy. If it is not practicable to vaccinate before splenectomy, immunisation should be delayed until at least 2 weeks after the operation (see the Green Book Chapter 25). Immunisation of these individuals should not be delayed if this is likely to result in a failure to vaccinate. For the timing of vaccination for individuals with leukaemia or anticipating bone marrow transplantation, see the Green Book Chapter 25. Individuals who have received a bone marrow transplant after vaccination should be considered for a reimmunisation programme for **all** routine vaccinations and for COVID-19 (see Chapter 7 and Chapter 25 of the Green Book). This is not covered by this PGD and should be provided through a PSD. Splenectomy, chemotherapy or radiotherapy should never be delayed in order to allow time for vaccination. **Individuals aged over 10 years** No further doses of PCV13 or PCV15 are routinely recommended for individuals aged over 10 years (with the exception of the severely immunocompromised). Table 25.3 in Chapter 25 recommends a single dose for individuals aged over 10 years who are unimmunised or partially immunised. If the clinician deems it clinically appropriate to offer a dose to these individuals, this should be administered using a PSD, as immunisation of these individuals is not covered by the criteria for inclusion in this PGD. Priority should be given to offering PPV23 to individuals listed in Appendix B from the age of 2 years. As outlined in the dose and frequency of administration section, further

	doses of PCV13 or PCV15 are not required if PPV23 has been given in the last 2 years. **Pneumococcal polysaccharide vaccine (PPV23)** Additionally, all individuals with a medical condition included in Appendix B should receive a dose of PPV23 on or after their second birthday (see the PTHB PPV23 PGD 0043).
Records to be kept	Record consultation details as required by local procedures. The practitioner must ensure the following is recorded: • 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 • advice given, including advice given if excluded or immunisation declined • 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 (Child Health Records Department) 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.

4.Key references

Key references	**Pneumococcal conjugate vaccine** • Immunisation Against Infectious Disease: The Green Book Chapter 7, January 2020 and Chapter 25, 27 July 2023 • Summary of Product Characteristics for Prevenar® 13 suspension for injection, Pfizer Ltd. Last updated 12 October 2021. https://www.medicines.org.uk/emc/product/453/smpc • Summary of Product Characteristics for Vaxneuvance® suspension for injection, Merck Sharpe and Dohme. Last updated 14 December 2023 https://www.medicines.org.uk/emc/product/13754 • Vaccination of individuals with uncertain or incomplete immunisation status, last updated 30 August 2024 https://www.gov.uk/government/publications/vaccination-of-individuals-with-uncertain-or-incomplete-immunisation-status **General** • 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. 2013. Available from: https://nwssp.nhs.wales/ourservices/specialist-estates-services/specialist-estates-services-documents/whtms-library/whtm-07-01-safe-management-of-healthcare-waste-pdf/ • NHSE Health Technical Memorandum 07-01: safe and sustainable management of healthcare waste. Updated 7 March 2023 https://www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-htm-07-01/ • National Minimum Standards and Core Curriculum for Immunisation Training for registered healthcare practitioners. Published February 2018. https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners • NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published 27 March 2017. https://www.nice.org.uk/guidance/mpg2 • NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. 4 January 2018 https://www.nice.org.uk/guidance/mpg2/resources

	• UKHSA 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 practice 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 (Authorising Manager)	Signature of senior representative authorising health professional (Authorising Manager)	Date

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			

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.

APPENDIX B: Clinical risk groups who should receive pneumococcal immunisation

(Green Book Chapter 25, Table 25.2)

Clinical risk group	Examples (decision based on clinical judgement)
Asplenia or dysfunction of the spleen	This also includes conditions such as homozygous sickle cell disease and coeliac syndrome that may lead to splenic dysfunction.
Chronic respiratory disease (chronic respiratory disease refers to chronic lower respiratory tract disease)	This includes chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema; and such conditions as bronchiectasis, cystic fibrosis, interstitial lung fibrosis, pneumoconiosis and bronchopulmonary dysplasia (BPD). Children with respiratory conditions caused by aspiration, or a neurological disease (such as cerebral palsy) with a risk of aspiration. Asthma is not an indication, unless so severe as to require continuous or frequently repeated use of systemic steroids (as defined in Immunosuppression below).
Chronic heart disease	This includes those requiring regular medication and/or follow-up for ischaemic heart disease, congenital heart disease, hypertension with cardiac complications, and chronic heart failure.
Chronic kidney disease	Nephrotic syndrome, chronic kidney disease at stages 4 and 5 and those on kidney dialysis or with kidney transplantation. (Re-immunisation with PPV23 is recommended every 5 years)
Chronic liver disease	This includes cirrhosis, biliary atresia and chronic hepatitis.
Diabetes	Diabetes mellitus requiring insulin or oral hypoglycaemic drugs. This does not include diabetes that is diet controlled.
Immunosuppression	Due to disease or treatment, including individuals undergoing chemotherapy leading to immunosuppression, bone marrow transplant, asplenia or splenic dysfunction, complement disorder, HIV infection at all stages, multiple myeloma or genetic disorders affecting the immune system (such as IRAK-4, NEMO) Individuals on or likely to be on systemic steroids for more than a month at a dose equivalent to prednisolone at 20mg or more per day (any age), or for children under 20kg, a dose of 1mg or more per kg per day.
Individuals with cochlear implants	It is important that immunisation does not delay the cochlear implantation. If not possible to schedule vaccination before the intervention, the vaccination should be given as soon as possible afterwards, as the risk of invasive pneumococcal disease is highest around the time of implant insertion.
Individuals with cerebrospinal fluid leaks	This includes leakage of cerebrospinal fluid such as following trauma or major skull surgery (does not include CSF shunts).