



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

by
registered Healthcare Professionals

to
individuals from 16 weeks to under 2 years of age in accordance with the national immunisation programme for active immunisation against pneumococcal disease

in
Powys Teaching Health Board
Version number: PGD 0140 E

Reference Number: PGD0140E

Valid from: 05/01/2026

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Change History		
Version number	Change details	Date
PGD0140	Initial issue	4/10/17
PGD0140-A	Review issue, to reflect new immunisation schedule and use of new PTHB template	20/04/2020
PGD0140-B	<p>Review in line with current 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 PGD and updated references. • remove from actions following exclusion, off label and dose/frequency sections, information pertaining to the 2+1 schedule • add in the exclusion section the recommendation to have minimum 4 weeks interval between PCV13 vaccinations • include in the off-label the information for partially immunised as per the 'Green Book', Chapter 25 13 January 2020 • provide detail to primary dose and schedule for premature infant in cautions section • include in the dose and frequency section immunisation recommendations for premature infants and unimmunised or partially immunised children as per Green Book Chapter 25, 13 January 2020 • include the special considerations information for immunisation for bone marrow transplant • update the dose and frequency in line with the Green Book Chapter 25, 13 January 2020 • updated safeguarding details 	11/03/2022

Reference Number: PGD0140E

Valid from: 05/01/2026

Review Date: 05/07/2028

Expiry Date: 05/01/2029

<p>PGD0140-C</p>	<p>Review in line with current UKHSA template v5.00 to include:</p> <ul style="list-style-type: none"> • minor rewording, layout and formatting changes for clarity and consistency with other UKHSA and PTHB PGDs • new PCV15-valent vaccine (Vaxneuvance®) • updated temperature excursion information for Prevenar®13 • update of adverse reactions in common to both PCV vaccines • clarity that outbreak doses are considered additional to the routine immunisation programme for unimmunised or partially immunised children under 2 years of age • updated safeguarding details • changes to the Off-label use section of the UKHSA PGD template, confirmed via email by the Immunisation Team at the UKHSA on 01/02/2024 • updates to appendix A 	<p>28/02/2024</p>
<p>PGD 0140 D</p>	<p>Review issue in line with UKHSA PGD template v6.0 to:</p> <ul style="list-style-type: none"> • incorporate the change in routine immunisation schedule for the first priming dose, from 12 weeks to 16 weeks of age. The second dose between one and 2 years of age remains unchanged • include registered healthcare professionals named in both the Additional Roles Reimbursement Scheme (ARRS) and HMR2012 under Characteristics of staff • enable vaccination in community settings of premature infants who were clinically stable when discharged from hospital • advise the dosing interval between priming and booster doses may be reduced to avoid further delay to other routine vaccines required at one year of age <p>Reviewed to include minor rewording of standard text, layout and formatting changes for clarity and consistency with other PTHB PGDs</p>	<p>01/07/2025</p>

Reference Number: PGD0140E

Valid from: 05/01/2026

Review Date: 05/07/2028

Expiry Date: 05/01/2029

PGD 0140 E	<p>Review issue in line with UKHSA PGD template v7.0 to:</p> <ul style="list-style-type: none"> • remove immunisation of individuals from 6 weeks of age in response to an outbreak of pneumococcal disease due to introduction of PCV20 for outbreaks • update 8-week dose interval to 4-week interval as per updated Green Book Chapter 25 • inform to use PCV20 PGD for routine programme for individuals who have asplenia, splenic dysfunction, complement disorder or severe immunocompromise • delete off label use of dose schedules as SPC states that the schedules should be in accordance with national recommendations • add Prevenar 13[®] is interchangeable with other PCV vaccines as per the Green Book Chapter 25 in off-label section • add minimum 4-week dose interval in accordance with the Green Book, Chapter 25 where 8-week dose interval is indicated in the SPCs in off-label section 	05/01/2026
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This Powys Teaching Health Board (PTHB) PGD is based on the UKHSA PGD template v7.0 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
Pharmacist (Lead Author)	Suki Hunjunt 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

Reference Number: PGD0140E

Valid from: 05/01/2026

Review Date: 05/07/2028

Expiry Date: 05/01/2029

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	Lead 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 Lockett	Senior Screening and Immunisation Manager, Screening and Immunisation Team – Kent and Medway, NHSE South East
Dr Vanessa MacGregor	Consultant in Communicable Disease Control, East Midlands Health Protection Team, UKHSA
Briony Mason	Vaccination Manager, NHSE West Midlands
Lesley McFarlane	Lead Immunisation Nurse Specialist, Immunisation Programmes, UKHSA
Tushar Shah	Lead Pharmacy Adviser, NHSE London

Reference Number: PGD0140E

Valid from: 05/01/2026

Review Date: 05/07/2028

Expiry Date: 05/01/2029

Name	Job Title and Organisation	Signature	Date
Senior Doctor Dr Kate Wright	Lead Doctor for PTHB	 DocuSigned by: Kate Wright 1F267952823F473...	1/14/2026
Chief Pharmacist Jonathan Boyd	Chief Pharmacist for PTHB	 Signed by: Jon Boyd 6D8ECFE8C9EB423...	1/16/2026
Senior representative of professional group using the PGD Paul Hooton	Executive Director of Nursing and Midwifery for PTHB	 Signed by: Paul Hooton EEABC83AC83F4B9...	1/14/2026
Clinical Governance Lead Amanda Edwards	Clinical Governance Lead for PTHB –Assistant Director for Innovation and Improvement	 DocuSigned by: Amanda Edwards 74A4E51A42E9473...	1/20/2026

PGD Authorisation

This PGD is not legally valid until it has had the relevant organisational authorisation.

It is the responsibility of the organisation that has legal authority to authorise the PGD, to ensure that all legal and governance requirements are met. The authorising body accepts governance responsibility for the appropriate use of the PGD.

[Appendix A](#) provides a staff accreditation sheet. Individual practitioners must be authorised by name, under the current version of this PGD, before working 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: PGD0140E

Valid from: 05/01/2026

Review Date: 05/07/2028

Expiry Date: 05/01/2029

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.

PGD adoption by the provider

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

1. Characteristics of staff

<p>Qualifications and professional registration</p>	<p>All practitioners should only administer vaccinations 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.</p> <p>Practitioners working to this PGD must also be one of the following registered professionals who can legally supply and administer under a PGD:</p> <ul style="list-style-type: none"> • 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) • dieticians, occupational therapists, paramedics, physiotherapists and podiatrists 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 and administration of medicines. Must have completed eLfh PGD eLearning Patient Group Directions training (available via learning@wales, 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),

Reference Number: PGD0140E

Valid from: 05/01/2026

Review Date: 05/07/2028

Expiry Date: 05/01/2029

	<p>Immunisation Against Infectious Disease (The Green Book) and national and local immunisation programmes</p> <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 co-ordinator for further information. • must be competent to undertake immunisation and to discuss issues related to immunisation • must be competent in intramuscular injection techniques • 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 <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 pneumococcal polysaccharide conjugate vaccine (13-valent or 15-valent, adsorbed) (PCV) vaccine.</p> <p>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).</p> <p>Evidence of ongoing PGD training to be submitted to Line Manager annually.</p> <p>Practitioners must be competent, recognise their own limitations and personal accountability and act accordingly.</p> <p>Practitioners must make a self-declaration of competency on PADR (if relevant). The personal development plan</p>

Reference Number: PGD0140E

Valid from: 05/01/2026

Review Date: 05/07/2028

Expiry Date: 05/01/2029

	<p>(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 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 outside of 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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2. Clinical condition or situation to which this PGD applies.

<p>Clinical condition or situation to which this PGD applies</p>	<p>Indicated for the active immunisation of:</p> <ul style="list-style-type: none"> • individuals from 16 weeks to under 2 years of age for the prevention of pneumococcal disease in accordance with the national immunisation programme and recommendations given in Chapter 25 of the Green Book. <p>For individuals under 2 years of age with asplenia, splenic dysfunction, complement disorder or severe immunocompromise use PCV20 PGD 0251.</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 immunisation. If there is any reason for concern, seek medical advice.</p>
<p>Criteria for inclusion</p>	<p>Individuals from 16 weeks to under 2 years of age who:</p> <ul style="list-style-type: none"> • require a primary dose of PCV13 or PCV15 • require a reinforcing booster dose of PCV13 or PCV15 against pneumococcal disease <p>Note: individuals with an underlying medical condition which puts them at increased risk from pneumococcal disease may require additional vaccination outside the inclusion criteria</p>

Reference Number: PGD0140E

Valid from: 05/01/2026

Review Date: 05/07/2028

Expiry Date: 05/01/2029

	<p>for this PGD - see PGD 0251 (PCV20) and Chapter 25 of the Green Book.</p> <ul style="list-style-type: none"> • 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 • Medical and drug history taken, no reason for exclusion <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 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</p>	<p>Individuals for whom no valid consent has been received (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 or carer section).</p> <p>Individuals who:</p> <ul style="list-style-type: none"> • are less than 16 weeks of age • are recommended PCV vaccination in response to an outbreak of pneumococcal disease (see PCV20 PGD 0251)are aged 2 years and over, with an underlying medical condition putting them at increased risk of pneumococcal disease as outlined in Table 25.2 of Chapter 25 of the Green Book (see PCV20 PGD 0251) • have received a dose of PCV13 or PCV15 within the last 4 weeks • have had a confirmed anaphylactic reaction to a previous dose of pneumococcal vaccine or to any component of the vaccine, including diphtheria toxoid • 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>Refer to sections "Action to be taken if the individual is excluded" or "Action to be taken if the individual or carer declines treatment".</p>

Reference Number: PGD0140E

Valid from: 05/01/2026

Review Date: 05/07/2028

Expiry Date: 05/01/2029

Cautions including any relevant action to be taken	<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>The immunogenicity of the vaccine could be reduced in immunosuppressed individuals and additional doses may be recommended, see the Green Book Chapter 7 and Chapter 25 and the PCV Risk Groups PGD (PGD0166).</p> <p>Premature infants should be vaccinated in accordance with the national routine immunisation schedule according to their chronological age. Very premature infants (born less than 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 hours. If the premature infant was stable at discharge and has no history of apnoea and/or respiratory compromise, further vaccinations may be given in the community setting.</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 individual 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: To generic email address: PowysTHB.Safeguarding@wales.nhs.uk</p>
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Reference Number: PGD0140E

Valid from: 05/01/2026

Review Date: 05/07/2028

Expiry Date: 05/01/2029

	<p>and</p> <ul style="list-style-type: none"> • Central Safeguarding number: 01686 252806 • Out of hours: 0345 0544847 <p>Advice can also be sought from local Safeguarding Leads</p>
<p>Action to be taken if the individual is excluded</p>	<p>Explain reason to individual/carer.</p> <p>If the individual is aged less than 6 weeks, defer immunisation and provide an appointment as appropriate.</p> <p>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).</p> <p>If aged 2 years and over, routine immunisation with pneumococcal vaccine is not indicated.</p> <p>If the individual is at increased risk of pneumococcal disease, vaccinate in accordance with the Green Book Chapter 7 and Chapter 25, refer to PCV20 PGD 0251</p> <p>The vaccine must be administered with caution to individuals with thrombocytopenia or a bleeding disorder since bleeding may occur following an intramuscular administration</p> <p>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.</p> <p>Inform or refer to the GP or a prescriber as appropriate.</p>

<p>Action to be taken if the individual 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. 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 the potential complications.</p> <p>Document advice given and the decision reached.</p> <p>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>
<p>Arrangements for referral for medical advice</p>	<p>Refer to GP, paediatrician or consultant in communicable disease control (CCDC) for clinical advice as necessary.</p> <p>Document any advice given.</p>

3. Description of treatment

<p>Name, strength and formulation of drug</p>	<p>Pneumococcal polysaccharide conjugate vaccine (adsorbed), either:</p> <ul style="list-style-type: none"> • Prevenar[®]13 (13-valent) suspension for injection in a pre-filled syringe • Vaxneuvance[®] (15-valent) suspension for injection in a pre-filled syringe
<p>Legal category</p>	<p>Prescription only medicine (POM)</p>
<p>Black triangle▼</p>	<p>YES</p> <p>Vaxneuvance[®].</p> <p>As a new vaccine product, the Medicines and Healthcare products Regulatory Agency (MHRA) has a specific interest</p>

Reference Number: PGD0140E

Valid from: 05/01/2026

Review Date: 05/07/2028

Expiry Date: 05/01/2029

	<p>in the reporting of adverse drug reactions for this product. All suspected adverse drug reactions should be reported using the MHRA Yellow Card scheme.</p>
<p>Off-label use</p>	<p>The SPC recommends that individuals who receive a first dose of Prevenar 13[®] complete the vaccination course with Prevenar 13[®], however, the vaccine can be interchanged in accordance with the national guidance as per the Green Book, Chapter 25.</p> <p>Where the SPCs for Prevenar 13[®] and Vaxneuvance[®] state that an 8-week interval from the last pneumococcal conjugate vaccination should be observed, the vaccine can be given at a minimum 4-week interval in accordance with the Green Book, Chapter 25.</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 Vaccine Incident Guidance. Where the vaccine is 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 in accordance with national guidance but out of product licence.</p>
<p>Route and method of administration</p>	<p>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.</p> <p>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.</p> <p>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.</p> <p>Individuals with bleeding disorders may be vaccinated intramuscularly if, in the opinion of a clinician familiar with</p>

Reference Number: PGD0140E

Valid from: 05/01/2026

Review Date: 05/07/2028

Expiry Date: 05/01/2029

	<p>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 be vaccinated via the intramuscular route. 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.</p> <p>For individuals with an unstable bleeding disorder (or where intramuscular injection is otherwise not considered suitable), vaccines normally given by the intramuscular route should be given by deep subcutaneous injection, in accordance with the recommendations in the Green Book Chapter 4.</p> <p>Prevenar®13 is a homogenous white suspension which may sediment during storage. Vaxneuvance® is an opalescent suspension. Shake the prefilled syringe well to uniformly distribute the suspension before administering the vaccine.</p> <p>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.</p> <p>The vaccine SPC provides further guidance on preparation and administration.</p>
<p>Dose and frequency of administration</p>	<p>Single 0.5ml dose per administration.</p> <p>A minimum interval of 4 weeks should be observed between any 2 doses of any PCV vaccine.</p> <p>1. Routine childhood immunisation schedule Infants should be offered a 1+1 PCV schedule, that is:</p>

Reference Number: PGD0140E

Valid from: 05/01/2026

Review Date: 05/07/2028

Expiry Date: 05/01/2029

	<ul style="list-style-type: none"> • a single priming dose of PCV13 or PCV15 to be administered from 16 weeks of age, followed by • a PCV13 or PCV15 booster dose to be administered at one year old, on or soon after their first birthday and before 2 years of age. <p>Routine immunisation with PCV13 or PCV15 is not offered after the second birthday.</p> <p>For individuals under 2 years of age with asplenia, splenic dysfunction, complement disorder or severe immunocompromise routine childhood immunisation schedule see PCV20 PGD 0251 (as PCV20 replaces PCV13 or PCV15).</p> <p>Note: Continue to use PCV risk groups PGD for individuals under 2 years of age with asplenia, splenic dysfunction, complement disorder or severe immunocompromise until stocks of PCV20 are available.</p> <p>For individuals with uncertain or incomplete vaccination see special considerations and additional information below. For public health management of clusters of severe pneumococcal disease in closed settings see PCV20 PGD 0251.</p> <p>For further information with reference to changeover from PCV13 and PCV15 to PCV 20 see Pneumococcal vaccination for older adults and for individuals in a clinical risk group: Information for healthcare practitioners and Chapter 25.</p>
Duration of treatment	See Dose and frequency of administration section above
Quantity to be supplied and administered	Single 0.5ml dose per administration.
Supplies	<p>Centrally purchased vaccines for the national immunisation programme for the NHS can only be ordered via ImmForm. Vaccines for use for the national immunisation programme are provided free of charge.</p> <p>Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see the Green Book Chapter 3).</p>

Reference Number: PGD0140E

Valid from: 05/01/2026

Review Date: 05/07/2028

Expiry Date: 05/01/2029

	<p>Also refer to All Wales Advisory document on Ordering Storage and Handling of Vaccines.</p>
<p>Storage</p>	<p>Store at between +2°C to +8°C.</p> <p>Store in original packaging in order to protect from light.</p> <p>Do not freeze.</p> <p>Following a single temperature excursion, Prevenar®13 is stable at temperatures up to 25°C for a maximum of 4 days. Prevenar®13 should be used within this timeframe or discarded in accordance with local procedures.</p> <p>Stability data indicates Vaxneuvance® is stable at temperatures up to 25°C for 48 hours.</p> <p>This information is only intended to guide health care professionals in case of temporary temperature excursions.</p> <p>Protocols for the storage and handling of vaccines should be followed to prevent vaccine wastage.</p>
	<p>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>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.</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 co-ordinator (Powys.Immunisations@wales.nhs.uk), Medicines Management Team</p>

Reference Number: PGD0140E
 Valid from: 05/01/2026
 Review Date: 05/07/2028
 Expiry Date: 05/01/2029

	<p>Info.MedicinesManagement.Powys@wales.nhs.uk and via PTHB Once for Wales Reporting System.</p>
Disposal	<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 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 Safe management of healthcare waste.</p>
Drug interactions	<p>Immunological response may be diminished in those receiving immunosuppressive treatment. Vaccination is recommended even if the antibody response may be limited.</p> <p>PCV13 or PCV15 may be given at the same time as other vaccines.</p> <p>A detailed list of drug interactions is available in the product's SPC.</p>
Identification and management of adverse reactions	<p>Local reactions following vaccination are very common such as pain, swelling or redness at the injection site.</p> <p>The most commonly reported adverse reactions include fever, irritability, decreased appetite, fatigue, headache, myalgia and somnolence.</p> <p>Other commonly reported reactions include rash.</p> <p>Vomiting and diarrhoea are commonly reported reactions to Prevenar[®]13.</p> <p>Hypersensitivity reactions, such as bronchospasm, angioedema and anaphylaxis can occur but are rare.</p> <p>A detailed list of adverse reactions is available in the product's SPC.</p>

Reference Number: PGD0140E

Valid from: 05/01/2026

Review Date: 05/07/2028

Expiry Date: 05/01/2029

	<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.</p> <p>In case of anaphylaxis:</p> <ul style="list-style-type: none"> • 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 patient notes • Ensure all patient records are marked ALLERGIC TO pneumococcal polysaccharide conjugate vaccine (13-valent or 15-valent, adsorbed) (PCV) stating the brand of vaccine • The patient may be advised to wear a MedicAlert or similar device to alert other healthcare providers <p>Report via Once for Wales Reporting System.</p>
<p>Reporting procedure of adverse reactions</p>	<p>Healthcare professionals and individuals, parents or 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> <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 the individual (or 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"> • A guide to immunisations for babies up to 13 months of age • A quick guide to childhood immunisation for the parents of premature babies

Reference Number: PGD0140E

Valid from: 05/01/2026

Review Date: 05/07/2028

Expiry Date: 05/01/2029

	<p>Further information for printing and website links suitable for the public 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>For resources in accessible formats and alternative languages, please visit Home- Health Publications.</p> <p>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.</p>
<p>Advice and follow up treatment</p>	<p>Inform the individual, parent or carer of possible side effects and their management.</p> <p>Give appropriate advice if medication is used 'off label'.</p> <p>Where vaccine has been exposed to a temporary temperature excursion but following an investigation it has been approved for 'off label' use in accordance with the manufacturers instructions, a leaflet is available to inform the individual, parent or carer: The use of vaccines that have been temporarily stored outside the recommended temperature range - A brief guide for parents, carers and patients</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. Advise the individual, parent or carer when any subsequent immunisations are due.</p> <p>When administration is postponed, advise the individual, parent or carer when to return for vaccination.</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> <p>For the management of clusters of severe pneumococcal disease in closed settings requiring pneumococcal vaccination see PCV20 PGD 0251</p> <p>Individuals with asplenia, splenic dysfunction, complement disorder and severe immunosuppression are at increased risk of pneumococcal disease and require additional doses of pneumococcal conjugate vaccine in accordance with the Green Book Chapter 7 and Chapter 25, see PCV20 PGD 0251</p> <p>Premature infants Premature infants should be vaccinated in accordance with the national routine immunisation schedule according to their chronological age, no matter how premature they are (see Green Book Chapter 25).</p> <p>Doses given before 16 weeks of age and the impact of the change in routine schedule from 12 to 16 weeks of age The immunogenicity of PCV13 or PCV15 will potentially provide lower protection if given before 12 weeks of age. Therefore, any dose given before this age should not be counted as the single priming dose for the 1+1 schedule. The routine PCV dose should be given once the infant reaches 16 weeks of age, leaving a minimum 4 week interval between the priming dose and any preceding dose.</p> <p>There may be a number of infants who received a dose of PCV at or around 12 weeks of age. Where an infant has been immunised at 12 weeks and not 16 weeks, this dose is considered valid and does not need to be repeated.</p> <p>Children who have not yet received their 12 week vaccinations by 1 July 2025, will be offered the vaccines in line with the new schedule. This includes children who attend late for their 12 week vaccinations.</p> <p>Unimmunised or partially immunised children</p>
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Reference Number: PGD0140E

Valid from: 05/01/2026

Review Date: 05/07/2028

Expiry Date: 05/01/2029

	<p>Unimmunised or partially immunised infants who do not have asplenia, splenic dysfunction, complement disorder or severe immunocompromise who:</p> <ul style="list-style-type: none"> • present late for vaccination, and before one year of age, should receive a primary dose of PCV13 or PCV15 before the age of one year, and a booster dose at one year of age, leaving a 4 week interval between the primary PCV13 or PCV15 dose and the booster. Where the infant is presented very late (such as at 11 months), then this interval may be reduced to enable the booster dose and all other routine vaccines at one year of age to be given on time • present for vaccination between one year and under 2 years of age should only have a single dose of PCV13 or PCV15 • do not have a reliable history of previous immunisation and are aged under 2 years at the time of first presentation, should be assumed to be unimmunised and the routine programme should be followed (see above) • have received one or more doses of PCV10 vaccine should be offered PCV13 or PCV15 vaccination in accordance with the UK PCV routine vaccination schedule (see above) with a minimum interval of 4 weeks between PCV13 or PCV15 vaccination and any preceding PCV10 dose. Where the infant is presented very late (such as at 11 months), then this interval may be reduced to enable the one year PCV booster to be given on time alongside all other routine immunisations at one year of age. • Unless the individual is at increased risk of pneumococcal disease (see PCV20 PGD 0251) there is little clinical benefit in offering PCV vaccination to unimmunised or partially immunised individuals aged over 2 years and above and therefore a dose of vaccine should not be given in such instances <p>See the algorithm for vaccination of individuals with uncertain or incomplete immunisation status</p> <p>Individuals who have received a bone marrow transplant after vaccination should be considered for a re-immunisation 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 Patient Specific Direction (PSD).</p>
<p>Records</p>	<p>Record consultation details as required by local procedures. The practitioner must 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 name and address of GP with whom the individual is registered • medical and drug history taken, including any allergies and previous adverse events • printed name and signature of health professional administering the medicine (if recording on paper). If recording directly on WIS or another digital system, then name only as the signature will be replaced by electronic logging of the user. • name and brand of vaccine • date and time 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 (include PGD title, number and version) <p>Records should be signed and dated (or password-controlled on e-records).</p> <p>All records should be clear, legible and contemporaneous.</p> <p>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.</p> <p>Where applicable, 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.</p> <p>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</p>
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Reference Number: PGD0140E

Valid from: 05/01/2026

Review Date: 05/07/2028

Expiry Date: 05/01/2029

	<p>documentation/pathway as required by any local or contractual arrangement (based in Brecon Hospital for under 5 years and Llandrindod Hospital for school age).</p> <p>A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.</p>
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Reference Number: PGD0140E

Valid from: 05/01/2026

Review Date: 05/07/2028

Expiry Date: 05/01/2029

4. Key references.

<p>Key references</p>	<p>Pneumococcal conjugate vaccine</p> <ul style="list-style-type: none"> • Immunisation Against Infectious Disease: The Green Book, Chapter 25, last updated 6 August 2025 www.gov.uk/government/publications/pneumococcal-the-green-book-chapter-25 • Summary of Product Characteristics for Prevenar®13 suspension for injection, Pfizer Ltd, last updated June 2025 www.medicines.org.uk/emc/medicine/22689 • Personal communication, Pfizer Ltd (Prevenar®13 suspension for injection). Contacted 23 November 2023. • Summary of Product Characteristics for Vaxneuvance® suspension for injection, Merck Sharpe and Dohme Ltd, last updated 14 December 2023 www.medicines.org.uk/emc/product/13754/smpc • Vaccination of individuals with uncertain or incomplete immunisation status, UKHSA 3 December 2025. www.gov.uk/government/publications/vaccination-of-individuals-with-uncertain-or-incomplete-immunisation-status • Changes to the routine childhood schedule letter, published 30 April 2025 www.gov.uk/government/publications/changes-to-the-routine-childhood-schedule-letter • The Joint Committee on Vaccination and Immunisation (JCVI) – (draft) minute of the meeting hold on 5 February 2025, published 19 March 2025, Item IV: Infant schedule, paragraph 69 www.gov.uk/government/groups/joint-committee-on-vaccination-and-immunisation#meetings-agendas-and-minutes • Pneumococcal vaccination for older adults and for individuals in a clinical risk group: Information for healthcare practitioners www.gov.uk/government/collections/immunisation • Change of vaccine for the routine adult pneumococcal vaccination programme and individuals at increased clinical risk letter Published 16 December 2025 www.gov.uk/government/publications/change-of-vaccine-for-the-routine-adult-pneumococcal-vaccination-programme-and-individuals-at-increased-clinical-risk/change-of-vaccine-for-the-routine-adult-pneumococcal-vaccination-programme-and-individuals-at-increased-clinical-risk-letter <p>General</p> <ul style="list-style-type: none"> • All Wales Advisory document on Ordering Storage and Handling of Vaccines 7th Edition, September 2017.
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Reference Number: PGD0140E

Valid from: 05/01/2026

Review Date: 05/07/2028

Expiry Date: 05/01/2029

	<ul style="list-style-type: none">• 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/• NHS sustainable management of healthcare waste, updated 26 January 2024 www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-htm-07-01/• National Minimum Standards and Core Curriculum for Immunisation Training published 31 July 2025. 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 www.nice.org.uk/guidance/mpg2• NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions, updated 4 January 2018 www.nice.org.uk/guidance/mpg2/resources• UKHSA Immunisation Collection www.gov.uk/government/collections/immunisation• Vaccine Incident Guidance www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors
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Reference Number: PGD0140E

Valid from: 05/01/2026

Review Date: 05/07/2028

Expiry Date: 05/01/2029

Appendix A – Staff Accredited to use 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 (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

Reference Number: PGD0140E

Valid from: 05/01/2026

Review Date: 05/07/2028

Expiry Date: 05/01/2029

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.