Docusign Envelope ID: C6B48E69-2083-44EE-8F92-93F66DF1D2F6

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. 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 (20-valent, adsorbed) (PCV20)

by

registered Healthcare Professionals

to

individuals from 65 years of age, individuals from 2 years of age in a clinical risk group and individuals under 2 years of age with asplenia, splenic dysfunction, complement disorder or severe immunocompromise in accordance with the national immunisation programme for active immunisation against pneumococcal disease and for the public health management of clusters of severe pneumococcal disease in closed settings in accordance with the UK guidelines in

Powys Teaching Health Board

Version number: PGD 0251

Reference Number: PGD 0251
Valid from: 17/12/2025
Review date: 17/07/2028
Expiry date: 17/12/2028

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Change History		
Version number	**Change details**	**Date**
PGD 0251	New PGD from UKHSA adopted for use by PTHB following the introduction of PCV20 vaccine to the immunisation programme for: • adults aged 65 years and over (as replacement for PPV23) • individuals from 2 years of age in a clinical risk group (as replacement for PPV23) • individuals under 2 years of age with asplenia, splenic dysfunction, complement disorder or severe immunocompromise (as replacement for PCV13 or PCV15) • public health management of clusters of severe pneumococcal disease in closed settings in accordance with the UK guidelines	09/12/2025

This Powys Teaching Health Board (PTHB) PGD is based on the UKHSA PGD template v1.00 developed by the following on behalf of the UKHSA and peer reviewed by the UKHSA Immunisations PGD Expert Panel in accordance with the UKHSA PGD and Protocol Policy (also ratified by the UKHSA Medicines Governance Committee).

The UKHSA template has been adapted for use in PTHB.

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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, Immunisation Programmes, UKHSA

Expert panel

Name	Designation
Nicholas Aigbogun	Consultant in Communicable Disease Control, Yorkshire and Humber Health Protection Team, UKHSA
Gayatri Amrithalingam	Consultant Epidemiologist, Immunisation Programmes, UKHSA
Jessica Baldasera	Health Protection Practitioner, North East Health Protection Team Regions Directorate, UKHSA
Alison Campbell	Screening and Immunisation Coordinator, Public Health Commissioning NHS England (NHS England) Midlands
Jane Freeguard	Deputy Director of Vaccination – Medicines and Pharmacy, NHSE
Rosie Furner	Advanced Specialist Pharmacist - Medicines Governance, Specialist Pharmacist Services (SPS)
Ed Gardner	Advanced Paramedic Practitioner/Emergency Care Practitioner, Medicines Manager, Proactive Care Lead
Shilan Ghafoor	Lead Pharmacist Medicines Governance, UKHSA
Helen Eley	Lead Immunisation Nurse Specialist, Immunisation Programmes, UKHSA
Naveen Dosanjh	Senior Clinical Advisor - Vaccinations, NHS England
Elizabeth Luckett	Senior Screening and Immunisation Manager, NHSE South West
Briony Mason	Vaccination Manager, Professional Midwifery Advocate, Vaccination and Screening, NHS England, 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...	12/24/2025
Chief Pharmacist **Jonathan Boyd**	Chief Pharmacist for PTHB	Signed by: Jon Boyd 6D8ECFE8C9EB423...	12/29/2025
Senior representative of professional group using the PGD **Paul Hooton**	Executive Director of Nursing and Midwifery for PTHB	Signed by: Paul Hooton EEABC83AC83F4B9...	12/29/2025
Clinical Governance **Alexandra Simmonds**	Clinical Governance Lead for PTHB – Deputy Director of Allied Health Professionals and Health Sciences	Signed by: Alexandra Simmonds 8AE04C1B9F8C4F8...	12/29/2025

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 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

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Practitioners and organisations must check that they are using the current version of the PGD. Amendments may become necessary prior to the published expiry date. Enquiries relating to the use of this PGD, availability of organisationally authorised PGDs and subsequent versions of this PGD should be directed to Medicines Management: 01874 712641.

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PGD adoption by the provider

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

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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 section below: Practitioners working to this PGD must also be a registered professional with one of the following bodies: • 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, physiotherapists, dieticians, podiatrists, and occupational therapists currently registered with the Health and Care Professions Council (HCPC) The practitioners above must also fulfil the Additional requirements detailed below. 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.
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/administration of medicines • must be competent in the use of PGDs (see NICE Competency framework for health professionals using PGDs) • 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 • must be competent in intramuscular injection techniques

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	• must be competent to undertake immunisation and to discuss issues related to immunisation • must be competent in the handling and storage of vaccines, and management of the cold chain • must be competent in the recognition and management of anaphylaxis • 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	Vaccinators must complete the appropriate Pneumococcal training, in line with National Minimum Standards for Immunisation & Vaccination Training. Updating as appropriate. 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). Evidence of ongoing PGD training to be submitted to Line Manager annually. Practitioners must be competent, recognise their own limitations and personal accountability and act accordingly. Practitioners must make a self-declaration of competency on PADR. Compliance with all mandatory NHS training (if relevant). Practitioners should be constantly alert to any subsequent recommendations Welsh Government and/or Public Health Wales and/or NHS Wales and the UKHSA, NHS England (NHSE) and other sources of medicines information. Note: The most current national recommendations should be followed but a Patient Specific Direction (PSD) or a prescription may be required to administer the vaccine in line with updated recommendations that are outside the criteria specified in this PGD

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

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 from 65 years of age, individuals from 2 years of age in a clinical risk group and individuals under 2 years of age with asplenia, splenic dysfunction, complement disorder or severe immunocompromise for the prevention of pneumococcal disease, and for the public health management of clusters of severe pneumococcal disease in closed settings, in accordance with the national immunisation programme and UK guidelines. **Note:** The remaining stocks of PPV23 should be used for individuals from 65 years of age and from 2 years of age in a clinical risk group before changing to PCV20. For reference, see Managing clusters of pneumococcal disease in closed settings and recommendations given in Chapter 25 of Immunisation Against Infectious Disease: the Green Book. **If used in PTHB Occupational Health Service for their own staff (including students and trainees), the PGD must be used in line with PTHB Occupational Immunisation policy.** **It is the responsibility of the administering healthcare professional to ensure that the individual is within the inclusion criteria, and that there are no reasons for exclusion before proceeding with the vaccination. If there is any reason for concern, seek medical advice.**
Criteria for inclusion	Individuals who: • are aged 65 years and over • are aged 2 years and over and have a medical condition included in the clinical risk groups defined in the Green Book Chapter 25, Table 25.2. • have asplenia, splenic dysfunction, or chronic kidney disease and require a pneumococcal vaccine booster (see Chapter 25)

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	• are under 2 years of age with asplenia, splenic dysfunction, complement disorder or severe immunocompromise (Chapter 25, Table 25.3) • are identified as requiring vaccination by the local Health Protection Team for the public health management of pneumococcal disease in accordance with Managing clusters of pneumococcal disease in closed settings **Note:** • Individuals at risk of frequent or continuous occupational exposure to metal fumes (such as welders) should be considered for immunisation taking into account exposure control measures in place. This is an occupational health vaccination and is not a NHS service. This is outside the remit of this PGD. 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 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 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 • are in a clinical risk group who have previously received PPV23 or PCV20 except individuals with asplenia, splenic dysfunction, complement disorder, severe immunocompromise or chronic kidney disease (see Green Book Chapter 25) • are not recommended to receive the vaccination in accordance with the Managing clusters of pneumococcal disease in closed settings guidelines. • have had a confirmed anaphylactic reaction to a previous dose of a pneumococcal vaccine or diphtheria toxoid or a confirmed anaphylactic

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	reaction to any component or residue from the manufacturing process (see SPC) • have received PPV23 or PCV (any valency) vaccine in the preceding 4 weeks • are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation)
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). The vaccine must be administered with caution to individuals with thrombocytopenia or a bleeding disorder since bleeding may occur following an intramuscular administration (see Route and administration). Individuals with impaired immune response, may have reduced immune responses to PCV20. Antibody levels are likely to decline rapidly in individuals with asplenia, splenic dysfunction (including sickle cell disease) or chronic renal disease and, therefore, re-immunisation with PCV20 is recommended. See dose and frequency and special considerations sections regarding appropriate timing of vaccination. Individuals with immunosuppression and HIV infection (regardless of CD4 count) should be given pneumococcal vaccines according to the recommendations in Chapter 25. Vaccination is recommended for all individuals with asplenia or splenic dysfunction, including individuals with coeliac disease who are diagnosed with splenic dysfunction and all individuals with haemoglobinopathies such as homozygous sickle cell disease Chapter 25 and Chapter 7. 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, paraesthsia 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 patient is taking, including topical or inhaled products, food

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	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 a single dose of PCV20 or PPV23 has previously been given to an individual over the age of 2 years **and** the individual does not have asplenia, splenic dysfunction, severe immunocompromise or chronic kidney disease (see Green Book Chapter 25) **and immunisation is not indicated** for the individual in line with Managing clusters of pneumococcal disease in closed settings, further PCV20 is **not** indicated. See Table 25.3 Chapter 25 footnote for examples of severe immunocompromise. If aged less than 6 weeks, defer immunisation and provide an appointment as appropriate at 8 weeks of age, or as soon as possible thereafter. Vaccination should not commence before the age of 8 weeks. Individuals who have had a confirmed anaphylactic reaction to a previous dose of pneumococcal vaccine or diphtheria toxoid or any components of the PCV20 vaccine, should be referred to a clinician for specialist advice and appropriate management. Individuals who have recently received PCV vaccine (any valency) should postpone PCV20 or PPV23 immunisation until 4 weeks has elapsed.

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	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. 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 GP or a prescriber as appropriate.
Action to be taken if the individual, parent 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. The patient information leaflet should be available to inform consent. Advise the individual, parent or carer about the protective effects of the vaccine, the risks of infection and potential complications of disease. Document advice given and the decision reached. Inform or refer to the GP or a prescriber as appropriate. For PTHB Occupational Health Service- refer to Occupational Health Consultant as necessary and document advice given. 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.

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	For PTHB Occupational Health Service- refer to Occupational Health Consultant as necessary. Document any advice given.

Description of treatment

Name, strength and formulation of drug	Prevenar®20 suspension for injection in pre-filled syringe Pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed) For full formulation details see SPC.
Legal category	Prescription only medicine (POM)
Black triangle▼	YES Prevenar®20 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 scheme.
Off-label use	The SPC recommends that individuals who receive a first dose of PCV20 complete the vaccination course with PCV20, however, the vaccine can be interchanged in accordance with the national guidance, see Chapter 25. Where the SPC states 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. Administration of a further dose of PCV20 to high-risk individuals who have already received a dose of PCV20 more than 12 months previously is off-label but may be recommended in accordance with the Managing pneumococcal disease in closed settings and Chapter 25. 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 vaccines are assessed in accordance with these

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	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 deltoid muscle of the upper arm or, for infants 1 year and under, into the anterolateral aspect of the thigh. When administering at the same time as other vaccines, care should be taken to ensure that the appropriate route of injection is used for all the vaccinations. The vaccines should be given at separate sites, preferably into different limbs. If given into the same limb, they should be given at least 2.5cm apart. The site at which each vaccine was given should be noted in the individual's records. Individuals with bleeding disorders may be vaccinated intramuscularly if, in the opinion of a doctor familiar with the individual's bleeding risk, vaccines or similar small volume intramuscular injections can be administered with reasonable safety by this route. Individuals on stable anticoagulation therapy, including individuals on warfarin who are up to date with their scheduled INR testing and whose latest INR was below the upper threshold of their therapeutic range, can be vaccinated via the intramuscular route. If the individual receives medication or other treatment to reduce bleeding, for example treatment for haemophilia, intramuscular vaccination can be scheduled shortly after such medication or other treatment is administered. A fine needle (equal to 23 gauge or finer calibre such as 25 gauge) should be used for the vaccination, followed by firm pressure applied to the site (without rubbing) for at least 2 minutes. The individual, parent or carer should be informed about the risk of haematoma from the injection. For individuals with an unstable bleeding disorder (or where intramuscular injection is otherwise not considered suitable), vaccines normally given by an intramuscular route should be given by deep

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	subcutaneous injection, in accordance with Chapter 4 of the Green Book. The vaccine's normal appearance is a homogeneous white suspension. The vaccine should be shaken well to obtain a white homogeneous suspension. The vaccine should be visually inspected for foreign particulate matter and other variation of expected appearance prior to preparation and administration. Should either occur, do not administer the dose and discard the vaccine in accordance with local procedures. The vaccine SPC provides further guidance on preparation and administration. Check expiry date and that the correct product has been chosen.
Dose and frequency of administration	Single 0.5ml dose. A minimum interval of 4 weeks should be observed between any 2 doses of any PCV vaccine (regardless of the valency). **Adults aged 65 years and over** • a single dose of 0.5ml of PCV20 If an individual has already received PPV23 or PCV20 because they are in a **clinical risk group**, they do not require another dose of PCV20 at 65 years of age and over, irrespective of the interval since they received PPV23 or PCV20. Whilst PPV23 is available for the routine programme for adults aged 65 years and over, if an individual **not in a clinical risk group** becomes eligible for PPV23 at age 65 years but has already received PCV20, PPV23 can still be offered at any interval after this but it is recommended that a minimum 4-week interval is observed (refer to PPV23 PGD and Pneumococcal vaccination for older adults and for individuals in a clinical risk group: Information for healthcare practitioners). **All clinical risk groups aged from 2 years of age (except severely immunocompromised)**

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	• a single dose of 0.5ml of PCV20 at 2 years of age, at least 4 weeks after the last PCV dose (**Note:** Start using PCV20 once the PPV23 stocks are exhausted) **Vaccination of individuals under 2 years of age with asplenia, splenic dysfunction, complement disorder or severe immunocompromise is as follows:** **Individuals under one year of age** • two doses of PCV20 at least 4 weeks apart, commencing with their first visit at 8 weeks of age, or as soon as possible thereafter • individuals diagnosed after 16 weeks who have already received PCV13 should receive two doses of PCV20 with an interval of at least 4 weeks between any doses **Individuals from 1 year to under 2 years of age** • a single dose of routine booster of PCV20 is administered at one year of age (on or after the first birthday) If the routine booster of PCV13 dose has been given at one year (on or after the first birthday), then give a single dose of PCV20 at least 4 weeks later. **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. **Severely immunocompromised individuals aged from 2 years of age** Examples of severe immunocompromise include bone marrow transplant patients, patients with acute and chronic leukaemia, multiple myeloma or genetic disorders affecting the immune system (such as IRAK-4, NEMO) (see Chapter 25). • two PCV20 doses, at 2 years of age, at least 4 weeks apart and at least 4 weeks after the last PCV dose (or if first diagnosed or presenting at any time after the 2nd birthday)

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	5 yearly booster doses Individuals with asplenia, splenic dysfunction (including sickle cell disease), or chronic kidney disease should be revaccinated at every 5 years with PCV20. Revaccination with PCV20 is currently not recommended for any other clinical risk groups or age groups. Testing of antibody levels prior to vaccination is not required for these or any other risk groups. **Pneumococcal outbreaks in closed settings** PCV20 should be offered to high-risk individuals recommended to receive vaccination by the local Health Protection Team for the public health management of pneumococcal disease in accordance with Managing pneumococcal disease in closed settings, unless they have received PPV23 or PCV20 in the previous 12 months. **Note:** PCV20 can be used, when available, instead of PPV23 in pneumococcal outbreaks in closed settings, including care homes. **Individuals with unknown or incomplete vaccination histories** For an individual in a clinical risk group, if their PCV dose in the routine programme is given very late (for example at 23 months), then a minimum interval of 4 weeks should be observed before giving a booster dose of PCV20. For further information for the changeover see Pneumococcal vaccination for older adults and for individuals in a clinical risk group: Information for healthcare practitioners.
Duration of treatment	Single 0.5ml dose, repeated at recommended intervals as outlined above in dose and frequency of administration.
Quantity to be supplied and administered	Single 0.5ml dose.
Supplies	Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see Green Book Chapter 3).

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	Also refer to All Wales Advisory document on Ordering Storage and Handling of Vaccines. Centrally purchased vaccines for the national immunisation programme for the NHS can only be ordered via ImmForm. Vaccines used for the national immunisation programme are provided free of charge.
Storage	Store at +2°C to +8°C. Store in original packaging in order to protect from light. Pre-filled syringes should be stored in the refrigerator horizontally to minimise the resuspension time. Do not freeze. Discard if the vaccine has been frozen. From a microbiological point of view, once removed from the refrigerator, the vaccine should be used immediately. Stability data indicate that the vaccine is stable for: • 96 hours when stored at temperatures from +8 °C to +25 °C, or • 72 hours when stored at temperatures from 0 °C to +2 °C At the end of these time periods the vaccine should be used or discarded. These data are intended to provide guidance in case of temporary temperature excursion only. During storage, a white deposit and clear supernatant may be observed in the pre-filled syringe containing the suspension. In the event of an inadvertent or unavoidable deviation of these conditions, vaccines that have been stored outside the conditions stated above should be quarantined and risk assessed on a case-by-case basis for suitability of continued off-label use or appropriate disposal. Refer to All Wales Advisory document on Ordering Storage and Handling of Vaccines and Vaccine Incident Guidance. See 'MMP 427 Safe and Secure Management of Refrigerated Medicines and Vaccines SOP' for details of actions required in the event of a fridge temperature excursion. Contact the Medicines Management Team where a temperature excursion occurs (for any length of time) Info.MedicinesManagement.Powys@wales.nhs.uk

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	Protocols for the storage and handling of vaccines should be followed to prevent vaccine wastage. 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), the Medicines Management Team Info.MedicinesManagement.Powys@wales.nhs.uk and via PTHB Datix reporting system Once for Wales Reporting System.
Disposal	Follow local clinical waste policy and NHS standard operating procedures to ensure safe and secure waste 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 authority arrangements and guidance in the Welsh Health Technical Memorandum 07-01 Safer management of healthcare waste.
Drug interactions	The immunological response may be diminished in those receiving immunosuppressive treatment, but it is important to still immunise this group. Vaccination is recommended even if the antibody response may be limited. PCV20 may be given at the same time as other vaccines (Chapter 25, Chapter 11 and SPC). A list of drug interactions associated with Prevenar®20 is available from the SPC.
Identification and management of adverse reactions	In children, the most common reactions are irritability, drowsiness, and pain at injection site, decreased appetite, drowsiness or increased sleep, restless sleep or decreased sleep, redness at the injection site, muscle pain, fatigue, swelling at the injection site, and fever ≥ 38.0°C. Most adverse reactions occurred within 1 to 2 days following vaccination and were mild or moderate and of short duration (1 to 2 days). In adults, the most commonly reported reactions were pain at the injection site, muscle pain, fatigue, headache and joint pain.

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	A detailed list of adverse reactions and from post marketing experience is available in the vaccine SPC. 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) PGD 0017 and anaphylaxis policy • Request medical assistance urgently. If the GP is not immediately available dial 999 to transfer to A&E • Ensure reaction is fully documented in patient notes • Ensure all patient records are marked **ALLERGIC TO PNEUMOCOCCAL POLYSACCHARIDE VACCINE PCV20 (Prevenar®20)** and specify type of reaction**.** • The patient may be advised to wear a MedicAlert or similar device to alert other healthcare providers Report via Datix Once for Wales Reporting system. Report any suspected adverse reactions to a doctor.
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 PTHB Once for Wales Reporting System.
Written information to be given to individual, parent or carer	Offer marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine. For resources in accessible formats and alternative languages, please visit Home – Discover Public Health Resource Library. Where applicable, inform the individual/parent/carer that the PIL with large print, Braille or audio CD can be ordered from the manufacturer (see electronic medicines compendium).

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	For resources in accessible formats and alternative languages, please visit Home- Health Publications. Immunisation promotional material may be provided as appropriate: Splenectomy leaflet See also Off-label vaccines - an introductory guide for healthcare professionals Further information for printing and website links suitable for patients can be found on the Public Health Wales intranet site Public Health Wales Immunisation and Vaccine Preventable Disease Programme, NHS 111 Wales and Health Information Resources.
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, splenic dysfunction and those who have received immunosuppressive therapy for any reason), should be advised regarding the possible need for early antimicrobial treatment in the event of severe, sudden febrile illness. 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. When administration is postponed, advise the individual, parent or carer when to return for vaccination. When applicable, advise the individual, parent or carer when to return for vaccination or when a subsequent vaccine dose is due. Give appropriate advice if medication is used off-label. Off-label vaccines - an introductory guide for healthcare professionals
Special considerations and additional information	Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a telephone at the time of vaccination.

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	The remaining stocks of PPV23 should be used for individuals from 65 years of age and from 2 years of age in a clinical risk group before changing to PCV20. In outbreak settings it is recommended to use PCV20 before all stocks of PPV23 have been used up. 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. All other individuals under 2 year of age should be fully vaccinated in accordance with the routine PCV immunisation programme (see the UKHSA PCV routine PGD and the Vaccination of individuals with uncertain or incomplete immunisation status guidance). Individuals who are a contact of pneumococcal disease do not usually require PCV20. Immunisation may be indicated where there is a confirmed cluster of severe pneumococcal disease in a closed setting and should be on the advice of your local Health Protection Team. Pneumococcal vaccines may be given to pregnant women when the need for protection is required without delay. There is no evidence of risk from vaccinating pregnant women or those who are breast-feeding with inactivated viral or bacterial vaccines or toxoids. Testing of antibody levels prior to vaccination is not required for any clinical risk groups (see Chapter 25). **Protection against pneumococcal disease** Prevenar®20 will only protect against Streptococcus pneumoniae serotypes included in the vaccine and will not protect against other microorganisms that cause invasive disease, pneumonia or otitis media (OM). As with any vaccine, Prevenar®20 may not protect all individuals receiving the vaccine from pneumococcal invasive disease, OM or pneumonia. **Premature infants** Premature infants should be vaccinated in accordance with the national routine immunisation schedule according to their chronological age. Premature infants should be vaccinated in accordance with the national guidance. Very premature infants (born ≤28 weeks of gestation) who are in hospital should have respiratory monitoring for 48 to 72 hours when given their first immunisation, particularly those with a previous history of respiratory immaturity. If the child has

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	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 can be given in the community setting. **Timing of vaccination** Individuals with immunosuppression and HIV infection (regardless of CD4 count) should be given pneumococcal vaccines according to the recommendations. Wherever possible, immunisation or boosting of immunosuppressed or HIV-positive individuals should be either carried out before immunosuppression occurs or deferred until an improvement in immunity has been seen. The optimal timing for any vaccination should be based upon a judgement about the relative need for rapid protection and the likely response. For individuals due to commence immunosuppressive treatments, inactivated vaccines should ideally be administered at least 2 weeks before treatment begins. In some cases, this will not be possible and therefore vaccination may be carried out at any time and re-immunisation considered after treatment is finished and recovery has occurred. Ideally, PCV20 should be given at least 4 weeks before elective splenectomy or initiation of treatment such as chemotherapy or radiotherapy. Where this is not possible, it can be given up to 2 weeks before treatment (see Green Book Chapter 25). If it is not practical to vaccinate 2 weeks or more before splenectomy, immunisation should be delayed until at least 2 weeks after the operation. If it is not practicable to vaccinate 2 weeks or more before initiation of either chemotherapy or radiotherapy (or both), immunisation should be delayed until at least 3 months after completion of therapy in order to maximise the response to the vaccine. Immunisation of these individuals should not be delayed if this is likely to result in failure to vaccinate.

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	For the timing of vaccination for individuals with leukaemia or anticipating bone marrow transplantation, see the Green Book Chapter 25. Splenectomy, chemotherapy or radiotherapy should never be delayed allowing time for vaccination. For further timings of vaccination see Chapter 25.
Records	Record consultation details as required by local procedures. The practitioner should 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 (or record where an individual is not registered with a GP) • medical and drug history taken, including any allergies and previous adverse events • Printed name and signature of the health professional administering the medicine (if recording on paper). If recording directly on WIS or another digital system then name only, 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 • any reasons for exclusion or referral, including actions taken • advice given, including advice given if excluded or declines immunisation • details of any adverse drug reactions and actions taken • administered via PGD, record PGD title and version number Records should be signed and dated (or password-controlled on e-records). All records should be clear, legible and contemporaneous.

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	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. Where applicable, the local Child Health Information Services (CHIS) 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.

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Key references

Key references	
Key references	**Pneumococcal polysaccharide vaccine** • 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 Characteristic for Prevenar®20 suspension for injection in pre-filled June 2025 www.medicines.org.uk/emc/product/13461/smpc • Guidelines for the public health management of clusters of severe pneumococcal disease in closed settings. Updated 21 February 2020 www.gov.uk/government/publications/managing-clusters-of-pneumococcal-disease-in-closed-settings • Pneumococcal vaccination for older adults and for individuals in a clinical risk group: Information for healthcare practitioners www.gov.uk/government/collections/immunisation **General** • NHS England Health Technical Memorandum 07-01: safe and sustainable management of healthcare waste, last updated 26 January 2024**Error! Bookmark not defined.** 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, updated 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 • 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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Appendix A – Staff Accredited to use the Patient Group Direction

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

Practitioner: By signing this PGD you are indicating that you agree to its contents and that you will work within it. PGDs do not remove inherent professional obligations or accountability. It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

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

Printed name of health professional	**Signature of health professional**	**Printed name of senior representative authorising health professional (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.

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

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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.

Reference Number: PGD0043E
Valid from: 01/09/24
Review Date: 01/09/26
Expiry Date: 01/03/27

Amendment - this should be:
Reference No. PGD 0251
Valid From: 17/12/2025
Review Date 17/07/2028
Expiry Date 17/12/2028