UK Health Security Agency

NHS

Publications gateway number: GOV-15880

Pneumococcal polysaccharide conjugate vaccine (adsorbed) Patient Group Direction (PGD)

This PGD is for the administration of pneumococcal polysaccharide conjugate vaccine (13-valent or 15-valent, adsorbed) (PCV) to individuals from 12 weeks to under 2 years of age in accordance with the national immunisation programme for active immunisation against pneumococcal disease and to individuals from 6 weeks of age recommended PCV13 or PCV15 in response to an outbreak of pneumococcal disease.

This PGD is for the administration of PCV13 or PCV15 by registered healthcare practitioners identified in Section 3, subject to any limitations to authorisation detailed in Section 2.

Reference no:	PCV PGD
Version no:	v5.00
Valid from:	28 February 2024
Review date:	30 November 2025
Expiry date:	31 May 2026

The UK Health Security Agency (UKHSA) has developed this PGD to facilitate the delivery of publicly funded immunisation in England in line with national recommendations.

Those using this PGD must ensure that it is organisationally authorised and signed in Section 2 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.**

Authorising organisations must not alter, amend or add to the clinical content of this document (sections 4, 5 and 6); such action will invalidate the clinical sign-off with which it is provided. In addition, authorising organisations must not alter section 3 (Characteristics of staff). Sections 2 and 7 can be edited within the designated editable fields provided, **but only for the purposes for which these sections are provided, namely the responsibilities and governance arrangements of the NHS organisation using the PGD. The fields in Section 2 and 7 cannot be used to alter, amend or add to the clinical content. Such action will invalidate the UKHSA clinical content authorisation which is provided in accordance with the regulations.**

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 completing Section 2 for 25 years after the PGD expires. Provider organisations adopting authorised versions of this PGD should also retain copies for the period specified above.

Individual practitioners must be authorised by name, under the current version of this PGD before working according to it.

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. Current versions of UKHSA PGD templates for authorisation can be found from: Immunisation patient group direction (PGD) templates

[1] This includes any relevant amendments to legislation.

Any concerns regarding the content of this PGD should be addressed to: immunisation@ukhsa.gov.uk

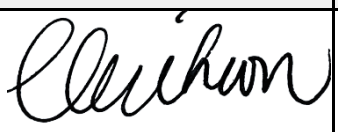
Enquiries relating to the availability of organisationally authorised PGDs and subsequent versions of this PGD should be directed to: england.londonimms@nhs.net

Change history

Version number	Change details	Date
v1.00	New PHE PGD template	19 January 2016
v2.00	PHE PCV PGD amended to: • include early administration from 6 weeks of age • include administration for the management of outbreaks • include additional healthcare practitioners in Section 3 • add paragraph on patient consent to the off-label section • reference the protocol for ordering storage and handling of vaccines • include additional stability data from product SPCs • refer to PHE vaccine incident guidance within the off-label and storage sections • include rewording, layout and formatting changes for clarity and consistency with other PHE PGDs	28 November 2018
v3.00	PHE PCV PGD amended to: • reflect the 1+1 schedule for individuals born on or after 1 Jan 2020 and immunisation from 12 weeks of age • refer to the PCV Risk Groups PGD for the immunisation of individuals with asplenia, splenic dysfunction, complement disorder and severe immunocompromise • include rewording, layout and formatting changes for clarity and consistency with other PHE PGDs	20 December 2019
v4.00	UKHSA PCV PGD amended to: • include minor rewording of standard text, layout and formatting changes for clarity and consistency with organisation change and other UKHSA PGD and updated references. • 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 section, information for partially immunised individuals as per the Green Book, Chapter 25 • provide detail regarding primary dose and schedule for premature infants 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 • include in the special considerations information for immunisation for bone marrow transplant • update the dose and frequency in line with the Green Book Chapter 25,	16 February 2022
v5.00	UKHSA PCV PGD amended to include: • minor rewording, layout and formatting changes for clarity and consistency with other UKHSA 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	25 January 2024

1. PGD development

This PGD has been developed by the following health professionals on behalf of the UKHSA:

Developed by:	Name	Signature	Date
Pharmacist (Lead Author)	Christina Wilson Lead Pharmacist - Immunisation Services, Immunisation and Vaccine Preventable Diseases Division, UKHSA		22 January 2024
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		22 January 2024
Registered Nurse (Chair of Expert Panel)	David Green Nurse Consultant for Immunisation, Immunisation and Vaccine Preventable Diseases Division, UKHSA		22 January 2024

This PGD has been peer reviewed by the UKHSA Immunisations PGD Expert Panel in accordance with the UKHSA PGD Policy. It has been ratified by the UKHSA Medicines Governance Committee.

Expert Panel

Name	Designation
Nicholas Aigbogun	Consultant in Communicable Disease Control, Yorkshire and Humber Health Protection Team, UKHSA
Alison Campbell	Screening and Immunisation Coordinator, Clinical, NHSE Midlands
Rosie Furner	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
Michelle Jones	Principal Medicines Optimisation Pharmacist, NHS Bristol North Somerset and South Gloucestershire Integrated Care Board
Jacqueline Lamberty	Medicines Governance Consultant Lead Pharmacist, UKHSA
Elizabeth Luckett	Senior Screening and Immunisation Manager, NHSE South West
Vanessa MacGregor	Consultant in Communicable Disease Control, East Midlands Health Protection Team, UKHSA
Lesley McFarlane	Lead Immunisation Nurse Specialist, Immunisation and Vaccine Preventable Diseases Division, UKHSA
Nikki Philbin	Screening and Immunisation Manager, Vaccination and Screening Programmes, NHSE Midlands
Tushar Shah	Lead Pharmacy Adviser, NHSE London
Laura Smeaton	IDPS Programme Projects Manager and Registered Midwife, NHS Infectious Diseases in Pregnancy Screening (IDPS) Programme, NHSE

2. Organisational authorisations

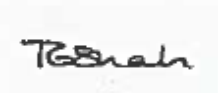
This PGD is not legally valid until it has had the relevant organisational authorisation.

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.

NHS England – London authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisations and/or services
This PGD must only be used by specified registered healthcare professionals working for providers that are directly commissioned by NHS England - London, or who are administering vaccinations as part of a national immunisation programme, and who have been named and authorised to practice under it.
Limitations to authorisation
None

Organisational approval (legal requirement)			
Role	**Name**	**Sign**	**Date**
Chief Nurse, NHS England - London	Jane Clegg		08/02/2024

Additional signatories according to locally agreed policy			
Role	**Name**	**Sign**	**Date**
Director of Nursing Leadership and Quality, NHS England – London	Gwen Kennedy		01/02/2024
Lead Pharmacy Adviser, NHS England – London	Tushar Shah		01/02/2024

Local enquiries regarding the use of this PGD may be directed to england.londonimms@nhs.net

Section 7 provides a practitioner authorisation sheet. Individual practitioners must be authorised by name to work to this PGD. Alternative practitioner authorisation sheets may be used where appropriate in accordance with local policy, but this should be an individual agreement or a multiple practitioner authorisation sheet as included at the end of this PGD.

3. Characteristics of staff

Qualifications and professional registration	Registered professional with one of the following bodies: • nurses and midwives currently registered with the Nursing and Midwifery Council (NMC) • pharmacists currently registered with the General Pharmaceutical Council (GPhC) (Note: This PGD is not relevant to privately provided community pharmacy services) • paramedics and physiotherapists currently registered with Health and Care Professions Council (HCPC) The practitioners above must also fulfil the Additional requirements detailed below. Check Section 2 (Limitations to authorisation) to confirm whether all practitioners listed above have organisational authorisation to work under this PGD.
Additional requirements	Additionally, practitioners: • must be authorised by name as an approved practitioner under the current terms of this PGD before working to it • must have undertaken appropriate training for working under PGDs for supply and administration of medicines • must 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 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	Practitioners must ensure they are up to date with relevant issues and clinical skills relating to immunisation and management of anaphylaxis, with evidence of appropriate Continued Professional Development (CPD). Practitioners should be constantly alert to any subsequent recommendations from the UKHSA, NHSE and other sources of medicines information. Note: the most current national recommendations should be followed, but a Patient Specific Direction (PSD) may be required to administer the vaccine in line with updated recommendations outside of criteria specified in this PGD.

4. 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 12 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. • individuals from 6 weeks of age recommended PCV13 or PCV15 in accordance with Guidelines for the public health management of clusters of severe pneumococcal disease in closed settings.
Criteria for inclusion	Individuals from 12 weeks to under 2 years of age who: • require a primary dose of PCV13 or PCV15 • require a reinforcing booster dose of PCV13 or PCV15 against pneumococcal disease Individuals from 6 weeks of age recommended PCV13 or PCV15 in accordance with Guidelines for the public health management of clusters of severe pneumococcal disease in closed settings. Note: individuals with an underlying medical condition which puts them at increased risk from pneumococcal disease may require additional vaccination outside the inclusion criteria for this PGD - see PCV Risk Groups PGD and Chapter 25 of the Green Book.
Criteria for exclusion[2]	Individuals for whom valid consent or a best-interests decision in accordance with the Mental Capacity Act 2005, has not been obtained (for further information on consent, see Chapter 2 of the Green Book). Several resources are available to inform consent (see written information to be given to individual or carer section). Individuals who: • are less than 12 weeks of age, unless PCV vaccination is recommended in response to an outbreak of pneumococcal disease • are aged 2 years and over, unless PCV vaccination is recommended in response to an outbreak of pneumococcal disease • 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 PCV Risk Groups PGD) • have received a dose of PCV13 or PCV15 within the last 4 weeks (Note: national schedule recommends an 8-week interval, see Dose and frequency of administration section) • 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)
Cautions including any relevant action to be taken	Facilities for management of anaphylaxis should be available at all vaccination sites (see Chapter 8 of the Green Book and advice issued by the Resuscitation Council UK).

[2] 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.

Cautions including any relevant action to be taken (continued)	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. Premature infants should be vaccinated in accordance with the national routine immunisation schedule according to their chronological age. The occurrence of apnoea following vaccination is especially increased in infants who are born very prematurely. Very premature infants (born ≤28 weeks of gestation) who are in hospital should have respiratory monitoring for 48-72 hrs when given their first immunisation, particularly those with a previous history of respiratory immaturity. 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.
Action to be taken if the individual is excluded	Immunisation can be administered to infants from 6 weeks of age if at increased risk of exposure due to an outbreak (see Dose and frequency of administration). If aged less than 6 weeks, defer immunisation and provide an appointment as appropriate. If a dose of PCV (irrespective of valency) was received within the last 4 weeks, defer immunisation for an appropriate interval (see Dose and frequency of administration). If aged 2 years and over, routine immunisation with pneumococcal vaccine is not indicated. If the individual is at increased risk of pneumococcal disease, in accordance with the Green Book Chapter 7 and Chapter 25, refer to the PCV risk groups PGD. Individuals suffering acute severe febrile illness should postpone immunisation until they have recovered. Immunisers should advise when the individual can be vaccinated and ensure another appointment is arranged. Seek appropriate advice from the local Screening and Immunisation Team, local Health Protection Team or the individual's clinician as required. The risk to the individual of not being immunised must be taken into account. Document the reason for exclusion and any action taken in the individual's clinical records. Inform or refer to the GP or a prescriber as appropriate.
Action to be taken if the individual or carer declines treatment	Informed consent, from the individual or a person legally able to act on the person's behalf, must be obtained for each administration. Advise the individual, parent or carer about the protective effects of the vaccine, the risks of infection and the potential complications. Document advice given and the decision reached. Inform or refer to the GP as appropriate.
Arrangements for referral for medical advice	As per local policy

5. Description of treatment

Name, strength and formulation of drug	Pneumococcal polysaccharide conjugate vaccine (adsorbed), either: • **Prevenar®13** (13-valent) suspension for injection in a pre-filled syringe. • **Vaxneuvance®** (15-valent) suspension for injection in a pre-filled syringe
Legal category	Prescription only medicine (POM)
Black triangle▼	Vaxneuvance®. As a new vaccine product, the Medicines and Healthcare products Regulatory Agency (MHRA) has a specific interest in the reporting of adverse drug reactions for this product. All suspected adverse drug reactions should be reported using the MHRA Yellow Card reporting scheme.
Off-label use	Administration of a 4-dose primary series of Prevenar®13 or Vaxneuvance® to pre-term infants <37 weeks gestation is contrary to the 3-dose primary schedule detailed in the SPC but is in accordance with the recommendations for the Vaccination of premature infants and Chapter 25 of the Green Book. Administration of a one-dose primary series of Prevenar®13 or Vaxneuvance® is contrary to the 2 or 3 dose primary schedule detailed in the SPC but is in accordance with the recommendations and Chapter 25 of the Green Book. A single dose schedule for previously unvaccinated individuals between 12 months and up to 2 years of age is contrary to the 2 dose schedule detailed in the Prevenar®13 and Vaxneuvance® SPCs but is in accordance with the national recommendations for the Vaccination of individuals with uncertain or incomplete immunisation status and Chapter 25 of the Green Book. A single dose schedule for partially immunised individuals between 12 months and up to 2 years of age is not consistent with the SPCs for Prevenar®13 or Vaxneuvance® but is in accordance with the national recommendations for the Vaccination of individuals with uncertain or incomplete immunisation status and Chapter 25 of the Green Book. Vaccines should be stored according to the conditions detailed in the Storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions, refer to 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. 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 (continued over page)	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. When administering at the same time as other vaccines, care should be taken to ensure that the appropriate route of injection is used for all vaccinations. The vaccines should be given at separate sites, preferably in different limbs. If given in the same limb, they should be given at least 2.5cm apart. The site at which each vaccine was given should be noted in the individual's records. Individuals with bleeding disorders may be vaccinated intramuscularly if, in the opinion of a doctor familiar with the individual's bleeding risk, vaccines or similar small volume intramuscular injections can be administered with reasonable safety by this route. If the individual receives medication or other treatment to reduce bleeding, for example treatment for haemophilia, intramuscular vaccination can be scheduled shortly after such medication or treatment is administered. Individuals on stable anticoagulation therapy, including individuals on warfarin who are up to date with their scheduled INR testing and whose latest INR was below the upper threshold of their therapeutic

Route and method of administration (continued)	range, can receive intramuscular vaccination. A fine needle (equal to 23 gauge or finer calibre such as 25 gauge) should be used for the vaccination, followed by firm pressure applied to the site (without rubbing) for at least 2 minutes. The individual or carer should be informed about the risk of haematoma from the injection. Prevenar®13 is a uniform white suspension which may sediment during storage. Vaxneuvance® is an opalescent suspension. Shake the prefilled syringe well to uniformly distribute the suspension before administering the vaccine. The vaccine should be visually inspected for foreign particulate matter and other variation of expected appearance prior to preparation and administration. Should either occur, do not administer the vaccine and discard the syringe in accordance with local procedures. Further guidance on administration is available from the vaccine SPC.
Dose and frequency of administration[3]	Single 0.5ml dose per administration. **1. Routine Childhood Immunisation Schedule** Infants should be offered a 1+1 PCV schedule, that is: • a single priming dose of PCV13 or PCV15 to be administered from 12 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. Routine immunisation with PCV13 or PCV15 is not offered after the second birthday. **2. Management of pneumococcal disease clusters and outbreaks in closed settings with high-risk individuals.** A single dose of PCV13 or PCV15 may be administered to adults and children from 6 weeks of age, identified as requiring PCV13 or PCV15 immunisation in accordance with Guidelines for the public health management of clusters of severe pneumococcal disease in closed settings. Note: PPV23 would ordinarily be used in an outbreak with the exception of serotype 6A/6C disease, in individuals under 2 years of age, and where PPV23 is unavailable or otherwise inappropriate. PCV doses administered in response to an outbreak are considered additional to those offered during the routine immunisation schedule (see information below). A dose of PCV13 or PCV15 is not required if a dose has been given in the last 12 months. **Infants and children under the age of 2 exposed to a pneumococcal outbreak requiring pneumococcal vaccination** Individuals aged 6 weeks and over but under 2 years of age recommended to receive a dose of PCV13 or PCV15 following a pneumococcal outbreak should receive such doses in addition to those offered in line with the national childhood immunisation schedule. In all circumstances, an 8 week interval between additional and scheduled doses is preferred, though if doing so risks delaying all other routine immunisations, then scheduled PCV13 or PCV15 doses can be given.
Duration of treatment	See Dose and frequency of administration section above

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

Quantity to be supplied and administered	Single 0.5ml dose per administration.
Supplies	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. Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see the Green Book Chapter 3).
Storage	Store at between +2°C to +8°C. Store in original packaging in order to protect from light. Do not freeze. Following a single temperature excursion, Prevenar®13 is stable at temperatures up to 25°C for a maximum of 4 days. Prevenar®13 should be used within this timeframe or discarded in accordance with local procedures. Stability data indicates Vaxneuvance® is stable at temperatures up to 25°C for 48 hours. This information is only intended to guide health care professionals in case of temporary temperature excursions. In the event of an inadvertent or unavoidable deviation of these conditions, vaccine that has been stored outside the conditions stated above should be quarantined and risk assessed for suitability of continued off-label use or appropriate disposal. Refer to Vaccine Incident Guidance and contact the manufacturer if specific advice on management of the temperature excursion is required.
Disposal	Equipment used for immunisation, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of safely in an UN-approved puncture-resistant sharps box, according to local authority arrangements and NHSE guidance (HTM 07-01): Management and disposal of healthcare waste.
Drug interactions	Immunological response may be diminished in those receiving immunosuppressive treatment. Vaccination is recommended even if the antibody response may be limited. May be given at the same time as other vaccines. A detailed list of drug interactions is available in the product's SPC.
Identification and management of adverse reactions	Local reactions following vaccination are very common such as pain, swelling or redness at the injection site The most commonly reported adverse reactions include fever, irritability, decreased appetite, fatigue, headache and myalgia. Other commonly reported reactions include rash. Vomiting and diarrhoea are commonly reported reactions to Prevenar®13. Hypersensitivity reactions, such as bronchospasm, angioedema and anaphylaxis can occur but are rare. A detailed list of adverse reactions is available in the product's SPC.

Reporting procedure of adverse reactions	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. Any adverse reaction to a vaccine should be documented in the individual's record and the individual's GP should be informed.
Written information to be given to the individual (or parent or carer)	Offer the marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine. Immunisation promotional material may be provided as appropriate: • A guide to immunisations for babies up to 13 months of age • A quick guide to childhood immunisation for the parents of premature babies For resources in accessible formats and alternative languages, please visit Home- Health Publications. Where applicable, inform the individual or carer that large print, Braille or audio CD PILs may be available from emc accessibility (freephone 0800 198 5000) by providing the medicine name and product code number, as listed in the product's SPC.
Advice and follow up treatment	Inform the individual, parent or carer of possible side effects and their management. 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. When administration is postponed, advise the individual, parent or carer when to return for vaccination.
Special considerations and additional information (continued over page)	Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a telephone at the time of vaccination. Individuals with asplenia, splenic dysfunction, complement disorder and severe immunosuppression are at increased risk of pneumococcal disease and require additional doses of PCV13 or PCV15 in accordance with the Green Book Chapter 7 and Chapter 25. The administration of PCV13 or PCV15 for these individuals is covered by the PCV Risk Groups PGD. **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). **Doses given before 12 weeks of age** Since the immunogenicity of PCV13 or PCV15 will be lower if given at a younger age, any dose given before 12 weeks of age should not be counted as the single priming dose for the 1+1 schedule and the routine PCV dose should be given once the infant reaches 12 weeks of age, leaving a minimum 4-week interval between the priming dose and any preceding dose. See Vaccination of premature infants for further information. **Unimmunised or partially immunised children** Unimmunised or partially immunised infants who do not have asplenia, splenic dysfunction, complement disorder or severe immunocompromise[3] who: • 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 an 8 week interval between the primary PCV13 or PCV15 dose and the booster. Where the infant is presented very

Special considerations and additional information (continued)	late (such as at 11 months), then a minimum interval of 4 weeks should be observed before the booster dose • 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 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 in another country (or vaccine of a differing valency to the UK schedule) 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 a minimum interval of 4 weeks should be observed between the PCV13 or PCV15 priming dose and booster dose. • 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. See flow chart for Vaccination of individual with uncertain or incomplete immunisation status 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).
Records	The practitioner must ensure the following is recorded: • that valid informed consent was given • name of individual, address, date of birth and GP with whom the individual is registered • name of immuniser • name and brand of vaccine • date of administration • dose, form and route of administration of vaccine • quantity administered • batch number and expiry date • anatomical site of vaccination • advice given, including advice given if excluded or immunisation declined • details of any adverse drug reactions and actions taken • supplied via PGD Records should be signed and dated (or password-controlled on e-records). All records should be clear, legible and contemporaneous. This information should be recorded in the individual's GP record. Where vaccine is administered outside the GP setting, appropriate health records should be kept and the individual's GP informed. 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. A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.

6. Key references

Key references	**Pneumococcal conjugate vaccine** • Immunisation Against Infectious Disease: The Green Book, Chapter 25, last updated 27 July 2023 https://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 12 October 2021 http://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 https://www.medicines.org.uk/emc/product/13754/smpc • Vaccination of individuals with uncertain or incomplete immunisation status, UKHSA. Updated 6 September 2023. https://www.gov.uk/government/publications/vaccination-of-individuals-with-uncertain-or-incomplete-immunisation-status • Changes to the infant pneumococcal conjugate vaccine schedule: Information for healthcare practitioners, last updated 23 July 2020. https://www.gov.uk/government/publications/pneumococcal-vaccination-guidance-for-health-professionals • Guidelines for the public health management of clusters of severe pneumococcal disease in closed settings, UKHSA. Last updated 21 February 2020 https://www.gov.uk/government/publications/managing-clusters-of-pneumococcal-disease-in-closed-settings **General** • NHSE Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Updated 7 March 2023 https://www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-htm-07-01/ • National Minimum Standards and Core Curriculum for Immunisation Training. Published February 2018. https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners • NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published March 2017. https://www.nice.org.uk/guidance/mpg2 • NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. Updated March 2017. • https://www.nice.org.uk/guidance/mpg2/resources • UKHSA Immunisation Collection https://www.gov.uk/government/collections/immunisation • Vaccine Incident Guidance https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors

7. Practitioner authorisation sheet

PCV PGD v5.00
Valid from: 28 February 2024 Expiry: 31 May 2026

Before signing this PGD, check that the document has had the necessary authorisations in section 2. Without these, this PGD is not lawfully valid.

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 PGD and that I am willing and competent to work to it within my professional code of conduct.			
Name	Designation	Signature	Date

Authorising manager

I confirm that the practitioners named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of the following named organisation …… for the above named health care professionals who have signed the PGD to work under it.			
Name	Designation	Signature	Date

Note to authorising manager

Score through unused rows in the list of practitioners to prevent practitioner additions post managerial authorisation.

This authorisation sheet should be retained to serve as a record of those practitioners authorised to work under this PGD.