UK Health Security Agency

NHS

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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 16 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:	v6.0
Valid from:	1 July 2025
Review date:	30 November 2026
Expiry date:	31 May 2027

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: Contacts listed on page 5&6 of this PGD

Change history

Version	Change details	Date
v1.0 to v3.0	New PHE PGD template	19 January 2016 to 16 February 2022
v4.0	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
v5.0	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
v6.0	UKHSA PCV PGD amended to: • include minor rewording, layout and formatting changes for clarity and consistency with other UKHSA PGDs • 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	2 June 2025

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 Programmes, UKHSA		23 May 2025
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		23 May 2025
Registered Nurse (Chair of Expert Panel)	David Green Nurse Consultant for Immunisation Programmes, UKHSA		23 May 2025

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

Expert Panel

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

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.
NHSE, Integrated Care Board or other authorised commissioner authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisations and/or services
Immunisation services or NHS Trust providing immunisation services commissioned by NHS England (NHSE), Integrated Care Boards (ICB) or other authorised commissioners of vaccination services and/or programmes.
Limitations to authorisation
Authorisation is limited to those registered practitioners listed in Section 3 who are employed by organisations / providers commissioned by NHS England (NHSE), Integrated Care Boards (ICB) or any other authorised commissioners of services to deliver immunisation programmes within the whole of the designated region or defined area.

Organisational approval (legal requirement)			
Role	**Name**	**Sign**	**Date**
Deputy Medical Director: System Improvement and Professional Standards NHS England - North East and Yorkshire	**Dr James Gossow**		**25th June 2025**

Additional signatories according to locally agreed policy			
Role	**Name**	**Sign**	**Date**
NHSE NEY screening and immunisation place lead	**Laura Brown**		**10th June 2025**
Medicines Optimisation Pharmacist Lead, NHS NECS	**Kurt Ramsden**		**12th June 2025**

Local enquiries regarding the use of this PGD may be directed to your local screening and immunisation teams. See area-specific contacts below:

For North East and North Cumbria Area (i.e. Northumberland, Tyne & Wear, Durham Darlington and Tees and North Cumbria) use the following:

NHS England Screening and Immunisation Team:

email england.cane.screeningimms@nhs.net

or NECS Medicine Optimisation Pharmacists: Kurt Ramsden: kurtramsden@nhs.net

or Sue White: sue.white14@nhs.net

Please note - All North East and North Cumbria PGDs can be found at:

https://medicines.necsu.nhs.uk/resources/patient-group-directions/

For Yorkshire and Humber Area use the following:

West Yorkshire - england.wysit@nhs.net

South Yorkshire and Bassetlaw - england.sybsit@nhs.net

North Yorkshire and Humber ENGLAND.NYAHSIT@nhs.net

or the Health Protection Team Acute Response Centre (ARC): Contact Number: 0113 3860 300.

Please note - All Yorkshire and Humber PGDs can be found at: https://www.england.nhs.uk/north-east-yorkshire/our-work/information-for-professionals/pgds /

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	**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.** Practitioners working to this PGD must also be one of the following registered professionals who can legally supply and administer under a PGD: • nurses and midwives currently registered with the Nursing and Midwifery Council (NMC) • pharmacists and pharmacy technicians currently registered with the General Pharmaceutical Council (GPhC) (Note: This PGD is not relevant to privately provided community pharmacy services) • dieticians, occupational therapists, paramedics, physiotherapists and podiatrists currently registered with the Health and Care Professions Council (HCPC) 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, NHS England (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 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. • 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 16 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 to have 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 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). Individuals who: • are less than 16 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: the 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 premises (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. 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. 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 the individual is 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. 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 or carer declines treatment	Informed consent, from the individual or a person legally able to act on the person's behalf, must be obtained for each administration and recorded appropriately. Where a person lacks the capacity, in accordance with the Mental Capacity Act 2005, a decision to vaccinate may be made in the individual's best interests. For further information on consent, see Chapter 2 of the Green Book. Advise the individual, parent or carer about the protective effects of the vaccine, the risks of infection and the potential complications. 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 scheme.
Off-label use	Administration of a 2 dose schedule of Prevenar®13 or Vaxneuvance® to pre-term infants less than 37 weeks gestation is contrary to the 4 dose 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 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. 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 in accordance with national guidance but of product licence.
Route and method of administration	Administer by intramuscular injection, preferably into the anterolateral aspect of the thigh in infants under one year of age. The deltoid muscle of the upper arm may be used in individuals over one year of age. 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 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 clinician familiar with the individual's bleeding risk, vaccines or similar small volume intramuscular injections can be administered with reasonable safety by this route. If the individual receives medication or other treatment to reduce bleeding, for example treatment for haemophilia, intramuscular vaccination can be scheduled shortly after such medication or treatment is administered. Individuals on stable anticoagulation therapy, including individuals on warfarin who are up to date with their scheduled INR testing and whose latest INR was below the upper threshold of their therapeutic range, can 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.

(continued over page)

Route and method of administration (continued)	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. 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. The vaccine should be visually inspected for foreign particulate matter and other variation of expected appearance prior to preparation and administration. Should either occur, do not administer the vaccine and discard the syringe in accordance with local procedures. The vaccine SPC provides further guidance on preparation and administration.
Dose and frequency of administration[3] (continued over page)	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 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. 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. The preferred vaccine for use in an outbreak is PPV23 except for: - individuals under 2 years of age or - when the cause is serotype 6A or 6C or - where PPV23 is unavailable or otherwise inappropriate when PCV13 or PCV15 should be used. PCV doses administered in response to an outbreak are considered additional to those offered during the routine immunisation schedule when given before the age of 12 weeks (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 12 weeks 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. Doses of PCV13 or PCV15 given before the age of 12 weeks should be repeated due to reduced immunogenicity in younger infants (see special considerations and additional information). In line with the principles outlined in managing pneumococcal disease in closed settings, health protection teams should ensure that infants and young children aged 12 weeks and under 2 years have been appropriately immunised in line with the routine childhood immunisation schedule.

[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).

Dose and frequency of administration[4] (continue)	Whilst a minimum interval of 4 weeks is advised between additional and scheduled doses, if doing so risks delaying all other routine immunisations, then scheduled PCV13 or PCV15 doses can be given at any interval.
Duration of treatment	See dose and frequency of administration section above
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 healthcare professionals in case of temporary temperature excursions. 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 Vaccine Incident Guidance. Contact the vaccine manufacturer where more specific advice is required about managing a temperature excursion.
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 an 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.
Drug interactions	Immunological response may be diminished in those receiving immunosuppressive treatment. Vaccination is recommended even if the antibody response may be limited. PCV13 or PCV15 may be given at the same time as other vaccines. A detailed list of drug interactions is available in the product's SPC.

[4] 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).

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, myalgia and somnolence. 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 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

Special considerations and additional information (continued)	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. 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. 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. **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 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 PCV risk groups PGD), 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 the algorithm for vaccination of individuals 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 (continued over page)	The practitioner must ensure the following is recorded: • that valid informed consent was given or a decision to vaccinate was made in the individual's best interests in accordance with the Mental Capacity Act 2005 • 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

Records (continued)	• 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. https://www.gov.uk/government/publications/vaccination-of-individuals-with-uncertain-or-incomplete-immunisation-status • 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 • Changes to the routine childhood schedule letter, published 30 April 2025 https://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 https://www.gov.uk/government/groups/joint-committee-on-vaccination-and-immunisation#meetings-agendas-and-minutes **General** • NHSE Health Technical Memorandum 07-01: safe and sustainable management of healthcare waste, updated 7 March 2023 https://www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-htm-07-01/ • National Minimum Standards and Core Curriculum for Immunisation Training, published 7 February 2018. https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners • NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions, published 27 March 2017 https://www.nice.org.uk/guidance/mpg2 • NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions, updated 4 January 2018 https://www.nice.org.uk/guidance/mpg2/resources • UKHSA Immunisation Collection https://www.gov.uk/government/collections/immunisation

(continued over page)

Key references (continued)	• Vaccine Incident Guidance https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors

7. Practitioner authorisation sheet

PCV PGD v6.0 Valid from: 1 July 2025 Expiry: 31 May 2027

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 **insert name of 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.