



Publications gateway number: **GOV-16528**

## **Pneumococcal polysaccharide vaccine (PPV23) Patient Group Direction (PGD)**

This PGD is for the administration of 23-valent pneumococcal polysaccharide vaccine (PPV23) to individuals from 65 years of age and individuals from 2 years of age in a clinical risk group in accordance with the national immunisation programme for active immunisation against pneumococcal disease and UK [guidelines](#) for the public health management of clusters of severe pneumococcal disease in closed settings.

This PGD is for the administration of PPV23 by registered healthcare practitioners identified in [Section 3](#), subject to any limitations to authorisation detailed in [Section 2](#).

Reference no: PPV23 PGD  
Version no: v5.00  
Valid from: 1 September 2024  
Review date: 1 September 2026  
Expiry date: 1 March 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 product is to be supplied, in accordance with Human Medicines Regulations 2012 (HMR2012)<sup>1</sup>. **The PGD is not legal or valid without signed authorisation in accordance with [HMR 2012 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 amended 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 organisations using the PGD. The fields in sections 2 and 7 cannot be used to alter, amend or add to the clinical contents. 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 8 years after the PGD expires if the PGD relates to adults only and for 25 years after the PGD expires if the PGD relates to children only, or adults and children. Provider organisations adopting authorised versions of this PGD should also retain copies for the periods specified above.

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

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<sup>1</sup> This includes any relevant amendments to legislation.

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 the UKHSA PGDs for authorisation can be found from:

[Immunisation patient group direction \(PGD\) templates](#)

Any concerns regarding the content of this PGD should be addressed to:

[immunisation@ukhsa.gov.uk](mailto:immunisation@ukhsa.gov.uk)


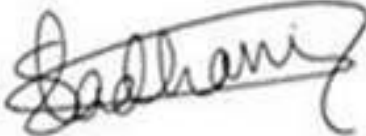

Enquiries relating to the availability of organisationally authorised PGDs and subsequent versions of this PGD should be directed to: Contacts listed on page 6 of this PGD

## Change history

| Version number  | Change details   | Date                            |
|-----------------|--|---------------------------------|
| v1.00 and v2.00 | See earlier versions of this PGD for change details  | 1 September 2016 to 18 May 2020 |
| v3.00           | PPV PGD amended to: <ul style="list-style-type: none"> <li>clarify abbreviation from PPV to PPV23 as used in the Green Book.</li> <li>recommend vaccination of contacts if not received PPV23 in the preceding 12 months.</li> <li>insert a note on immunisation of welders in the inclusion section and remove mention elsewhere</li> <li>update off-label section in line with revised SPC</li> <li>include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates</li> </ul>   | 19 May 2020                     |
| v4.00           | PPV PGD amended to: <ul style="list-style-type: none"> <li>include minor rewording of standard text, layout and formatting changes for clarity and consistency with organisation change and other UKHSA PGDs</li> <li>amend NHS England and NHS Improvement (NHSEI) to NHSE following completion of merger on 1<sup>st</sup> July 2022</li> <li>remove NHS England DES (2020/21) cohort 64 years turning 65 years old by 31 March statement and related footnote from criteria for inclusion as PPV is now part of General Medical Services Statement of Financial Entitlements Directions 2022/23 (GMS SFE)</li> <li>remove the generic pneumococcal polysaccharide vial from name, dose and strength section as it has been discontinued by the manufacturer</li> <li>update supplies section following the change to supply route on 1 July 2021</li> <li>remove from special considerations section the generic statement from Green Book Chapter 7 regarding the timing of the vaccination in immunosuppressive treatments and aligned it to the specific guidance in Chapter 25</li> <li>update references</li> <li>delete Appendix A for consistency</li> </ul> | 29 June 2022                    |
| v5.00           | PPV PGD amended to: <ul style="list-style-type: none"> <li>include minor rewording of standard text, layout and formatting changes for clarity and consistency with other UKHSA PGDs</li> <li>confirm that PPV administration for occupational exposure should be under a Patient Specific Direction (PSD)</li> <li>include an updated list of known adverse reactions</li> <li>remove details of specific supply information for PPV (the supply route is now well embedded)</li> <li>reflect clinical exceptions to the recommended 8 week interval between PCV and PPV vaccination in <a href="#">special considerations and additional information</a> section</li> </ul>  | 29 July 2024                    |

## 1. PGD development

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

| Developed by:                                      | Name  | Signature  | Date         |
|--|---|--|--------------|
| <b>Pharmacist</b><br>(Lead Author)                 | Christina Wilson<br>Lead Pharmacist Immunisation Services,<br>Immunisation and Vaccine Preventable<br>Diseases Division, UKHSA  |  | 24 July 2024 |
| <b>Doctor</b>                                      | Professor Shamez Ladhani<br>Paediatric Infectious Diseases Consultant,<br>St George's Hospital London, Professor of<br>Paediatric Infections and Vaccinology, St<br>George's University London and Consultant<br>Epidemiologist, Immunisation and Vaccine<br>Preventable Diseases Division, UKHSA |  | 24 July 2024 |
| <b>Registered Nurse</b><br>(Chair of Expert Panel) | David Green<br>Nurse Consultant, Immunisation and<br>Vaccine Preventable Diseases Division,<br>UKHSA  |  | 24 July 2024 |

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   |
|---------------------|---|
| Nicholas Aigbogun   | Consultant in Communicable Disease Control, Yorkshire and Humber Health Protection Team, UKHSA  |
| Alison Campbell     | Screening and Immunisation Coordinator, Clinical, NHSE Midlands   |
| Jane Freeguard      | Deputy Director of Vaccination – Medicines and Pharmacy, NHSE   |
| Rosie Furner        | Specialist Pharmacist - Medicines Governance, Patient Group Directions and Medicines Mechanisms, NHS Specialist Pharmacist Services (SPS) |
| Ed Gardner          | Advanced Paramedic Practitioner / Emergency Care Practitioner, Medicines Manager, Primary Care based, Southbourne Surgery                 |
| Gemma Hudspeth      | Senior Health Protection Practitioner, North East Health Protection Team Regions Directorate, UKHSA                                       |
| Jacqueline Lamberty | Medicines Governance Consultant Lead Pharmacist, UKHSA  |
| Michelle Jones      | Principal Medicines Optimisation Pharmacist, NHS Bristol North Somerset and South Gloucestershire Integrated Care Board (ICB)             |
| 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  |


## 2. Organisational authorisations



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.

**NHSE North East and Yorkshire** authorises this PGD for use by the services or providers listed below:

| Authorised for use by the following organisations and/or services   |
|---|
| NHS England (NHSE) commissioned immunisation services or NHS Trust providing immunisation services.   |
| Limitations to authorisation  |
| Authorisation is limited to those registered practitioners listed in Section 3 who are employed by organisations/providers commissioned by NHSE North East and Yorkshire (NEY) to deliver immunisation programmes within the whole of the NHSE region of North East and Yorkshire |

| Organisational approval (legal requirement)                                    |                        |  |                                    |
|--|------------------------|--|------------------------------------|
| Role   | Name                   | Sign   | Date                               |
| Assistant Medical Director and Responsible Officer,<br><b>NHS England –NEY</b> | <b>Dr James Gossow</b> |  | <b>12<sup>th</sup> August 2024</b> |

| Additional signatories according to locally agreed policy   |                     |  |                                   |
|---|---------------------|--|-----------------------------------|
| Role  | Name                | Sign   | Date                              |
| <b>NHSE NEY PGD Governance assurance review</b><br>(Medicines Optimisation Pharmacist Lead, NHS NECS)   | <b>Kurt Ramsden</b> |   | <b>7<sup>th</sup> August 2024</b> |
| <b>Screening and Immunisation Place Lead Public Health Programme Team –</b><br>Yorkshire and the Humber<br><br>NHS England (NE and Yorkshire) | <b>Laura Brown</b>  |  | <b>31<sup>st</sup> July 2024</b>  |

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](mailto:england.cane.screeningimms@nhs.net)

or NECS Medicine Optimisation Pharmacists: Kurt Ramsden: [kurtramsden@nhs.net](mailto:kurtramsden@nhs.net)

or Sue White: [sue.white14@nhs.net](mailto: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](mailto:england.wysit@nhs.net)

South Yorkshire and Bassetlaw - [england.sybsit@nhs.net](mailto:england.sybsit@nhs.net)

North Yorkshire and Humber [ENGLAND.NYAHSIT@nhs.net](mailto: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

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| <p><b>Qualifications and professional registration</b></p> | <p><b>All practitioners should only administer vaccinations where it is within their scope of clinical practice to do so. Practitioners must also fulfil the <a href="#">additional requirements</a> and <a href="#">continued training requirements</a> to ensure their competency is up to date, as outlined in the sections below.</b></p> <p>Practitioners working to this PGD must also be a registered professional with one of the following bodies:</p> <ul style="list-style-type: none"> <li>• nurses and midwives currently registered with the Nursing and Midwifery Council (NMC)</li> <li>• pharmacists currently registered with the General Pharmaceutical Council (GPhC) (Note: This PGD is not relevant to privately provided community pharmacy services)</li> <li>• paramedics and physiotherapists currently registered with the Health and Care Professions Council (HCPC)</li> </ul> <p>Check <a href="#">Section 2</a> (Limitations to authorisation) to confirm whether all practitioners listed above have organisational authorisation to work under this PGD.</p>   |
| <p><b>Additional requirements</b></p>                      | <p>Additionally, practitioners:</p> <ul style="list-style-type: none"> <li>• must be authorised by name as an approved practitioner under the current terms of this PGD before working to it</li> <li>• must have undertaken appropriate training for working under PGDs for supply/administration of medicines</li> <li>• must be competent in the use of PGDs (see <a href="#">NICE Competency framework for health professionals using PGDs</a>)</li> <li>• must be familiar with the vaccine product and alert to changes in the Summary of Product Characteristics (SPC), Immunisation Against Infectious Disease (the <a href="#">Green Book</a>), and national and local immunisation programmes</li> <li>• must have undertaken training appropriate to this PGD as required by local policy and in line with the <a href="#">National Minimum Standards and Core Curriculum for Immunisation Training</a></li> <li>• must be competent to undertake immunisation and to discuss issues related to immunisation</li> <li>• must be competent in the handling and storage of vaccines, and management of the cold chain</li> <li>• must be competent in the recognition and management of anaphylaxis</li> <li>• must have access to the PGD and associated online resources</li> <li>• should fulfil any additional requirements defined by local policy</li> </ul> <p><b>The individual practitioner must be authorised by name, under the current version of this PGD before working according to it.</b></p> |
| <p><b>Continued training requirements</b></p>              | <p>Practitioners must ensure they are up to date with relevant issues and clinical skills relating to immunisation and management of anaphylaxis, with evidence of appropriate Continued Professional Development (CPD).</p> <p>Practitioners should be constantly alert to any subsequent recommendations from the UKHSA, NHS England (NHSE) and other sources of medicines information.</p> <p>Note: The most current national recommendations should be followed but a Patient Specific Direction (PSD) may be required to administer the vaccine in line with updated recommendations that are outside the criteria specified in this PGD.</p>  |



#### 4. Clinical condition or situation to which this PGD applies

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| <b>Clinical condition or situation to which this PGD applies</b>                       | <p>Indicated for the active immunisation of individuals from 65 years of age and individuals from 2 years of age in a clinical risk group, for the prevention of pneumococcal disease in accordance with the national immunisation programme and UK guidelines for the public health management of clusters of severe pneumococcal disease in closed settings. For reference, see <a href="#">Managing clusters of pneumococcal disease in closed settings</a> and recommendations given in <a href="#">Chapter 25</a> of Immunisation Against Infectious Disease: the Green Book.</p>   |
| <b>Criteria for inclusion</b>  | <p>Individuals who:</p> <ul style="list-style-type: none"> <li>• are aged 65 years and over</li> <li>• are aged 2 years and over and have a medical condition included in the clinical risk groups defined in the Green Book <a href="#">Chapter 25, Table 25.2</a>.</li> <li>• have asplenia, splenic dysfunction or chronic kidney disease (see <a href="#">Chapter 25, Table 25.2</a>) and require a pneumococcal polysaccharide vaccine (PPV23) booster</li> <li>• are identified as requiring vaccination by the local Health Protection Team for the public health management of pneumococcal disease in accordance with <a href="#">managing pneumococcal disease in closed settings</a></li> </ul> <p>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 indication is outside the remit of this PGD and should therefore be administered under either a written instruction or a PSD.</p>  |
| <b>Criteria for exclusion<sup>2</sup></b>  | <p>Individuals who have not given valid consent (or for whom a best-interests decision in accordance with the <a href="#">Mental Capacity Act 2005</a> has not been obtained). For further information on consent, see <a href="#">Chapter 2</a> of the Green Book. Several resources are available to inform consent (see <a href="#">written information to be given to individual, parent or carer</a> section).</p> <p>Individuals who:</p> <ul style="list-style-type: none"> <li>• are less than 2 years of age</li> <li>• have previously received PPV23 over the age of 2 years, except individuals with asplenia, splenic dysfunction and chronic kidney disease (see Green Book <a href="#">Chapter 25</a>) and those recommended for vaccination in the <a href="#">public health management of clusters of severe pneumococcal disease in closed settings</a></li> <li>• have had a confirmed anaphylactic reaction to a previous dose of PPV23 or to any component of the vaccine</li> <li>• have received pneumococcal conjugate vaccine (PCV) in the preceding 8 weeks</li> <li>• are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation)</li> </ul> |
| <b>Cautions including any relevant action to be taken</b><br><br>(continued over page) | <p>Facilities for management of anaphylaxis should be available at all vaccination premises (see <a href="#">Chapter 8</a> of the Green Book and advice issued by the <a href="#">Resuscitation Council UK</a>).</p> <p>Individuals with a bleeding disorder may develop a haematoma at the injection site (see <a href="#">route and method of administration</a>).</p> <p>Antibody response may be impaired in those with immunological impairment and those with an absent or dysfunctional spleen (see <a href="#">special considerations</a>)</p>   |

<sup>2</sup>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



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| <p><b>Cautions including any relevant action to be taken</b><br/>(continued)</p>       | <p><a href="#">and additional information</a> section regarding appropriate timing of vaccination).</p> <p>Syncope (fainting) can occur following, or even before any vaccination, especially in adolescents as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from faints.</p>  |
| <p><b>Action to be taken if the individual is excluded</b></p>                         | <p>If the individual is under the age of 2 years, PPV23 is not indicated. Ensure PCV immunisation is up to date instead (see <a href="#">PCV PGD</a> or <a href="#">PCV Risk Groups PGD</a> as applicable).</p> <p>If PPV23 has previously been given to an individual over the age of 2 years <b>and</b> the individual does not have asplenia, splenic dysfunction or chronic kidney disease (see Green Book <a href="#">Chapter 25</a>) <b>and immunisation is not indicated</b> for the individual in line with <a href="#">public health management of severe pneumococcal disease in closed settings</a>, further PPV23 is <b>not</b> indicated.</p> <p>Individuals who have recently received PCV should postpone PPV immunisation until 8 weeks has elapsed.</p> <p>In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated and ensure another appointment is arranged at the earliest opportunity.</p> <p>Seek appropriate advice from the local Screening and Immunisation Team, local Health Protection Team or the individual's clinician as required.</p> <p>The risk to the individual of not being immunised must be taken into account.</p> <p>Document the reason for exclusion and any action taken in the individual's clinical records.</p> <p>Inform or refer to the GP or a prescriber as appropriate.</p> |
| <p><b>Action to be taken if the individual, parent or carer declines treatment</b></p> | <p>Informed consent, from the individual or a person legally able to act on the person's behalf, must be obtained for each administration and recorded appropriately. Where a person lacks the capacity in accordance with the <a href="#">Mental Capacity Act 2005</a>, a decision to vaccinate may be made in the individual's best interests. For further information on consent, see <a href="#">Chapter 2</a> of the Green Book.</p> <p>Advise the individual, parent or carer about the protective effects of the vaccine, the risks of infection and potential complications of disease.</p> <p>Document advice given and the decision reached.</p> <p>Inform or refer to the GP as appropriate.</p>  |
| <p><b>Arrangements for referral for medical advice</b></p>                             | <p>As per local policy</p>   |

## 5. Description of treatment

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| <b>Name, strength and formulation of drug</b> | Pneumovax® 23 solution for injection in a pre-filled syringe<br>Each 0.5ml dose contains 25 micrograms of each of the following 23 pneumococcal polysaccharide serotypes: 1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19F, 19A, 20, 22F, 23F, 33F.   |
| <b>Legal category</b>                         | Prescription only medicine (POM)   |
| <b>Black triangle▼</b>                        | No.  |
| <b>Off-label use</b>                          | <p>Administration of a further dose of PPV23 to high-risk individuals who have already received a dose of PPV23 more than 12 months previously is off-label but may be recommended in accordance with <a href="#">Managing pneumococcal disease in closed settings</a>.</p> <p>Vaccines should be stored according to the conditions detailed in the <a href="#">storage</a> section below. However, in the event of an inadvertent or unavoidable deviation of these conditions, refer to <a href="#">Vaccine Incident Guidance</a>. Where vaccines are assessed in accordance with these guidelines as appropriate for continued use, this would constitute off-label administration under this PGD.</p> <p>Where a vaccine is recommended off-label consider, as part of the consent process, informing the individual, parent or carer that the vaccine is being offered outside of product licence but in accordance with national guidance.</p>  |
| <b>Route and method of administration</b>     | <p>Administer by intramuscular or subcutaneous injection, preferably into the deltoid muscle of the upper arm. The intramuscular route is routinely used because localised reactions are more common when vaccines are given subcutaneously.</p> <p>When administering at the same time as other vaccines, care should be taken to ensure that the appropriate route of injection is used for all 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.</p> <p>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.</p> <p>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 subcutaneous injection, in accordance with <a href="#">Chapter 4</a> of the Green Book.</p> <p>The vaccine's normal appearance is a clear colourless solution..</p> <p>The vaccine should be visually inspected for foreign particulate matter and other variation of expected appearance prior to preparation and administration. Should either occur, do not administer the dose and discard the vaccine in accordance with local procedures.</p> <p>The vaccine <a href="#">SPC</a> provides further guidance on preparation and administration.</p> |

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| <b>Dose and frequency of administration</b>               | <p>Single 0.5ml dose.</p> <p>Individuals with asplenia, splenic dysfunction or chronic kidney disease (see <a href="#">Chapter 25</a>) should be revaccinated at 5 year intervals.</p> <p>PPV23 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 <a href="#">Managing pneumococcal disease in closed settings</a>, unless they have received PPV23 in the previous 12 months.</p> <p>Revaccination is not routinely indicated for other individuals.</p> |
| <b>Duration of treatment</b>                              | Single 0.5ml dose (see <a href="#">dose and frequency of administration</a> regarding indications for revaccination).   |
| <b>Quantity to be supplied and administered</b>           | Single 0.5ml dose.  |
| <b>Supplies</b>   | <p>Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see Green Book <a href="#">Chapter 3</a>).</p> <p>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</p>  |
| <b>Storage</b>  | <p>Store at +2°C to +8°C.</p> <p>Store in original packaging in order to protect from light. Do not freeze.</p> <p>In the event of an inadvertent or unavoidable deviation of these conditions, vaccines that have been stored outside the conditions stated above should be quarantined and risk assessed on a case-by-case basis for suitability of continued off-label use or appropriate disposal. Refer to <a href="#">Vaccine Incident Guidance</a>.</p> <p>Contact the vaccine manufacturer where more specific advice is required about managing a temperature excursion.</p>                 |
| <b>Disposal</b>   | <p>Follow local clinical waste policy and NHS standard operating procedures to ensure safe and secure waste disposal.</p> <p>Equipment used for immunisation, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of safely in an UN-approved puncture-resistant sharps box, according to local authority arrangements and NHSE guidance (<a href="#">HTM 07-01: safe and sustainable management of healthcare waste</a>).</p>  |
| <b>Drug interactions</b>                                  | <p>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.</p> <p>PPV23 may be given at the same time as other vaccines.</p> <p>A list of drug interactions associated with Pneumovax®23 is available from the <a href="#">SPC</a>.</p>   |
| <b>Identification and management of adverse reactions</b> | <p>Local reactions following vaccination are very common including pain, swelling, soreness, warmth, induration and/or redness at the injection site. These reactions occur within 3 days of vaccination and resolve by day 5.</p> <p>A low-grade fever may occur.</p> <p>The most common systemic adverse events reported are asthenia/fatigue, myalgia and headache.</p>  |

(continued over page)

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| <b>Identification and management of adverse reactions</b><br>(continued)              | <p>Rarely, injection-site cellulitis (with a short onset time from vaccine administration) has been reported.</p> <p>Other adverse events have been reported in clinical trials and post-marketing surveillance but the frequency of these is not known.</p> <p>A detailed list of adverse reactions is available in the vaccine <a href="#">SPC</a>.</p>  |
| <b>Reporting procedure of adverse reactions</b>                                       | <p>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 <a href="#">Yellow Card reporting scheme</a> or by searching for MHRA Yellow Card in the Google Play or Apple App Store.</p> <p>Any adverse reaction to a vaccine should be documented in the individual's record and the individual's GP should be informed.</p>   |
| <b>Written information to be given to individual, parent or carer</b>                 | <p>Offer the marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine.</p> <p>Immunisation promotional material may be provided as appropriate:</p> <ul style="list-style-type: none"> <li>• <a href="#">Splenectomy leaflet</a></li> </ul> <p>For resources in accessible formats and alternative languages, please visit <a href="#">Home- Health Publications</a>.</p> <p>Where applicable, inform the individual, parent 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 on the product <a href="#">SPC</a>.</p>   |
| <b>Advice and follow up treatment</b>   | <p>Inform the individual, parent or carer of possible side effects and their management.</p> <p>Vaccination may not result in complete protection in all recipients.</p> <p>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.</p> <p>The individual, parent or carer should be advised to seek medical advice in the event of an adverse reaction and report this via the <a href="#">Yellow Card reporting scheme</a>.</p> <p>When applicable, advise the individual, parent or carer when to return for vaccination or when a subsequent vaccine dose is due.</p>  |
| <b>Special considerations and additional information</b><br><br>(continued over page) | <p>Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a telephone at the time of vaccination.</p> <p>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.</p> <p>Individuals who are a contact of pneumococcal disease do not usually require PPV23. 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.</p> <p>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.</p> |

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| <p><b>Special considerations and additional information</b><br/>(continued)</p> | <p><b>Timing of vaccination</b></p> <p>Individuals with immunosuppression and HIV infection (regardless of CD4 count) should be given pneumococcal vaccines according to the recommendations.</p> <p>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, PPV23 should be given 4 to 6 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 <a href="#">Chapter 25</a>).</p> <p>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.</p> <p>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.</p> <p>Splenectomy, chemotherapy or radiotherapy should never be delayed to allow time for vaccination.</p> <p><b>Co-administration with PCV</b></p> <p>An 8 week interval between administration of PCV 13 or PCV15 and PPV23 vaccination is advised, to ensure optimum immunogenicity for the common vaccine serotypes covered by both vaccines.</p> <p>The clinical exceptions to the requirement for an 8 week interval are:</p> <ul style="list-style-type: none"> <li>(i) when PPV23 is given in error of PCV13 or PCV15. In such cases, PCV13 or PCV15 can be given at the same visit or as soon as possible after the PPV23 dose with no limit to the interval between doses. This contrasts with previous recommendations to leave a longer interval between doses, because of a small risk of hyporesponsiveness and</li> <li>(ii) an individual recently immunised with PCV13 or PCV15 is recommended for immunisation as part of a pneumococcal outbreak where the responsible pneumococcal serotype is in PPV23 (but not in PCV13 or PCV15). In such cases, the benefits of early protection from the additional PPV23 serotypes outweighs the improved immunogenicity offered from maintaining an 8 week interval between the 2 vaccines.</li> </ul> <p>Local procedures for medicines error reporting should be followed. A PSD should be used to co-administer both vaccines. Refer to <a href="#">Vaccine Incident Guidance</a>.</p> <p><b>Note:</b> although this specific advice above is not presently advocated in <a href="#">Chapter 25</a>, it is anticipated the updated Chapter will do so in due course.</p> |
| <p><b>Records</b><br/><br/>(continued over page)</p>                            | <p>The practitioner should ensure the following is recorded:</p> <ul style="list-style-type: none"> <li>• that valid informed consent was given or a decision to vaccinate was made in the individual's best interests in accordance with the <a href="#">Mental Capacity Act 2005</a></li> <li>• name of individual, address, date of birth and GP with whom the individual is registered</li> <li>• name of immuniser</li> <li>• name and brand of vaccine</li> </ul>   |

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| <b>Records</b><br>(continued) | <ul style="list-style-type: none"> <li>• date of administration</li> <li>• dose, form and route of administration of vaccine</li> <li>• quantity administered</li> <li>• batch number and expiry date</li> <li>• anatomical site of vaccination</li> <li>• advice given, including advice given if excluded or declines immunisation</li> <li>• details of any adverse drug reactions and actions taken</li> <li>• supplied via PGD</li> </ul> <p>Records should be signed and dated (or password-controlled on e-records).</p> <p>All records should be clear, legible and contemporaneous.</p> <p>This information should be recorded in the individual's GP record. Where vaccine is administered outside the GP setting appropriate health records should be kept and the individual's GP informed.</p> <p>The local Child Health Information Services team must be notified using the appropriate documentation or pathway as required by any local or contractual arrangement.</p> <p>A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.</p> |
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## 6. Key references

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| <b>Key references</b> | <p><b>Pneumococcal polysaccharide vaccine</b></p> <ul style="list-style-type: none"><li>• Immunisation Against Infectious Disease: the Green Book Chapter 25, last updated 14 August 2023<br/><a href="https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book">https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book</a></li><li>• Summary of Product Characteristic for Pneumovax® 23 vaccine, Merck Sharp &amp; Dohme Limited. Last updated 16 December 2022</li><li>• <a href="https://www.medicines.org.uk/emc/product/9692/smpc">https://www.medicines.org.uk/emc/product/9692/smpc</a></li><li>• Guidelines for the public health management of clusters of severe pneumococcal disease in closed settings. Updated 21 February 2020<br/><a href="https://www.gov.uk/government/publications/managing-clusters-of-pneumococcal-disease-in-closed-settings">https://www.gov.uk/government/publications/managing-clusters-of-pneumococcal-disease-in-closed-settings</a></li></ul> <p><b>General</b></p> <ul style="list-style-type: none"><li>• NHSE Health Technical Memorandum 07-01: safe and sustainable management of healthcare waste, last updated 7 March 2023<b>Error! Bookmark not defined.</b><br/><a href="https://www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-htm-07-01/">https://www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-htm-07-01/</a></li><li>• National Minimum Standards and Core Curriculum for Immunisation Training, published 7 February 2018<br/><a href="https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners">https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners</a></li><li>• NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions, updated 27 March 2017 <a href="https://www.nice.org.uk/guidance/mpg2">https://www.nice.org.uk/guidance/mpg2</a></li><li>• NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions, updated 4 January 2018<br/><a href="https://www.nice.org.uk/guidance/mpg2/resources">https://www.nice.org.uk/guidance/mpg2/resources</a></li><li>• Immunisation Collection<br/><a href="https://www.gov.uk/government/collections/immunisation">https://www.gov.uk/government/collections/immunisation</a></li><li>• Vaccine Incident Guidance<br/><a href="https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors">https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors</a></li></ul> |
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## 7. Practitioner authorisation sheet

**PPV23 PGD v5.00      Valid from: 1 September 2024      Expiry: 1 March 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 |
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### 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 <b>insert name of organisation</b> 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.