

Publications gateway number: **GOV-12712**

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: v04.00
Valid from: 31 August 2022
Review date: 1 March 2024
Expiry date: 1 September 2024

The UK Health Security Agency (UKHSA) has developed this PGD to facilitate the delivery of publicly funded in England immunisation 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)¹. **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'. Only sections 2 and 7 can be amended within the designated editable fields provided.

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.

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:

<https://www.gov.uk/government/collections/immunisation>

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

¹ This includes any relevant amendments to legislation.

Enquiries relating to the availability of organisationally authorised PGDs and subsequent versions of this PGD should be directed to The Screening and Immunisation Team, NHS England – Midlands, responsible for your area:

East (Derbyshire & Nottinghamshire and Leicester, Leicestershire, Rutland, Lincolnshire & Northamptonshire) england.emids-imms@nhs.net


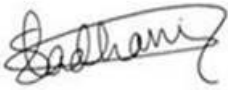

West (Shropshire, Staffordshire, Birmingham, Coventry, Dudley, Herefordshire, Sandwell, Solihull, Walsall, Warwickshire, Wolverhampton & Worcestershire)
england.wmid-imms@nhs.net

Change history

Version number	Change details	Date
V01.00	New PHE PGD template	1 September 2016
V02.00	PPV PGD amended to: <ul style="list-style-type: none"> include vaccination in accordance with UK guidelines for the public health management of clusters of serious pneumococcal disease in closed settings include 64year olds who may be immunised during the influenza season and who will turn 65 years by the 31 March include both vial and pre-filled syringe presentations of PPV include additional healthcare practitioners in Section 3 refer to PHE vaccine incident guidance within the off-label and storage sections include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates 	8 August 2018
V03.00	PPV PGD amended to: <ul style="list-style-type: none"> clarify abbreviation from PPV to PPV23 as used in the the Green Book. recommend vaccination of contacts if not received PPV23 in the preceding 12 months. insert a note on immunisation of welders in the inclusion section and remove mention elsewhere update off-label section in line with revised SPC include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates 	19 May 2020
V04.00	PPV PGD amended to: <ul style="list-style-type: none"> include minor rewording of standard text, layout and formatting changes for clarity and consistency with organisation change and other UKHSA PGDs amend NHS England and NHS Improvement (NHSEI) to NHSE following completion of merger on 1st July 2022 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) remove the generic pneumococcal polysaccharide vial from name, dose and strength section as it has been discontinued by manufacturer update supplies section following the change to supply route on 1 July 2021 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 update references delete Appendix A for consistency 	29 June 2022

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)	Suki Hunjunt Lead Pharmacist Immunisation Services, Immunisation and Vaccine Preventable Diseases Division, UKHSA		29 June 2022
Doctor	Shamez Ladhani Consultant Paediatric Infectious Disease Consultant, UKHSA		29 June 2022
Registered Nurse (Chair of Expert Panel)	David Green Nurse Consultant, Immunisation and Vaccine Preventable Diseases Division, UKHSA		29 June 2022

This PGD has been peer reviewed by the UKHSA Immunisations PGD Expert Panel in accordance with the UKHSA PGD Policy. It has been approved by the UKHSA Medicines Governance Group and ratified by the UKHSA Clinical Quality and Oversight Board.

Expert Panel

Name	Designation
Nicholas Aigbogun	Consultant in Communicable Disease Control, Yorkshire and Humber Health Protection Team, UKHSA
Sarah Dermont	Clinical Project Coordinator and Registered Midwife, NHS Infectious Diseases in Pregnancy Screening Programme, NHS England (NHSE)
Ed Gardner	Advanced Paramedic Practitioner / Emergency Care Practitioner, Medicines Manager, Proactive Care Lead
Beth Graham	Lead Pharmacist, Immunisation Services, Immunisation and Vaccine Preventable Diseases Division, UKHSA
Jacqueline Lamberty	Lead Pharmacist Medicines Governance, UKHSA
Michelle Jones	Principal Medicines Optimisation Pharmacist, NHS Bristol, North Somerset and South Gloucestershire Integrated Care Board (ICB)
Vanessa MacGregor	Consultant in Communicable Disease Control, East Midlands Health Protection Team, UKHSA
Alison Mackenzie	Consultant in Public Health Medicine, Screening and Immunisation Lead, NHSE (South West)
Gill Marsh	Principal Screening and Immunisation Manager, NHSE (North West)
Lesley McFarlane	Screening and Immunisation Manager: Clinical (COVID-19 and Influenza), NHSE (Midlands)
Tushar Shah	Lead Pharmacy Advisor, NHSE (London Region)


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.

NHS England -Midlands authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisations and/or services
Primary care services and/or all organisations commissioned or contracted by NHS England and NHS Improvement – Midlands to provide immunisation services in: Derbyshire, Nottinghamshire, Leicestershire, Lincolnshire, Northamptonshire, Shropshire, Staffordshire, Birmingham, Coventry, Dudley, Herefordshire, Sandwell, Solihull, Walsall, Warwickshire, Wolverhampton and Worcestershire
Limitations to authorisation
None

Organisational approval (legal requirement)			
Role	Name	Sign	Date
Director of Primary Care and Public Health Commissioning – NHS England - Midlands	Trish Thompson		03.08.2022

Additional signatories according to locally agreed policy			
Role	Name	Sign	Date

Local enquiries regarding the use of this PGD may be directed to The Screening and Immunisation Team, NHS England – Midlands, responsible for your area:

East (Derbyshire & Nottinghamshire and Leicester, Leicestershire, Rutland, Lincolnshire & Northamptonshire) england.emids-imms@nhs.net

West (Shropshire, Staffordshire, Birmingham, Coventry, Dudley, Herefordshire, Sandwell, Solihull, Walsall, Warwickshire, Wolverhampton & Worcestershire)
england.wmid-imms@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	<p>Registered professional with one of the following bodies:</p> <ul style="list-style-type: none"> • 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 the Health and Care Professions Council (HCPC) <p>The practitioners above must also fulfil the Additional requirements detailed below.</p> <p>Check Section 2 Limitations to authorisation to confirm whether all practitioners listed above have organisational authorisation to work under this PGD.</p>
Additional requirements	<p>Additionally, practitioners:</p> <ul style="list-style-type: none"> • must be authorised by name as an approved practitioner under the current terms of this PGD before working to it • must have undertaken appropriate training for working under PGDs for supply/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 <p>The individual practitioner must be authorised by name, under the current version of this PGD before working according to it.</p>
Continued training requirements	<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 and/or 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

Clinical condition or situation to which this PGD applies	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 (see Managing clusters of pneumococcal disease in closed settings) and recommendations given in Chapter 25 of Immunisation Against Infectious Disease: the 'Green Book'.
Criteria for inclusion	<p>Individuals who:</p> <ul style="list-style-type: none"> • are aged 65 years and over • are aged 2 years and over and have a medical condition included in the clinical risk groups defined in the Green Book Chapter 25 Table 25.2. • have asplenia, splenic dysfunction or chronic kidney disease (see Chapter 25 Table 25.2) and require a pneumococcal polysaccharide vaccine (PPV23) booster • are recommended vaccination by the local Health Protection Team for the public health management of pneumococcal disease in accordance with Managing clusters of pneumococcal disease in closed settings <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.</p>
Criteria for exclusion²	<p>Individuals for whom no valid consent has been received.</p> <p>Individuals who:</p> <ul style="list-style-type: none"> • are less than 2 years of age • have previously received PPV23 over the age of 2 years, except individuals with asplenia, splenic dysfunction and chronic kidney disease (see Green Book Chapter 25) and those recommended vaccination for the public health management of clusters of severe pneumococcal disease in closed settings • have had a confirmed anaphylactic reaction to a previous dose of PPV23 or to any component of the vaccine • have received pneumococcal conjugate vaccine (PCV) in the preceding 8 weeks • are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation)
Cautions including any relevant action to be taken	Antibody response may be impaired in those with immunological impairment and those with an absent or dysfunctional spleen (see Special considerations / additional information section regarding appropriate timing of vaccination).
Action to be taken if the patient is excluded Continued over page	If aged less than 2 years PPV23 is not indicated, ensure PCV immunisation is up to date.

²Exclusion under this PGD does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation will be required

<p>Action to be taken if the patient is excluded (continued)</p>	<p>If PPV23 has previously been received over the age of 2 years and the individual does not have asplenia, splenic dysfunction or chronic kidney disease (see Green Book Chapter 25) and the individual is not recommended vaccination for the public health management of clusters of severe pneumococcal disease in closed settings, further PPV23 is not indicated.</p> <p>Individuals who have received PCV in the preceding 8 weeks postpone 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>Action to be taken if the patient or carer declines treatment</p>	<p>Informed consent, from the individual or a person legally able to act on the person's behalf, must be obtained for each administration. For further information on consent see Chapter 2 of the 'Green Book'.</p> <p>Advise the individual/parent/carers 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>Arrangements for referral for medical advice</p>	<p>As per local policy</p>

5. Description of treatment

Name, strength and formulation of drug	Pneumovax® 23 solution for injection in a pre-filled syringe 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.
Legal category	Prescription only medicine (POM)
Black triangle▼	No
Off-label use	<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 the Managing clusters of pneumococcal disease in closed settings.</p> <p>Vaccine 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 vaccine is assessed in accordance with these guidelines as appropriate for continued use this would constitute off-label administration under this PGD.</p> <p>Where a vaccine is recommended off-label consider, as part of the consent process, informing the individual/parent/carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence.</p>
Route and method of administration	<p>Administer by intramuscular or subcutaneous injection. The preferred site is the deltoid region of the upper arm.</p> <p>The intramuscular route is routinely used because localised reactions are more common when vaccines are given subcutaneously. However, for individuals with a bleeding disorder, vaccines may alternatively be given by subcutaneous injection to reduce the risk of bleeding in accordance in the Green Book Chapter 4.</p> <p>When administering at the same time as other vaccines care should be taken to ensure that the appropriate route of injection is used for all the vaccinations.</p> <p>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.</p> <p>The vaccine's normal appearance is a clear colourless solution..</p> <p>The vaccine should be visually inspected for particulate matter and discoloration prior to administration. In the event of any foreign particulate matter and/or variation of physical aspect being observed, do not administer the vaccine.</p> <p>The vaccine's SPC provides further guidance on administration and is available from the electronic Medicines Compendium website.</p>
Dose and frequency of administration Continued over page	<p>Single 0.5ml dose.</p> <p>Individuals with asplenia, splenic dysfunction or chronic kidney disease (see Chapter 25) should be revaccinated at 5 year intervals.</p>

Dose and frequency of administration (continued)	PPV23 should be offered to high-risk individuals recommended vaccination by the local Health Protection Team for the public health management of pneumococcal disease in accordance with Managing clusters of pneumococcal disease in closed settings , unless they have received PPV23 in the previous 12 months. Revaccination is not routinely indicated for other individuals.
Duration of treatment	Single 0.5ml dose (see Dose and frequency of administration regarding indications for revaccination).
Quantity to be supplied and administered	Single 0.5ml dose.
Supplies	From 1 July 2021 changes were made to the supply route of PPV for the use in the NHS pneumococcal polysaccharide immunisation programme to bring the supply in line with the other national immunisation programmes. Vaccines are available to order from the ImmForm website for the routine immunisation programme and immunisation of those with underlying medical conditions (see Change to the supply route of Pneumococcal Polysaccharide Vaccine (Pneumovax®23), vaccine for the national immunisation programme). Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see Green Book Chapter 3).
Storage	Store at +2°C to +8°C. Store in original packaging in order to protect from light. Do not freeze. 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 .
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 guidance in the Health Technical Memorandum 07-01: Safe management of healthcare waste (Department of Health, 2013).
Drug interactions	Immunological response may be diminished in those receiving immunosuppressive treatment, but it is important to still immunise this group. PPV23 may be given at the same time as other vaccines. PPV23 can also be given at the same time as shingles vaccine, Zostavax®, as recommended in the ' Green Book ' following assessment of the evidence, concluding that there is no reduction in the effectiveness of Zostavax®.
Identification and management of adverse reactions Continued over page	Local reactions following vaccination are very common including pain, swelling, soreness, warmth, induration and/or redness at the injection site. A low-grade fever may occur.

<p>Special considerations and additional information (continued)</p>	<p>Timing of vaccination</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 two weeks before commencement. 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 four to six weeks before elective splenectomy or initiation of treatment such as chemotherapy or radiotherapy. Where this is not possible, it can be given up to two weeks before treatment (see Green Book Chapter 25).</p> <p>If it is not practicable to vaccinate two weeks or more before splenectomy, immunisation should be delayed until at least two weeks after the operation.</p> <p>If it is not practicable to vaccinate two weeks or more before initiation of chemotherapy and/or radiotherapy, immunisation should be delayed until at least three months after completion of therapy in order to maximise the response to the vaccine.</p> <p>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>Records</p> <p>Continued over page</p>	<p>Record:</p> <ul style="list-style-type: none"> • 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 declines immunisation • details of any adverse drug reactions and actions taken • supplied via PGD <p>Records should be signed and dated (or a password-controlled immuniser's record 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>

Records (continued)	<p>The local Child Health Information Services team must be notified using the appropriate documentation/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

Key references	<p>Pneumococcal polysaccharide vaccine</p> <ul style="list-style-type: none"> Immunisation Against Infectious Disease: The Green Book Chapter 25 last updated 13 January 2020. https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book Summary of Product Characteristic for Pneumovax® 23vaccine, Merck Sharp & Dohme Limited. Last updated 29 January 2021. https://www.medicines.org.uk/emc/product/9692/smpc Guidelines for the public health management of clusters of severe pneumococcal disease in closed settings. Updated 21 February 2020. https://www.gov.uk/government/publications/managing-clusters-of-pneumococcal-disease-in-closed-settings Pneumococcal polysaccharide vaccine: change to the supply route from June 2021 letter https://www.gov.uk/government/publications/pneumococcal-polysaccharide-vaccine-change-to-the-supply-route-from-june-2021-letter <p>General</p> <ul style="list-style-type: none"> Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20 March 2013 Error! Bookmark not defined. https://www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-hm-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. March 2017. https://www.nice.org.uk/guidance/mpg2/resources 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
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7. Practitioner authorisation sheet

PPV23 PGD v04.00 Valid from: 31 August 2022 Expiry: 1 September 2024

Before signing this PGD, check that the document has had the necessary authorisations in section two. 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 <u>insert name of organisation</u> 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.