Public Health England

**PHE publications gateway number:** GW-357

# PATIENT GROUP DIRECTION (PGD)

Administration of pneumococcal polysaccharide conjugate vaccine (13-valent, adsorbed) (PCV13) to individuals with an underlying medical condition which puts them at increased risk from pneumococcal disease.

This PGD is for the administration of pneumococcal polysaccharide conjugate vaccine (13-valent, adsorbed) (PCV13) by registered healthcare practitioners identified in Section 3, subject to any limitations to authorisation detailed in Section 2.

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| Reference no: | PCV Risk Groups PGD |
| Version no: | v03.00 |
| Valid from: | 1 June 2019 |
| Review date: | 1 December 2020 |
| Expiry date: | 31 May 2021 |

**Public Health England has developed this PGD to facilitate the delivery of publicly funded 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 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'. 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.

**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 PHE PGD templates for authorisation can be found from: https://www.gov.uk/government/collections/immunisation-patient-group-direction-pgd

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

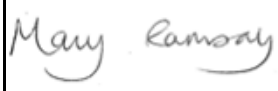
[1] This includes any relevant amendments to legislation (eg 2013 No.235, 2015 No.178 and 2015 No.323).

## Change history

| Version number | Change details | Date |
|---|---|---|
| V01.00 | New PHE PGD template | 03/02/2017 |
| V02.00 | PHE PCV13 Risk Groups PGD amended to:<br>• reworded inclusion criteria to be specific to those at risk of pneumococcal disease requiring additional PCV13<br>• reworded dose section to reflect revised Green Book chapter 25 and clarify when you would provide PCV13 to previously unvaccinated or partially vaccinated individuals | 10/05/2017 |
| V03.00 | PHE PCV13 Risk Groups PGD amended to:<br>• include additional healthcare practitioners in Section 3<br>• refer to vaccine incident guidelines in off-label and storage sections<br>• include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates | 14/02/2019 |

## 1. PGD development

This PGD has been developed by the following health professionals on behalf of Public Health England:

| Developed by: | Name | Signature | Date |
|---|---|---|---|
| **Pharmacist** (Lead Author) | Elizabeth Graham<br>Lead Pharmacist - Immunisation and Countermeasures, PHE |  | 26/03/2019 |
| **Doctor** | Mary Ramsay<br>Consultant Epidemiologist and Head of Immunisation and Countermeasures, PHE |  | 25/03/2019 |
| **Registered Nurse** (Chair of Expert Panel) | David Green<br>Nurse Consultant – Immunisation and Countermeasures, PHE |  | 21/03/2019 |

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

**Expert Panel**

| Name | Designation |
|---|---|
| Ed Gardner | Advanced Paramedic Practitioner / Emergency Care Practitioner, Medicines Manager, Proactive Care Lead |
| Michelle Jones | Senior Medicines Optimisation Pharmacist, NHS Bristol North Somerset & South Gloucestershire CCG |
| Shamez Ladhani | Paediatric Infectious Disease Consultant, Public Health England |
| Jacqueline Lamberty | Lead Pharmacist Medicines Management Services, Public Health England |
| Vanessa MacGregor | Consultant in Communicable Disease Control, Public Health England, East Midlands Health Protection Team |
| Alison Mackenzie | Consultant in Public Health Medicine / Screening and Immunisation Lead, Public Health England / NHS England South (South West) |
| Gill Marsh | Senior Screening and Immunisation Manager, Public Health England / NHS England (Lancashire and South Cumbria) |
| Lesley McFarlane | Screening and Immunisation Co-ordinator, NHS England / Public Health England Leicestershire, Lincolnshire and Northamptonshire |
| Sally Millership | Consultant in Communicable Disease Control, Public Health England, East of England Health Protection Team |
| Tushar Shah | Pharmacy Advisor, NHS England London Region |
| Sharon Webb | Programme Manager / Registered Midwife, NHS Infectious Diseases in Pregnancy Screening Programme, Public Health England |

## 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 and NHS Improvement - 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 all organisations commissioned to, or contracted by, NHS England and NHS Improvement – Midlands to provide immunisation services. Each provider organisation using this PGD should formally adopt it via a signature from the provider's authorised governance lead/s or lead practitioner. |
| **Limitations to authorisation** |
| None. |

| **Organisational approval (legal requirement)** | | | |
|---|---|---|---|
| **Role** | **Name** | **Sign** | **Date** |
| Medical Director<br>NHS England and NHS Improvement - Midlands | Ken Deacon |  | **2/5/19** |

| **Additional signatories according to locally agreed policy** | | | |
|---|---|---|---|
| **Role** | **Name** | **Sign** | **Date** |
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Local enquiries regarding the use of this PGD may be directed to: The Screening and Immunisation Teams, NHS England and NHS Improvement - Midlands
Derbyshire/Nottinghamshire mailto:ENGLAND.SCRIMMS@nhs.net
Shropshire/Staffordshire mailto:PHE.sssit@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

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| **Qualifications and professional registration** | Registered professional with one of the following bodies:<br>• nurses and midwives currently registered with the Nursing and Midwifery Council (NMC)<br>• pharmacists currently registered with the General Pharmaceutical Council (GPhC) (Note: This PGD is not relevant to privately provided community pharmacy services)<br>• paramedics and physiotherapists currently registered with the Health and Care Professions Council (HCPC)<br><br>The practitioners above must also fulfil the Additional requirements detailed below.<br><br>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:<br>• must be authorised by name as an approved practitioner under the current terms of this PGD before working to it<br>• must have undertaken appropriate training for working under PGDs for supply/administration of medicines<br>• must be competent in the use of PGDs (see NICE Competency framework for health professionals using PGDs)<br>• 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<br>• 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<br>• must be competent to undertake immunisation and to discuss issues related to immunisation<br>• must be competent in the handling and storage of vaccines, and management of the 'cold chain'<br>• must be competent in the recognition and management of anaphylaxis<br>• must have access to the PGD and associated online resources<br>• should fulfil any additional requirements defined by local policy<br><br>**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).<br><br>Practitioners should be constantly alert to any subsequent recommendations from Public Health England and/or NHS England and other sources of medicines information.<br>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. |

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

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| **Clinical condition or situation to which this PGD applies** | Indicated for the active immunisation of individuals with an underlying medical condition which puts them at increased risk from pneumococcal disease in accordance with the national immunisation programme and recommendations given in Chapter 7 and Chapter 25 of Immunisation Against Infectious Disease: 'The Green Book'.<br><br>This PGD does not cover the routine childhood PCV13 immunisation programme which is covered by the PHE PCV PGD. |
| **Criteria for inclusion** | Individuals who are:<br>• under 2 years who have asplenia, splenic dysfunction, a complement disorder or are severely immunocompromised<br>• from 2 years to under 10 years of age who are previously unvaccinated or partially vaccinated (such that they did not complete their 2+1 PCV course as part of the national schedule) and who have a medical condition included in Appendix A<br>• over 2 years of age and severely immunocompromised<br><br>Note: all individuals with a medical condition included in Appendix A should receive a dose of PPV23 after their second birthday (see PPV PGD). |
| **Criteria for exclusion[2]** | Individuals for whom no valid consent has been received.<br><br>Individuals who:<br>• have had a confirmed anaphylactic reaction to a previous dose of pneumococcal vaccine or to any component of the vaccine including diphtheria toxoid<br>• have received a dose of PCV13 within the last 4 weeks (Note: national schedule recommends 8 week interval, see dose section)<br>• 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** | The immunogenicity of the vaccine could be reduced in immunosuppressed subjects, however vaccination is still recommended.<br><br>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 patient is excluded** | If a dose of PCV13 was received within the last 4 weeks defer immunisation for an appropriate interval (see Dose and frequency of administration).<br><br>In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated and ensure another appointment is arranged. |

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[2] Exclusion under this Patient Group Direction 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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| **Action to be taken if the patient is excluded** (continued) | Seek appropriate advice from the local Screening and Immunisation Team, local Health Protection or the individual's clinician as required.<br>The risk to the individual of not being immunised must be taken into account.<br>Document the reason for exclusion and any action taken in the individual's clinical records.<br>In a GP practice setting, inform or refer to the GP or a prescriber as appropriate. |
| **Action to be taken if the patient 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.<br>Advise the individual/parent/carer about the protective effects of the vaccine, the risks of infection and potential complications of disease.<br>Document advice given and the decision reached.<br>In a GP practice setting, inform or refer to the GP as appropriate. |
| **Arrangements for referral for medical advice** | As per local policy |

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## 5. Description of treatment

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| **Name, strength & formulation of drug** | Pneumococcal polysaccharide conjugate vaccine (13-valent, adsorbed), PCV13:<br>• Prevenar® 13 suspension for injection in a pre-filled syringe |
| **Legal category** | Prescription only medicine (POM) |
| **Black triangle▼** | No |
| **Off-label use** | 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 PHE 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.<br>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. |
| **Route / method of administration** | Administer by intramuscular injection. The deltoid region of the upper arm may be used in individuals over one year of age.<br>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 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.<br>For individuals with a bleeding disorder, vaccines normally given by an intramuscular route should be given by deep subcutaneous injection to reduce the risk of bleeding (see 'The Green Book' Chapter 4).<br>The vaccine's normal appearance is a uniform white suspension which may sediment during storage. Shake the prefilled syringe well to uniformly distribute the suspension before administering the vaccine.<br>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.<br>The SPC provides further guidance on administration and is available from the electronic Medicines Compendium website: www.medicines.org.uk |
| **Dose and frequency of administration** | Single 0.5ml dose per administration<br>**Individuals under 1 year of age**<br>All individuals should be fully vaccinated in accordance with the routine PCV13 immunisation programme (see the PHE PCV PGD and the vaccination of individuals with uncertain or incomplete immunisation status guidance). |

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| **Dose and frequency of administration** (continued) | An additional PCV13 booster dose is also recommended between 1 and 2 years of age for individuals with asplenia, splenic dysfunction, a complement disorder or severely immunocompromised[3]. An interval of 2 months is required between the routine PCV13 booster (usually given at 12 months) and the additional PCV13 booster dose (see below).<br><br>**Individuals from 1 year to under 2 years of age**<br><br>Individuals with asplenia or splenic dysfunction (see Appendix A), a complement disorder, or severely immunocompromised[3], aged between their first and second birthday should receive an additional booster dose of PCV13 with an interval of 2 months between the routine PCV13 booster (usually given at 12 months) and the additional PCV13 booster dose. Note: This is the schedule to follow regardless of whether the child had none, one or both of the routine primary doses of PCV13 in infancy. The intervals may be reduced to one month if necessary to ensure that the immunisation schedule is completed.<br><br>**Individuals from 2 years to under 10 years of age**<br><br>Individuals from 2 years to under 10 years of age, with a medical condition included in Appendix A (excluding the severely immunocompromised[3]), who have completed the routine PCV immunisation schedule (with PCV7 or PCV13) do not require further PCV13.<br><br>Individuals from 2 years to under 10 years of age who are previously unvaccinated or partially vaccinated (such that they did not complete their 2+1 PCV course as part of the national schedule) and who have a medical condition included in Appendix A should receive a single dose of PCV13.<br><br>Severely immunocompromised[3] individuals should be offered a single dose of PCV13 irrespective of any routine childhood vaccinations they have already received.<br><br>**Individuals from 10 years of age**<br><br>Individuals from 10 years of age, with a medical condition included in Appendix A (excluding the severely immunocompromised[4]) do not require PCV13.<br><br>Severely immunocompromised[3] individuals should be offered a single dose of PCV13 irrespective of any routine childhood vaccinations they have already received.<br><br>**Pneumococcal polysaccharide vaccine (PPV23)**<br><br>Additionally, all individuals with a medical condition included in Appendix A should receive a dose of PPV23 after their second birthday (see PPV PGD).<br><br>Individuals eligible for both PCV13 and PPV23 should have the PCV13 dose first followed by PPV23 at least 2 months later. |
| **Duration of treatment** | Single 0.5ml dose |

[3] Examples of severely immunocompromised include bone marrow transplant patients, patients with acute and chronic leukaemia, multiple myeloma or genetic disorders affecting the immune system (e.g. IRAK-4, NEMO, complement deficiency)

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| **Quantity to be supplied / administered** | Single 0.5ml dose per administration. |
| **Supplies** | PCV13 for additional doses for at risk groups is not centrally procured and these should be ordered from the manufacturer/wholesaler. Details are given in the Green Book Chapter 25.<br><br>Centrally purchased vaccines for the national childhood routine PCV13 immunisation programme for the NHS can only be ordered via ImmForm. Vaccines for use for the national childhood routine immunisation programme are provided free of charge.<br><br>Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see protocol for ordering storage and handling of vaccines and Green Book Chapter 3). |
| **Storage** | Store at +2°C to +8°C.<br>Store in original packaging in order to protect from light.<br>Do not freeze.<br><br>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 PHE Vaccine Incident Guidance.<br><br>Note: Prevenar 13 is stable at temperatures up to 25°C for four days. At the end of this period Prevenar 13 should be used or discarded. These data are intended to guide health care professionals in case of inadvertent temporary temperature excursions only. |
| **Disposal** | Equipment used for immunisation, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of safely in a UN-approved puncture-resistant 'sharps' box, according to local authority regulations and guidance in the 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. Vaccination is recommended even if the antibody response may be limited.<br><br>May be given at the same time as other vaccines.<br><br>A detailed list of interactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk |
| **Identification & management of adverse reactions**<br><br>Continued over page | Local reactions following vaccination are very common ie pain, swelling or redness at the injection site. A small painless nodule may form at the injection site.<br><br>The most commonly reported adverse reactions include vaccination-site reactions, fever, irritability, decreased appetite, increased and/or decreased sleep, rash, vomiting, diarrhoea, arthralgia, myalgia and headache.<br><br>Hypersensitivity reactions, such as bronchospasm, angioedema, urticaria, and anaphylaxis can occur but are very rare. |

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| **Identification & management of adverse reactions** (continued) | A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk |
| **Reporting procedure of adverse reactions** | Healthcare professionals and individuals/parents/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: http://yellowcard.mhra.gov.uk<br><br>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 patient or carer** | Offer the marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine.<br><br>Immunisation promotional material may be provided as appropriate:<br>• Splenectomy leaflet<br>Available from: www.gov.uk/government/collections/immunisation |
| **Patient advice / follow up treatment** | Inform the individual/carer of possible side effects and their management.<br><br>Vaccination may not result in complete protection in all recipients.<br><br>Individuals at especially increased risk of serious pneumococcal infection (eg asplenics 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.<br><br>The individual/carer should be advised to seek medical advice in the event of an adverse reaction. |
| **Special considerations / additional information** | Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a telephone at the time of vaccination.<br><br>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.<br><br>Individuals on Eculizumab (Soliris®) therapy are not at increased risk of pneumococcal disease and do not require PPV23 or additional doses of PCV13.<br><br>Wherever possible, immunisation or boosting of immunosuppressed individuals should be either carried out before immunosuppression occurs or deferred until an improvement in immunity has been seen (see Chapter 25). Immunisation of these individuals should not be delayed if this is likely to result in failure to vaccinate.<br><br>Splenectomy, chemotherapy or radiotherapy should never be delayed to allow time for vaccination. |
| **Records**<br><br>Continued over page | Record:<br>• that valid informed consent was given<br>• name of individual, address, date of birth and GP with whom the individual is registered<br>• name of immuniser<br>• name and brand of vaccine<br>• date of administration<br>• dose, form and route of administration of vaccine |

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| **Records**<br>(continued) | • quantity administered<br>• batch number and expiry date<br>• anatomical site of vaccination<br>• advice given, including advice given if excluded or declines immunisation<br>• details of any adverse drug reactions and actions taken<br>• supplied via PGD<br><br>Records should be signed and dated (or a password controlled immuniser's record on e-records).<br><br>All records should be clear, legible and contemporaneous.<br><br>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.<br><br>The local Child Health Information Services team (Child Health Records Department) must be notified using the appropriate documentation/pathway as required by any local or contractual arrangement.<br><br>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**<br>• Immunisation Against Infectious Disease: The Green Book chapter 25. Last updated 16 January 2018. https://www.gov.uk/government/publications/pneumococcal-the-green-book-chapter-25<br>• Summary of Product Characteristics for Prevenar 13 suspension for injection, Pfizer Ltd. 3 October 2018. http://www.medicines.org.uk/emc/medicine/22689<br>• NHS public health functions agreement 2018-19. Service specification No.8. Pneumococcal immunisation programme. September 2018. https://www.england.nhs.uk/publication/public-health-national-service-specifications/<br>• Vaccination of individuals with uncertain or incomplete immunisation status. Public Health England. Updated 13 November 2017. https://www.gov.uk/government/publications/vaccination-of-individuals-with-uncertain-or-incomplete-immunisation-status<br>**General**<br>• Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20 March 2013. https://www.gov.uk/government/publications/guidance-on-the-safe-management-of-healthcare-waste<br>• 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<br>• NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published March 2017. https://www.nice.org.uk/guidance/mpg2<br>• NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. Updated March 2017. https://www.nice.org.uk/guidance/mpg2/resources<br>• PHE Immunisation Collection https://www.gov.uk/government/collections/immunisation<br>• PHE Vaccine Incident Guidance https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors<br>• Protocol for ordering storage and handling of vaccines. April 2014. https://www.gov.uk/government/publications/protocol-for-ordering-storing-and-handling-vaccines |
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## 7. Practitioner authorisation sheet

**PCV Risk Groups PGD v03.00 Valid from: 01/06/2019 Expiry: 31/05/2021**

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 patient group direction you are indicating that you agree to its contents and that you will work within it.

Patient group directions do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

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

## APPENDIX A

### Clinical risk groups who should receive the pneumococcal immunisation

(Green Book Chapter 25 Table 25.1)

| Clinical risk group | Examples (decision based on clinical judgement) |
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| **Asplenia or dysfunction of the spleen** | This also includes conditions such as homozygous sickle cell disease and coeliac syndrome that may lead to splenic dysfunction.<br>(Re-immunisation with PPV23 is recommended every 5 years) |
| **Chronic respiratory disease** | This includes chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema; and such conditions as bronchiectasis, cystic fibrosis, interstitial lung fibrosis, pneumoconiosis and bronchopulmonary dysplasia (BPD). Children with respiratory conditions caused by aspiration, or a neurological disease (e.g. cerebral palsy) with a risk of aspiration. Asthma is not an indication, unless so severe as to require continuous or frequently repeated use of systemic steroids (as defined in Immunosuppression below). |
| **Chronic heart disease** | This includes those requiring regular medication and/or follow-up for ischaemic heart disease, congenital heart disease, hypertension with cardiac complications, and chronic heart failure. |
| **Chronic kidney disease** | Nephrotic syndrome, chronic kidney disease at stages 4 and 5 and those on kidney dialysis or with kidney transplantation.<br>(Re-immunisation with PPV23 is recommended every 5 years) |
| **Chronic liver disease** | This includes cirrhosis, biliary atresia and chronic hepatitis. |
| **Diabetes** | Diabetes mellitus requiring insulin or oral hypoglycaemic drugs. This does not include diabetes that is diet controlled. |
| **Immunosuppression** | Due to disease or treatment, including patients undergoing chemotherapy leading to immunosuppression, bone marrow transplant, asplenia or splenic dysfunction, HIV infection at all stages, multiple myeloma or genetic disorders affecting the immune system (e.g. IRAK-4, NEMO, complement deficiency)<br>Individuals on or likely to be on systemic steroids for more than a month at a dose equivalent to prednisolone at 20mg or more per day (any age), or for children under 20kg, a dose of 1mg or more per kg per day. |
| **Individuals with cochlear implants** | It is important that immunisation does not delay the cochlear implantation. |
| **Individuals with cerebrospinal fluid leaks** | This includes leakage of cerebrospinal fluid such as following trauma or major skull surgery. |