# PATIENT GROUP DIRECTION

**NHS England – Midlands & East (Central Midlands)**

Patient Group Direction for the administration of

**Pneumococcal Polysaccharide Vaccine 23-valent (PPV)** for adults aged 65 years and above and individuals from 2 years of age in a clinical risk group

<table>
<thead>
<tr>
<th>NHS England document reference</th>
<th>SIPGD013</th>
</tr>
</thead>
<tbody>
<tr>
<td>Version number</td>
<td>2.0</td>
</tr>
<tr>
<td>Group responsible for document</td>
<td>NHS England PGD Group</td>
</tr>
<tr>
<td>Date of authorisation</td>
<td>28th October 2016</td>
</tr>
<tr>
<td>Expiry date</td>
<td>31st October 2019</td>
</tr>
</tbody>
</table>

**File reference**

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<table>
<thead>
<tr>
<th>Version no.</th>
<th>Amendment date</th>
<th>Brief description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.0</td>
<td></td>
<td>First version</td>
</tr>
<tr>
<td>2.0</td>
<td>28th October 2016</td>
<td>Leics/Lincs version transferred to (revised) standard local PGD template and adopted for use across Central Midlands. Clinical risk groups added to inclusion criteria.</td>
</tr>
</tbody>
</table>
Introduction and supporting information

Legal and professional framework

Health care professionals must be aware of their legal position when administering a vaccine that has not been individually prescribed by a doctor or other independent prescriber.

Patient Group Directions (PGDs) are the legal mechanism by which a prescription only medicine (POM) can be supplied or administered to a patient for whom no individual prescription exists. All vaccines are in the legal category of POMs.

PGDs were introduced via legislation enacted in 2000; the current legislation for PGDs is included in The Human Medicines Regulations 2012¹,²

PGDs are written agreements for the supply and administration of medicines to groups of patients who may not be individually identified before presentation for treatment. They can be used for homogenous patient groups where presenting characteristics and requirements are sufficiently consistent to be catered for by such a non-specific direction, although patients who can be identified before they need a specific medicine may receive that medicine on a patient specific basis (via a prescription or Patient Specific Direction (PSD)).

The need for the following PGD to be developed has been established according to the protocol recommended by NICE¹. It enables identified health care professionals to administer the stated vaccines in accordance with national guidelines³ however:

**PGDs DO NOT REMOVE INHERENT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY.**

Further information about this is provided in the final section of this document, Health care professional and employer authorisation.

The criteria under which individuals will be eligible for inclusion in this PGD are defined in the Green Book³.

Healthcare professionals are reminded that, in some circumstances, the recommendations regarding vaccines given in the Green Book may differ from those in the Summary of Product Characteristics (SPC) for a particular vaccine. When this occurs the recommendations in the Green Book, which are based on current expert advice from the Joint Committee on Vaccination and Immunisation (JCVI), should always be followed. If the Green Book or contractual requirements change after this PGD has been issued, another form of authorisation will be required until the PGD has been updated to reflect these.
To support the information contained within this PGD, staff should consult additional sources of information.

**Cold chain**

Vaccines stored above the temperature range detailed in the SPC often remain both safe and effective, although subject to a reduced shelf-life. Close monitoring of the cold chain will ensure that the necessary information is available to make an assessment about vaccine safety and effectiveness in the event of a cold chain breach. However once a breach of the cold chain has occurred vaccines that remain suitable for use cannot, unless otherwise stated, be supplied or administered under a PGD, and another form of authorisation will be required. Vaccines that have been frozen must never be used.

Further information about the vaccine to which this document refers, including advice about specific vaccine use following a cold chain breach, is available from local Medicines Information Services:

**Leicestershire and Northamptonshire:** Leicester Royal Infirmary, telephone 0116 258 6491 or 0116 204 7918, e-mail medicines.info@uhl-tr.nhs.uk

**Lincolnshire:** Lincoln County Hospital, telephone 01522 573802, e-mail medicines.information@ulh.nhs.uk

**Note:** These services do not have the capacity to assist with enquiries from other counties.

**Bedfordshire, Hertfordshire, Luton and Milton Keynes:** contact the (Central Midlands) South public health/screening and immunisation team for advice: england.immsqa@nhs.net

**PGD development**

This PGD has been developed by the NHS England Midlands and East (Central Midlands) PGD Group, which serves the areas covered by the North and Central (Leicestershire, Lincolnshire and Northamptonshire) and South (Bedfordshire, Hertfordshire, Luton and Milton Keynes) public health/screening and immunisation teams. In line with current NICE guidance\(^1\), this group includes a lead doctor and pharmacist. Other professionals who have been directly involved in the development of this PGD are:
Cath Fenton, Consultant lead for screening and immunisation, NHS England Midlands and East (Central Midlands) South

Chloe Leggat, Screening and immunisation co-ordinator, NHS England Midlands and East (Central Midlands) North and Central

Lesley McFarlane, Screening and immunisation co-ordinator, NHS England Midlands and East (Central Midlands) North and Central

Anna Crane, Practice Nurse, Downing Drive Surgery Leicester & Practice Nurse Advisor for Leicester City CCG

Jeannie Szumski, Nurse Partner, Lea Vale Medical Group Luton and Practice Nurse on Luton CCG Board

Clinical authorisation

**Authorising doctor**

Dr Tim Davies, Consultant lead for screening and immunisation, NHS England Midlands and East (Central Midlands) North and Central

Signature:

Date: 07 October 2016

**Authorising pharmacist**

Tina Goudie, Pharmacist and Medication Safety Officer, Medical Directorate, NHS England, Midlands & East (Central Midlands)

Signature:

Date: 07 October 2016

Organisational authorisation

**On behalf of NHS England Midlands and East (Central Midlands)**

Dr Aly Rashid, Medical Director

Signature:

Date: 28th October 2016
### 1. Clinical condition

<table>
<thead>
<tr>
<th>Clinical condition or situation to which this PGD applies</th>
<th>Active immunisation against disease (including pneumonia and meningitis) caused by <em>Streptococcus pneumoniae</em> (pneumococcal) serotypes included in the vaccine. The objective of the pneumococcal immunisation programme is to protect all of those for whom pneumococcal infection is likely to be more common and / or serious:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>- those aged 65 years or over</td>
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<tr>
<td></td>
<td>- individuals from 2 years of age in a clinical risk group</td>
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| Criteria for inclusion | All adults aged 65 years and above, as part of the routine immunisation schedule. Individuals aged 2 years and over who have a medical condition included in the clinical risk groups defined in the *Green Book* Chapter 25 Table 25.1 (copy provided at Appendix A, page 14) Individuals who have asplenia, splenic dysfunction or chronic kidney disease (see Appendix A, page 14) and require a pneumococcal polysaccharide vaccine (PPV) booster Individuals for whom it cannot be established, with certainty, whether or not they have received the required number of doses of this antigen may be vaccinated using this PGD |

<table>
<thead>
<tr>
<th>Criteria for exclusion</th>
<th>Individuals who have had a confirmed anaphylactic reaction to a previous dose of pneumococcal vaccine or to any component of Pneumococcal Polysaccharide Vaccine 23 valent (PPV) (see SPC(^8) for full list). Individuals who:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>- have previously received PPV over the age of 2 years, except individuals with asplenia, splenic dysfunction and chronic kidney disease (see Appendix A, page 14)</td>
</tr>
<tr>
<td></td>
<td>- have asplenia, splenic dysfunction or chronic kidney disease (see Appendix A, page 14) and received PPV in the preceding 5 years</td>
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<tr>
<td></td>
<td>- have received pneumococcal conjugate vaccine (PCV) in the preceding 2 months</td>
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</tbody>
</table>
### Criteria for exclusion (continued)

- are suffering from acute severe febrile illness
- are a contact of pneumococcal disease (indication not covered by this PGD)
- are at risk of frequent or continuous occupational exposure to metal fume (e.g. welders) (indication not covered by this PGD)

**No exclusion for:**
- Minor illness without fever or systemic upset
- Non-anaphylactic allergic reactions, such as a rash

### Action to be taken if the patient is excluded

Document reason for exclusion in the clinical records.

Contact your local Screening and Immunisation Team or Health Protection Team if further advice is necessary.

### Action to be taken if the patient declines treatment

Advise patient about the protective effects of the vaccine, and the risks of infection and disease, including potential treatment.

Document advice given and decision reached.

Inform, or refer the patient to their GP, as appropriate.

### 2. Description of treatment

#### Name, strength and formulation of vaccines

Pneumococcal polysaccharide vaccine 23-valent, solution for injection in a vial.

As detailed in SPC or package leaflet, check injection is of expected appearance (correct colour, etc.) before administration.

Each 0.5ml dose of vaccine contains 25 micrograms of each of the 23 pneumococcal polysaccharide serotypes.

Refer to the SPC for the full list of vaccine components.

#### Legal category

Prescription Only Medicine (POM)

#### Black Triangle ▼

No

#### Off-label use

The SPC advises against administration of Zostavax at the same time as pneumococcal polysaccharide vaccine due to a reduced immune response. The Green Book however advises that this is acceptable. Different injection sites and different needles should be used.
### Off-label use (continued)

Pneumococcal polysaccharide vaccine can therefore be given at the same time as, or at any interval from, any other vaccine. The specific site at which each vaccine was given should be noted in the patient’s records.

### Route / method of administration

Intramuscular (IM) administration into the upper arm (deltoid).

For individuals with a bleeding disorder, the vaccine should be administered as a deep subcutaneous injection to reduce the risk of bleeding. NB: subcutaneous administration increases the risk of a local reaction.

It must not be given intravenously.

Refer to the manufacturer’s leaflet (SPC)⁶ for instructions about preparation of the vaccine prior to administration.

### Dose and frequency of administration, duration of treatment and quantity to be administered

A single 0.5ml dose, given once only except for:

- Individuals with asplenia, splenic dysfunction or chronic kidney disease (see Appendix A, page 14) who should be revaccinated at 5 year intervals.

Revaccination is not routinely indicated for other individuals.

### Storage

Store in the original packaging at +2°C to +8°C and the product should be protected from light.

### Disposal

Equipment used for immunisation, including used vials, ampoules, or partially discharged vaccines in a syringe or other applicator, should be disposed of by sealing in a proper, puncture-resistant, lidded, yellow ‘sharps’ receptacle for incineration³,⁴

### Drug interactions

Refer to British National Formulary (BNF) and SPC for complete list

Pneumococcal vaccine can be administered simultaneously with other vaccines as long as different needles and injection sites are used.

See off label use above for concurrent administration with Zostavax®.

The immunogenicity of the vaccine could be reduced by immunosuppressive treatment (and conditions, e.g. HIV), however vaccination is still recommended even if the antibody response might be limited. Re-immunisation should be considered after
### Drug interactions (continued)

Treatment is finished and/or the patient’s condition has stabilised. Specialist advice may be required. Any such additional doses would be outside the remit of this PGD.

### Identification and management of adverse reactions

The most common adverse reactions reported from trials were as follows: injection site reactions, fever, asthenia/fatigue, myalgia and headache; symptomatic treatment resulted in complete recovery in most cases.

### Reporting procedure for adverse reactions

Health care professionals and patients are encouraged to report the following suspected adverse drug reactions (ADRs) to the Medicines and Healthcare Products Regulatory Agency (MHRA) using the Yellow Card reporting scheme⁵, ⁶

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason
- all suspected ADRs associated with new drugs and vaccines (identified by the black triangle symbol: ▼)

A healthcare professional completing a yellow card should fully document the ADR in the patient’s record, noting that a yellow card has been sent.

The patient’s GP should be informed.

### Advice and written information to be given to patient and follow up treatment

Offer marketing authorisation holder’s patient information leaflet (PIL) provided with the vaccine. Advise:

- about possible local and systemic side effects and their management.
- to seek medical advice in the event of a severe adverse reaction.
- when the next dose of vaccine should be given, if appropriate.

### Special considerations / additional information

There must be **immediate** access to:

- Adrenaline (Epinephrine) 1:1000 (1mg/ml) injection
Special considerations / additional information (continued)

- the means to administer it
- a telephone.

Vaccine recipients should be observed for immediate adverse reactions. Advice on their management can be found in Chapter 8 of the *Green Book*, including adrenaline doses to be given in the event of anaphylaxis. These are reproduced in the table below. In some cases, several doses may be needed, particularly if improvement is transient. Registered health care professionals do not require access to an adrenaline PGD, prescription or PSD in order to administer adrenaline in an emergency.

Auto-injectors (Epipens® and Anapens®) for self-administration of adrenaline are not suitable for the treatment of anaphylaxis, other than by patients or their carers, and should not be used as a substitute for a proper anaphylaxis pack.

<table>
<thead>
<tr>
<th>Age</th>
<th>Dose of adrenaline (epinephrine): volumes stated are 1:1000 (1mg/ml) adrenaline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Under 6 months</td>
<td>150 micrograms IM (0.15ml)</td>
</tr>
<tr>
<td>Over 6 months but under 6 years</td>
<td>150 micrograms IM (0.15ml)</td>
</tr>
<tr>
<td>6 years to 12 years inclusive</td>
<td>300 micrograms IM (0.30 ml)</td>
</tr>
<tr>
<td>Over 12 years and adult</td>
<td>500 micrograms IM (0.50ml)</td>
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<tr>
<td></td>
<td>(300 micrograms IM (0.30ml) if patient is small or prepubertal)</td>
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</table>

Those who are likely to mount a reduced immune response to PPV should have their immunisation delayed unless this is likely to result in a failure to vaccinate, but vaccine given within these periods may need to be repeated. This includes patients who are within 2 weeks of splenectomy, or who have recently either started or completed a course of chemotherapy or radiotherapy. Expert
### Special considerations / additional information (continued)

Advice should be sought about appropriate timing for the individual. Any such additional doses would be outside the remit of this PGD.

### Records

A written and / or electronic entry must be made in the patient’s General Practitioner medical record, and in other patient records as appropriate. All records should be clear, legible and contemporaneous. Record:

- That valid informed consent was given
- Name of patient, address, date of birth and General Practitioner with whom the patient is registered (if this does not already form part of the record in which the entry is being made)
- Name of member of staff who administered the medicine (sign and print name if the record is a written one)
- Date of administration
- Dose and form of vaccine administered
- Name, brand, route and site of administration
- Batch number and expiry date
- Advice given (including advice if excluded or declines treatment)
- Details of any adverse drug reactions and actions taken
- Supplied via patient group direction.

In addition:

- A computerised or manual record of all individuals receiving treatment under this patient group direction should also be kept for audit purposes
3. Characteristics of staff

| Qualifications and professional registration required | Nurses currently registered with the Nursing and Midwifery Council (NMC).  
Paramedics currently registered with the Health and Care Professions Council (HCPC).  
Pharmacists currently registered with the General Pharmaceutical Council (GPhC).  
Additionally, these staff must be working on behalf of a general medical practice from which NHS England Midlands and East (Central Midlands) commissions immunisation services. |
|------------------------------------------------------|

| Additional requirements | Staff must:  
- be authorised by name as an approved practitioner under the current terms of this patient group direction before working to it  
- have undertaken appropriate training for working under PGDs for the supply/administration of medicines  
- have access to the current [online] version of the Green Book and to DH/PHE/NHS England letters regarding immunisation;  
- have a working knowledge of the above documents and comply with current recommendations  
- have undertaken training in all aspects of immunisation, and be competent to administer them and to discuss issues related to them  
- have specific knowledge of, and be competent to carry out clinical assessment of patients for the vaccines detailed within this PGD  
- have undertaken training in basic life support and the recognition and management of anaphylaxis and in line with current guidance? |

| Continued training requirements | Staff must:  
- keep their immunisation knowledge up to date and maintain their competence; if asked, they should be able to provide |
<table>
<thead>
<tr>
<th>(continued)</th>
<th>evidence of relevant continued professional development (CPD)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• annually attend an immunisation update</td>
</tr>
<tr>
<td></td>
<td>• annually undertake a basic life support and anaphylaxis update</td>
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<tr>
<td></td>
<td>• be constantly alert to any subsequent recommendations from the Department of Health and other sources of medicines information</td>
</tr>
</tbody>
</table>
References


APPENDIX A

Clinical risk groups who should receive the pneumococcal immunisation


<table>
<thead>
<tr>
<th>Clinical risk group</th>
<th>Examples (decision based on clinical judgement)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asplenia or dysfunction of the spleen</td>
<td>This also includes conditions such as homozygous sickle cell disease and coeliac syndrome that may lead to splenic dysfunction.</td>
</tr>
<tr>
<td>Chronic respiratory disease</td>
<td>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).</td>
</tr>
<tr>
<td>Chronic heart disease</td>
<td>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.</td>
</tr>
<tr>
<td>Chronic kidney disease</td>
<td>Nephrotic syndrome, chronic kidney disease at stages 4 and 5 (not CKD3) and those on kidney dialysis or with kidney transplantation.</td>
</tr>
<tr>
<td>Chronic liver disease</td>
<td>This includes cirrhosis, biliary atresia and chronic hepatitis.</td>
</tr>
<tr>
<td>Diabetes</td>
<td>Diabetes mellitus requiring insulin or oral hypoglycaemic drugs. This does not include diabetes that is diet controlled.</td>
</tr>
<tr>
<td>Immunosuppression</td>
<td>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)</td>
</tr>
<tr>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>Individuals with cochlear implants</td>
<td>It is important that immunisation does not delay the cochlear implantation.</td>
</tr>
<tr>
<td>Individuals with cerebrospinal fluid leaks</td>
<td>This includes leakage of cerebrospinal fluid such as following trauma or major skull surgery.</td>
</tr>
</tbody>
</table>
Health care professional and employer authorisation

HEALTH CARE PROFESSIONALS MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT

Only those health care professionals listed in section 3 of this document, Characteristics of staff: Qualifications and professional registration required (above) may work under this PGD. They must first complete and sign the individual authorisation in order to do so.

PGDs DO NOT REMOVE INHERENT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY

It is the responsibility of each health care professional to practice only within the bounds of their own competence and in accordance with the requirements of their profession’s regulatory framework, and any specific medicines management standards and guidance published by their profession’s regulatory body.

The use of PGDs is not compulsory and each practitioner should exercise personal and professional judgement as to whether to accept the responsibility that the role will place upon them.

Each authorised health care professional should have a copy of the current version of this document available in the clinical room (or other care setting) when administering this medicine. This may include the document being open on a computer screen.

Each health care professional authorised to work under this PGD should be provided with and retain an individual copy of their, and their employer’s signed authorisation.
SIPGD 013 Pneumococcal Polysaccharide Vaccine 23 valent (PPV) for adults age 65 and above and individuals from 2 years of age in a clinical risk group

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**Individual authorisation by the health care professional**

By signing this document you are confirming that you have read, understood and agree with its contents, and that you agree to work within it. Once it is signed you are legally bound by and must strictly adhere to it. If you are unsure about any of the content you must seek clarification prior to signing.

Please complete the checklist and sign below:

<table>
<thead>
<tr>
<th>Tick</th>
<th>I am a member of a health care profession listed in section 3 of this document and have current registration.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>I confirm that I have read and understood the content of this patient group direction for Pneumococcal Polysaccharide Vaccine 23 valent (PPV) vaccine.</td>
</tr>
<tr>
<td></td>
<td>I confirm that I have the necessary competence, training and knowledge to apply it.</td>
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<tr>
<td></td>
<td>I confirm that I am willing to work within this PGD and agree to administer these vaccines <em>only</em> in accordance with its content.</td>
</tr>
<tr>
<td></td>
<td>I will ensure that I <em>always</em> have a copy of this PGD available to which to refer when working to it.</td>
</tr>
</tbody>
</table>

**Name and job title / profession (print):**

**Signature:**

**Date:**
Employer authorisation

Any health care professional who fulfils all of the requirements listed in this PGD can work according to it. In doing so they are providing care which has been delegated to them by their employer, who is therefore required to provide a signed authorisation. The signatory must be satisfied that the named health care professional has the required knowledge and training and has been appropriately assessed as competent to carry out this role.

Tick

I confirm that ______________ [insert staff member’s name] has been assessed as competent to work under this PGD and that they have the practice’s approval to do so

Authorising manager’s name and job title / role (print):

On behalf of (print name of practice):

Signature:  Date: