Public Health England

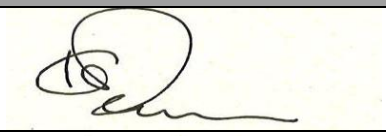
NHS England

Document Title:	**Patient Group Direction for Pneumovax II (23-Valent Pneumococcal Vaccine (PPV))**		
Area Team Ref.:	PGD	**Version No.:**	7/2014
NHS Doc Ref.:	http://www.england.nhs.uk/mids-east/ss-at/immunisations/		
Author:	Hitesh Patel Pharmaceutical Adviser		
Owner:	Rebecca Woods, Head of Public Health Commissioning		
File Reference:	I:\NHS_ENGLAND\AngleseyHouse\Commissioning Directorate\Primary Care & Specialised Commissioning\Public Health\Immunisation\2014-15\10) PGDs\Approved		
Owner:	**Rebecca Woods, Head of Public Health Commissioning**		
Document Overseeing Group:	PGD Working Group		
Placement in Framework:			
Approval Level:	Medicines Management Committee		
Date of Approval:	November 2014		
Review Date:	November 2016		
Amendment Dates:	**Page(s)**	**Brief Description**	
October 2014		Updated to new PGD format	

Patient Group Direction for administration of Pneumovax II (23-Valent Pneumococcal polysaccharide) (PPV)

Please note:
There are 2 pneumococcal vaccines, this PGD applies to the 23-valent unconjugated pneumococcal polysaccharide vaccine (PPV) only. There is a separate PGD relating to pneumococcal conjugate vaccine (PCV) which is intended for use in children under 5 years of age.

Approved By

NHS England and Staffordshire Area Team	Name	Signature
Medical Director	Dr Ken Deacon	
LPN Pharmacy Chair	Dr Manir Hussain	
Head of Public Health Commissioning	Rebecca Woods	

Date of patient group direction approved	Nov 2014
Date this patient group direction becomes due for review	Nov 2016 or in response to new local/national guidelines.

STAFF CHARACTERISTICS

- Provider of NHS services within NHS England (Shropshire & Staffordshire Area Team)
- Registered nurse with current NMC registration

Specialist competencies or qualifications:

- The health care professional must have a good understanding of the NICE Good Practice Guidance on Patient Group Directions.
- The NICE competency framework: For health professionals using Patient Group Directions should be used by health care professionals planning to work under this PGD to identify any gaps in their knowledge. The gaps should be addressed before the healthcare professional is authorised to work under this PGD.
- The clinical manager/ lead GP/commissioner must have evidence that the health care professional has undertaken training to carry out clinical assessment of patient leading to confirmation that the patient requires treatment according to the indications listed in the PGD.
- The healthcare professional must provide evidence of training, appropriate annual updates and continued professional development undertaken to support their competence for administration of this treatment.
- The clinical manager/ lead GP must have assessed the competency of the healthcare professional to work to this Patient Group Direction. The NICE competency framework: For health professionals using Patient Group Directions should be used to support this assessment.
- The health care professional must have undertaken training and annual updates in the recognition and treatment of anaphylaxis, including practical in Basic Life Support and has immediate access to an in-date supply of adrenaline 1mg in 1ml (1:1000) at the time of the consultation. (The practitioner must be deemed competent in basic life support and in emergency administration of adrenaline)
- The health care professional must have access to all relevant sources of information e.g. information issued by the Department of Health (Green Book), British National Formulary (BNF), Summary of Product Characteristics (SPC), and the clinical guideline concerning medicine(s) within this Patient Group Direction (PGD).
- The practitioner must be competent and knowledgeable in vaccine cold chain standards.
- The registered health care practitioner is professionally accountable for supply or administration under the PGD as defined in their own profession's Code of Professional Conduct and Ethics.

YOU MUST BE AUTHORISED BY NAME BY YOUR CLINICAL LEAD UNDER THE CURRENT VERSION OF THIS PGD BEFORE YOU ATTEMPT TO WORK ACCORDING TO IT

PGDs DO NOT REMOVE INHERENT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY

<table>
<tr><th colspan="2">CLINICAL CONDITION</th></tr>
<tr><td>Clinical need addressed</td><td>Active immunisation against pneumococcal disease in accordance with the national immunisation programme</td></tr>
<tr><td>Inclusion criteria</td><td>Informed consent obtained

All those aged 65 years and over.

All ‘at risk’ children (see below) aged 2 years to five years who have received the pneumococcal conjugated vaccine (PCV) in accordance with the PCV PGD

All ‘at risk’ children over 5yrs and adults

<table>
<tr><th>Clinical Risk Category</th><th>Examples (decision based on clinical judgement)</th></tr>
<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, including asthma</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 neuromuscular 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 renal disease</td><td>Including nephrotic syndrome, chronic renal failure, 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 asplenia or splenic dysfunction and HIV infection at all stages. Patients undergoing chemotherapy leading to immunosuppression. 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.

However, some immunocompromised patients may have a suboptimal immunological response to the vaccine.</td></tr>
</table>
</td></tr>
</table>

	<table><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></table> Primary care staff should identify patients for whom vaccine is recommended and use all opportunities to ensure that they are appropriately immunised for example: • When immunising against influenza • At all other routine consultations especially on discharge after hospital admission
Exclusion criteria (for full details of interacting medicines refer to current Summary of Product Characteristics (SPC) www.medicines.org.uk & BNF)	• Patients under 2 years of age • Declined consent patient parent/guardian • Hypersensitivity to any component of the vaccine • Acute febrile illness • Patients who have received pneumococcal vaccine. NB: Do not revaccinate anyone without referring to medical practitioner. • Patients who are receiving immunosuppressive therapy or who have received it within the last 3 months - refer to medical practitioner • Pregnancy or breast feeding – refer to practitioner. (Pneumococcal containing vaccines may be given to pregnant women when the need for protection is required without delay a patient specific direction should be used for this purpose).
Caution/need for further advice /Interactions	If the vaccine is administered to patients who are immunosuppressed due to either an underlying condition or medical treatment (e.g. immunosuppressive therapy such as cancer chemotherapy or radiation therapy), the expected serum antibody response may not be obtained after a first or second dose. Accordingly, such patients may not be as well protected against pneumococcal disease as immunocompetent individuals Pneumococcal vaccines can be given at the same time as other vaccines such as DTaP/IPV/Hib, MMR, MenC, Hib/MenC and influenza. 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.
Management of excluded patients	• Document in the individual's notes, advise and counsel accordingly. • Refer to medical practitioner or seek appropriate advice from a Consultant in Health Protection if necessary • For individuals temporarily excluded due to acute or febrile illness advise when the vaccine may be given and arrange another appointment.
Action for patients not wishing to receive care under this PGD	• Advise the individual about the protective effects of the vaccine, the risks of infection, including potential complications. • Document action and advice given (record declined vaccine in the individuals clinical record). • Refer to doctor or independent prescriber.

<table>
<tr><th colspan="2">Treatment and Drug details</th></tr>
<tr><td>Name form and strength of medicine</td><td>Pneumovax II
Pneumococcal (23-valent) polysaccharide vaccine (PPV)</td></tr>
<tr><td>Legal classification</td><td>POM – Prescription only medicine.</td></tr>
<tr><td>Black triangle warning
Suspected adverse reactions. Should be reported using the Yellow Card reporting scheme (www.yellowcard.gov.uk).</td><td>No</td></tr>
<tr><td>Method of obtaining supply</td><td>Order through the ImmForm website (www.immform.dh.gov.uk)</td></tr>
<tr><td>Site for treatment</td><td>• GP surgeries
• Health Centres</td></tr>
<tr><td>Route/method</td><td>Intramuscular injection preferably into the deltoid muscle or lateral aspect of mid-thigh. If given at the same time as the influenza vaccine it should be given in a different limb.

For patients with bleeding disorders vaccine should be given by deep subcutaneous injection to reduce the risk of bleeding.</td></tr>
<tr><td>Dose</td><td>A single dose of 0.5ml of PPV23</td></tr>
<tr><td>Number of times treatment may be administered</td><td>Adults over 65 years of age, and patients in clinical at- risk groups over 2 years of age: One dose

Antibody levels are likely to decline rapidly in individuals with no spleen, splenic dysfunction or chronic renal disease and therefore re-immunisation with 23-valent PPV is recommended every five years in these groups. Re-vaccination is well tolerated. Testing of antibody levels prior to vaccination is not required.
Although there is evidence of a decline in protection with time there are no studies showing additional protection from boosting individuals with other indications, including age, and therefore routine revaccination is not currently recommended.

Vaccination Schedule for those in clinical risk group

<table>
<tr><th rowspan="2">Patient age at presentation</th><th colspan="2">Vaccine given and when to immunise</th></tr>
<tr><th>13-valent PCV (See PCV PGD)</th><th>23-valent PPV</th></tr>
<tr><td>At-risk children 2 months to under 12 months of age</td><td>Vaccination according to the routine immunisation schedule at 2, 4 and between 12 and 13 months of age (i.e within a month of the first birthday)</td><td>One dose after the second birthday</td></tr>
<tr><td>At-risk children 2 months to under 12 months of age who have asplenia or splenic dysfunction or who</td><td>Vaccination according to the routine immunisation schedule at 2, 4 and</td><td>One dose after the second birthday</td></tr>
</table>
</td></tr>
</table>

	are immunosuppressed	between 12 and 13 months of age (i.e within a month of the first birthday)	
	At risk children 12 months to under 5 years of age	One dose	One dose after the second birthday and at least 2 months after the final dose of PCV
	At-risk children 12 months to under 5 years of age who have asplenia or splenic dysfunction or who are immunosuppressed	Two doses with an interval of 2 months between doses	One dose after the second birthday and at least 2 months after the final dose of PCV
	At-risk children aged over 5 years and at-risk adults	PCV is not recommended	One dose

Quantity to be supplied or administered	Single dose as per immunisation guidelines
Side effects *Full details of side effects are available in the SPC.* *www.medicines.org.uk* *Suspected adverse reactions to drugs including vaccines should be reported on the yellow card available at the back of the BNF. Also at www.yellowcard.gov.uk*	Common adverse reactions • Fever (≤ 38.8°C) (lasting one to three days) • Injection site reactions: erythema, induration, pain, soreness, swelling, warmth
Additional Information (including storage and disposal)	• Store in a refrigerator (+2^{0}C to + 8^{0}C) • Do not freeze • Store in original packaging • Protect from light • Equipment used for vaccination should be disposed of by placing in a proper, puncture-resistant 'sharps' box according to local authority regulations and guidance in Health Technical Memorandum 07-01: Safe management of healthcare waste (Department of Health, 2013)
Advice to patient/carer	BEFORE TREATMENT**:** • Advise parent/guardian of possible side effects. For full details see product's summary of product characteristics. Advise action to be taken if side effects are experienced • Advise may experience fever (≤ 38° C) lasting one to three days, malaise, myalgia, arthralgia, headache, rash. AFTER TREATMENT: • Provide patient information leaflet • Advise patients to seek advice from nurse if they are concerned about local reactions at site of injection

Follow up	Inform possible side effects and their management. Any serious adverse reaction to the vaccine should be documented in a child's health records and on their medical records. GP should also be informed.
Suspected adverse reactions	Patient presenting with suspected adverse drug reaction should be referred to a doctor for further investigations. All serious suspected reactions following vaccination should be documented in the patient's medical record and reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card scheme at http://yellowcard.mhra.gov.uk/
Error reporting	Any incidents or near-miss issues must be reported via the organisation's internal reporting system
RECORD KEEPING	
Documentation needed/treatment records to be kept for audit purposes *A computer or manual record of all individuals receiving treatment under this Patient Group Direction should also be kept for audit purposes.*	• Patient's name, address, date of birth and registered GP • Record of informed consent • Manufacturer, vaccine name, product name, batch number, expiry date • Dose administered • Date of administration • Anatomical site of vaccination • Route of administration • Advice given to patient (including advice given if vaccination is declined) • Details of staff who administered (sign and print name) • Details of any adverse drug reactions, and action taken including informing GP • Record as supplied via Patient Group Direction (PGD) in patient's clinical record All records should be clear, legible and contemporaneous. This information should be recorded as appropriate in the patient's General Practitioner record or other patient record, depending on location. For children record in the personal Child Health record (PCHR) – the Red Book. A computerised or manual record of all individuals receiving treatment under this Patient Group Direction should also be kept for audit purposes. If vaccination has been completed by a provider other than the GP practice, timely communication to the GP practice to enable the patient's record to be updated must be completed. Any noted adverse effects following vaccination must also be reported be to the GP practice. Clinical records must be kept for at least 8 years following completion of treatment. In patients who are aged under 17 years, clinical records must be kept until the patient's 25th birthday, or for 8 years following a child's death. Data must be stored in accordance with Caldicott guidance and the Data Protection Act. • Reconciliation – stock balances should be reconcilable with receipts, administration records and disposal.

Register of practitioners qualified to administer and/or supply Pneumovax II (23-Valent Pneumococcal Vaccine) under this Patient Group Direction	
Name of clinical manager/GP Lead/Commissioner	
Signature of clinical manager/GP Lead / commissioner	Date:
A copy of this page should be retained by the authorising manager for 2 years for audit purposes	
Please state clinical area where this PGD is in use	

Healthcare professional individual declaration

I have read and understood the Patient Group Direction and agree to supply this medicine only in accordance with this PGD

- **PGDs DO NOT REMOVE INHERENT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY**.
- It is the responsibility of each professional to practice only within the bounds of their own competence.
- All practitioners operating in accordance with this PGD should have a current, signed copy of it readily available for reference.
- If a practitioner is asked to supply, or administer a medicine not covered by this or any other PGD then a patient specific direction is required from a doctor, dentist or independent prescriber.

Name of professional (please print)	Signature	Authorising Manager (Must sign against each entry)	Date of authorisation

The clinical lead should review competency of authorised practitioners annually.
Authorisation to use this PGD does not remove inherent professional responsibility and accountability

References

DH Immunisation against infectious disease 'Green Book' Chapter 25 Pneumococcal

Summary of Product Characteristics, Sanofi Pasteur MSD, Pneumovax II www.emc.medicines.org.uk