

## Patient Group Direction (PGD) for the Administration of

### PNEUMOCOCCAL VACCINE (Prevenar 13<sup>®</sup> and Pneumococcal Polysaccharide Vaccine)

by Registered Professionals to Individuals Accessing NHS Services in  
Durham, Darlington, Tees, North Cumbria, Northumberland and Tyne & Wear

YOU MUST BE AUTHORISED BY NAME,  
UNDER THE CURRENT VERSION OF  
THIS PGD BEFORE YOU ATTEMPT TO  
WORK ACCORDING TO IT.

Direction Number: - **NECSAT 2018/002**

Valid from: 1<sup>st</sup> June 2018

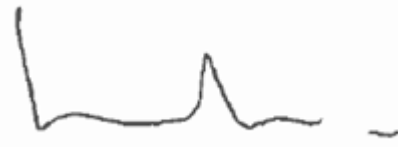
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#### This patient group direction has been developed & produced by: -

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#### This PGD has been approved for use in Cumbria and North East by: -

Title	Name	Signature	Date
<i>Medical Director</i> (NHS England, Cumbria and North East)	<b>Dr Jonathan Slade</b> (Governance Authorisation)		29/05/18

# 1. Clinical Condition or Situation to Which the Direction Applies

## Indication (defines situation or condition)

### Active immunisation against Pneumococcal disease:

- Routine childhood vaccination for those 2 months to 2 years of age.
- Patients in clinical risk groups who have been identified as being at risk of pneumococcal disease (see inclusion).
- All patients aged 65 years old or over (who have not had vaccination before).

## Objectives of care

- To protect all of those for whom pneumococcal infection is likely to be more common and/or serious;
- To reduce morbidity and mortality from pneumococcal disease.

## Inclusion criteria (as per Public Health England (PHE) Green Book Guidance)

Only use those criteria that are specific to your authorised role & competence.

Ensure appropriate consent has been obtained before commencing any vaccination.

- **All previously unvaccinated children aged from 2 months and under 2 years of age:**
  - As part of the routine childhood immunisation programme (use 13-valent pneumococcal conjugate vaccine (PCV13)).
- **All un-immunised adults aged 65 years and over** (use 23-valent pneumococcal polysaccharide vaccine (PPV23));
- **All those aged 2 months and over in the following clinical at-risk groups** as defined in chapter 25 v7.0, Immunisation Against Infectious Disease, Green Book Guidance (see current on-line version for full details) :-
  - a) **Asplenia or dysfunction of spleen**, including conditions such as homozygous sickle cell disease and coeliac syndrome that may lead to splenic dysfunction.
  - b) **Chronic respiratory disease** - This includes chronic obstructive pulmonary disease (COPD), etc. Children with respiratory conditions caused by aspiration, or a neurological disease (e.g. cerebral palsy). Asthma is not an indication, unless so severe as to require continuous or frequently repeated use of systemic steroids (as defined in immunosuppression below)
  - c) **Chronic heart disease**
  - d) **Chronic liver disease**
  - e) **Chronic kidney disease** – Nephrotic syndrome, chronic kidney disease (Stages 4 and 5) and those on kidney dialysis or with kidney transplantation
  - f) **Diabetics** – Diabetes Mellitus requiring insulin or oral hypoglycaemic drugs (Not dietary controlled)
  - g) **Immunosuppression due to disease or treatment** - Including asplenia or splenic dysfunction; bone marrow transplant; HIV infection at all stages; patients undergoing chemotherapy leading to immunosuppression: multiple myeloma or genetic disorders affecting the immune system.

Individuals on or likely to be on systemic steroids for >1month at a dose equivalent to prednisolone at  $\geq 20\text{mg/day}$  (any age) or for children under 20kg a dose of 1mg or more per kg per day.

However, it should be noted that some immuno-compromised patients may have a suboptimal immunological response to the vaccine.
  - h) **Prior to cochlear implant (ideally at least 2 weeks before) or to unimmunised 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. Conditions related to CSF leaks include all CSF shunts.

## Exclusion criteria

**General exclusions** (Refer to current Summary of Product Characteristics (SPC) &/or BNF for full list of details): -

- Children under 2 months of age;
- Healthy adults under 65 years old;
- No valid consent (if applicable).
- Patient is acutely unwell (postpone vaccination until recovered. Minor infections without fever or systemic upset are not reasons to postpone immunisation).
- Confirmed anaphylaxis to any component of the vaccine.
- Severe general reaction to previously administered dose of any type of pneumococcal vaccine.
- Severe hypersensitivity to any ingredient or component of the vaccine(s). – **(please also refer to precautions section)**.
- Received a dose of pneumococcal vaccine within the previous 4 weeks (Note national schedule recommends 8 week interval - see dose schedule).

**Specific exclusions:** -

- Prevenar 13<sup>®</sup> : - hypersensitivity to diphtheria toxoid
- Pneumococcal Polysaccharide Vaccine: - not to be used in children under 2 years of age.

Refer to current SPC/ Green Book (current on-line version)/ BNF for full list of details

## Precautions

- Pregnancy (known or suspected) or breast feeding
  - NB. The current on-line Green Book states that, "Pneumococcal vaccines may be given to pregnant women when the need for protection is required without delay. There is no evidence of risk from vaccinating pregnant women or those who are breast feeding with inactivated viral or bacterial vaccines, or toxoids."
- Ideally, pneumococcal vaccine 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. If it is not practicable to vaccinate two weeks before splenectomy, immunisation should be delayed until at least 2 weeks after operation.
- Premature infants must have their immunisations at the appropriate chronological age, according to the schedule. The occurrence of apnoea following vaccination is especially increased in infants who were born very prematurely. Very premature infants (born  $\leq$  28 weeks of gestation) who are in hospital should have respiratory monitoring for 48-72 hours when given their first immunisation, particularly those with a previous history of respiratory immaturity. If the child has apnoea, bradycardia or desaturations after the first immunisation, the second immunisation should also be given in hospital, with respiratory monitoring for 48-72 hours. As the benefit of vaccination is high in this group of infants, vaccination should not be withheld or delayed.
- Hypersensitivity reactions to previous dose of vaccine or component of vaccine:
  - NB. "Local adverse reactions that generally start within a few hours of the injection and are usually mild and self-limiting. Although these are often referred to as 'hypersensitivity reactions', they are not allergic in origin, but may be either due to high titres of antibody or a direct effect of the vaccine product, e.g. endotoxin in whole-cell bacterial vaccines. The occurrence or severity of such local reactions does not contraindicate further doses of immunisation with the same vaccine or vaccines containing the same antigens

## Action if excluded

- Discuss with or refer to clinician/doctor. Ensure all actions/decisions are documented.
- The risk to the individual of not being immunised must be taken into account.
- If postponement due to acute illness, arrange a future date for immunisation.

## Circumstances in which further advice should be sought from a doctor and/or specialist

- Patient meeting the exclusion criteria
- Patient requires additional information in order to decide whether or not to have the vaccination

## Action if vaccination refused

- Ensure patient/guardian/carer fully understands the risks of declining vaccination.
- Advise about protective effects of vaccine & the risks of infection and disease complications. If postponement due to acute illness, arrange a future date for immunisation
- Document refusal, advice given, actions/decisions in notes (written or electronic). Inform or refer to doctor as appropriate

## Special Considerations / Additional Information

### • Individuals with unknown or incomplete vaccination histories:

Unimmunised or partially immunised children who present late for vaccination and before the age of one year should receive two doses of PCV13 two months apart\*, and a further dose on their first birthday, at least two months after the last PCV13 dose)\*. An unimmunised or partially immunised child aged between one and under two years of age should have a single dose of PCV13 (\*this interval may be reduced to 1month if necessary to ensure that the immunisation schedule is completed)

- **At risk** children who present late for vaccination should be immunised as stated above.
- Pneumococcal vaccine can be administered simultaneously with most other vaccines, as long as different needles and injection sites are used, preferably in a different limb or at least 2.5cm from the concomitant immunisation. **NB.** Never give PPV23 (Pneumococcal Polysaccharide) vaccine and PCV13 (Prevenar 13®) vaccine together.

## 2. Description of treatment

### Name, strength & formulation of drug

#### **Prevenar 13® (Pfizer): 13-valent pneumococcal polysaccharide conjugate vaccine (PCV13)**

- 0.5ml suspension for injection in pre-filled syringe (Type I glass) with a plunger stopper (latex-free chlorobutyl rubber) and protective-tip cap (latex-free isoprene bromobutyl rubber) containing 13 pneumococcal serotypes in conjugated form
- Before use, the vaccine should be well shaken to obtain a homogeneous, white suspension prior to expelling air from the syringe and be inspected visually for any particulate matter.
- Do not use injection if the content appears otherwise or it contains remaining particulate matter.
- Upon storage, a white deposit and clear supernatant can be observed. This does not constitute a sign of deterioration

#### **Pneumococcal Polysaccharide Vaccine (Merck Sharp and Dohme Ltd): 23-valent pneumococcal polysaccharide vaccine (PPV23)**

- 0.5ml solution for injection vial containing 25mcg of each of the 23 main different pneumococcal serotypes
- Solution is available in a vial (type 1 glass) with stopper (rubber) with a flip off cap (plastic). The vaccine is clear, colourless solution.

### Legal Status:

#### **POM –Prescription Only Medicines**

(The use of the vaccine in this PGD in some circumstances is off-label but follows current NHS England guidance)

## Dosage / Dose range

<b>Prevenar 13® ▼</b>	<b>: 2 months old &amp; over:</b>	<b>0.5ml</b>
<b>Pneumococcal Polysaccharide Vaccine</b>	<b>: 2 years old &amp; over:</b>	<b>0.5ml</b>

## Route/Method

**Intra-muscular (IM) injection** is the preferred route

- Deltoid region in older children and adults, anterolateral thigh in infants.
- Not to be given intravenously or intradermally
- For individuals with a bleeding disorder vaccines should be given by deep subcutaneous injection.

If given at the same time as other vaccines it should be given at separate sites, preferably in a different limb.

(Please refer to the manufacturer's SPCs and on line version of the Green Book for detailed information).

## Frequency of Administration

<b>ROUTINE IMMUNISATION – Which vaccine to give and when to immunise</b> (See also following link: <a href="https://www.gov.uk/government/publications/the-complete-routine-immunisation-schedule">https://www.gov.uk/government/publications/the-complete-routine-immunisation-schedule</a> )		
Age	13-valent pneumococcal conjugate vaccine (PCV13) - (Prevenar 13®)	23-valent pneumococcal polysaccharide vaccine (PPV23)
2 months to under 1 year of age	<b>Primary course - 2 doses</b> 1st dose at 2 months old, 2 <sup>nd</sup> dose at 4 months old. A total of two doses given 2 months apart. - If primary course is interrupted then give a dose of PCV13 as soon as possible, followed by booster dose on or after 1 <sup>st</sup> birthday allowing an interval of 2months between doses.	Not recommended
	<b>Individuals with unknown or incomplete vaccination histories</b> † - Those who present late for vaccination & before age of one year should receive two doses of PCV13 two months apart*, and a further dose on their 1 <sup>st</sup> birthday, at least 2months after last PCV13 dose* *(The intervals may be reduced to one month if necessary to ensure immunisation schedule is completed)	
1 year to under 2 years old	<b>1 dose</b> (a reinforcing booster dose given on or after 1 <sup>st</sup> birthday)	Not recommended
	<b>Individuals with unknown or incomplete vaccination histories</b> † - An unimmunised or partially immunised child between 1 and under two years of age should have <b>1 single dose of PCV13</b> . (Routine immunisation with PCV is not offered after 2 <sup>nd</sup> birthday unless individual is at increased risk of pneumococcal).	
65 years old & over	Not recommended.	1 dose

† (Link to PHE document: <https://www.gov.uk/government/publications/vaccination-of-individuals-with-uncertain-or-incomplete-immunisation-status>)

**AT RISK GROUPS – Which vaccine to give and when to immunise**

Age diagnosed (or first presenting as at risk)	PCV13 (Prevenar 13® )	(PPV23) - Pneumococcal Polysaccharide Vaccine
<b>From birth to under 2 years of age</b>	<p><b>Give PCV13 according to routine immunisation schedule above</b> (i.e. 1<sup>st</sup> dose at 2mths old, 2<sup>nd</sup> dose at 4mths old &amp; 3<sup>rd</sup> dose at 12 months of age)</p> <p><b>For those who present late:</b> Immunise according to “Individuals with unknown or incomplete vaccination histories” (see previous table and link below)*.</p>	<p><b>1 single dose</b> after the 2<sup>nd</sup> birthday, at least 2 months after the last PCV13 dose</p>
<b>2 to under 10 years of age</b>	<p><b>Not recommended</b> – for those who have completed routine PCV13 imms schedule</p> <p><b>1 dose of PCV13</b> – for children who are previously unvaccinated or partially vaccinated* for PCV should receive 1 dose of PCV13, (followed by a single dose of PPV23 at least 2months later).</p>	<p><b>1 single dose</b> (at least 2 months after final dose of PCV13).</p>
<b>Children aged over 10years &amp; adults</b>	Not recommended	<p><b>1 single dose</b> (Regardless of prior PCV vaccination) (Given at least 2 months after final dose of PCV13).</p> <p>No additional PPV23 is recommended when they reach 65yrs of age</p>

\*(Link to PHE algorithm document: <https://www.gov.uk/government/publications/vaccination-of-individuals-with-uncertain-or-incomplete-immunisation-status>)

**CHILDREN & ADULTS REQUIRING SPLENECTOMY OR COMMENCING IMMUNOSUPPRESSIVE THERAPY**

**Vaccinate according to age-specific advice outlined for “At Risk Groups” above.**

- Ideally, vaccinate 4 to 6 weeks before elective splenectomy or initiation of treatment such as chemotherapy or radiotherapy. Where this is not possible, pneumococcal vaccine can be given up to 2 weeks before treatment.  
(If not possible to vaccinate beforehand, splenectomy, chemotherapy or radiotherapy should never be delayed).
- If it's not practicable to vaccinate 2weeks before splenectomy, immunisation should be delayed at least 2wks after operation.
- If it is not practicable to vaccinate two weeks before initiation of chemotherapy and/or radiotherapy, immunisation can be delayed until 3 months after completion of therapy. (Immunisation of these patients should not be delayed if this is likely to result in a failure to vaccinate).



<b>INDIVIDUALS with ASPLENIA, SPLENIC DYSFUNCTION COMPLIMENT DISORDERS</b> (Including those receiving complement inhibitor therapy*).		
Age first diagnosed at	<b>13-valent pneumococcal conjugate vaccine (PCV13) - (Prevenar 13® )</b>	<b>23-valent pneumococcal polysaccharide vaccine (PPV23)</b>
<b>2 months to under 1 year of age</b>	<p><b>Children should be fully immunised according to the routine immunisation schedule,</b></p> <p>(See link: <a href="https://www.gov.uk/government/publications/the-complete-routine-immunisation-schedule">https://www.gov.uk/government/publications/the-complete-routine-immunisation-schedule</a> )</p> <p>Children should also receive <b>an extra dose of PCV13*</b> (To be given 2 months after the routine booster due on their 1<sup>st</sup> birthday<sup>1</sup>)</p> <p><sup>1</sup>(the intervals may be reduced to 1month if necessary to ensure that the immunisation schedule is completed)</p>	<p><b>1 single dose*, ** of</b></p> <p>PPV 23 to be given after the second birthday, at least 2 months after the last PCV13 dose-</p>
<b>1 year to under 2 years old</b>	<p><b>If not yet administered give the routine 12-month PCV13 dose.</b></p> <p>Follow the “Vaccination of individuals with uncertain or incomplete immunisation status” algorithm. (<a href="https://www.gov.uk/government/publications/vaccination-of-individuals-with-uncertain-or-incomplete-immunisation-status">https://www.gov.uk/government/publications/vaccination-of-individuals-with-uncertain-or-incomplete-immunisation-status</a> )</p> <p><b>An extra dose of PCV13* (To be given 2 months after the routine booster due on their 1<sup>st</sup> birthday<sup>1</sup>)</b></p> <p><sup>1</sup>(the intervals may be reduced to 1month if necessary to ensure that the immunisation schedule is completed)</p>	
<b>2 years to under 10 years of age</b> (Ensure children are immunised according to national schedule)	<p>Ensure children are immunised according to the national schedule.</p> <p>(NB. Children in this group who are partially or unvaccinated should receive one dose of PCV13)</p>	<p><b>1 single dose*</b></p> <p>Given after the 2<sup>nd</sup> birthday and at least 2 months after the final dose of conjugate vaccine (PCV13)</p>
<b>10 years of age onwards</b> (regardless of vaccination history)	Not recommended	<p><b>1 single dose*</b></p> <p>(Given at least 2 months after the final dose of PCV13)</p>
<p>* (Patients on Eculizumab (Solaris) therapy are not at increased risk of pneumococcal disease and do not require PPV23 or additional doses of PCV13)</p> <p>** (Patients with splenic dysfunction should receive boosters of PPV at five yearly intervals)</p>		

<b>For Leukaemia and bone marrow transplant patients</b>		
<b>Those diagnosed with</b>	13-valent pneumococcal conjugate vaccine (PCV13) - (Prevenar 13® )	23-valent pneumococcal polysaccharide vaccine (PPV23)
<b>Leukaemia</b>	<b>1 dose.</b> Give 6months after completion of chemotherapy	Not recommended
<b>Bone marrow transplant patients</b>	<b>1 dose.</b> Give 9-12 months following transplantation	Not recommended

## Frequency of Administration continued (please also refer to Green Book Chapters 7 and 25v7)

### Severely immunocompromised children diagnosed from birth onwards and adults

Diagnosed	13-valent pneumococcal conjugate vaccine (PCV13) - (Prevenar 13®)	23-valent pneumococcal polysaccharide vaccine (PPV23)
<b>Severely immunocompromised</b> <sup>2</sup> (including bone marrow transplant patients, patients with acute and chronic leukaemia, multiple myeloma or genetic disorders affecting the immune system (e.g. IRAK-4, NEMO, compliment deficiency))		
<b>From birth to two years of age</b>	<b>Give PCV13 according to routine schedule.</b> (See link: <a href="https://www.gov.uk/government/publications/the-complete-routine-immunisation-schedule">https://www.gov.uk/government/publications/the-complete-routine-immunisation-schedule</a> ). See also additional link below.*  <b>Give a second (additional) PCV13 dose</b> Should be given at least 2 months after the routine booster dose due on the 1 <sup>st</sup> birthday. (NB. The intervals may be reduced to one month if necessary to ensure that the immunisation schedule is completed).	<b>Give 1 single dose</b>  Should be given when they reach the age of two years, at least 2 months after last dose of PCV13
<b>2 years to under 10 years old</b>	<b>1 single additional dose of PCV13</b> Followed by PPV23 at least 2 months later (irrespective of any routine childhood vaccinations they have already received).  Patients who have already received PPV23 should wait at least six months after the PPV23 dose before being offered PCV13 in order to reduce the theoretical risk of pneumococcal serotype-specific hypo responsiveness	<b>1 dose</b>  at least 2 months after PCV13
<b>10 years onwards and adults</b>	<b>1 single dose of PCV13</b> Followed by PPV23 at least 2 months later (irrespective of their previous pneumococcal vaccinations). If PPV23 has already been administered, then wait at least 6 months after the PPV23 dose to give PCV13 in order to reduce the theoretical risk of pneumococcal serotype-specific hypo responsiveness	<b>1 dose</b>  at least 2 months after PCV13

NB. For re-immunisation see "Follow-up treatment" section. See also "Special considerations/additional notes" section).

Please also see Public Health England document – Immunisation against infectious diseases (The Green Book) chapter 25v7

\* (<https://www.gov.uk/government/publications/pneumococcal-the-green-book-chapter-25>)

### Maximum dose

As above

### Follow up treatment

- Revaccinate with PPV23 every 5 years for individuals with no spleen, splenic dysfunction and nephrotic syndrome (Chronic kidney disease stage 4-5)
- (See Immunisation Against Infectious Diseases (Green Book on-line); updated chapter 25v.7)



### 3. Further Aspects of Treatment

#### Relevant Warnings & Potential Adverse Effects

**Relevant Warnings:** - See manufacturers SPC for full details / current Green Book online Chapter 25 & 9

**Potential Adverse Effects/ Reactions:** - Usually transient and only last a few days after vaccination.

**Please be aware of Resuscitation Council Guideline changes (2010)**

	<b>Prevenar 13<sup>®</sup></b> PCV13 - Pneumococcal conjugate vaccine	<b>Pneumococcal polysaccharide - vaccine</b> PPV23
<b>Very Common &amp; Common reactions</b>	Warmth, soreness and induration/swelling at injection site. Fever (>39 °C)  Decreased appetite; irritability; somnolence; poor quality sleep, rash	Mild swelling, erythema, redness and induration at injection site. Decreased appetite and Fever (≤ 38.8°C)
<b>Less Common Effects</b>	Vomiting & diarrhoea, urticaria, headaches,	Fever (> 38.8°C), rash malaise, myalgia, rash, nausea, headache etc.
<b>Rarely</b>	Anaphylactic reaction, erythema multiforme	Anaphylactic reaction, Injection site cellulitis

This list is not exhaustive. Please also refer to current manufacturers SPC for details of all potential adverse reactions.

#### Identification and Management of Adverse Reactions

- Patient/ Carer / Guardian requested to report side effects
- Advice on management including anaphylaxis: - Chapter 8 of Green Book provides detailed advice on managing adverse drug reactions following immunisation, e.g. Analgesia for pain &/or fever; prevention of dehydration; drinking plenty of clear fluids).
- Refer to doctor/specialist if appropriate

#### Reporting Procedure of Adverse Effects

- Report to doctor if appropriate & document in patient's medical records.
- All adverse reactions due to ▼ vaccines should be reported to the MHRA using the yellow card system.
- For established vaccines only report serious adverse reaction. Please refer to [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) and the online Green Book - Chapter 9.

#### Advice to Patient / Carer (verbal or written)

- Explain protection level expected from vaccine.
- Provide a patient information leaflet and discuss as required.
- Provide advice on & explain potential warnings & side effects and request to report them if they occur.
- Provide advice on management of adverse reactions (see above and manufacturers SPC).
- Explain procedure for dealing with anaphylaxis /severe allergic reactions.
- Explain the "Out of Hours" procedure. Give date of next vaccine if applicable.
- Provide patient with vaccination record card (to include date of next vaccination, completion of course or blood test) if applicable.
- Complete patient-held vaccination record

## Arrangements for Referral to Medical Advice

- Doctor/specialist appointment as and when appropriate

## Records

In all cases manual records including the Personal Held Child Record, computerised records and data collection for Child Health Information Services (CHIS) should include: -

- Patient's name and date of birth;
- Reason vaccination required;
- Date of administration;
- Whom administered by and signature of vaccinator (if not recorded on computer).
- Confirmation that there are no contraindications; That side effects have been discussed;
- Support literature given (where applicable);
- Signature and printed name and designation (in black ink) for paper records. For computer records, ensure data authentication of practitioner delivering care.
- Confirmation that consent has been obtained;
- Dose, site and route of injection;
- Brand name, batch number and expiry date of vaccine;

## Additional Facilities

- Access to updated online Green Book information; the latest SPC and BNF.
- Store in a refrigerator (+2°C to +8°C). Have access to a telephone.
- Stock control & storage of vaccines in accordance with national and local policies / protocols/ guidelines.
- Emergency equipment available including immediate access to Epinephrine (Adrenaline) 1in 1000 injection (as a minimum). (Please refer to PGD for adrenaline as applicable)

## References

- NICE Good Practice Guidance : Patient Group Directions Aug 2013, updated March 2017
- Public Health England (2013): Immunisation Against Infectious Disease - The "Green Book" Chapter 25: Pneumococcal <https://www.gov.uk/government/publications/pneumococcal-the-green-book-chapter-25> and Chapter 7: Immunisation of individuals with underlying medical conditions <https://www.gov.uk/government/publications/immunisation-of-individuals-with-underlying-medical-conditions-the-green-book-chapter-7>, Accessed on 30/01/2018.
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- Nursing and Midwifery Council (NMC), 2007: Record Keeping Advice Sheet.
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- Resuscitation Council (UK), October 2010: Emergency Medical Treatment of anaphylactic reaction by first medical responders and community nurses. <https://www.resus.org.uk/>
- Merck Sharp & Dohme Limited, Pneumococcal Polysaccharide - Summary of Product Characteristics (SPC), accessed from Electronic Medicines Compendium <https://www.medicines.org.uk/emc/product/1061> on 30.01.18.
- Pfizer Ltd, Prevenar 13® - Summary of Product Characteristics (SPC) accessed from Electronic Medicines Compendium <https://www.medicines.org.uk/emc/product/453> on 30.01.18.
- Public Health England, Service Specification Enhanced Service Specification, Seasonal influenza and pneumococcal polysaccharide vaccination programme 2017/18. <https://www.england.nhs.uk/wp-content/uploads/2017/03/sfl-pneumococcal-2017-18-service-specification.pdf> accessed 30.01.18
- Public Health England, Vaccination of individuals with uncertain or incomplete immunisation status IMW 86.03 <https://www.gov.uk/government/publications/vaccination-of-individuals-with-uncertain-or-incomplete-immunisation-status> accessed 30.01.18
- Public Health England; The complete routine immunisation schedule <https://www.gov.uk/government/publications/the-complete-routine-immunisation-schedule> accessed 30.10.18

## 4. Characteristics of Healthcare Professional Staff

Only those healthcare professionals that have been specifically authorised by their clinical lead/supervisor/manager may use this PGD for the indications defined within it.

Under current legislation, only the following currently registered healthcare professionals may work under Patient Group Directions (PGDs). These professionals may only supply or administer medicines under a PGD as named individuals. These professionals include -

Pharmacists	Nurses	Chiropodists/Podiatrists
Health Visitors	Physiotherapists	Midwives
Dieticians	Optometrists	Registered Orthoptists
Prosthetists and Orthotists	Radiographers	Occupational Therapists
Speech and Language Therapists	Dental Hygienists	Dental Therapists

State registered paramedics or individuals who hold a certificate of proficiency in ambulance paramedic skills issued by the Secretary of State, or issued with his approval.

### Qualifications required (professional registration applies to specific professions)

Professionals using this PGD must be currently registered with their relevant professional body, e.g.

- For Nurses: - Nursing & Midwifery Council (NMC)
- For Pharmacists: - General Pharmaceutical Council (GPhC)
- For Allied Health Professionals: - Health Professions Council

### Additional requirements (applies to all staff)

- Maintain knowledge of vaccinations; either through a recognised course or through in-house training supported by attendance at vaccination study day(s).
- Meet the HPA National minimum standards in immunisation training 2005 either through training or professional competence ensuring that annual training is offered to all staff
- Have up to date resuscitation skills and anaphylaxis training (and competent to recognise & manage anaphylaxis).
- Competent to undertake immunisations and have a current authorised Adrenaline PGD.
- Will have undertaken training in the role, care and administration of the medicine specified in the PGD.
- Have access to a current BNF and *Immunisation Against Infectious Disease* (Green Book online version).
- Any additional training requirements as deemed necessary by your organisation or authorising body.

### Continued training requirements (applies to all staff)

- Annual attendance at an accredited update on resuscitation skills and the management of anaphylaxis within the community/primary care (**mandatory**).
- Maintenance of own level of updating and competence with evidence of continued professional development.
- Annual updates in immunisation (**recommended**).
- Any continued training requirements as deemed necessary by your organisation or the authorising body.

**Individual Healthcare Professional Authorisation**

*This form can be used for the purpose of managing, monitoring and authorising the use of this Patient Group Direction by the named healthcare professional.*

- **This page is to be retained by the individual healthcare professional/practitioner.**
- This PGD is to be read, agreed to and signed by all registered Healthcare Professionals it applies to. Healthcare Professionals must be authorised by the person(s) named below before using the PGD.
- By signing this document, the healthcare professional confirms that they understand the PGD, that they are competent to work under this PGD, that they will practice in accordance with the parameters of the PGD and accept full clinical responsibility for any decisions made with using this PGD).
- Patient Group Directions should be used in conjunction with reference to national or local policies, guidelines or standard text (e.g. manufacturers Summary of Product Characteristics) and DO NOT replace the need to refer to such sources.

Name of Healthcare Professional: - \_\_\_\_\_

I have read and understood the Patient Group Direction

**Pneumococcal vaccine (Prevenar 13<sup>®</sup> & Pneumococcal Polysaccharide)**

I agree to administer Pneumococcal vaccine only in accordance with this Patient Group Direction (NECSAT 2018/002)

Signature of Healthcare Professional: - \_\_\_\_\_

Date signed: - \_\_\_\_\_

State profession: - \_\_\_\_\_

**Authorisation to use this PGD by: -**

This above named healthcare professional has been authorised to work under this PGD by:

Name of Manager/Clinical Lead: - \_\_\_\_\_

Signature of Manager/Clinical Lead: - \_\_\_\_\_

Date signed: - \_\_\_\_\_

PGD Valid from: 1 <sup>st</sup> June 2018	Review Date: - Feb. 2020	<b>Expiry Date: - 31<sup>st</sup> May, 2020</b>
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# Management & Monitoring of Patient Group Direction NECSAT 2018/002

## Pneumococcal vaccine (Prevenar 13<sup>®</sup> & Pneumococcal Polysaccharide)

### Healthcare Professional Authorisation (service/practice list)

***This form can be used for the purpose of managing, monitoring and authorising the use of this Patient Group Direction by the named healthcare professionals.***

- This page should be signed by all healthcare professionals authorised to use this PGD and retained and kept on file by the service/practice manager as a record of all practitioners authorised to use this PGD

The following healthcare professionals are authorised to administer

**Pneumococcal (Prevenar 13<sup>®</sup> & Pneumococcal Polysaccharide) vaccine** under the Patient Group Direction (NECSAT 2018/002)

**PGD Valid from date:** 1<sup>st</sup> June 2018

**PGD Expiry Date:** 31<sup>st</sup> May, 2020

Healthcare Professional			Authorised by:		
Name	Signature	Date	Name	Signature	Date

PGD Valid from: 1 <sup>st</sup> June 2018	Review Date: - Feb. 2020	<b>Expiry Date: - 31<sup>st</sup> May, 2020</b>
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