Public Health Scotland

Administration of pneumococcal polysaccharide conjugate vaccine (PCV) Prevenar 20®

Patient group direction (PGD) template

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Version 1.0

Translations and other formats are available on request at:

phs.otherformats@phs.scot

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Most recent changes

Version	Date	Summary of changes
1.0	28 January 2026	• Version 1.0 new PGD created

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Authorisation

PGD pneumococcal polysaccharide conjugate vaccine (PCV) Prevenar 20

This specimen Patient Group Direction (PGD) template has been produced by Public Health Scotland to assist NHS Boards. NHS Boards should ensure that the final PGD is considered and approved in line with local clinical governance arrangements for PGDs.

The qualified health professionals who may administer pneumococcal polysaccharide conjugate vaccine (PCV) Prevenar 20 under this PGD can only do so as named individuals. It is the responsibility of each professional to practice within the bounds of their own competence and in accordance with their own Code of Professional Conduct and to ensure familiarity with the manufacturer's product information/Summary of Product Characteristics (SmPC) for all vaccines administered in accordance with this PGD. NHS Board governance arrangements will indicate how records of staff authorised to operate this PGD will be maintained. Under PGD legislation there can be no delegation. Administration of the vaccine has to be by the same practitioner who has assessed the patient under the PGD.

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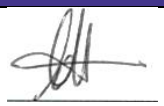
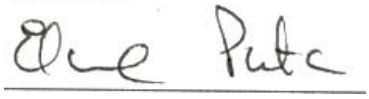
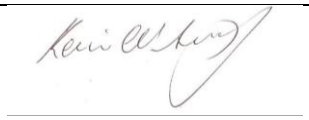
Approved on behalf of NHS Greater Glasgow and Clyde by ADTC Patient Group Direction Sub Committee representatives:

Chair	Dr Craig Harrow	
Director of Pharmacy representative	Elaine Paton, Senior Prescribing Adviser	
Director of Nursing Representative	Kevin McAuley, Chief Nurse North Sector	

Effective from: 28 January 2026 Expires: 31 December 2028

1. Clinical situation

1.1. Indication

Active immunisation against invasive disease caused by Streptococcus pneumoniae serotypes 1, 3, 4, 5, 6A, 6B, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F, 33F.

1.2. Inclusion criteria

- Adults aged 65 years and over not in a clinical risk group as defined in **The Green Book Pneumococcal Chapter (25)** Table 25.2 and not previously vaccinated with PCV20 or PPV23.
- Individuals aged under 2 years of age with asplenia, splenic dysfunction, complement disorder or severe immunocompromise (see **The Green Book Pneumococcal Chapter (25)** Table 25.3).

- Individuals aged 2 years and over and have a medical condition included in the clinical risk groups defined in **The Green Book Pneumococcal Chapter (25)**, Table 25.2.*

- Individuals with asplenia, splenic dysfunction, or chronic kidney disease who require a pneumococcal vaccine booster (see **The Green Book Pneumococcal Chapter (25)**).

- Individuals who are recommended vaccination by the local Health Protection Team for the public health management of pneumococcal disease in accordance with **Guidelines for the public health management of clusters of severe pneumococcal disease in closed settings.**

- Individuals who have received a haematopoietic stem cell transplant or CAR-T therapy and who require revaccination, in accordance with the **Scottish Haematology Society Revaccination Schedule.**

Valid consent has been given to receive the vaccine.

* This includes a single vaccination for individuals over 18 years of age with coeliac disease without known splenic dysfunction.

1.3. Exclusion criteria

Individuals who:

- are younger than 6 weeks of age.

- have had an anaphylactic reaction to a previous dose of PCV20 or any component of the vaccine.

- have a history of severe (i.e. anaphylactic reaction) to latex where the vaccine is not latex free.

- are in a clinical risk group who have previously received PPV23 or PCV20 except individuals with asplenia, splenic dysfunction, complement disorder, severe immunocompromise or chronic kidney disease (see **The Green Book**

Pneumococcal Chapter (25)) or those recommended for vaccination in the **Guidelines for the public health management of clusters of severe pneumococcal disease in closed settings**.

- have received a pneumococcal polysaccharide or conjugate vaccine of any valency in the preceding 4 weeks.
- are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation).

1.4. Cautions/need for further advice/circumstances when further advice should be sought from a doctor

The Green Book Pneumococcal chapter (25) advises that there are very few individuals who cannot receive PCV20 vaccine. Where there is doubt, rather than withholding vaccination, appropriate advice should be sought from the relevant specialist, or from the local immunisation or health protection team.

The presence of a neurological condition is not a contraindication to immunisation but if there is evidence of current neurological deterioration, deferral of vaccination may be considered, to avoid incorrect attribution of any change in the underlying condition. The risk of such deferral should be balanced against the risk of the preventable infection, and vaccination should be promptly given once the diagnosis and/or the expected course of the condition becomes clear.

Those requiring splenectomy or commencing immunosuppressive treatment should be vaccinated according to the age-specific advice in **The Green Book Pneumococcal chapter (25)**. Ideally, the vaccines should be given 4-6 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 possible to vaccinate beforehand, splenectomy, chemotherapy or radiotherapy should never be delayed.

If it is not practicable to vaccinate two weeks before splenectomy, immunisation should be delayed until at least two weeks after the operation because functional antibody responses may be better from this time. If it is not practicable to vaccinate two weeks before starting chemotherapy/radiotherapy, immunisation should be delayed until at least three months after completion of therapy to maximise vaccine response. Immunisation of these patients should not be delayed if this is likely to result in a failure to vaccinate.

Co-administration with other vaccines

Pneumococcal vaccines can be given at the same time as other vaccines such as DTaP/IPV/Hib/HepB, meningococcal B vaccines, MMRV, meningococcal ACWY, rotavirus and influenza.

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.

Syncope

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.

Pregnancy and breastfeeding

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.

1.5 Action if excluded

Specialist advice should be sought on the vaccine and circumstances under which it could be given as vaccination using a patient specific direction may be indicated. The risk to the individual of not being immunised must be taken into account.

Document the reason for exclusion and any action taken in accordance with local procedures.

Inform or refer to the clinician in charge.

If PCV20 or PPV23 has previously been received over the age of 2 years in a clinical risk group **and** the individual does **not** have asplenia, splenic dysfunction or chronic kidney disease **or** the individual is **not** recommended vaccination for the **public health management of clusters of severe serious pneumococcal disease in closed settings**, additional doses of PCV20 are **not** indicated.

For those individuals who have received a pneumococcal conjugate vaccine of any valency in the preceding 4 weeks postpone immunisation until 4 weeks has elapsed.

In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated and ensure another appointment is arranged.

1.6. Action if patient declines

Advise the individual about the protective effects of the vaccine, the risks of infection and potential complications of disease.

Advise how future immunisation may be accessed if they subsequently decide to receive the vaccine.

Document advice given and decision reached.

Inform or refer to the clinician in charge.

2. Description of treatment

2.1. Name of medicine/form/strength

20-valent pneumococcal polysaccharide conjugate vaccine (PCV) Prevenar 20® suspension for injection.

Pneumococcal polysaccharide conjugate vaccine 0.5ml suspension for injection in a pre-filled syringe, with each 0.5ml dose containing each of the following 20 pneumococcal polysaccharide serotypes conjugated to CRM_{197} carrier protein: 1, 3, 4, 5, 6A, 6B, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F, 33F.

2.2. Route of administration

Administer by intramuscular (IM) injection, preferably into the deltoid muscle of the upper arm, or for small infants the anterolateral thigh may be used.

For individuals with an unstable bleeding disorder (or where intramuscular injection is otherwise not considered suitable), vaccines normally given by the intramuscular route should be given by deep subcutaneous injection, in accordance with the recommendations in **The Green Book Immunisation Procedures chapter (4)**.

The vaccine should be shaken vigorously to obtain a homogenous white suspension and should be inspected visually for any particulate matter and/or variation of physical aspect prior to administration.

In the event of any foreign particulate matter and/or variation of physical aspect being observed, do not administer the vaccine.

2.3. Dosage

0.5ml

2.4. Frequency

Single 0.5ml dose.

A minimum interval of 4 weeks should be observed between any 2 doses of any pneumococcal vaccine (regardless of the valency).

Adults aged 65 years and over not in a clinical risk group

- a single dose of 0.5ml of PCV20

If an individual has already received PPV23 or PCV20 because they are in a **clinical risk group**, they do **not** require another dose of PCV20 at 65 years of age and over, irrespective of the interval since they received PPV23 or PCV20.

All clinical risk groups aged from 2 years of age (except severely immunocompromised)

- a single dose of 0.5ml of PCV20 from 2 years of age, at least 4 weeks after the last PCV dose

Vaccination of individuals when first diagnosed or presenting under 2 years of age with asplenia, splenic dysfunction, complement disorder or severe immunocompromise (please refer to **The Green Book Pneumococcal Chapter (25)**, Table 25.3) **is as follows:**

Individuals under one year of age

- two doses of PCV20 with an interval of at least 4 weeks, commencing with their first visit at 8 weeks of age, or as soon as possible thereafter.

- individuals diagnosed after 16 weeks who have already received PCV13 should receive two doses of PCV20 with an interval of at least 4 weeks between any doses.

These individuals will require a booster of PCV20 at 2 years of age with an interval of at least 4 weeks after their last PCV dose as per **The Green Book Pneumococcal Chapter (25)**, Table 25.3). This booster dose is covered under this PGD.

Individuals from 1 year to under 2 years of age

- a single dose of routine booster of PCV20 is administered at one year of age (on or after the first birthday).

If the routine booster of PCV13 dose has been given at one year (on or after the first birthday), then give a single dose of PCV20 with an interval of at least 4 weeks between any doses.

These individuals will require a booster of PCV20 at 2 years of age with an interval of at least 4 weeks after their last PCV dose as per **The Green Book Pneumococcal Chapter (25)**, Table 25.3). This booster dose is covered under this PGD.

Severely immunocompromised individuals aged from 2 years of age

Examples of severe immunocompromise include patients with acute and chronic leukaemia, multiple myeloma or genetic disorders affecting the immune system (such as IRAK-4, NEMO) (see **The Green Book Pneumococcal Chapter (25)**).

- a single dose of PCV20 administered from 2 years of age.

A minimum interval of 4 weeks should be observed between any 2 doses of any pneumococcal vaccine (regardless of the valency).

These individuals will require a booster of PCV20 with an interval of at least 4 weeks after their last PCV dose as per **The Green Book Pneumococcal Chapter (25)**, Table 25.3). This booster dose is covered under this PGD.

5 yearly booster doses

Individuals with asplenia, splenic dysfunction (including sickle cell disease), or chronic kidney disease should be revaccinated every 5 years with PCV20. Booster doses are covered under this PGD.

Revaccination with PCV20 is currently **not** recommended for any other clinical risk groups or age groups. This includes those individuals over 18 years of age with coeliac disease without known splenic dysfunction.

Testing of antibody levels prior to vaccination is **not** required for these or any other risk groups.

Individuals with unknown or incomplete vaccination histories

Individuals who are unvaccinated, incompletely vaccinated or have an unknown vaccination status should be vaccinated in accordance with the **vaccination of individuals with uncertain or incomplete immunisation status flow chart.**

Revaccination of individuals who have received a haemopoietic stem cell transplant:

In accordance with the schedule recommended by the Scottish Haematology Society **Revaccination of patients following haematopoietic stem cell transplant or CAR-T treatment**.

Management of a pneumococcal disease clusters and outbreaks:

In accordance with advice from local Health Protection Team and informed by **Guidelines for the public health management of clusters of severe serious pneumococcal disease in closed settings.**

2.5. Duration of treatment

See frequency section.

2.6. Maximum or minimum treatment period

See frequency section.

2.7. Quantity to supply/administer

See frequency section.

2.8. ▼ black triangle medicines

Yes.

2.9. Legal category

Prescription only medicine (POM).

2.10. Is the use outwith the SmPC?

The SmPC recommends that individuals who receive a first dose of PCV20 complete the vaccination course with PCV20, however, the vaccine can be interchanged in accordance with the national guidance, see **The Green Book Pneumococcal Chapter (25)**.

Where the SmPC states that an 8-week interval from the last pneumococcal conjugate vaccination should be observed, the vaccine can be given at a minimum 4-week interval in accordance with **The Green Book Pneumococcal Chapter (25)**.

Administration of a further dose of PCV20 to high-risk individuals who have already received a dose of PCV20 more than 12 months previously is off-label but may be recommended in accordance with the **Managing pneumococcal disease in closed**

settings and the Green Book Pneumococcal **The Green Book Pneumococcal Chapter (25)**.

Revaccination of individuals following haematopoietic stem cell transplant or CAR-T treatment is considered off-label but is in accordance with the **Scottish Haematology Society schedule.**

Vaccine should be stored according to the conditions detailed below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to NHS Board guidance on storage and handling of vaccines or National Vaccine Incident Guidance. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use, administration under this PGD is allowed.

Where a vaccine is recommended off-label consider, as part of the consent process, informing the individual, parent or carer that the vaccine is being offered outside of product licence but in accordance with national guidance.

2.11. Storage requirements

Vaccine should be stored at a temperature of +2° to +8°C.

Pre-filled syringes should be stored in the refrigerator horizontally to minimise the resuspension time.

Store in the original packaging to protect from light.

Do not freeze.

NHS Board guidance on Storage and Handling of vaccines should be observed.

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 use or appropriate disposal.

2.12. Additional information

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.

Premature infants should be vaccinated in accordance with the national routine immunisation schedule according to their chronological age. Premature infants should be vaccinated in accordance with the national guidance. Very premature infants (born ≤28 weeks of gestation) who are in hospital should have respiratory monitoring for 48 to 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 to 72 hours. If the premature infant was stable at discharge and has no history of apnoea and/or respiratory compromise, further vaccinations can be given in the community setting.

3. Adverse reactions

3.1. Warnings including possible adverse reactions and management of these

In children, the most common reactions are irritability, drowsiness, and pain at injection site, decreased appetite, drowsiness or increased sleep, restless sleep or decreased sleep, redness at the injection site, muscle pain, fatigue, swelling at the injection site, and fever ≥ 38.0°C.

Most adverse reactions occurred within 1 to 2 days following vaccination and were mild or moderate and of short duration (1 to 2 days).

In adults, the most commonly reported reactions were pain at the injection site, muscle pain, fatigue, headache and joint pain.

For full details/information on possible side effects, refer to the marketing authorisation holder's SmPC.

As with all vaccines there is a very small possibility of anaphylaxis and facilities for its management must be available.

In the event of severe adverse reaction the individual should be advised to seek medical advice.

3.2. Reporting procedure for adverse reactions

Healthcare professionals and individuals/carers should report all suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on **http://www.mhra.gov.uk/yellowcard.**

Any adverse reaction to a vaccine should be documented in accordance with locally agreed procedures in the individual's record and the individual's GP should be informed.

3.3. Advice to patient or carer including written information

Written information to be given to individual:

- Provide manufacturer's consumer information leaflet/patient information leaflet (PIL) provided with the vaccine.
- Provide copy of Public Health Scotland post-vaccination leaflet.

Individual advice/follow-up treatment:

- Individuals at especially increased risk of serious pneumococcal infection (such as those with asplenia or 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.
- Inform the individual/carer of possible side effects and their management.
- The individual should be advised to seek medical advice in the event of a severe adverse reaction.
- Inform the individual that they can report suspected adverse reactions to the MHRA using the Yellow Card reporting scheme on: **http://yellowcard.mhra.gov.uk.**

3.4. Observation following vaccination

As syncope (fainting) can occur following vaccination, all vaccinees should either be driven by someone else or should not drive for 15 minutes after vaccination.

Following immunisation, patients remain under observation in line with NHS Board policy.

3.5. Follow up

Not applicable.

3.6. Additional facilities

A protocol for the management of anaphylaxis and an anaphylaxis pack must always be available whenever vaccines are given. Immediate treatment should include early treatment with intramuscular adrenaline, with an early call for help and further IM adrenaline every 5 minutes.

The health professionals overseeing the immunisation service must be trained to recognise an anaphylactic reaction and be familiar with techniques for resuscitation of a patient with anaphylaxis.

4. Characteristics of staff authorised under the PGD

4.1. Professional qualifications

The following classes of registered healthcare practitioners are permitted to administer this vaccine:

- nurses and midwives currently registered with the Nursing and Midwifery Council (NMC)
- pharmacists currently registered with the General Pharmaceutical Council (GPhC)
- pharmacy technicians currently registered with the General Pharmaceutical Council (GPhC)
- chiropodists/podiatrists, dieticians, occupational therapists, orthoptists, orthotists/prosthetists, paramedics, physiotherapists, radiographers and speech and language therapists currently registered with the Health and Care Professions Council (HCPC)
- dental hygienists and dental therapists registered with the General Dental Council
- optometrists registered with the General Optical Council.

4.2. Specialist competencies or qualifications

Persons must only work under this PGD where they are competent to do so.

All persons operating this PGD:

- must be authorised by name by their employer as an approved person under the current terms of this PGD before working to it.

- must be familiar with the vaccine product and alert to changes in the manufacturers product information/summary of product information.
- must be competent to undertake immunisation and to discuss issues related to immunisation to assess patients for vaccination and obtain consent.
- must be competent in the correct storage of vaccines and management of the cold chain if receiving, responsible for, or handling the vaccine.
- must be competent in the recognition and management of anaphylaxis or under the supervision of persons able to respond appropriately to immediate adverse reactions.
- must have access to the PGD and associated online resources.
- should fulfil any additional requirements defined by local policy.

Employer

The employer is responsible for ensuring that persons have the required knowledge and skills to safely deliver the activity they are employed to provide under this PGD.

As a minimum, competence requirements stipulated in the PGD must be adhered to.

4.3. Continuing education and training

All practitioners operating under the PGD are responsible for ensuring they remain up to date with the use of vaccines included. If any training needs are identified these should be discussed with the individuals in the organisation responsible for authorising individuals to act under this PGD.

5. Audit trail

Record the following information:

- valid informed consent was given
- name of individual, address, date of birth and GP with whom the individual is registered if possible
- name of person that undertook assessment of individual's clinical suitability and subsequently administered the vaccine
- name and brand of vaccine
- date of administration
- dose, form and route of administration of vaccine
- batch number
- where possible expiry date
- anatomical site of vaccination
- advice given, including advice given if excluded or declines immunisation
- details of any adverse drug reactions and actions taken
- administered under PGD

Records should be kept in line with local procedures

Local policy should be followed to encourage information sharing with the individual's General Practice

All records should be clear, legible and contemporaneous and in an easily retrievable format.

6. Additional references

- **Immunisation against Infectious Disease [The Green Book].**
- **Immunisation against Infectious Disease [The Green Book], Pneumococcal Chapter (25).**
- **Immunisation against Infectious Disease [The Green Book], Immunisation of individuals with underlying medical conditions chapter (7).**
- **UK guidelines for the public health management of clusters of severe pneumococcal disease in closed settings.**
- **Scottish Haematology Society advice on the revaccination of patients following haematopoietic stem cell transplant or CAR-T treatment.**
- Current edition of British National Formulary.
- **Marketing authorisation holder's Summary of Product Characteristics**.
- All relevant Scottish Government Health Directorate advice including the relevant **CMO letter(s).**
- **Professional Guidance on the Administration of Medicines in Healthcare Settings 2019.**
- **Professional Guidance on the Safe and Secure Handling of Medicines.**
- **Educational resources for registered professionals produced by National Education for Scotland.**
- **UKHSA Guidance - Pneumococcal vaccination for older adults and for individuals in a clinical risk group: Information for healthcare practitioners.**

7. PGD for administration of pneumococcal polysaccharide conjugate vaccine (PCV) Prevenar 20® V1.0 (valid from 28 January 2026 and expires 31 December 2028): authorisation

Practitioner

This PGD does not remove professional obligations and accountability. It is the responsibility of each professional to practice within the bounds of their own competence and in accordance with their Code of Professional Conduct and to ensure familiarity with the marketing authorisation holder's summary of product characteristics for all vaccines administered in accordance with this PGD.

By signing this Patient Group Direction, you are indicating that you agree to its contents and that you will work within it. I agree to administer pneumococcal polysaccharide conjugate vaccine (PCV) Prevenar 20 only in accordance with this PGD.

Name of professional	Signature	Date

Authorising manager

I confirm that the practitioners named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of **NHS Greater Glasgow and Clyde** for the above-named health care professionals who have signed the PGD to work under it.

Lead clinician for the service area:

Name …….

Signature ……..

Date ……

Authorised staff should be provided with an individual copy of the clinical content of the PGD and a photocopy of the document showing their authorisation.

This authorisation sheet should be retained to serve as a record of those practitioners authorised to work under this PGD.

8. Version history

Version	Date	Summary of changes
1.0	28 January 2026	Version 1.0 new PGD