

**Patient Group Direction for the Administration of Pneumococcal
 Conjugate Vaccine (PCV13) (Prevenar 13®) by Approved Healthcare
 Professionals Working Within NHS Grampian, Highland, Orkney,
 Shetland, Tayside and Western Isles**

Lead Author: Adapted from Public Health Scotland Administration of Pneumococcal Conjugate Vaccine (PCV13) (Prevenar 13®) Patient group direction (PGD) template Version 8.0 – PHS Publication date 1 st June 2024		Approver: NoS PGD Group Authorisation: NHS Grampian
---	--	--

Signature: 		Signature: 
--	--	--

NoS Identifier: NoS/PGD/PCV13/1547	Review Date: 28 th February 2026 Expiry Date: 28 th February 2026	Date Approved by NoS: 6 th November 2024 (Amended November 2024)
--	--	--

NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles have
 authorised this Patient Group Direction to help individuals by providing them with
 more convenient access to an efficient and clearly defined service within the NHS
 Boards. This Patient Group Direction cannot be used until Appendix 1 and 2 are
 completed.

Uncontrolled when printed

Version 8.01 (Amended November 2024)

Revision History for NoS:

NoS PGD that has been superseded	Supersedes NoS/PGD/PCV13/1457, Version 8
---	--

Most recent changes NoS

Version	Date of change	Summary of Changes	Section heading
8.0	04 July 2024	Reference to NoS Appendix 1 and 2	Authorisation
		Training requirements for NoS	Continuing education and training
8.01	21 November 2024	Administrative error – incorrect identifier number previously given. Now amended.	Throughout

PHS recent changes

Version	Date	Summary of changes
8.0	1 June 2024	<p>The following changes to version 7.1 of the PGD have been made:</p> <ul style="list-style-type: none"> • Version 7 of this PGD has expired • Minor rewording, layout and formatting changes for clarity and consistency with other PHS PGDs • Inclusion criteria, frequency, is the use out with the SmPC and additional reference sections updated to include reference to the Scottish Haematology Society schedule for the revaccination of individuals following haematopoietic stem cell transplant or CAR-T treatment. • Frequency section updated to align with advice for at-risk patients. • Inclusion criteria amended to include individuals invited, or eligible in accordance with the recommendations in Green Book and/or in line with subsequent correspondence/publications from Scottish Government. • Observation following vaccination section updated to include advice on driving post-immunisation.

Review date: The review date for a PGD needs to be decided on a case-by-case basis in the interest of safety. The expiry date should not be more than 3 years, unless a change in national policy or update is required.

Contents

Authorisation	1
1. Clinical Situation	2
2. Description of Treatment	4
3. Adverse Reactions	9
4. Characteristics of Staff Authorised Under the PGD	11
5. Audit Trail	12
6. Additional References	13
8. PHS Version History	13
Appendix 1 - Healthcare Professional Agreement to Administer Medicine(s) Under Patient Group Direction	16
Appendix 2 - Healthcare Professionals Authorisation to Administer Medicine(s) Under Patient Group Direction	17

Authorisation


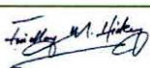

This specimen Patient Group Direction (PGD) template has been produced by Public Health Scotland and adapted by North of Scotland PGD Group (NoS) to assist NHS Boards. NHS Boards should ensure that the final PGD is considered and approved in line with local clinical governance arrangements for PGDs.

The qualified health professionals who may administer vaccine 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.

All authorised staff are required to read the PGD and sign the Agreement to Administer Medicines under PGD ([Appendix 1](#)).


A Certificate of Authorisation ([Appendix 2](#)) signed by the authorising professional/manager should be supplied. This should be held in the individual health professional's records, or as agreed within the individual Health Board.

This PGD has been produced for NoS by:					
Doctor	Susan Laidlaw	Signature		Date Signed	04/10/2024
Pharmacist	Findlay Hickey	Signature		Date Signed	17/09/2024
Nurse	Jackie Donachie	Signature		Date Signed	03/10/2024

Approved for use within NoS by:

NoS Group Chair	Signature	Date Signed
Lesley Coyle		05/12/2024

Authorised and executively signed for use within NoS by:

NHS Grampian Chief Executive	Signature	Date Signed
Adam Coldwells – Interim Chief Executive		06/11/2024

Version 8.01 – Approved for NoS from 5th December 2024

1. Clinical Situation

1.1. Indication

Active immunisation against invasive disease caused by *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F.

1.2. Inclusion criteria

- Individuals as part of the Scottish childhood immunisation programme.
- Individuals with uncertain or incomplete immunisation status in accordance with the [vaccination of individuals with uncertain or incomplete immunisation status flow chart](#).
- Individuals with an underlying medical condition that puts them at increased risk from pneumococcal disease and are invited, or eligible in accordance with the recommendations given in The Green Book, [chapters 7](#) and [25](#), and/or in line with subsequent correspondence/publications from Scottish Government.
- Individuals from 6 weeks of age who are recommended vaccination by the local Health Protection Team for the public health management of pneumococcal disease in accordance with [UK guidelines for the public health management of clusters of serious 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.

1.3. Exclusion criteria

Individuals who:

- are <6 weeks of age.
- have had a confirmed anaphylactic reaction to a previous dose of pneumococcal vaccine.
- have had a confirmed anaphylactic reaction to any component of PCV13 vaccine or diphtheria toxoid.
- are suffering from severe acute febrile illness – consider postponing immunisation until patient has fully recovered.
- have received a dose of PCV13 within the last 4 weeks.
- are aged 10 years or above and have received a dose of PPV23 within the previous two years.

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

The Green Book advises that there are very few individuals who cannot receive PCV13 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.

Those requiring splenectomy or commencing immunosuppressive treatment should be vaccinated according to the age-specific advice above. 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.

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.

Minor illnesses without fever or systemic upset are not valid reasons to postpone immunisation.

Co-administration with other vaccines

PCV13 vaccine can be given at the same time as other vaccines administered as part of the childhood immunisation programme including BCG. If the vaccine is given in the same limb as other vaccines, 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 must be sought on the vaccine and circumstances under which it could be given. Immunisation 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.

Temporary exclusion

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

Pneumococcal polysaccharide conjugate vaccine (13 valent, adsorbed) (PCV13),
Brand name Prevenar13[®] vaccine.

Pre-filled syringe containing suspension for injection.

2.2. Route of administration

Intramuscular injection.

Preferred site for individuals older than 12 months is deltoid area of upper arm.
Preferred site for infants is anterolateral thigh.

PCV13 vaccine should be administered via the intramuscular route except where there is a bleeding disorder when the deep subcutaneous route should be used.

The vaccine should be well shaken 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

Routine immunisation schedule

A single priming dose from 12 weeks of age, followed by:

- a booster dose at one year of age (on or after their first birthday but before 2 years of age)
- Infants who have a reason to have their second set of primary immunisations administered earlier than 12 weeks should nevertheless receive their PCV13 from 12 weeks of age, either with their third set of primary immunisations or on its own, if the third set of primary immunisations is likely to be given beyond 16 weeks.
- Routine immunisation with PCV13 is not offered after the second birthday.

For children and adults in clinical risk groups, refer to Table 25.2, Green Book [Chapter 25](#) and the section below.

Infants diagnosed with clinical risk conditions from birth to 1 year of age:

- At clinical risk infants from birth to 1 year of age, excluding those with asplenia, splenic dysfunction, complement disorder or severely immunocompromised¹, should receive the routine dose at 12 weeks and then their routine booster on or after their first birthday.
- At clinical risk infants from birth to 1 year of age with asplenia, splenic dysfunction, complement disorder or severely immunocompromised¹ should receive:

- two doses of PCV13 vaccine eight weeks apart (commencing no earlier than 6 weeks of age), in the first year of life and then
- a booster dose at one year (on or after the first birthday) and then
- an additional booster dose at least 8 weeks later

Infants diagnosed with clinical risk conditions from one year to under two years of age:

- Children in this age group with asplenia, splenic dysfunction, complement disorder or severely immunocompromised¹ should receive:
 - the routine PCV13 booster at one year of age (on or after first birthday) and
 - an additional booster dose given at least 8 weeks later

Note: This is the schedule to follow regardless of whether the child had none, one or two routine primary doses of PCV13 in infancy. The intervals may be reduced to one month if necessary, to ensure that the immunisation schedule is completed.

Children diagnosed with clinical risk conditions from two years to under ten years of age:

- Individuals from 2 years to under 10 years of age, with a clinical risk condition included in the green book [chapter 25](#) (excluding the severely immunocompromised¹), who have completed the routine PCV immunisation schedule do not require further PCV13.
- All children diagnosed (or first presenting as) at clinical risk aged from two to under ten years of age who are previously unvaccinated or partially vaccinated for PCV should receive a single dose of PCV13.
- Severely immunocompromised¹ individuals should be offered a single dose of PCV13 even if unimmunised or partially immunised.

Children aged 10 years onwards and adults diagnosed (or first presenting) with clinical risk conditions:

- Individuals from 10 years of age, with a clinical risk condition included in [The Green Book chapter 25](#) (excluding the severely immunocompromised¹) do not require PCV13.
- Severely immunocompromised¹ should be offered a single dose of PCV13.
- PCV13 or additional PPV23 are not needed if the individual received PPV23 in the previous 2 years.

¹ 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).

Pneumococcal polysaccharide vaccine (PPV23) (please see separate PGD):

- Additionally, all individuals with a medical condition included in The Green Book should receive a dose of PPV23 on or after their second birthday (see PPV23 PGD).
- Individuals eligible for both PCV13 and PPV23 should have the PCV13 dose first followed by PPV23 at least 8 weeks later.

Individuals with unknown or incomplete vaccination histories:

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 Public Health Protection Team and informed by [Guidelines for the public health management of clusters and outbreaks of pneumococcal disease in closed settings with high-risk individuals](#).

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

No

2.9. Legal category

Prescription only medicine (POM).

2.10. Is the use out with the SmPC?

The marketing authorisation holder's SmPC states: in preterm infants, the recommended immunisation series consists of four doses. This is superseded by The Green Book recommendation to give two doses to all infants.

A single dose priming schedule for previously unvaccinated individuals is contrary to the two dose priming schedule in the SmPC. This is superseded by The Green Book recommendation to give a single dose.

The marketing authorisation holder's SmPC states there are no data from the use of PCV13 in pregnant women and therefore the use of PCV13 should be avoided during pregnancy. This is superseded by The Green Book recommendation that pneumococcal vaccines may be given to pregnant women when the need for protection is required without delay.

Revaccination of individuals following haematopoietic stem cell transplant of 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 in the Storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to National Vaccine Incident Guidance. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use this would constitute off-label administration under this PGD.

2.11. Storage requirements

Store at between +2°C to +8°C. However, PCV13® is stable at temperatures up to 25°C for four days. At the end of this period, PCV13 should be used or discarded. This data is intended to guide health care professionals in case of temporary temperature excursions.

Store in original packaging in order 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 off-label use or appropriate disposal.

2.12. Additional information

Very premature infants (born ≤ 28 weeks of gestation) who are in hospital should have respiratory monitoring for 48 to 72 hrs 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 hrs.

The immunogenicity of the vaccine could be reduced in immunosuppressed individuals. However, vaccination should proceed in accordance with national recommendations.

3. Adverse Reactions

3.1. Warnings including possible adverse reactions and management of these

Very common or common reactions reported include:

- decreased appetite
- pyrexia
- irritability
- redness at injection site
- induration/swelling or pain/tenderness at injection site
- increased and/or decreased sleep

Hypersensitivity reactions, such as bronchospasm, angioedema, urticaria, and anaphylaxis can occur but are very rare and facilities for its management must be available.

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 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.
- Supply immunisation promotional material as appropriate.
- Individual advice / follow up treatment:
- Individuals at especially increased risk of serious pneumococcal infection (such as asplenic and those who have received immunosuppressive therapy for any reason), should be advised regarding the possible need for early antimicrobial treatment in the event of severe, sudden febrile illness.
- 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

If appropriate remind carer that further doses will be required to complete the course.

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)
- 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 manufacturer's 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.

- Have undertaken NoS PGD module training on [TURAS](#) Learn
- Have attended basic life support training either face to face or online and updated in-line with individual Board requirements
- Have undertaken immunisation training where available
- Have undertaken NHS e-anaphylaxis training or equivalent which covers all aspects of the identification and management of anaphylaxis updated in-line with individual Board requirements
- Maintain their skills, knowledge and their own professional level of competence in this area according to their individual Code of Professional Conduct.

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

Practitioners operating the PGD must be familiar with:

- [Immunisation against Infectious Disease \[Green Book\]](#).
- [Immunisation against Infectious Disease \[Green Book\] chapter 25 Pneumococcal disease.](#)
- [The Green book of immunisation - chapter 7 - Immunisation of immunocompromised individuals \(publishing.service.gov.uk\).](#)
- [PHE Guidelines for the public health management of clusters of severe pneumococcal disease in closed settings.](#)
- [Vaccination of individuals with uncertain or incomplete immunisation](#)
- [Scottish Haematology Society advice on the revaccination of patients following haematopoietic stem cell transplant or CAR-T treatment](#)
- Current edition of British National Formulary (BNF) and BNF for children.
- Marketing authorisation holder's Summary of Product Characteristics.
- All relevant Scottish Government 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.](#)

8. PHS Version History

Version	Date	Summary of changes
5.0	January 2020	<ul style="list-style-type: none"> • Exclusion criteria updated to remove anaphylactic reaction to latex as an exclusion; to amend the exclusion on an anaphylactic reaction to a previous pneumococcal vaccine rather than PCV vaccine and to add an exclusion for individuals aged 10 years or above who have received a dose of PPV23 within the previous two years. • Frequency section updated to reflect change to a single dose for routine immunisation from age 12 weeks and to changes in the schedule for clinical risk groups. • Use out with the SmPC section updated to reflect change to a single dose for primary immunisation and updated to recommend assessment following inadvertent or unavoidable deviation from recommended storage conditions. This section has also been update to indicate that the vaccine can be used in pregnancy for individuals in a clinical risk group. • Storage section updated to include action required following inadvertent or unavoidable deviation from recommended storage conditions. • Additional information section updated on administration with other vaccines.

6.0	1 April 2022	<ul style="list-style-type: none"> • Version 6.0 produced following expiry of Version 5.0. • This PGD has undergone minor rewording, layout, formatting changes for clarity and consistency with other PHS national specimen PGDs. <p>The following changes have been made:</p> <ul style="list-style-type: none"> • Inclusion criteria of age >6 weeks removed and replaced with individuals in accordance with the UK childhood immunisation programme. • Frequency section updated to include further information on vaccinating individuals with unknown or incomplete vaccination history. • Frequency section updated to clarify additional booster dose for those in clinical risk groups to be at least 8 weeks after routine booster. • Storage requirements section updated to include information on temporary temperature excursions.
7.0	1 June 2022	<ul style="list-style-type: none"> • Inclusion criteria expanded to include other patient groups out with the Scottish childhood immunisation programme. • Exclusion criteria updated to include individuals who have received a dose of PCV13 within the last 4 weeks. • Frequency section updated to include dosing information for the other patient groups out with the Scottish childhood immunisation programme. • Cautions/need for further advice section updated to include advice on timing of vaccination in relation to planned splenectomy or immunosuppression.
7.1	1 December 2022	<ul style="list-style-type: none"> • Route of administration section updated to remove reference to expelling air from the prefilled syringe prior to administration.
8.0	1 June 2024	<p>The following changes to version 7.1 of the PGD have been made:</p> <ul style="list-style-type: none"> • Version 7 of this PGD has expired • minor rewording, layout and formatting changes for clarity and consistency with other PHS PGDs • Inclusion criteria, frequency, is the use out with the SmPC and additional reference sections updated to include reference to the Scottish Haematology Society schedule for the revaccination of individuals following haematopoietic stem cell transplant or CAR-T treatment. • Frequency section updated to align with advice for at-risk patients. • Inclusion criteria amended to include individuals invited, or eligible in accordance with the recommendations in Green Book and/or in line with

		<p>subsequent correspondence/publications from Scottish Government.</p> <ul style="list-style-type: none"> • Observation following vaccination section updated to include advice on driving post-immunisation
--	--	--

NoS Version History

Version	Date of change	Summary of Changes	Section heading
8.0	04 July 2024	Reference to NoS Appendix 1 and 2	Authorisation
		Training requirements for NoS	Continuing education and training
8.01	21 November 2024	Administrative error – incorrect identifier number previously given. Now amended.	Throughout



Appendix 1 - Healthcare Professional Agreement to Administer Medicine(s) Under Patient Group Direction

I: _____ (Insert name)

Working within: _____ e.g. Area, Practice

Agree to administer the medicine(s) contained within the following Patient Group
Direction:

Patient Group Direction for the Administration of Pneumococcal Conjugate Vaccine (PCV13) (Prevenar 13[®]) by Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles, Version 8.01

I have completed the appropriate training to my professional standards enabling me to
administer the medicine(s) under the above direction. I agree not to act beyond my
professional competence, nor out with the recommendations of the direction.

Signed: _____

Print Name: _____

Date: _____

Profession: _____

Professional Registration
number/PIN: _____



Appendix 2 - Healthcare Professionals Authorisation to Administer Medicine(s) Under Patient Group Direction

The Lead manager/Professional of each clinical area is responsible for maintaining records of all clinical areas where this PGD is in use, and to whom it has been disseminated.

The Senior Nurse/Professional who approves a healthcare professional to administer the medicine(s) under this PGD is responsible for ensuring that they are competent, qualified and trained to do so, and for maintaining an up-to-date record of such approved persons.

The Healthcare Professional that is approved to administer the medicine(s) under this PGD is responsible for ensuring that they understand and are qualified, trained and competent to undertake the duties required. The approved person is also responsible for ensuring that administration is carried out within the terms of the direction, and according to their individual code of professional practice and conduct.

Patient Group Direction for the Administration of Pneumococcal Conjugate Vaccine (PCV13) (Prevenar 13®) by Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles, Version 8.01

Local clinical area(s) where the listed healthcare professionals will operate under this PGD:

Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date

Patient Group Direction for the Administration of Pneumococcal Conjugate Vaccine (PCV13) (Prevenar 13®) by Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles, Version 8.01

Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date