NHS Grampian | NHS Highland | NHS Orkney | NHS Shetland | NHS Tayside | NHS Eileanan Siar Western Isles

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 PHS National PGD by the Medicines Management Specialist Nurse NHSG	**Consultation Group:** See relevant page in the PGD	**Approver:** NoS PGD Group **Authorisation:** NHS Grampian
Signature:		**Signature:**
NoS Identifier: NoS/PGD/PCV13/MGPG 1303	**Review Date:** September 2024 **Expiry Date:** September 2025	**Date Approved:** September 2022

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 3

Revision History:

Reference and approval date of PGD that has been adapted and/or superseded	PGD adapted from PHS national PGD and supersedes NHSG/PGD/PCV13/MGPG1084 Version 2	
Date of change	**Summary of Changes**	**Section heading**
July 2022	PGD adapted from new version of PHS national PGD	
August 2022	NHST specific inclusion for children requiring booster following chemotherapy added.	Inclusion criteria and Frequency of dose/Duration of treatment

NoS Identifier: NoS/PGD/PCV13/MGPG1303 Version 3
Keyword(s): PGD Patient Group Direction vaccine immunisation childhood pneumococcal Prevenar PCV13

Policy Statement:
It is the responsibility of the individual healthcare professional and their line managers to ensure that they work within the terms laid down in this PGD and to ensure that staff are working to the most up to date PGD. By doing so, the quality of the services offered will be maintained, and the chances of staff making erroneous decisions which may affect individual, staff or visitor safety and comfort will be reduced. Supervisory staff at all levels must ensure that staff using this PGD act within their own level of competence.

The lead author is responsible for the review of this PGD and for ensuring the PGD is updated in line with any changes in clinical practice, relevant guidelines, or new research evidence.

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.

Document:	Drafted:	July 2022
	Completed:	August 2022
	Approved:	September 2022 (published – September 2022)
	Amended & reauthorised:	

Organisational Authorisations

This PGD is not legally valid until it has had the relevant organisational authorisation.

PGD Developed/Reviewed by;

Medical practitioner	**Name:** Dr Maggie Watts **Health Board:** NHSWI **Title:** Director of Public Health **Contact email:** maggie.watts@nhs.scot **Signature** **Date:**08/09/2022
Senior representative of the professional group who will provide care under the direction	**Name:** Jackie Donachie **Health Board:** NHST **Title:** Vaccination Programmes Manager **Contact email:** jacqueline.donachie2@nhs.scot **Signature** ..... **Date:** 08/09/2022
Lead author	**Name:** Frances Adamson **Health Board:** NHSG **Title :** Medicines Management Specialist Nurse **Contact email:** frances.adamson@nhs.scot **Signature** ..... **Date:** 08/09/2022
Pharmacist	**Name:** Findlay Hickey **Health Board:** NHSH **Title :** Pharmacist **Contact email:** findlay.hickey2@nhs.scot **Signature** ..... **Date:** 09/09/2022

Approved for use within NoS Boards by;

North of Scotland (NoS) PGD Group Chair	Signature	Date Signed
Lesley Coyle		08/09/2022

Authorised and executively signed for use within NoS Boards by;

NHS Grampian Chief Executive	Signature	Date Signed
Professor Caroline Hiscox		13/09/2022

Management and Monitoring of Patient Group Direction

PGD Consultative Group

The consultative group is legally required to include a medical practitioner, a pharmacist and a representative of the professional group who will provide care under the direction.

Name:	**Title:**
Frances Adamson	**Lead Author:** Medicines Management Specialist Nurse NHSG
Findlay Hickey	**Pharmacist:** Pharmacist NHSH
Dr Maggie Watts	**Medical Practitioner:** Director of Public Health NHSWI
Jackie Donachie	**Senior Representative:** Vaccination Programmes Manager NHST
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Clinical indication to which this PGD applies

Definition of situation/Condition	This Patient Group Direction (PGD) will authorise approved healthcare professionals as detailed in the characteristics of staff authorised to work under this PGD to administer Pneumococcal Conjugate Vaccine (PCV13) (Prevenar 13®) to individuals for active immunisation against invasive disease caused by *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F. This PGD should be used in conjunction with the recommendations in the current British National Formulary (BNF), British National Formulary for Children (BNFC), The Green Book and the individual Summary of Product Characteristics (SmPC).
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 in accordance with the recommendations given in chapters 7 and 25 of The Green Book. • Individuals from 6 weeks of age who are recommended vaccination by the local Health Protection Team (HPT) 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. • Revaccination of individuals who have received a haemopoietic stem cell transplant. **The following inclusion is relevant to NHS Tayside only and does not apply in any other NoS Board -** Children requiring booster doses 6 months after completing chemotherapy as per NHST local guidance. Prior to the administration of the vaccine, valid consent to receiving treatment under this PGD must be obtained.

	Consent must be in line with current individual NHS Boards consent policy.
Exclusion criteria	Individuals who: • Are less than 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 Prevenar13® 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 (**Note:** This exclusion doesn't apply for NHST in relation to boosters following chemotherapy). Individuals for whom no valid consent has been received.
Precautions and special warnings	Minor illness without fever or systemic upset is not a valid reason to postpone immunisation. If an individual is acutely unwell, immunisation may be postponed until they have fully recovered. 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 HPT. 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. However, 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.
Action if excluded from treatment	Medical advice must be sought – refer to relevant medical practitioner for advice on the vaccine and circumstances under which it could be given using a patient specific direction. The risk to the individual of not being immunised must be taken into account. Discussion of the risk and benefits of vaccination should take place. Discussions and decisions taken should be documented in clinical records. In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated at a later date and ensure another appointment is arranged. Document the reason for exclusion under the PGD and any action taken in the individual's appropriate clinical records.
Action if treatment is declined	Advise about the protective effects of the vaccine and the risk of infection and disease complications. Ensure they have additional reading material e.g. the Patient Information Leaflet (PIL) available to print here. Document advice given and decision reached. Inform/refer to the relevant medical practitioner if individual/parent/carer declines treatment. Document that the administration of the vaccine was declined, the reason and advice given in appropriate clinical records.

Description of vaccine available under the PGD

Name form and strength of vaccine	Pneumococcal polysaccharide conjugate vaccine suspension for injection in pre-filled syringe (13 valent, adsorbed), Brand name Prevenar13® vaccine.

Legal status	Prevenar13® vaccine is a Prescription-only Medicine (POM).
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 pneumococcal 13-valent conjugate vaccine in pregnant women and therefore the use of Prevenar 13® 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. There is no evidence of risk from vaccinating pregnant women or those who are breast-feeding with inactivated viral or bacterial vaccines or toxoids. 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 PHS vaccine incident guidance. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use, administration under this PGD is allowed.
Dosage/Maximum total dose	0.5mL
Frequency of dose/Duration of treatment	**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, Chapter 25 of The Green Book 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 immunocompromised*, 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 immunocompromised* 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 immunocompromised* 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 immunocompromised*), 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 immunocompromised* individuals, who have not received an additional booster of PCV13 recommended between one and two years of age, should be offered a single dose of PCV13 irrespective of any routine childhood vaccinations they have already received. **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 immunocompromised*) do not require PCV13. • Severely immunocompromised* who have not already received an additional booster of PCV13, should be offered a single dose of PCV13 irrespective of any routine childhood vaccinations they have already received. PCV13 or additional PPV23 are not needed if the individual received PPV23 in the previous 2 years. ***** 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 NoS PPV PGD)** • Additionally, all individuals with a medical condition included in The Green Book Chapter 25 should receive a dose of PPV23 on or after their second birthday (see NoS PPV 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** • Unimmunised or partially immunised children who present late for vaccination **before the age of one year** should receive a single priming dose of PCV13, followed by a booster dose at one year of age (on or after their first birthday), leaving an 8-week interval between the primary PCV13 dose and the booster.

	If the first PCV13 dose is given very late (such as at 11 months), then a minimum interval of four weeks should be observed before the booster dose to ensure appropriate boosting of the immune response. • An unimmunised or partially immunised child **aged between one and under two years of age** should have a single dose of PCV13. • Routine immunisation with PCV13 is not offered after the second birthday. Any child eligible for PCV13 vaccination, who has received one or more doses of PCV10 vaccine in another country should be offered an additional dose of PCV13 at least 4 weeks later. This ensures that the infants are protected against the same pneumococcal serotypes as those vaccinated according to the UK national immunisation schedule. These infants should receive one PCV13 dose from 12 weeks of age and a booster dose at one year of age (on or after their first birthday), allowing an 8-week (ideal) or 4-week (minimum) interval between the two PCV13 doses. **Revaccination of individuals who have received a haemopoietic stem cell transplant:** In accordance with the schedule recommended by the Scottish Haematology Society vaccination policy (Post HSC Transplantation): Scottish Haematology Society - Vaccination Policy (Post HSC Transplantation) (scothaem.org) **Management of a pneumococcal disease clusters and outbreaks:** In accordance with advice from Public HPT and informed by Guidelines for the public health management of clusters and outbreaks of pneumococcal disease in closed settings with high-risk individuals. **NHS Tayside ONLY:** **Revaccination of children aged up to 16 years who have received chemotherapy within the last 6 months** In accordance with the schedule recommended in the Vaccinations For Paediatric Patients Treated With Standard-Dose Chemotherapy And Haemopoietic Stem Cell Transplantation (HSCT) Recipients.
Maximum or minimum treatment period	See Frequency of dose/Duration of treatment section.
Route/Method of administration	Intramuscular injection.

	Preferred site for children older than 12 months is deltoid area of upper arm. Preferred site for infants is anterolateral thigh. Prevenar13® 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 prior to expelling air from the syringe, 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. PCV13 vaccine can be given at the same time as the other vaccines administered as part of the childhood immunisation programme including BCG. When administering at the same time as other vaccines care should be taken to ensure that the appropriate route of injection is used for each of the vaccinations. The vaccines should be given when possible in different limbs to allow monitoring of local reactions to Pneumococcal polysaccharide conjugate vaccine. If given in the same limb they should be given at different sites at least 2.5cm apart (American Academy of Paediatrics 2003). The site at which each vaccine was administered should be noted in the individual's records.
Quantity to be administered	0.5mL dose per administration.
Storage requirements	Vaccine will be stored in a temperature controlled refrigerator between +2°C and +8°C. Refrigerators should have maximum and minimum temperatures recorded daily. However, Prevenar13® is stable at temperatures up to 25°C for four days. At the end of this period, Prevenar 13® should be used or discarded. There data are intended to guide health care professionals in case of temporary temperature excursions. Store in original packaging in order to protect from light. Individual NHS Board guidance on the storage, handling and cold chain in relation to vaccines must be observed. Likewise, individual NHS Board guidance in relation to waste management and the disposal of all spent, partially spent or unused vaccines must also 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.

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.
Follow-up (if applicable)	Following immunisation patients should remain under observation in line with individual NHS Board policy. Individuals should not leave if they are feeling unwell without speaking to the healthcare professional who administered the vaccine first. If necessary a doctor or the individuals GP should be contacted for advice.
Advice (Verbal)	• Advise individual/parent/carer what to expect and of the possible side effects and their management. • Individuals at especially increased risk of serious pneumococcal infection (such as those with asplenia 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. • The individual should be advised to seek medical advice in the event of a severe adverse reaction. • Individuals/carers should be advised to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme. When administration is postponed advise the individual/parent/carer when to return for vaccination. If appropriate, advise when subsequent doses are due and if any follow up is required.
Advice (Written)	The PIL contained in the medicine(s) should be made available to the individual/parent/carer. Where this is unavailable, or unsuitable, sufficient information should be given in a language that they can understand. More information regarding this vaccine can be found at: https://www.nhsinform.scot/healthy-living/immunisation

Identifying and managing possible adverse reactions	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. The most commonly seen reactions are minor local injection site reactions such as hardening of the skin, oedema, pain and redness. A small painless nodule may form at the injection site. 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. As with all vaccines there is a very small possibility of anaphylaxis and facilities for its management must be available. **This list is not exhaustive. Please also refer to current BNF/BNFC and manufacturers SmPC for details of all potential adverse reactions.** **BNF/BNFC**: BNF British National Formulary - NICE BNF for Children British National Formulary - NICE **SmPC/PIL/Risk Minimisation Material:** Home - electronic medicines compendium (emc) MHRA Products | Home RMM Directory - (emc) If an adverse reaction does occur give immediate treatment and inform relevant medical practitioner as soon as possible. Document in accordance with locally agreed procedures in the individual's record.

	Report any suspected adverse reactions using the Yellow Card System. Yellow Card Scheme - MHRA
Facilities and supplies required	The following are to be available at sites where the vaccine is to be administered: • Pharmaceutical refrigerator (or a validated cool box for storing vaccine if mobile unit) • An acceptable level of privacy to respect individual's right to confidentiality and safety • Basic airway resuscitation equipment (e.g. bag valve mask) • Immediate access to Epinephrine (Adrenaline) 1 in 1000 injection • Access to a working telephone • Another competent adult, who can summon urgent emergency support if required should ideally be present • Access to medical support (this may be via the telephone) • Approved equipment for the disposal of used materials • Clean and tidy work areas, including access to hand washing facilities or alcohol hand gel • A copy of this PGD in print or electronically

Characteristics of staff authorised to administer vaccine under PGD

Professional qualifications	The following classes of registered healthcare practitioners are permitted to administer vaccines as identified and included in individual Board immunisation delivery plans: • 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.
Specialist competencies	**Approved by the organisation as:** • Competent to assess the individual's/parent's/carer's capacity to understand the nature and purpose of vaccination in order to give or refuse consent

	• Familiar with the vaccine product and alert to changes in the product information. • Competent to undertake administration of the vaccine and discuss issues related to vaccination • Competent in the recognition and management of anaphylaxis or under the supervision of persons able to respond appropriately to immediate adverse reactions • Competent in the handling and storage of vaccines, and management of the "cold chain" • Competent to work under this PGD and authorised by name as an approved person to work under the terms of the PGD.

Ongoing training and competency	**All professionals working under this PGD must:**
	• 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
	• 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. **Note:** All practitioners operating under the PGD are responsible for ensuring they remain up to date with the use of the vaccine. If any training needs are identified these should be discussed with those responsible for authorisation to act under the PGD.
	• Have knowledge and familiarity of the following;
	  ○ Current edition of the Green Book
	  ○ SmPC for the vaccine to be administered in accordance with this PGD
	  ○ Relevant policy relating to vaccine storage and immunisation procedures for use within their Health Board
	  ○ Relevant Scottish Government Health Directorate advice including the relevant CMO letter(s).

Responsibilities of professional manager(s)	**Professional manager(s) will be responsible for;** Ensuring that the current PGD is available to all staff providing care under this direction. Ensuring that staff have received adequate training in all areas relevant to this PGD and meet the requirements above.

	Maintain up to date record of all staff authorised to administer the vaccine specified in this direction.

Documentation

Authorisation of administration	Qualified registered healthcare professionals working within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles listed and approved in legislation as able to operate under PGD can be authorised to administer the vaccine specified in this PGD in accordance with local delivery plans and by agreement at individual Board level as per the following: Nurses, midwives and health visitors can be authorised by their line manager. Pharmacists working within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles can be authorised to administer the medicine(s) specified in this PGD when they have completed local Board requirements for service registration. The following list of healthcare professionals can be authorised by their Line Manager, Head of Service or Vaccine Coordinator: Chiropodists, dental hygienists, dental therapists, dieticians, occupational therapists, optometrists, orthoptists, orthotist/prosthetists, paramedics, physiotherapists, podiatrists, radiographers and speech and language therapists. 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.
Record of administration	An electronic or paper record must be completed to allow audit of practice. An electronic/Hospital Electronic Prescribing and Medicines Administration (HEPMA) record of the screening and subsequent administration, or not of the medicine(s) specified in this PGD should be made in accordance with individual Health Board electronic/HEPMA recording processes. If a paper record is used for recording the screening of individuals and the subsequent administration, or not of the

	medicine(s) specified in this PGD, it should include as a minimum: • Date and time of vaccine administration • Individuals name, address and CHI • GP with whom the individual is registered • Exclusion criteria, record why the vaccine was not administered (if applicable) • Record that valid consent to treatment under this PGD was obtained • The name, brand, dose, form, batch number, expiry date, route/and anatomical site of the vaccination administered • Advice given, including advice given if excluded or declined vaccination under this PGD • Signature and name in capital letters of the healthcare professional who administered the vaccine, and who undertook the assessment of the individual's clinical suitability for the vaccine • Where childhood immunisations are given information of the administration must be provided to the GP Practice and Practitioner Services Division (PSD) for inclusion on the Scottish Immunisation Recall System (SIRS). • Record of any adverse effects and the actions taken (advise individuals' GP/relevant medical practitioner). Depending on the clinical setting where administration is undertaken, the information should be recorded manually or electronically on the individual service specific system, as appropriate. • Child Health Information Services if appropriate • Hand–held records such as red book if appropriate • Individual's GP records if appropriate • HEPMA • Occupational health systems • Individual service specific systems. Local policy should be followed with respect to sharing information with the individual's General Practitioner. All records should be clear, legible and contemporaneous and in an easily retrievable format.
Audit	All records of the vaccine specified in this PGD will be filed with the normal records of medicines in each practice/service. A designated person within each practice/service where the PGD will be used will be responsible for annual audit to ensure a system of recording medicines administered under a PGD.

References	Electronic Medicines Compendium http://www.medicines.org.uk Prevenar13® – Date of revision of text March 2021 accessed 13/07/22. British National Formulary for Children and the British National Formulary accessed 13/07/22. Department of Health (2006): Immunisation against Infectious Disease [Green Book] https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book Pneumococcal: the green book, chapter 25 - GOV.UK (www.gov.uk) Immunisation of individuals with underlying medical conditions: the green book, chapter 7 - GOV.UK (www.gov.uk) Vaccinations For Paediatric Patients Treated With Standard-Dose Chemotherapy And Haemopoietic Stem Cell Transplantation (HSCT) Recipients (2020) American Academy of Pediatrics (2003) Active immunisation. In: Pickering LK (ed.) Red Book: 2003 Report of the Committee on Infectious Diseases, 26th edition. Elk Grove Village, IL: American Academy of Pediatrics, p 33.

NHS Grampian NHS Highland NHS Orkney NHS Shetland NHS Tayside NHS Eileanan Siar Western Isles

Appendix 1

Healthcare Professional Agreement to Administer Vaccine Under Patient Group Direction

I: _____ (Insert name)

Working within: _____ e.g. Area, Practice

Agree to administer the vaccine 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

I have completed the appropriate training to my professional standards enabling me to administer the vaccine 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 _____

NHS Grampian NHS Highland NHS Orkney NHS Shetland NHS Tayside NHS Eileanan Siar Western Isles

Appendix 2

Healthcare Professionals Authorisation to Administer Vaccine 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 vaccine 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 vaccine 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
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					
Name of Healthcare Professional	**Signature**	**Date**	**Name of Manager**	**Signature**	**Date**