



PATIENT GROUP DIRECTION

Issued under Part 2 of the Medicines (Prescription Only) Regulations, 1987 by the Director of Public Health with the consent of the Minister

for

Pneumococcal polysaccharide conjugate vaccine (13-valent, adsorbed) PCV13: Prevenar®13 Patient Group Direction (PGD)

	LEGAL STATEMENT			
Protocol Issuer	Director of Public Health Gibraltar Health Authority (GHA) St. Bernard's Hospital Gibraltar Contact Telephone: +(350) 20079160			
Date effective	12 th May 2023	12 th May 2023		
Date of expiry	12 th May 2025	12 th May 2025		
Staff characteristics	See below (section 1)	See below (section 1)		
Professional Authorisation		SIGNATURE	DATE	
Lead Doctor	Dr Helen Carter Director of Public Health ¹			
In Consultation with		SIGNATURE	DATE	
Lead Pharmacist	Ms Melanie Gordon Chief Pharmacist			
Lead Nurse	Ms Sandra Gracia Director of Nursing			
Legal Authorisation		SIGNATURE	DATE	
With the consent of Minister	The Honourable Minister for ² Health Albert Isola MP			

This PGD has been taken for peer review at the Gibraltar Health Authority Immunisation Committee. This PGD has been peer reviewed by the GHA immunisation committee. It has been ratified by the GHA Executive Team.

¹ A Patient Group Direction issued shall only have effect if it is signed by the Director of Public Health with the consent of the Minister.

² See footnote 1.

1. Characteristics of staff

Qualifications and professional registration	Registered professional with one of the following bodies: • nurses or midwives currently registered with the Gibraltar Nursing Registration Board (GNRB) • practitioners currently registered with the Gibraltar Medical Registration Board (GMRB) • Anyone deemed by the Director of Public Health, Gibraltar to be competent who meets the additional requirements below.
Additional requirements	 Additionally practitioners: must be authorised by name as an approved practitioner under the current terms of this PGD before working to it must have undertaken appropriate training for working under PGDs for supply/administration of medicines must be competent in the use of PGDs (see NICE Competency framework for health professionals using PGDs) must be familiar with the vaccine product and alert to changes in the Summary of Product Characteristics (SPC), Immunisation Against Infectious Disease (the 'Green Book'), and national and local immunisation programmes must have undertaken training appropriate to this PGD as required by local policy and in line with the National Minimum Standards and Core Curriculum for Immunisation Training must be competent to assess individuals for suitability for vaccination, identify any contraindications or precautions, obtain informed consent (or 'best interests' decision in accordance with the Lasting Powers of Attorney and Capacity Act 2018 and the Mental Health Act 2016 must be competent in the handling and storage of vaccines, and management of the cold chain must be competent in the recognition and management of anaphylaxis must have access to the PGD and associated online resources should fulfil any additional requirements defined by local policy THE INDIVIDUAL PRACTITIONER MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING IT

Continued training requirements

- Practitioners must ensure they are up to date with relevant issues and clinical skills relating to immunisation and management of anaphylaxis, with evidence of appropriate Continued Professional Development (CPD).
- Practitioners should be constantly alert to any subsequent recommendations from Public Health Gibraltar and/or the GHA and other sources of medicines information.

Note: The most current national recommendations should be followed. But a Patient Specific Direction (PSD) may be required to administer the vaccine in line with updated recommendations that are outside the criteria specified in this PGD.

2. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies

Indicated for the active immunisation of:

- individuals from 12 weeks to under 2 years of age for the prevention of pneumococcal disease in accordance with the NHS-UK and recommendations given in Chapter 25 of Immunisation Against Infectious Disease: the 'Green Book'.
- •individuals from 6 weeks of age recommended PCV13 in accordance with Guidelines for the public health management of clusters and outbreaks of pneumococcal disease in closed settings with high-risk individuals

Criteria for inclusion

Individuals from 12 weeks to under 2 years of age who:

- require a primary dose of PCV13
- require a reinforcing booster dose of PCV13 against pneumococcal disease

Individuals from 6 weeks of age recommended PCV13 in accordance with Guidelines for the public health management of clusters and outbreaks of pneumococcal disease in closed settings with high-risk individuals.

Note: Individuals with an underlying medical condition which puts them at increased risk from pneumococcal disease may require additional vaccination outside the inclusion criteria for this PGD - see PCV Risk Groups PGD and Chapter 25 of the 'Green Book'.

Criteria for exclusion³

Individuals for whom valid consent, or 'best-interests' decision in accordance with the <u>Lasting Powers of Attorney and Capacity Act 2018</u> and the <u>Mental Health Act 2016</u>, has not been obtained (for further information on consent see <u>Chapter 2</u> of <u>The Green Book</u>). The Patient information leaflet (PIL) for the vaccine to be used should be available to inform consent.

Individuals who:

- are less than 12 weeks of age, unless PCV13 is recommended in response to an outbreak of pneumococcal disease or are at high risk of an outbreak, as risk assessed by the Director of Public Health and proposal ratified by the GHA Executive Team.
- are aged 2 years and over, unless PCV13 is recommended in response to an outbreak of pneumococcal disease or are at high risk of an outbreak, as risk assessed by the Director of Public Health and proposal ratified by the GHA Executive Team.
- have received a dose of PCV13 within the last 4 weeks (Note: national schedule recommends an 8-week interval, see Dose and frequency of administration section)
- have had a confirmed anaphylactic reaction to a previous dose of pneumococcal vaccine or to any component of the vaccine, including diphtheria toxoid
- are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation)

³ Exclusion under this PGD does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation will be required

Cautions including any relevant action to be taken

The immunogenicity of the vaccine could be reduced in immunosuppressed individuals and additional doses may be recommended, see the 'Green Book' Chapter 7 and Chapter 25 and the PCV Risk Groups PGD.

Premature infants should be vaccinated in accordance with the national routine immunisation schedule according to their chronological age.

The occurrence of apnoea following vaccination is especially increased in infants who are born very prematurely. Very premature infants (born ≤28 weeks of gestation) who are in hospital should have respiratory monitoring for 48-72 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 48-72 hrs.

Action to be taken if the patient is excluded

Immunisation can be administered to infants from 6 weeks of age if at increased risk of exposure due to an outbreak (see Dose and frequency of administration).

If aged less than 6 weeks defer immunisation and provide an appointment as appropriate.

If aged 2 years and over routine immunisation with pneumococcal vaccine is not indicated. If the individual is at increased risk of pneumococcal disease, in accordance with the 'Green Book' Chapter 7 and Chapter 25, refer to the PCV Risk Groups PGD.

Individuals suffering acute severe febrile illness should postpone immunisation until they have recovered. Immunisers should advise when the individual can be vaccinated and ensure another appointment is arranged.

Seek appropriate advice from the Director of Public Health Gibraltar or the individual's clinician as required.

The risk to the individual of not being immunised must be taken into account.

Document the reason for exclusion and any action taken in the individual's clinical records.

Inform or refer to the GP or a prescriber as appropriate.

Action to be taken if the patient or carer declines treatment	Informed consent, from the individual or a person legally able to act on the person's behalf, must be obtained for each administration and recorded appropriately.	
	Where a person lacks the capacity, in accordance with the <u>Lasting Powers of Attorney and Capacity Act 2018</u> and the <u>Mental Health Act 2016</u> , a decision to vaccinate may be made in the individual's best interests.	
	For further information on consent see <u>Chapter 2</u> of ' <u>The Green Book</u> '.	
	Advise the individual/carer about the protective effects of the vaccine, the risks of infection and potential complications.	
	Document advice given and the decision reached.	
	In a GP practice setting, inform or refer to the GP as appropriate.	
Arrangements for referral for medical advice	As per local GHA policy	

3. Description of treatment

Name, strength & formulation of drug	Pneumococcal polysaccharide conjugate vaccine (13-valent, adsorbed), PCV13: Prevenar®13 suspension for injection in a pre-filled syringe		
Legal category	Prescription only medicine (POM)		
Black triangle	No		
Off-label use	Administration of a two-dose primary series of Prevenar®13 to pre-term infants <37 weeks gestation is contrary to the three-dose primary schedule detailed in the SPC but is in accordance with the recommendations for the Vaccination of premature infants and Chapter 25 of the 'Green Book'.		
	Administration of a one-dose primary series of Prevenar®13 is contrary to the two or three dose primary schedule detailed in the SPC but is in accordance with the recommendations and Chapter 25 of the 'Green Book'.		
	A single dose schedule for previously unvaccinated individuals between 12 months and up to 2 years of age is contrary to the 2-dose schedule detailed in the SPC but is in accordance with the national recommendations for the Vaccination of individuals with uncertain or incomplete immunisation status and Chapter 25 of the 'Green Book'.		
	A single dose schedule for partially immunised individuals between 12 months and up to 2 years of age is not consistent with the SPC but is in accordance with the national recommendations for the <u>vaccination of individuals with uncertain or incomplete immunisation status</u> and <u>Chapter 25</u> of the 'Green Book'.		
	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 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.		
	Where a vaccine is recommended off-label consider, as part of the consent process, informing the individual/parent/carer that the vaccine is being		

offered in accordance with national guidance but that this is outside the product licence.

Route / method of administration

Administer by intramuscular injection, preferably into the anterolateral aspect of the thigh in infants under one year of age. The deltoid region of the upper arm may be used in individuals over one year of age.

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.

For individuals with a bleeding disorder, vaccines normally given by an intramuscular route should be administered in accordance with the recommendations in the 'Green Book' Chapter 4 to reduce the risk of bleeding.

The vaccine's normal appearance is a uniform white suspension which may sediment during storage. Shake the prefilled syringe well to uniformly distribute the suspension before administering the vaccine.

The vaccine should be visually inspected prior to administration and should not be used if discoloured or foreign particles are present.

The vaccine's SPC provides further guidance on administration and is available from the <u>electronic Medicines Compendium website</u>.

Dose and frequency of administration

Single 0.5ml dose per administration

Routine Childhood Immunisation Schedule

Infants, who do not have asplenia, splenic dysfunction, complement disorder or severe immunocompromise⁴, (see Green Book <u>Chapter 25, Table 25.2</u>) should be offered a 1+1 PCV schedule, that is:

- •a single priming dose of PCV13 to be administered from 12 weeks of age, followed by
- •a PCV13 booster dose to be administered at one year old, on or soon after their first birthday and before 2 years of age.

Routine immunisation with PCV13is not offered after the second birthday.

⁴ Examples of severe immunocompromise include bone marrow transplant patients, patients with acute and chronic leukaemia, multiple myeloma or genetic disorders affecting the immune system (such as IRAK-4, NEMO)

Premature infants

Premature infants should be vaccinated in accordance with the national routine immunisation schedule according to their chronological age, no matter how premature they are (see 'Green Book' <u>Chapter 25</u>). Since the immunogenicity of PCV13 will be lower if given at a younger age, any dose given before 12 weeks of age should not be counted as the single priming dose for the 1+1 schedule and the routine PCV dose should be given once the infant reaches 12 weeks of age, leaving a minimum 4-week interval between the priming dose and any preceding dose.

Use PCV Risk Groups PGD for:

Individuals with asplenia, splenic dysfunction, complement disorder and severe immunocompromise3 should be vaccinated in accordance with the <u>PCV Risk Groups PGD</u>, <u>Chapter 7</u> and <u>Chapter 25</u> of the 'Green Book'.

Unimmunised or partially immunised children

Unimmunised or partially immunised infants who do not have asplenia, splenic dysfunction, complement disorder or severe immunocompromise3 who:

- •present late for vaccination, and before one year of age, should receive a primary dose of PCV13 before the age of one year, and a booster dose at one year of age, leaving an 8-week interval between the primary PCV13 dose and the booster. Where the infant is presented very late (such as at 11 months), then a minimum interval of four weeks should be observed before the booster dose
- •present for vaccination between one year and under two years of age should only have a single dose of PCV13
- •do not have a reliable history of previous immunisation should be assumed to be unimmunised and the routine programme should be followed (see above)
- •have received one or more doses of PCV10 vaccine in another country should be offered PCV13 vaccination in accordance with the UK PCV13 vaccination schedule (see above) with a minimum interval of 4 weeks between PCV13 vaccination and any preceding PCV10 dose. Where the infant is presented very late (such as at 11 months), then a minimum interval of four weeks should be observed between the PCV13 priming dose and booster dose.

Dose and frequency of administration (continued)

See flow chart for <u>Vaccination of individual with uncertain or incomplete</u> immunisation status.

Management of a pneumococcal disease clusters and outbreaks in closed settings with high-risk individuals.

A single dose of PCV 13 may be administered to adults and children from 6 weeks of age who have not received PCV13 vaccine in the preceding 4 weeks and who are identified as requiring PCV13 immunisation in accordance with Guidelines for the public health management of clusters and outbreaks of pneumococcal disease in closed settings with high-risk individuals.

Note: PPV23 would ordinarily be used in an outbreak with the exception of serotype 6A/6C disease, individuals under 2 years of age, and where PPV23 is unavailable or otherwise inappropriate.

Duration of treatment	See Dose and frequency of administration section above		
Quantity to be supplied / administered	Single 0.5ml dose per administration.		
Supplies	GHA clinics should order/receive PNEUMOCOCCAL POLYSACCHARIDE CONJUGATE VACCINE from the St Bernard's Hospital pharmacy dept. The pharmacy dept will source the vaccine via the national appointed supply route for the GHA.		
	NHS/GHA standard operating procedures should be followed for appropriate ordering, storage, handling, preparation, administration and waste minimisation of PNEUMOCOCCAL POLYSACCHARIDE CONJUGATE VACCINE, which ensure use is in accordance with the product's SPC and official national/GHA recommendations.		
Storage	Store at between +2°C to +8°C.		
	Store in original packaging in order to protect from light.		
	Do not freeze.		
	Prevenar®13 is stable at temperatures up to 25°C for four days. At the end of this period Prevenar®13 should be used or discarded. These data are intended to guide health care professionals in case of temporary temperature excursions.		
	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. Refer to Vaccine Incident Guidance		
Disposal	Follow local clinical waste policy and GHA/NHS standard operating procedures and ensure safe and secure waste disposal.		
	Equipment used for vaccination, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of safely and securely according to local GHA arrangements and guidance in the technical memorandum 07-01 : Safe management of healthcare waste (Department of Health, 2013).		
Drug interactions	Immunological response may be diminished in those receiving immunosuppressive treatment. Vaccination is recommended even if the antibody response may be limited.		
	May be given at the same time as other vaccines.		
	A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website.		

Identification & Local reactions following vaccination are very common such as pain, swelling or redness at the injection site. A small painless nodule may form at the management of adverse reactions injection site. The most commonly reported adverse reactions include, fever, irritability, decreased appetite, increased and/or decreased sleep, rash, vomiting and diarrhoea. Hypersensitivity reactions, such as bronchospasm, angioedema, urticaria, and anaphylaxis can occur but are very rare. A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website. Reporting procedure of Healthcare professionals and individuals/carers should report suspected adverse reactions adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme Any adverse reaction to a vaccine should also be documented in the individual's record and the individual's GP should be informed. All suspected adverse reactions are to inform the Director of Public Health immediately via telephone if severe (hospitalised and/or critically unwell), if not then notify DPH via email. (See Immunisation Adverse Reactions Workflow) Written information to be Offer marketing authorisation holder's patient information leaflet (PIL) given to patient or carer provided with the vaccine. Immunisation promotional material may be provided as appropriate: • A guide to immunisations for babies up to 13 months of age • A guick guide to childhood immunisation for the parents of premature babies Available from: www.gov.uk/government/collections/immunisation Patient advice / follow up Inform the individual/parent/carer of possible side effects and their treatment management. Give advice regarding normal reaction to the injection, for example redness and pain at the injection site.

The individual/carer should be advised to seek medical advice in the event of an adverse reaction.

The individual/parent/carer should be advised to seek medical advice in the event of an adverse reaction. Advise the individual/parent/carer when any subsequent immunisations are due.

When administration is postponed advise the individual/parent/carer when to return for vaccination.

Special considerations / additional information

Ensure there is immediate access to adrenaline (epinephrine) 1 in 1,000 injection and access to a telephone at the time of vaccination.

Individuals at increased risk of pneumococcal disease and require additional doses of PCV13 in accordance with the 'Green Book' <u>Chapter 7</u> and <u>Chapter 25</u>. The administration of PCV13 for these individuals is covered by the PCV Risk Groups PGD.

Individuals who have received a bone marrow transplant after vaccination should be considered for a re-immunisation programme for all routine vaccinations and for COVID-19 (see Chapter 25 of the 'Green Book'). This is not covered by this PGD and should be provided through a Patient Specific Direction (PSD).

IMMEDIATE ACCESS TO OXYGEN IS NOT A NECESSITY UNDER THIS PGD. BASIC LIFE SUPPORT & CALLING EMERGENCY SERVICES IS SUFFICIENT FOR IMMEDIATE RESUSCITATIN.

Records

Record:

- that valid informed consent was given or a decision to vaccinate made in the individual's best interests in accordance with the <u>Lasting Powers of</u>
 Attorney and Capacity Act 2018 and the Mental Health Act 2016.
- •name of individual, address, date of birth and GP with whom the individual is registered (or record where an individual is not registered with a GP)
- •name of immuniser
- name and brand of vaccine
- date of administration
- •dose, form and route of administration of vaccine
- quantity administered
- •batch number and 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

*supplied via PGD Records should be signed and dated (or a password-controlled immuniser's record on e-records).

All records should be clear, legible and contemporaneous.

This information should be recorded in the individual's GP record. Where vaccine is administered outside the GP setting appropriate health records should be kept and the individual's GP informed. The simplest way to do this is recording on the EMIS record; templates will be made available to help facilitate this.

A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.

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Key references

Pneumococcal conjugate vaccine

•Immunisation Against Infectious Disease: The Green Book Chapter 25 January 2020.

https://www.gov.uk/government/publications/pneumococcal-the-green-book-chapter-25

•Summary of Product Characteristics for Prevenar® 13 suspension for injection, Pfizer Ltd. 12 October 2021.

http://www.medicines.org.uk/emc/medicine/22689

• Vaccination of individuals with uncertain or incomplete immunisation status. Public Health England. 26 August 2021.

https://www.gov.uk/government/publications/vaccination-of-individuals-with-uncertain-or-incomplete-immunisation-status

•Changes to the infant pneumococcal conjugate vaccine schedule: Information for healthcare practitioners. Public Health England. 13 December 2019.

https://www.gov.uk/government/publications/pneumococcal-vaccination-guidance-for-health-professionals

•Guidelines for the public health management of clusters and outbreaks of pneumococcal disease in closed settings with high-risk individuals. Public Health England 21 January 2020

https://www.gov.uk/government/publications/managing-clusters-of-pneumococcal-disease-in-closed-settings

General

•Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20 March 2013

https://www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-htm-07-01/ National Minimum Standards and Core Curriculum for Immunisation Training. Published February 2018. https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners

• Lasting Powers of Attorney and Capacity Act 2018 and the Mental Health Act, 2016.

https://www.gibraltarlaws.gov.gi/

- •NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published March 2017. https://www.nice.org.uk/guidance/mpg2
- •NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. Updated March 2017. https://www.nice.org.uk/guidance/mpg2/resources
- UKHSA Immunisation Collection

https://www.gov.uk/government/collections/immunisation

•Vaccine Incident Guidance

https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors

5. Practitioner authorisation sheet

Pneumococcal polysaccharide conjugate vaccine (13-valent, adsorbed) Patient Group Direction (PGD). Valid from: 12/05/23 Expiry from: 12/05/25.

Before signing this PGD, check that the document has had the necessary authorisations in section two. Without these, this PGD is not lawfully valid.

Practitioner

By signing this patient group direction you are indicating that you agree to its contents and that you will work within it.

Patient group directions do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct.

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Name	Designation	Signature	Date

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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 the **GHA** for the above named health care professionals who have signed the PGD to work under it.

Name	Designation	Signature	Date

Note to authorising manager

Score through unused rows in the list of practitioners to prevent practitioner additions post managerial authorisation.

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