Gibraltar Health Authority

PATIENT GROUP DIRECTION

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

PNEUMOCOCCAL POLYSACCHARIDE CONJUGATE VACCINE (13-VALENT or 15-VALENT, ADSORBED) PREVENAR 13

LEGAL STATEMENT			
Protocol Issuer	Director of Public Health Gibraltar Health Authority St. Bernard's Hospital Gibraltar Contact Telephone: +(350) 20079160		
Date effective	16th January 2025		
Date of expiry	16th January 2027		
Staff characteristics	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 Health [2]Gemma Arias-Vasquez MP		

[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 (NRB) • practitioners currently registered with the Gibraltar Medical Registration Board (MRB) • Anyone deemed by the Director of Public Health 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) and to discuss issues related to vaccination • 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 • 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. **THE INDIVIDUAL PRACTITIONER MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT**

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 national immunisation programme and recommendations given in Chapter 25 of Immunisation Against Infectious Disease: the 'Green Book'. •individuals from 6 weeks of age recommended PCV13 or PCV15 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 or PCV15 •require a reinforcing booster dose of PCV13 or PCV15 against pneumococcal disease Individuals from 6 weeks of age recommended PCV13 or PCV15 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'. In an outbreak situation, under written instruction from the Director of Public Health, specific additional groups of the population may be offered an inactivated seasonal influenza vaccine as specified in the written instruction.

Criteria for exclusion[3]	Individuals for whom no valid consent has been received, or a best-interests decision in accordance with the Mental Capacity Act, has not been obtained. Individuals who: • are less than 12 weeks of age, unless PCV13 or PCV15 is recommended in response to an outbreak of pneumococcal disease. • are aged 2 years and over, unless PCV13 or PCV15 is recommended in response to an outbreak of pneumococcal disease. • are aged 2 years and over with an underlying medical condition putting them at increased risk of pneumococcal disease as outlined in Table 25.2 of Chapter 25 of the Green Book (see PCV Risk Groups PGD) . • have received a dose of PCV13 or PCV15 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. • 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	Facilities for management of anaphylaxis should be available at all vaccination sites (see Chapter 8 of the Green Book and advice issued by the Resuscitation Council UK). 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. 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.

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 a dose of PCV (irrespective of valency) was received within the last 4 weeks, defer immunisation for an appropriate interval (see Dose and frequency of administration).

	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 local Screening and Immunisation Team, local Health Protection Team 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. Advise the individual/carer about the protective effects of the vaccine, the risks of infection and potential complications if not immunised. 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 GHA policy

3. Description of treatment

Name, strength & formulation of drug	Pneumococcal polysaccharide conjugate vaccine (13-valent, adsorbed), PCV13: **Prevenar®13** (13-valent) suspension for injection in a pre-filled syringe **Vaxneuvance®** (15-valent) suspension for injection in a pre-filled syringe
Legal category	Prescription only medicine (POM)
Black triangle	Vaxnuevance®. As a new vaccine product, the Medicines and Healthcare products Regulatory Agency (MHRA) has a specific interest in the reporting of adverse drug reactions for this product. All suspected drug reactions should be reported to the MHRA using the Yellow Card scheme and to the Director of Public Health.
Off-label use	Administration of a 4-dose primary series of Prevenar®13 or Vaxneuvance® to pre-term infants <37 weeks gestation is contrary to the 3-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 Vaxneuvance®is contrary to the 2 or 3 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 for Prevenar®13 or Vaxneuvance® 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'. 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. Individuals with bleeding disorders may be vaccinated intramuscularly if, in the opinion of a doctor familiar with the individual's bleeding risk, vaccines or similar small volume intramuscular injections can be administered with reasonable safety by this route. If the individual receives medication or other treatment to reduce bleeding, for example treatment for haemophilia, intramuscular vaccination can be scheduled shortly after such medication or treatment is administered. Individuals on stable anticoagulation therapy, including individuals on warfarin who are up to date with their scheduled INR testing and whose latest INR was below the upper threshold of their therapeutic range, can receive intramuscular vaccination. A fine needle (equal to 23 gauge or finer calibre such as 25 gauge) should be used for the vaccination, followed by firm pressure applied to the site (without rubbing) for at least 2 minutes. The individual or carer should be informed about the risk of haematoma from the injection. Prevenar®13 is a uniform white suspension which may sediment during storage. Vaxneuvance® is an opalescent suspension. 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 electronic Medicines Compendium website.

Dose and frequency of administration	Single 0.5ml dose per administration **1.Routine Childhood Immunisation Schedule** Infants should be offered a 1+1 PCV schedule, that is: •a single priming dose of PCV13 or PCV15 to be administered from 12 weeks of age, followed by •a PCV13 or PCV15 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 PCV13 or PCV15 is not offered after the second birthday. **2. Management of pneumococcal disease clusters and outbreaks in closed settings with high-risk individuals.** A single dose of PCV13 or PCV15 may be administered to adults and children from 6 weeks of age, identified as requiring PCV13 or PCV15 immunisation in accordance with Guidelines for the public health management of clusters of severe pneumococcal disease in closed settings. **Note:** PPV23 would ordinarily be used in an outbreak with the exception of serotype 6A/6C disease, in individuals under 2 years of age, and where PPV23 is unavailable or otherwise inappropriate. PCV doses administered in response to an outbreak are considered additional to those offered during the routine immunisation schedule (see information below). A dose of PCV13 or PCV15 is not required if a dose has been given in the last 12 months. **Infants and children under the age of 2 exposed to a pneumococcal outbreak requiring pneumococcal vaccination** Individuals aged 6 weeks and over but under 2 years of age recommended to receive a dose of PCV13 or PCV15 following a pneumococcal outbreak should receive such doses in addition to those offered in line with the national childhood immunisation schedule. In all circumstances, an 8 week interval between additional and scheduled doses is preferred, though if doing so risks delaying all other routine immunisations, then scheduled PCV13 or PCV15 doses can be given.
Duration of treatment	See Dose and frequency of administration section above
Quantity to be supplied / administered	Single 0.5ml dose per administration.

Supplies	Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see the 'Green Book' Chapter 3).
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. This information is only 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	Equipment used for immunisation, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of safely in an UN-approved puncture-resistant 'sharps' box, according to local authority 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 & management of adverse reactions	Local reactions following vaccination are very common such as pain, swelling or redness at the injection site. The most commonly reported adverse reactions include fever, irritability, decreased appetite, fatigue, headache and myalgia. Other commonly reported reactions include rash. Vomiting and diarrhoea are commonly reported reactions to Prevenar®13. Hypersensitivity reactions, such as bronchospasm, angioedema and anaphylaxis can occur but are rare. A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website.
Reporting procedure of adverse reactions	Healthcare professionals and individuals/carers should report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme or search for MHRA Yellow Card in the Google Play or Apple App Store and send a copy of the Yellow card to the Director of Public Health. Any adverse reaction to a vaccine should also be documented in the individual's record and the individual's GP should be informed. **INFORM GIBRALTAR DIRECTOR OF PUBLIC HEALTH IMMEDIATELY IF SEVERE ADVERSE REACTION IS SUSPECTED**
Written information to be given to patient or carer	Offer marketing authorisation holder's patient information leaflet (PIL) 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 quick guide to childhood immunisation for the parents of premature babies Available from: Immunisation - GOV.UK

Patient advice / follow up treatment	Inform the individual/parent/carer of possible side effects and their management. The individual, parent or carer should be advised to seek medical advice in the event of an adverse reaction and report this via the Yellow Card reporting scheme. Advise the individual, parent or 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 or PCV15 in accordance with the 'Green Book' Chapter 7 and Chapter 25. The administration of PCV13 or PCV15 for these individuals is covered by the PCV Risk Groups PGD. **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 Chapter 25). **Doses given before 12 weeks of age** Since the immunogenicity of PCV13 or PCV15 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. See Vaccination of premature infants for further information. **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 or PCV15 before the age of one year, and a booster

	dose at one year of age, leaving an 8 week interval between the primary PCV13 or PCV15 dose and the booster. Where the infant is presented very late (such as at 11 months), then a minimum interval of 4 weeks should be observed before the booster dose •present for vaccination between one year and under 2 years of age should only have a single dose of PCV13 or PCV15 •do not have a reliable history of previous immunisation and are aged under 2 at the time of first presentation, 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 (or vaccine of a differing valency to the UK schedule) should be offered PCV13 or PCV15 vaccination in accordance with the UK PCV routine vaccination schedule (see above) with a minimum interval of 4 weeks between PCV13 or PCV15 vaccination and any preceding PCV10 dose. Where the infant is presented very late (such as at 11 months), then a minimum interval of 4 weeks should be observed between the PCV13 or PCV15 priming dose and booster dose. •There is little clinical benefit in offering PCV vaccination to unimmunised or partially immunised individuals aged over 2 years and above and therefore a dose of vaccine should not be given in such instances. See flow chart for Vaccination of individual with uncertain or incomplete immunisation status 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 7 and 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 RESUSCITATION.**

Records	The practitioner must ensure the following is recorded: •that valid informed consent was given •name of individual, address, date of birth and GP with whom the individual is registered •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. A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.

4. Key references	**Pneumococcal conjugate vaccine** •Immunisation Against Infectious Disease: The Green Book, Chapter 25, last updated 27 July 2023 https://www.gov.uk/government/publications/pneumococcal-the-green-book-chapter-25 •Summary of Product Characteristics for Prevenar®13 suspension for injection, Pfizer Ltd, last updated 12 October 2021 http://www.medicines.org.uk/emc/medicine/22689 •Personal communication, Pfizer Ltd (Prevenar®13 suspension for injection). Contacted 23 November 2023. •Summary of Product Characteristics for Vaxneuvance® suspension for injection, Merck Sharpe and Dohme Ltd, last updated 14 December 2023 https://www.medicines.org.uk/emc/product/13754/smpc •Vaccination of individuals with uncertain or incomplete immunisation status, UKHSA. Updated 6 September 2023. 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, last updated 23 July 2020. https://www.gov.uk/government/publications/pneumococcal-vaccination-guidance-for-health-professionals •Guidelines for the public health management of clusters of severe pneumococcal disease in closed settings, UKHSA. Last updated 21 February 2020 https://www.gov.uk/government/publications/managing-clusters-of-pneumococcal-disease-in-closed-settings **General** •NHSE Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Updated 7 March 2023 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

	•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 and 15-valent adsorbed), PCV13 and PCV15:
Prevenar®13 suspension for injection in a pre-filled syringe:
Vaxneuvance®15 suspension for injection in a pre-filled syringe:
PGD valid from 11th April 2025 until 11th April 2027

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.			
Name	Designation	Signature	Date

Authorising manager

I confirm that the practitioners named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of 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.