Gibraltar Health Authority

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

- MENINGOCOCCAL GROUP B VACCINE PGD (RDNA, component, adsorbed),BEXSERO

LEGAL STATEMENT			
Protocol Issuer	Director of Public Health Gibraltar Health Authority St. Bernard's Hospital Gibraltar Contact Telephone: +(350) 20079160		
Date effective	11th April 2025		
Date of expiry	11th April 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 Gemma Arias-Vasquez MP [2]		

[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) • must be familiar with, and alert to changes in relevant chapters of Immunisation Against Infectious Disease: the Green Book • must be familiar with, and alert to changes in the relevant GHA standard operating procedures (SOPs) and arrangements for the Gibraltar small pox vaccination programme • must have undertaken training appropriate to this PGD as required by local policy and national NHS standard operating procedures • 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 Capacity Act 2016) and to discuss issues related to vaccination • must be competent in the correct handling and storage of vaccines, and management of the cold chain • must be competent in the handling of the vaccine product, procedure for dilution of the vaccine and use of the correct technique for drawing up the correct dose • must be competent in the injection technique • must be competent in the recognition and management of anaphylaxis, have completed basic life support training and be able to respond appropriately to immediate adverse reactions • must have access to the PGD • should fulfil any other additional requirements defined by local policy

	THE INDIVIDUAL PRACTITIONER MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO 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 8 weeks of age against Neisseria meningitidis group B and for the prevention of secondary cases of meningococcal group B disease, in accordance with the recommendations given in Chapter 22 of Immunisation Against Infectious Disease: The Green Book and Guidance for Public Health Management of Meningococcal Disease in the UK.

Criteria for inclusion	Individuals who: • are aged from 8 weeks up to their second birthday and require routine immunisation. • require vaccination for the prevention of secondary cases of Men B, following specific advice from Public Health England Health Protection Teams. **Note:** Individuals, from 2 years of age, with an underlying medical condition which puts them at increased risk from Neisseria meningitidis group B, that is individuals with asplenia, splenic dysfunction or complement disorders (including those on, or due to receive, complement inhibitor treatment such as eculizumab), may require additional 'routine' vaccination outside the inclusion criteria for this PGD - see MenB Risk Groups PGD and Chapter 7 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. Individuals who: • are less than 8 weeks old • are from 2 years of age, unless advised by PHE for the prevention of secondary cases of MenB infection • have had a confirmed anaphylactic reaction to a previous dose of the vaccine • have had a confirmed anaphylactic reaction to any constituent or excipient of the vaccine including kanamycin • require vaccination for occupational health reasons, for instance laboratory workers working with meningococci • have a history of anaphylactic allergy to latex • 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	Tip cap of the syringe may contain natural rubber latex. For latex allergies other than anaphylactic allergies (such as a history of contact allergy to latex gloves), vaccines supplied in vials or syringes that contain latex can be administered. Very premature infants (born ≤28 weeks of gestation) who are in hospital should have respiratory monitoring for 48-72 hours when given their first immunisation, particularly those with a previous history of respiratory immaturity. If the child has apnoea, bradycardia or desaturations after the first immunisation, the second immunisation should also be given in hospital, with respiratory monitoring for 48-72 hours. The immunogenicity of the vaccine could be reduced in immunosuppressed subjects. However, vaccination should proceed in accordance with national recommendations. 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	If aged less than 8 weeks 4CMenB is not routinely indicated, advise when the individual can be vaccinated. If aged from 2 years and not in a clinical risk group or requiring vaccination for the prevention of secondary cases of MenB disease, the individual/parent/carer should be advised that 4CMenB is not indicated. Individuals at increased risk of invasive meningococcal infection with asplenia, splenic dysfunction or complement disorders (including those on complement inhibitor treatment such as eculizumab) should be vaccinated in accordance with the recommended schedules in Chapter 7 and Chapter 22 of 'The Green Book' (see MenB Risk Groups PGD).

Action to be taken if the patient is excluded (contined)	Individuals requiring vaccination for occupational health reasons, such as laboratory workers working with meningococci, should be referred to their occupational health service provider for vaccination. Individuals who have a history of anaphylactic allergy to latex should not be administered 4CMenB unless the benefit of vaccination outweighs the risk of an allergic reaction – a PSD will be required. 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	In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated and ensure another appointment is arranged. Seek appropriate advice from the Director of Public Health or the individual's clinician where appropriate. 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. Informed consent, from the individual or a person legally able to act on the person's behalf, must be obtained for each administration. Where a person lacks the capacity, in accordance with the Mental Capacity Act 2018, a decision to vaccinate may be made in the individual's best interests. For further information on consent see Chapter 2 of 'The Green Book'. Advise the individual/parent/carer about the protective effects of the vaccine, the risks of infection and potential complications. Document advice given, and the decision reached. Inform, or refer to the GP or a practitioner as appropriate.

Arrangements for referral for medical advice	As per GHA policy

3. Description of treatment

Name, strength & formulation of drug	Meningococcal group B Vaccine (rDNA, component, adsorbed), 4CMenB: • Bexsero® suspension for injection, 0.5ml, in a pre-filled syringe
Legal category	Prescription only medicine (POM)
Black triangle	No
Off-label use	The vaccine schedule differs from the current Bexsero SPC. However, the national routine schedule is as recommended by the Joint Committee of Vaccination and Immunisation (JCVI) and public health England, in line with

	Chapter 22 of the ''Green book'' and the vaccine schedule for the prevemtion of secondary cases of MenB disease is in accordance with the Guidance for Public Health Management of Meningococcal Disease in the UK. Administration by deep subcutaneous injection to individuals with a bleeding disorder is off-label administration in line with advice in Chapter 4 and Chapter 22 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 PHE 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	4CMenB is given as a 0.5ml dose by intramuscular injection. In infants and for the routine booster dose, PHE recommend that all doses of 4CMenB be given in the anterolateral aspect of the left thigh, ideally on their own, so that any local reactions can be monitored more accurately. Vaccine may alternatively be administered in the deltoid muscle region of the upper arm in older subjects (from 1 year of age). If another vaccine needs to be administered 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. The vaccine must not be injected intravenously or intradermally and must not be mixed with other vaccines in the same syringe. The vaccine must not be given subcutaneously except to individuals with a bleeding disorder when vaccines normally given by an IM route should be given by deep subcutaneous injection to reduce the risk of bleeding (see Green Book Chapter 4). The vaccine is a white opalescent liquid suspension. Upon storage a fine off-white deposit may be observed in the pre-filled syringe containing the suspension. Before use, the pre-filled syringe should be well shaken in order to form a homogeneous suspension. The vaccine should be visually inspected for particulate matter and discoloration prior to administration. In the event of any foreign particulate matter and/or variation of physical aspect being observed, do not administer the vaccine. The vaccine's SPC provides further guidance on administration and is available from the electronic Medicines Compendium website: www.medicines.org.uk

Dose and frequency of administration	**Routine Immunisation Schedule** The UK national recommendation for infants is for a two dose primary course of 4CMenB, routinely starting at 8 weeks of age, to be administered with an 8 week interval and a booster dose to be administered, usually on or after their first birthday, although it may be administered until 2 years of age. 4CMenB 0.5ml should ideally be given as follows: • first primary immunisation visit (usually at age 8 weeks) • third primary immunisation visit (usually at age 16 weeks) • booster on or after the first birthday **Individuals with unknown or incomplete vaccination history** Where there is no reliable history of previous immunisation, it should be assumed that they are unimmunised and the full UK recommendations should be followed (see Chapter 11). Infants younger than 12 months should receive the first dose of 4CMenB and second dose of 4CMenB eight weeks later followed by the 4CMenB booster. Doses of MenB should ideally be given 8 weeks apart. They can be given 4 weeks apart in order for the primary MenB immunisation schedule to be completed before the first birthday if possible (if schedule started after 10 months of age). Children aged one year to less than two years who received less than 2 4CMenB doses in the first year of life should receive two doses of 4CMenB at least 8 weeks apart in the second year of life. Doses of MenB can be given 4 weeks apart if necessary to ensure the 2 dose schedule is completed (if schedule started at 22 months of age). **Prevention of secondary cases of Men B disease** Vaccination for the prevention of secondary cases of MenB disease should be in accordance with recommendations from the local Public Health England Health Protection Team and informed by the Public Health England Guidance for Public Health Management of Meningococcal Disease in the UK.
Dose and frequency of administration	
Duration of treatment	See dose section above
Quantity to be supplied / administered	Single dose of 0.5ml per an administration
Supplies	Vaccines for private prescriptions, occupational health use or travel, are NOT provided free of charge and should be ordered from the manufacturer/wholesalers. Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see Green Book Chapter 3).

Storage	Store between +2°C to +8°C. Store in original packaging in order to protect from light. Do not freeze. 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 PHE 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 a UN-approved puncture-resistant 'sharps' box, according to local authority regulations 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 individuals receiving immunosuppressant treatment. Vaccination is recommended even if the antibody response may be limited. 4CMenB can be given at the same time as the other vaccines.

Identification & management of adverse reactions	The most common local and systemic adverse reactions observed in in adolescents and adults after administration of 4CMenB are injection site reactions (including pain, swelling, induration and erythema) malaise, rash, myalgia, arthralgia, nausea and headache. The common or very commonly adverse reactions seen in infants and children (up to 10 years of age) include diarrhoea and vomiting, eating disorders, sleepiness, unusual crying, headache, arthralgia, injection site reactions (including tenderness, erythema, swelling and induration), fever (≥ 38 °C) and irritability and the development of a rash. Rarely, in infants and children (up to 10 years of age), seizures (including febrile seizures), pallor, eczema and fever (≥ 40 °C) can occur. In infants and children under two years of age, fever ≥38°C (occasionally ≥39°C) was more common when 4CMenB was administered at the same time as routine vaccines (see Chapter 11) than when 4CMenB was given alone. The fever peaks at around 6 hours and has usually gone by 48 hours after vaccination. Due to the high incidence of fever when primary doses of 4CMenB are administered with other routine immunisations, prophylactic use of paracetamol is recommended by the JCVI for infants under one year of age. Advise the parent/carer that a 2.5ml dose of liquid paracetamol (infant paracetamol 120mg/5ml) should be given orally as soon as possible after the vaccination, followed by a second 2.5 ml dose after 4-6 hours and a third 2.5 ml dose 4-6 hours after the second dose. Should fever persist following the third dose and provided that the child appears otherwise well, additional doses of paracetamol may be administered at intervals of four to six hours for up to 48 hours (see paracetamol SPC for doses and frequencies). Parents should be advised to seek medical advice if their child is noticeably unwell with a fever present, or if the fever occurs at other times. Ibuprofen appears to be less effective than paracetamol at controlling fever following vaccination and is not therefore recommended (see Using paracetamol to prevent and treat fever after MenB vaccination guidance and Written information to be given to patient or carer below). Paracetamol prophylaxis is not required if the immunisation visit does not include 4CMenB (for instance the 3-month routine vaccinations) or with the 4CMenB booster after the first birthday (because 4CMenB does not increase the rates of fever at this age). Fever rates in infants receiving 4CMenB alone are similar to the other routine immunisations so paracetamol prophylaxis is not required. A detailed list of adverse reactions is available in the vaccine's 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: • Documents relating to the Meningococcal B (MenB) vaccination programme. • Protecting your baby against meningitis and septicaemia caused by meningococcal B bacteria • 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: www.gov.uk/government/collections/immunisation
Patient advice / follow up treatment	4CMenB is not expected to provide protection against all circulating meningococcal group B strains. Individuals should continue to seek prompt medical attention at the first signs of possible meningitis or septicaemia. Inform individual/parent/carer of possible side effects and their management. If appropriate, advise the individual/parent/carer about the use and timing of paracetamol doses to reduce the risk, intensity and duration of fever (see Identification and management of adverse reactions). The individual/parent/carer should be advised to seek medical advice in the event of an adverse reaction or if they are concerned that their child is unwell at any time. When applicable, advise the individual/parent/carer when the subsequent vaccine dose is 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. Vaccination of preterm infants using Bexsero is indicated (without correction for prematurity) if the infant is clinically stable. As the benefit of vaccination is high in premature and very premature infants, vaccination should not be withheld or delayed (see Cautions). For further information on preventing secondary cases see the Public Health England Guidance for Public Health Management of Meningococcal Disease in the UK.

Records	Record: • 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.

Records (Continued)	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 local Child Health Information Systems team (Child Health Records Department) must be notified using the appropriate documentation/pathway as required by any local or contractual arrangement. 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

Key references	**Meningococcal B Vaccination** • Immunisation Against Infectious Disease: The Green Book, Chapter 4, last updated June 2012, Chapter 7, last updated 10 January 2020 and Chapter 22 last updated 20 September 2016 https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book • Bexsero® Summary of Product Characteristics, GlaxoSmithKline UK. Updated 13 July 2020. https://www.medicines.org.uk/emc/product/5168 • Meningococcal B (MenB) vaccination programme. Last updated 19 October 2018. https://www.gov.uk/government/collections/meningococcal-b-menb-vaccination-programme • Guidance for Public Health Management of Meningococcal Disease in the UK, Public Health England, updated Updated 6 August 2019. https://www.gov.uk/government/publications/meningococcal-disease-guidance-on-public-health-management • Vaccination of individuals with uncertain or incomplete immunisation status. Public Health England. Updated 16 December 2019. https://www.gov.uk/government/publications/vaccination-of-individuals-with-uncertain-or-incomplete-immunisation-status **General** • Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20 March 2013 https://www.gov.uk/government/publications/guidance-on-the-safe-management-of-healthcare-waste • 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 • PHE Immunisation Collection https://www.gov.uk/government/collections/immunisation • PHE Vaccine Incident Guidance https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors

5. Practitioner authorisation sheet

Meningococcal group B Vaccine (rDNA, component, adsorbed), 4CMenB: Bexsero® suspension for injection, 0.5ml, in a pre-filled syringe
DATE OF ISSUE 11th April 2025 DATE OF EXPIRY: 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.