Bwrdd Iechyd Addysgu Powys
Powys Teaching Health Board

Bronllys Hospital, Bronllys, Brecon, Powys, LD3 0LU

This Patient Group Direction (PGD) must only be used by registered healthcare professionals who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used. Health professionals should always access the PGD via the PTHB internet to ensure that they are always working to the most up to date version

Patient Group Direction

for the administration of

Meningococcal Group B vaccine (rDNA, component, adsorbed) (4CMenB)

by registered healthcare practitioners

to

individuals from 8 weeks of age eligible for the national routine immunisation programme and to individuals for the prevention of secondary cases of meningococcal group B disease

in Powys Teaching Health Board

Version number: PGD 0092 E

Reference Number: PGD 0092E
Valid from: 01/07/2025
Review Date: 01/09/2027
Expiry Date: 28/02/2028

Change history		
Version number	**Change details**	**Date**
PGD0092	Initial Issue	01/09/2015
PGD0092-A	Review issue and put in new PTHB template	14/09/2018
PGD0092-B	PHE adoption PHE MenB PGD amended to: • update off-label section because SPC now includes administration of 2+1 schedule starting at 2 months • update adverse drug reactions section • include a caution relating to immunosuppressed individuals • update adverse drug reactions section include rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates	16/04/2021
PGD0092-C	Updated according to UKHSA template v6.00, amended to: • include minor rewording of standard text, layout and formatting changes for clarity and consistency with organisation change and other UKHSA and PTHB PGDs • amend NHS England and Improvement (NHSE) to NHS England (NHSE) following completion of merger on 1 July 2022 • align the management of anaphylaxis with other UKHSA PGDs in cautions section • add the formulation and strength to the name of the drug • update the advice for individuals with unknown or incomplete history of vaccination in dose and frequency section • include in dose and frequency premature infants, HIV and immunosuppressed cohorts • update drug interactions in accordance with SPC update • update adverse reactions in accordance with updated SPC • update advice for administration of paracetamol in adverse reactions section • update references • remove the table for schedule guidance for secondary prevention of MenB disease as linked in references and through the PGD	02/02/2023

PGD 0092D	Review issue in line with UKHSA MenB PGD template v7.0 to: • include minor rewording of standard text, layout and formatting changes for clarity and consistency with organisation change and other UKHSA and PTHB PGDs • update qualifications and professional registration with reference to clinical scope • update expert panel • add pharmacy technicians in Section 1; qualifications and professional registration • delete allergy to latex as per updated SPC • update off-label use to include interval of 4 weeks for doses in individuals with unknown or incomplete vaccination history • clarify the monitoring requirements for the very premature infants in cautions including any relevant action to be taken • clarify use of paracetamol section in Identification and management of adverse reactions • update the formulation • update dose intervals for individuals with unknown or incomplete vaccination history as per updated Vaccination of individuals with uncertain or incomplete immunisation guidance • update references Removal of appendix B, as this is not in the UKHSA PGD template.	28/02/2025
PGD 0092 E	Review issue in line with UKHSA MenB PGD template v8.0 to: • update the primary dose schedule, for 4CMenB to be given at 8 and 12 weeks as per JCVI recommendations • update the interval between doses to four weeks for the vaccination of individuals with uncertain or incomplete immunisation • update qualifications and professional registration section to include dieticians, podiatrists, and occupational therapists • update expert panel members • update references Added a statement to "Identification and management of adverse reactions" regarding premature babies and use of paracetamol.	01/07/2025

This Powys Teaching Health Board (PTHB) PGD is based on the UKHSA PGD template v8.0 developed by the following health professionals on behalf of the UKHSA and peer reviewed by the UKHSA Immunisations PGD Expert Panel in accordance with the UKHSA PGD and Protocol Policy (also ratified by the UKHSA Medicines Governance Committee). The UKHSA template has been adapted for use in PTHB.

Developed by the following health professionals on behalf of the UKHSA:

Developed by:	Name
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Expert Panel:

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PGD Authorisation

Name	Job title and organisation	Signature	Date
Senior doctor **Dr Kate Wright**	Lead doctor for PTHB	DocuSigned by: Kate Wright 1F267952823F473...	6/16/2025
Chief Pharmacist **Jonathan Boyd**	Chief Pharmacist for PTHB	Signed by: Jon Boyd 6D8ECFE8C9EB423..	6/17/2025
Clinical Governance Lead **Amanda Edwards**	Clinical Governance Lead for PTHB- Assistant Director for Innovation and Improvement	DocuSigned by: Amanda Edwards 74A4E51A42E9473...	6/17/2025
Senior representative of professional group using the PGD **Claire Roche**	Executive Director of Nursing and Midwifery for PTHB	DocuSigned by: Claire Roche F07413E114E04B1...	6/16/2025

The PGD is not legally valid until it has had the relevant organisational authorisation. It is the responsibility of the organisation that has legal authority to authorise the PGD, to ensure that all legal and governance requirements are met. The authorising body accepts governance responsibility for the appropriate use of the PGD. Appendix A provides a staff accreditation sheet. Individual practitioners must be authorised by name, under the current version of this PGD before working according to it.

Those using this PGD must ensure that it is organisationally authorised and signed by an appropriate authorising person, relating to the class of person by whom the product is to be supplied, in accordance with Human Medicines Regulations 2012 (HMR2012)[1]. **The PGD is not legal or valid without signed authorisation in accordance with HMR2012 Schedule 16 Part 2.**

Operation of this PGD is the responsibility of commissioners and service providers. The final authorised copy of this PGD should be kept by the authorising organisation for 25 years after the PGD expires. Provider organisations adopting authorised versions of this PGD should also retain copies for 25 years after the PGD expires. Practitioners and organisations must check that they are using the current version of the PGD. Amendments may become necessary prior to the published expiry date. Enquiries relating to the availability of organisationally authorised PGDs and subsequent versions of this PGD should be directed to: info.medicinesmanagement.powys@wales.nhs.uk

[1] This includes any relevant amendments to legislation.

PGD adoption by the provider

Name	Job title and organisation	Signature	Date
Signatures to be determined locally, if relevant			

1. Characteristics of staff

Qualifications and professional registration	All practitioners should only administer vaccination where it is within their clinical scope of practice to do so. Practitioners must also fulfil the additional requirements and continued training requirements to ensure their competency is up to date, as outlined in the section below. Registered professional with one of the following bodies: • nurses and midwives currently registered with the Nursing and Midwifery Council (NMC) • pharmacists and pharmacy technicians currently registered with the General Pharmaceutical Council (GPhC) (Note: this PGD is not relevant to privately provided community pharmacy services) • paramedics, physiotherapists, dieticians, podiatrists, and occupational therapists currently registered with the Health and Care Professions Council (HCPC) The practitioners above must also fulfil the Additional requirements detailed below. Check Appendix A – Staff Accredited to use this Patient Group Direction to confirm whether all practitioners listed above have organisational authorisation to work under this PGD.
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 have completed eLfH PGD eLearning Patient Group Directions training (available via learning@wales, PTHB staff to access via ESR). Evidence of ongoing PGD training to be submitted to Line Manager annually– this should include an annual completion certificate of PGD e-learning or a dated screenshot of the PGD e-learning assessment results as proof of completion. • must be competent in the use of PGDs (see NICE Competency framework for health professionals using PGDs). Individuals operating under this PGD must be assessed as competent (see Appendix A). • 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 and online training. Please contact PTHB immunisation co-ordinator for further information. • must be competent to undertake immunisation and to discuss issues related to immunisation • must be competent in the handling and storage of vaccines, and management of the cold chain. Completion of cold chain training (also available via ESR). • must be familiar with All Wales Advisory document on Ordering Storage and Handling of Vaccines • must be competent in intramuscular and subcutaneous injection techniques • must be competent in the recognition, management and reporting of recognised adverse reactions, including anaphylaxis. Must be competent in the administration of adrenaline 1 in 1000 and have up to date Basic Life Support skills • 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 to it.**
Continued training requirements	Updating at least every 2 years on the administration of Meningococcal group B Vaccine (rDNA, component, adsorbed), 4CMenB vaccine. 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 must make a self-declaration of competency on PADR (if relevant). The **personal development plan** (yellow) section of the PADR booklet should be used to record completion of Statutory and Mandatory training, including annual PGD e-learning. Compliance with all mandatory NHS training (if relevant).

	Practitioners should be constantly alert to any subsequent recommendations from Welsh Government and/or Public Health Wales and/or NHS Wales and/or the UKHSA and/or NHSE 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. **It is the responsibility of the healthcare professional to maintain their own competency to practice within 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. **It is the responsibility of the administering healthcare professional to ensure that the individual is within the inclusion criteria, and that there are no reasons for exclusion before proceeding with the vaccination. If there is any reason for concern, seek medical advice.**
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 UKHSA Health Protection Teams and in accordance with Guidance for Public Health Management of Meningococcal Disease in the UK 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 Meningococcal Group B Vaccine Risk Groups PGD 0199 and Chapter 7 of 'The Green Book'. • Medical and drug history taken, no reason for exclusion • Informed consent, from the individual or a person legally able to act on the individual's behalf, must be obtained prior to administration. NB Refer to PTHB Consent to Treatment and Examination Policy Any vulnerable adult or child protection concerns should be referred to Safeguarding and PTHB safeguarding policies followed. Where there are safeguarding concerns (Child Protection or Protection of Vulnerable Adults, POVA) advice from the local Safeguarding team should be sought (see below).
Criteria for exclusion (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)	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 the UKHSA for the prevention of secondary cases of MenB infection • have had a confirmed anaphylactic reaction to a previous dose of the vaccine or to any constituent or excipient of the vaccine including kanamycin • require vaccination for occupational health reasons, travel or going to reside abroad • are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation) Refer to sections action to be taken if the patient is excluded and action to be taken if the patient or carer declines.
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. 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. If the premature infant was stable at discharge and has no history of apnoea/respiratory compromise, further vaccinations can be given in the community setting. As the benefit of immunisation is high in this group of infants, immunisation should not be withheld or delayed. The immunogenicity of the vaccine could be reduced in individuals who are immunosuppressed and individuals with HIV. However, vaccination should proceed in accordance with national recommendations (see Chapter 22). 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. Check for any other medications that the individual is taking, including topical or inhaled products, food supplements and herbal or homeopathic products. (Refer to BNF/SPC for full list). Under Section 128 and 130 of the Social Services and Wellbeing (Wales) Act 2014, staff have a duty to inform the Local Authority if they have reasonable cause to suspect that an adult or child is at risk. Any vulnerable adult or child protection concerns should be referred to Safeguarding and the PTHB safeguarding policies followed. Consider discussing with GP. Any safeguarding concerns need to be directed to Safeguarding Hub: • to generic email address: PowysTHB.Safeguarding@wales.nhs.uk and • Central Safeguarding number: 01686 252806 • Out of hours: 0345 0544847

	Advice can also be sought from local Safeguarding leads
Action to be taken if the patient is excluded	If aged less than 8 weeks, 4CMenB is not routinely indicated, advise the parent/carer when the infant 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 Meningococcal Group B Vaccine Risk Groups PGD 0199). Individuals requiring vaccination for occupational health reasons should be referred to their occupational health service provider for vaccination. There are currently no recommendations for 4CMenB vaccination for individuals who are travelling or going to reside abroad. 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 PTHB Infection Control 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. Explain reason to individual / carer. 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. The patient information leaflet should be available to inform consent. Advise the individual/parent/carer about the protective effects of the vaccine, the risks of infection and potential complications of disease. Document advice given and the decision reached. Inform or refer to the GP or a prescriber as appropriate. Inform the Child Health department if appropriate – if any vaccination is declined for a child under 19 years, Child Health must be informed and appropriate form completed. Where appropriate, inform the GP using the local agreed system.
Arrangements for referral for medical advice	Refer to GP, paediatrician or consultant in communicable disease control (CCDC) for clinical advice as necessary. Document any advice given.

3. Description of treatment

Name, strength and formulation of drug	Meningococcal group B Vaccine (rDNA, component, adsorbed), 4CMenB: Bexsero® suspension for injection, 0.5ml, in a pre-filled syringe One dose of 0.5ml suspension contains: Recombinant Neisseria meningitidis group B NHBA fusion protein — 50microgram Recombinant Neisseria meningitidis group B NadA protein — 50microgram Recombinant Neisseria meningitidis group B fHbp fusion protein — 50microgram Outer membrane vesicles (OMV) from Neisseria meningitidis group B strain NZ98/254 measured as amount of total protein containing the PorA P1.4 — 25microgram
Legal category	Prescription Only Medicine (POM)
Black triangle▼	No

Off-label use	Administration by deep subcutaneous injection to individuals with a bleeding disorder is off-label, however, it is in line with advice given in Chapter 4 and Chapter 22 of 'The Green Book'. The SPC states that doses of MenB should be given eight weeks apart. However, the Green Book supports the use of the doses being given four weeks apart. (see Dose and frequency of administration below). 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 the All Wales Advisory document on Ordering Storage and Handling of Vaccines and 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 and method of administration	4CMenB is given as a 0.5ml dose by intramuscular injection. In infants and for the routine booster dose, the UKHSA recommends that all doses of 4CMenB be given in the anterolateral aspect of the left thigh. 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. See Green book chapter 4. 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.
Dose and frequency of administration	**Routine Immunisation Schedule** The national recommendation for infants is a two-dose primary course of 4CMenB, routinely starting at 8 weeks of age, to be administered with a four 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) • second primary immunisation visit (usually at age 12 weeks) • booster on or after the first birthday From 1 July 2025, all infants should receive the second dose of 4CMenB vaccine at their second primary immunisation visit (usually at age 12 weeks). If the second dose is not given at the second visit, it may be given at the third primary immunisation visit (usually at 16 weeks). **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 two doses of 4CMenB at least four weeks apart followed by the 4CMenB booster on or after the first birthday. There should be a minimum interval of four weeks between the second dose of 4CMenB and the booster dose. Children aged one year to less than two years who received less than two 4CMenB doses in the first year of life should receive two doses of 4CMenB in their second year of life. Doses of 4CMenB should be given four weeks apart. If the schedule is started at 23 months, two doses of 4CMenB should be given four weeks apart to ensure the schedule is completed. For further information see Guidance Vaccination of individuals with uncertain or incomplete immunisation status. **Prevention of secondary cases of Men B disease** Vaccination for the prevention of secondary cases of MenB disease should be given in accordance with recommendations from the UKHSA Health Protection Team and informed by the Guidance for Public Health Management of Meningococcal Disease in the UK.
Duration of treatment	See dose section above
Quantity to be administered	Single dose of 0.5ml per administration
Supplies	Centrally purchased vaccines for the national immunisation programme can only be ordered via ImmForm. Vaccines for use for the national immunisation programme or for the prevention of secondary cases of MenB disease are provided free of charge. Vaccines for private prescriptions, occupational health use or travel or for individuals going to reside abroad are NOT provided free of charge and should be ordered from the manufacturer or wholesalers. Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see Green Book Chapter 3). Also refer to All Wales Advisory document on Ordering Storage and Handling of Vaccines.

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 Vaccine Incident Guidance and All Wales Advisory document on Ordering Storage and Handling of Vaccines. See 'MMP 427 Safe and Secure Management of Refrigerated Medicines and Vaccines SOP' for details of actions required in the event of a fridge temperature excursion. Any loss of vaccines due to expiry date or fridge failure/breaches in cold chain must be reported on ImmForm, to PTHB Immunisation co-ordinator (Powys.Immunisations@wales.nhs.uk), and via PTHB Datix reporting system Once for Wales Reporting System.
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: Health Technical Memorandum 07-01: Safe and sustainable management of healthcare waste (NHSE) and guidance in the Welsh Health Technical Memorandum 07-01 Safer management of healthcare waste.
Drug interactions	Individuals with impaired immune responsiveness, whether due to the use of immunosuppressive therapy, a genetic disorder, or other causes, may have reduced antibody response to active immunisation. Vaccination is recommended even if the antibody response may be limited. 4CMenB can be given at the same time as the other vaccines. A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk

Identification and management of adverse reactions	The most common local and systemic adverse reactions observed 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 common 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. **NB. For premature babies, check with a doctor or NNU outreach to confirm the correct dose of paracetamol to be given, according to the infant's weight at the time of vaccination.** 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 16 weeks 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.
	
	Report any suspected adverse reactions to a doctor.
	
	In case of an acute anaphylactic reaction occurring, adequate treatment provision must be available for immediate use:
	Anaphylaxis and resuscitation equipment including adrenaline (1 in 1000) injection and a working telephone. In case of anaphylaxis:-
	• Refer to adrenaline (epinephrine) PGD0017 and anaphylaxis procedure
	  • Request medical assistance urgently. If the GP is not immediately available dial 999 to transfer to A&E
	  • Ensure reaction is fully documented in patient notes
	  • Ensure all patient records are marked **ALLERGIC TO Meningococcal group B Vaccine (rDNA, component, adsorbed), 4CMenB** (Bexsero®)
	  • The patient may be advised to wear a MedicAlert or similar device to alert other healthcare providers
	Report via Datix Once for Wales Reporting system

Reporting procedure of adverse reactions	As with all vaccines, healthcare professionals and individuals/parents/carers are encouraged to 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. Any adverse reaction to a vaccine should be documented in the individual's record and the individual's clinician should be informed. All significant adverse drug reactions and any administration errors must be recorded via the Once for Wales Reporting System.
Written information to be given to patient or carer	Offer marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine. For resources in accessible formats and alternative languages, please visit Home - Health Publications. Where applicable, inform the individual/parent/carer that the PIL with large print, Braille or audio CD can be ordered from the manufacturer (see electronic medicines compendium). 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 • Using paracetamol to prevent and treat fever after MenB vaccination (translated leaflets are also available to download from the health publications website) Available from: www.gov.uk/government/collections/immunisation Further information for printing and website links suitable for patients can be found on the Public Health Wales intranet site Public Health Wales Immunisation and Vaccine Preventable Disease Programme, NHS 111 Wales and Health Information Resources.
Patient advice and 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 individuals who are immunosuppressed or individuals with HIV that the immunogenicity of the vaccine could be reduced. 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 and additional information	Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a telephone at the time of vaccination. It is important that premature infants have their immunisations at the appropriate chronological age, according to the schedule. As the benefit of vaccination is high in premature and very premature infants, vaccination should not be withheld or delayed. The occurrence of apnoea following vaccination is especially increased in infants who were born very prematurely (see Cautions). Meningococcal vaccines may be given to pregnant women when clinically indicated. There is no evidence of risk from vaccinating pregnant women or those who are breast-feeding with inactivated bacterial vaccines. **Immunosuppression and HIV infection** Individuals with immunosuppression and human immunodeficiency virus (HIV) infection (regardless of CD4 count) should be given meningococcal vaccines in accordance with the routine schedule (see Cautions). For further information on preventing secondary cases see the UK Health Security Agency Guidance for Public

	Health Management of Meningococcal Disease in the UK.
Records	Record consultation details as required by local procedures. In addition, record: • that valid informed consent was given or a decision to vaccinate made in the individual's best interests in accordance with the Mental Capacity Act 2005. Record name of representative who gave consent if appropriate. • name of individual, address, date of birth and GP with whom the individual is registered • medical and drug history taken, including any allergies and previous adverse events • printed name and signature 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 • any reasons for exclusion or referral, including actions taken • advice given, including advice received from medical cover and/or advice given if excluded or declines immunisation • details of any adverse drug reactions and actions taken • administered via PGD, record PGD title and version number 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 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. If a vaccine is administered to a child up to 19 years of age, forward a notification of vaccination given to Child Health Department using the appropriate

	documentation/pathway as required by any local or contractual arrangement (based in Brecon Hospital for under 5 years and Llandrindod Hospital for school age). 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, Chapter 7, and Chapter 22 • Bexsero® Summary of Product Characteristics, GlaxoSmithKline UK. Updated 21 July 2023. Bexsero Meningococcal Group B vaccine for injection in pre-filled syringe - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk) • Meningococcal B (MenB) vaccination programme. https://www.gov.uk/government/collections/meningococcal-b-menb-vaccination-programme • Guidance for Public Health Management of Meningococcal Disease in the UK Health Security Agency https://www.gov.uk/government/publications/meningococcal-disease-guidance-on-public-health-management • Vaccination of individuals with uncertain or incomplete immunisation status. UK Health Security Agency. Updated 30 August 2024. https://www.gov.uk/government/publications/vaccination-of-individuals-with-uncertain-or-incomplete-immunisation-status • Meningococcal B: vaccine information for healthcare professionals https://www.gov.uk/government/publications/meningococcal-b-vaccine-information-for-healthcare-professionals • Using paracetamol to prevent and treat fever after MenB vaccination guidance updated 24 November 2022 www.gov.uk/government/publications/menb-vaccine-and-paracetamol/using-paracetamol-to-prevent-and-treat-fever-after-menb-vaccination • Guidance; changes to the routine childhood schedule letter, 30 April 2025 www.gov.uk/government/publications/changes-to-the-routine-childhood-schedule-letter • JCVI minutes, 11 February 2025 www.gov.uk/government/groups/joint-committee-on-vaccination-and-immunisation#meetings-agendas-and-minutes **General** • Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. NHSE

	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 • All Wales Advisory document on Ordering Storage and Handling of Vaccines 7th Edition, September 2017. • Welsh Health Technical Memorandum 07-01 Safer management of healthcare waste. Available from: https://nwssp.nhs.wales/ourservices/specialist-estates-services/specialist-estates-services-documents/whtms-library/whtm-07-01-safe-management-of-healthcare-waste-pdf/

Appendix A – Staff Accredited to use the Patient Group Direction

Authorising Manager: I confirm that the practitioners named below have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of Powys Teaching Health Board or a Powys GP practice for the named healthcare professionals below who have signed the PGD to work under it. *The authorising manager must use the competency checklist (below).*

Practitioner: By signing this PGD you are indicating that you agree to its contents and that you will work within it. PGDs do not remove inherent professional obligations or accountability. It is the responsibility of each professional to practice 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.

Printed name of health professional	Signature of health professional	Printed name of senior representative authorising health professional	Signature of senior representative authorising health professional	Date

The authorising manager should retain a copy of the list, which will be requested for audit purposes. This list should be kept by PTHB (or the provider organisation adopting an authorised version of the PGD) for 25 years after the PGD expires.

The healthcare professional should retain a copy of the document after signing.

Competency check list for manager or senior team lead to use as part of the authorising process for health professionals to work to a Patient Group Direction (PGD). Review of authorisation will take place on each PGD update and at the individual's annual PADR.

Name: **Role:**		Sign / Initial	Further training identified (Y/N) Specify in " comments "	Comments
1	The PGD sign off is for the following PGD:(document the exact title and PGD number) _____			
2	We have discussed the expiry of the PGD and are using a version accessed electronically			
3	The member of staff has the appropriate qualifications and professional registration as outlined in the PGD			
4	The Patient Group Direction has been read in full by the staff member			
5	The identified training has been completed as specified in the PGD and is in date			
6	We have discussed some examples of inclusion criteria and exclusion criteria			
7	The staff member is confident in the administration method and doses			

Staff member print & sign name		Date
Manager or senior team lead to print & sign name		Date