



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

Meningococcal Group B Vaccine Risk Groups Patient Group Direction (PGD)

for the administration of

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

by registered healthcare practitioners

to

individuals from 2 years of age, with an underlying medical condition which puts them at increased risk from *Neisseria meningitidis* group B

in Powys Teaching Health Board

Version number: PGD 0199 A

Change history

Version number	Change details	Date
PGD 0199	New issue according to UKHSA PGD template v4.00	28/02/2023
PGD 0199 A	Review issue in line with UKHSA PGD template v5.0 to: <ul style="list-style-type: none"> • 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 the formulation • update references 	28/02/2025

This Powys Teaching Health Board (PTHB) PGD is based on the UKHSA template v5.0 developed by the following on behalf of the UKHSA and peer reviewed by the UKHSA Immunisations PGD Expert Panel in accordance with the UKHSA PGD 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
Pharmacist (Lead Author)	Suki Hunjunt Lead Pharmacist Immunisation Programmes, UKHSA
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Registered Nurse (Chair of Expert Panel)	David Green Nurse Consultant for Immunisation Programmes UKHSA

Expert Panel:

Nicholas Aigbogun	Consultant in Communicable Disease Control, Yorkshire and Humber Health Protection Team, UKHSA
Gayatri Amrithalingam	Consultant Epidemiologist, Immunisation Programmes, UKHSA
Jessica Baldasera	Health Protection Practitioner, North East Health Protection Team, Regions Directorate, UKHSA
Alison Campbell	Screening and Immunisation Coordinator, Public Health Commissioning NHS England (NHSE) Midlands
Naveen Dosanjh	Senior Clinical Advisor - Medicines and Pharmacy Vaccinations Sub-Directorate - NHSE
Jane Freeguard	Deputy Director of Vaccination – Medicines and Pharmacy NHS England
Rosie Furner	Advanced Specialist Pharmacist - Medicines Governance, Specialist Pharmacist Services (SPS)
Ed Gardner	Advanced Paramedic Practitioner/Emergency Care Practitioner, Medicines Manager, Proactive Care Lead
Greta Hayward	Consultant Midwife – Immunisation Programmes, UKHSA
Jacqueline Lamberty	Medicines Governance Consultant Lead Pharmacist, UKHSA
Shamez Ladhani	Paediatric Infectious Disease Consultant, UKHSA
Elizabeth Lockett	Senior Screening and Immunisation Manager NHSE South West
Vanessa MacGregor	Consultant in Communicable Disease Control, East Midlands Health Protection Team, UKHSA
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Tushar Shah	Lead Pharmacy Adviser, NHSE London

PGD Authorisation

Name	Job title and organisation	Signature	Date
Senior doctor Dr Kate Wright	Lead doctor for PTHB	DocuSigned by: <i>Kate Wright</i> 1F267952823F473...	2/4/2025
Chief Pharmacist Jacqui Seaton	Chief Pharmacist for PTHB	Signed by: <i>Jacqueline Seaton</i> 71E8089DE3634C4...	2/4/2025
Clinical Governance Lead Amanda Edwards	Clinical Governance Lead for PTHB- Assistant Director for Innovation and Improvement	DocuSigned by: <i>Amanda Edwards</i> 74A4E51A42E9473...	2/6/2025
Senior representative of professional group using the PGD Claire Roche	Executive Director of Nursing and Midwifery for PTHB	DocuSigned by: <i>Claire Roche</i> F07413E114E04B1...	2/4/2025

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 PTHB 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

¹ This includes any relevant amendments to legislation.

Reference Number: PGD 0199 A

Valid from: 28/02/2025

Review Date: 01/09/2027

Expiry Date: 28/02/2028

subsequent versions of this PGD should be directed to:
Info.MedicinesManagement.Powys@wales.nhs.uk

PGD adoption by the provider

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

1. Characteristics of staff

<p>Qualifications and professional registration</p>	<p>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.</p> <p>Registered professional with one of the following bodies:</p> <ul style="list-style-type: none"> • 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 and physiotherapists currently registered with the Health and Care Professions Council (HCPC) <p>The practitioners above must also fulfil the Additional requirements detailed below.</p> <p>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.</p>
<p>Additional requirements</p>	<p>Additionally, practitioners:</p> <ul style="list-style-type: none"> • 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 Patient Group Directions training (available via eLfh PGD eLearning programme. 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

	<p>Infectious Disease (The 'Green Book'), and national and local immunisation programmes</p> <ul style="list-style-type: none"> • 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 <p>The individual practitioner must be authorised by name, under the current version of this PGD before working according to it.</p>
<p>Continued training requirements</p>	<p>Updating at least every 2 years on the administration of Meningococcal group B (rDNA, component, adsorbed), 4CMenB vaccine.</p> <p>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).</p> <p>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.</p>

	<p>Practitioners should be constantly alert to any subsequent recommendations from Welsh Government and/or Public Health Wales and/or NHS Wales and the UKHSA and other sources of medicines information.</p> <p>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.</p> <p>Compliance with all mandatory NHS training (if relevant).</p> <p>It is the responsibility of the healthcare professional to maintain their own competency to practice within this PGD.</p>
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2. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	<p>Indicated for the active immunisation of individuals, from 2 years of age, with an underlying medical condition which puts them at increased risk from <i>Neisseria meningitidis</i> group B, in accordance with the recommendations given in Chapter 7 and Chapter 22 of Immunisation Against Infectious Disease: 'The Green Book'.</p> <p>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.</p>
Criteria for inclusion	<p>Individuals from 2 years of age who are at increased risk of invasive meningococcal infection with asplenia, splenic dysfunction or complement disorders (including those on, or to commence, complement inhibitor treatment such as eculizumab).</p> <p>Note: This includes individuals with medical conditions accompanied by functional hyposplenism (such as sickle cell disease) but does not include those with coeliac disease unless concurrent hyposplenism has been diagnosed.</p> <ul style="list-style-type: none"> • Medical and drug history taken, no reason for exclusion

	<ul style="list-style-type: none"> • 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 <p>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).</p>
<p>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)</p>	<p>Individuals for whom no valid consent has been received.</p> <p>Individuals who:</p> <ul style="list-style-type: none"> • are less than 2 years of age • 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 use, 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) • have completed the routine 2+1 schedule for 4CMenB or received two doses of 4CMenB after their first birthday <p>Refer to sections action to be taken if the patient is excluded and action to be taken if the patient or carer declines treatment.</p>
<p>Cautions including any relevant action to be taken</p>	<p>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.</p> <p>The immunogenicity of the vaccine could be reduced in individuals who are immunosuppressed and in individuals with HIV (see Special Considerations below). However, vaccination should proceed in accordance with national recommendations (see Chapter 22).</p> <p>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-</p>

	<p>clonic limb movements during recovery. It is important that procedures are in place to avoid injury from faints.</p> <p>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)</p> <p>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:</p> <ul style="list-style-type: none"> • to generic email address: PowysTHB.Safeguarding@wales.nhs.uk <p>and</p> <ul style="list-style-type: none"> • Central Safeguarding number: 01686 252806 • Out of hours: 0345 0544847 <p>Advice can also be sought from local Safeguarding leads</p>
<p>Action to be taken if the patient is excluded</p>	<p>If aged less than 2 years provide 4CMenB in accordance with the national routine immunisation schedule (see Meningococcal Group B Vaccine PGD0092).</p> <p>Individuals requiring vaccination for occupational health reasons, should be referred to their occupational health service provider for vaccination.</p> <p>There are currently no recommendations for 4CMenB vaccination for individuals who are travelling or going to reside abroad.</p> <p>Individuals suffering from 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.</p> <p>Individuals who have completed the routine 2+1 schedule for 4CMenB or received two doses of 4CMenB after their first birthday do not require further immunisation in accordance with the Green Book Chapter 22.</p>

	<p>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.</p> <p>The risk to the individual of not being immunised must be taken into account.</p> <p>Document the reason for exclusion and any action taken in the individual's clinical records.</p> <p>Explain reason to patient / carer.</p> <p>Inform or refer to the individual's GP or a prescriber as appropriate.</p>
<p>Action to be taken if the patient or carer declines treatment</p>	<p>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.</p> <p>Advise the individual/parent/carer about the protective effects of the vaccine, the risks of infection and potential complications of disease.</p> <p>Document advice given and the decision reached.</p> <p>Inform or refer to the individual's GP or a prescriber as appropriate.</p> <p>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.</p>
<p>Arrangements for referral for medical advice</p>	<p>Refer to GP, paediatrician or consultant in communicable disease control (CCDC) for clinical advice as necessary.</p> <p>Document any advice given.</p>

3. Description of treatment

Name, strength and formulation of drug	<p>Meningococcal group B vaccine (rDNA, component, adsorbed), 4CMenB:</p> <p>Bexsero® suspension for injection, 0.5ml, in a pre-filled syringe</p> <p>One dose of 0.5ml suspension contains:</p> <table border="0" style="width: 100%;"> <tr> <td style="padding-right: 20px;">Recombinant Neisseria meningitidis group B NHBA fusion protein</td> <td style="text-align: right;">50micrograms</td> </tr> <tr> <td>Recombinant Neisseria meningitidis group B NadA protein</td> <td style="text-align: right;">50micrograms</td> </tr> <tr> <td>Recombinant Neisseria meningitidis group B fHbp fusion protein</td> <td style="text-align: right;">50micrograms</td> </tr> <tr> <td>Outer membrane vesicles (OMV) from Neisseria meningitidis group B strain NZ98/254 measured as amount of total protein containing the PorA P1.4</td> <td style="text-align: right;">25micrograms</td> </tr> </table>	Recombinant Neisseria meningitidis group B NHBA fusion protein	50micrograms	Recombinant Neisseria meningitidis group B NadA protein	50micrograms	Recombinant Neisseria meningitidis group B fHbp fusion protein	50micrograms	Outer membrane vesicles (OMV) from Neisseria meningitidis group B strain NZ98/254 measured as amount of total protein containing the PorA P1.4	25micrograms
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Legal category	Prescription Only Medicine (POM)								
Black triangle▼	No.								
Off-label use	<p>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'.</p> <p>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.</p> <p>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.</p>								
Route and method of administration	4CMenB is given as a 0.5ml dose by intramuscular injection usually into the deltoid muscle region of the upper arm in older individuals.								

	<p>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 (see Green Book Chapter 4).</p> <p>The vaccine must not be injected intravenously or intradermally and must not be mixed with other vaccines in the same syringe.</p> <p>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).</p> <p>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.</p> <p>Before use, the pre-filled syringe should be well shaken in order to form a homogeneous suspension.</p> <p>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.</p> <p>The vaccine's SPC provides further guidance on administration and is available from the electronic Medicines Compendium website.</p>
<p>Dose and frequency of administration</p>	<p>Individuals over 2 years of age should receive vaccination with 4CMenB in accordance with Chapter 7 of 'The Green Book':</p> <p>First diagnosed or presenting under 1 year of age Children should be fully immunised according to the national schedule (refer to Meningococcal Group B Vaccine PGD0092)</p> <p>First diagnosed or presenting from 2 years to under 10 years of age Check individuals are immunised according to the national schedule. If they have not received the routine</p>

	<p>2+1 schedule for 4CMenB, ensure they have received two doses of MenB 8 weeks apart since first birthday</p> <p>First diagnosed at age 10 years and over Older children and adults should receive one dose of 4CMen B, regardless of previous vaccination, and an additional 4CMenB vaccine dose 4 weeks after the first dose</p> <p>Individuals who receive eculizumab therapy Individuals should be vaccinated at least two weeks prior to commencement of therapy. If it cannot be given before initiating treatment, then it can be given at any time. This advice applies to all newly diagnosed individuals.</p>
Duration of treatment	See dose section above.
Quantity to be administered	Single dose of 0.5ml per an administration.
Supplies	<p>Centrally purchased vaccines can be ordered via ImmForm for use under this PGD and are provided free of charge.</p> <p>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/wholesalers.</p> <p>Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see Green Book Chapter 3).</p> <p>Also refer to All Wales Advisory document on Ordering Storage and Handling of Vaccines.</p>
Storage	<p>Store between +2°C to +8°C.</p> <p>Store in original packaging in order to protect from light.</p> <p>Do not freeze.</p> <p>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 All Wales Advisory document on Ordering Storage</p>

	<p>and Handling of Vaccines and Vaccine Incident Guidance.</p> <p>Protocols for the storage and handling of vaccines should be followed to prevent vaccine wastage.</p> <p>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.</p> <p>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.</p>
Disposal	<p>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.</p>
Drug interactions	<p>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.</p> <p>4CMenB can be given at the same time as the other vaccines.</p> <p>A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk</p>
Identification and management of adverse reactions	<p>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.</p>

	<p>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 ($\geq 38\text{ }^{\circ}\text{C}$) and irritability and the development of a rash.</p> <p>Rarely, in infants and children (up to 10 years of age), seizures (including febrile seizures), pallor, eczema and fever ($\geq 40\text{ }^{\circ}\text{C}$) can occur (see Chapter 22).</p> <p>A detailed list of adverse reactions is available in the vaccine's SPC, which is available from the electronic Medicines Compendium website.</p> <p>Report any suspected adverse reactions to a doctor.</p> <p>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.</p> <p>In case of anaphylaxis: -</p> <ul style="list-style-type: none"> • Refer to adrenaline (epinephrine) PGD0017 and anaphylaxis procedure <ul style="list-style-type: none"> • 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 • 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
<p>Reporting procedure of adverse reactions</p>	<p>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 MHRA Yellow Card in the Google Play or Apple App Store.</p>

	<p>Any adverse reaction to a vaccine should be documented in the individual's record and the individual's GP should be informed.</p> <p>All significant adverse drug reactions and any administration errors must be recorded via the Once for Wales Reporting System.</p>
<p>Written information to be given to patient or carer</p>	<p>Offer marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine.</p> <p>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).</p> <p>Immunisation promotional material may be provided as appropriate:</p> <ul style="list-style-type: none"> • Splenectomy leaflet • Documents relating to the Meningococcal B (MenB) vaccination programme <p>Available from: www.gov.uk/government/collections/immunisation</p> <p>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.</p>
<p>Patient advice and follow up treatment</p>	<p>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.</p> <p>Inform individuals who are immunosuppressed or individuals with HIV that the immunogenicity of the vaccine could be reduced.</p> <p>Inform individual/parent/carer of possible side effects and their management.</p> <p>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.</p>

	<p>When applicable, advise individual/parent/carer when the subsequent vaccine dose is due.</p> <p>When administration is postponed advise the individual/parent/carer when to return for vaccination.</p>
<p>Special considerations and additional information</p>	<p>Medical conditions such as coeliac disease, sickle cell disease and other haemoglobinopathies may be accompanied by functional hyposplenism. However, hyposplenism in coeliac disease is uncommon in children, and the prevalence correlates with the duration of exposure to gluten. Therefore, individuals diagnosed with coeliac disease early in life and well managed are unlikely to require additional MenB vaccine (see Chapter 7). Only those with known splenic dysfunction should be vaccinated in accordance with this PGD.</p> <p>Individuals receiving complement inhibitor therapy (eculizumab) are at heightened risk of meningococcal infection and should be vaccinated with both MenACWY and MenB vaccines (see MenACWY Risk Groups PGD0179), ideally at least two weeks prior to commencement of therapy.</p> <p>Prophylactic paracetamol is not indicated when 4CMenB is given to children from 2 years of age but may be used to manage a fever should one occur.</p> <p>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.</p> <p>Wherever possible, immunisation or boosting of immunosuppressed or HIV-positive individuals should be either carried out before immunosuppression occurs or deferred until an improvement in immunity has been seen. The optimal timing for any vaccination should be based upon a judgement about the relative need for rapid protection and the likely response. For individuals due to commence immunosuppressive treatments, inactivated vaccines should ideally be administered at least two weeks before commencement. In some cases, this will not be possible and therefore vaccination may be carried out at any time and re-immunisation considered after treatment is finished and recovery has occurred. For further information on vaccination in individuals with immunosuppression, see Chapter 7.</p>

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 or advice given if excluded or declines immunisation
- details of any adverse drug reactions and actions taken
- administered via PGD, record PGD 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 Services 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

	<p>under 5 years and Llandrindod Hospital for school age).</p> <p>A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.</p>
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4. Key references

<p>Key references</p>	<p>Meningococcal B Vaccination</p> <ul style="list-style-type: none"> • 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) • Immunisation Against Infectious Disease: The Green Book, Chapter 22 last updated 17 May 2022 and Chapter 7, last updated 10 January 2020. www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book • Meningococcal B: vaccine information for healthcare professionals www.gov.uk/government/publications/meningococcal-b-vaccine-information-for-healthcare-professionals <p>General</p> <ul style="list-style-type: none"> • Health Technical Memorandum 07-01: Safe Management of Healthcare Waste, NHSE www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-hm-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
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	<ul style="list-style-type: none">• 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. 2013. 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/
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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

Please send a copy of this completed form to individual’s line manager and to the staff member, in conjunction with the PGD Appendix A authorisation sheet. A copy of this form should also be kept by service lead in the training file.