



Publications gateway number: GOV-13818

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

This PGD is for the administration of meningococcal group B vaccine (rDNA, component, adsorbed) (4CMenB) to individuals, from 2 years of age, with an underlying medical condition which puts them at increased risk from *Neisseria meningitidis* group B.

This PGD is for the administration of 4CMenB by registered healthcare practitioners identified in [Section 3](#), subject to any limitations to authorisation detailed in [Section 2](#).

Reference no: MenB Risk Groups PGD  
Version no: v4.00  
Valid from: 28 February 2023  
Review date: 1 September 2024  
Expiry date: 28 February 2025

**The UK Health Security Agency (UKHSA) has developed this PGD to facilitate the delivery of publicly funded immunisation in England in line with national recommendations.**

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

Authorising organisations must not alter, amend or add to the clinical content of this document (sections 4, 5 and 6); such action will invalidate the clinical sign-off with which it is provided. In addition, authorising organisations must not alter section 3 'Characteristics of staff'. Only sections 2 and 7 can be amended within the designated editable fields provided.

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 completing Section 2 for 8 years after the PGD expires if the PGD relates to adults only and for 25 years after the PGD expires if the PGD relates to children only, or adults and children. Provider organisations adopting authorised versions of this PGD should also retain copies for the periods specified above.

**Individual practitioners must be authorised by name, under the current version of this PGD before working according to it.**

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. Current versions of the UKHSA PGD templates for authorisation can be found from:

[www.gov.uk/government/collections/immunisation-patient-group-direction-pgd](http://www.gov.uk/government/collections/immunisation-patient-group-direction-pgd)

Any concerns regarding the content of this PGD should be addressed to:  
[immunisation@ukhsa.gov.uk](mailto:immunisation@ukhsa.gov.uk)

Enquiries relating to the availability of organisationally authorised PGDs and subsequent versions of this PGD should be directed to: The Screening and Immunisation Team, NHS England – Midlands, responsible for your area:

<sup>1</sup> This includes any relevant amendments to legislation

**East** (Derbyshire & Nottinghamshire and Leicester, Leicestershire, Rutland, Lincolnshire & Northamptonshire) [england.emids-imms@nhs.net](mailto:england.emids-imms@nhs.net)

**West** (Shropshire, Staffordshire, Birmingham, Coventry, Dudley, Herefordshire, Sandwell, Solihull, Walsall, Warwickshire, Wolverhampton & Worcestershire)  
[england.wmid-imms@nhs.net](mailto:england.wmid-imms@nhs.net)


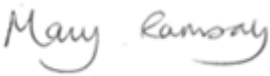

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## Change history

Version number	Change details	Date
V1.00	New MenB Risk Groups PHE PGD Template	8 December 2016
V2.00	MenB Risk Groups PGD amended to: <ul style="list-style-type: none"> <li>• include additional healthcare practitioners in Section 3</li> <li>• remove black triangle</li> <li>• refer to vaccine incident guidelines in off-label and storage sections</li> <li>• include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates</li> </ul>	21 December 2018
V3.00	MenB Risk Groups PGD amended to: <ul style="list-style-type: none"> <li>• update off-label and dose section to reflect changes in the summary of product characteristics, which now includes administration at not less than one month interval from 2 years of age</li> <li>• exclude those who have completed a course of 4CMenB</li> <li>• include a caution relating to immunosuppressed individuals</li> <li>• update adverse drug reactions section</li> <li>• clarify supplies section</li> <li>• include rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates</li> </ul>	28 January 2021
V4.00	MenB Risk Groups PGD amended to: <ul style="list-style-type: none"> <li>• include minor rewording of standard text, layout and formatting changes for clarity and consistency with organisation change and other UKHSA PGDs</li> <li>• amend NHS England and NHS Improvement (NHSE) to NHS England (NHSE) following completion of merger on 1 July 2022</li> <li>• align the management of anaphylaxis with other UKHSA PGDs in cautions section</li> <li>• add the formulation and strength to the name of the drug</li> <li>• clarify dose and frequency for 2-10years, over 10 years and individuals who are receiving eculizumab therapy</li> <li>• update drug interactions and adverse reaction sections</li> <li>• include cohorts for whom supplies are not free</li> <li>• update references</li> </ul>	7 December 2022

## 1. PGD development

This PGD has been developed by the following health professionals on behalf of the UKHSA:

Developed by:	Name	Signature	Date
<b>Pharmacist</b> (Lead Author)	Suki Hunjunt Lead Pharmacist Immunisation Services, Immunisation and Vaccine Preventable Diseases Division, UKHSA		15 December 2022
<b>Doctor</b>	Mary Ramsay Consultant Epidemiologist, Immunisation and Vaccine Preventable Diseases Division, UKHSA		15 December 2022
<b>Registered Nurse</b> (Chair of Expert Panel)	David Green Nurse Consultant for Immunisation, Immunisation and Vaccine Preventable Diseases Division, UKHSA		15 December 2022

This PGD has been peer reviewed by the UKHSA Immunisations PGD Expert Panel in accordance with the UKHSA PGD Policy. It has been approved by the UKHSA Medicines Governance Group and ratified by the UKHSA Clinical Quality and Oversight Board.

### Expert Panel

Nicholas Aigbogun	Consultant in Communicable Disease Control, Yorkshire and Humber Health Protection Team, UKHSA
Gayatri Amrithalingam	Consultant Epidemiologist, Immunisation and Vaccine Preventable Diseases Division, UKHSA
Sarah Dermont	Clinical Project Coordinator and Registered Midwife, NHS Infectious Diseases in Pregnancy Screening Programme, NHS England (NHSE)
Ed Gardner	Advanced Paramedic Practitioner/Emergency Care Practitioner, Medicines Manager, Proactive Care Lead
Jacqueline Lamberty	Lead Pharmacist, Medicines Governance, UKHSA
Michelle Jones	Principal Medicines Optimisation Pharmacist, Bristol North Somerset and South Gloucestershire Integrated Care Board
Shamez Ladhani	Paediatric Infectious Disease Consultant, UKHSA
Elizabeth Lockett	Senior Screening & Immunisation Manager NHSE South West
Vanessa MacGregor	Consultant in Communicable Disease Control, East Midlands Health Protection Team, UKHSA
Alison Mackenzie	Consultant in Public Health Medicine, Screening and Immunisation Lead, NHSE South West
Lesley McFarlane	Lead Immunisation Nurse Specialist Immunisation and Vaccine Preventable Diseases Division, UKHSA
Gill Marsh	Principal Screening and Immunisation Manager, NHSE North West
Tushar Shah	Lead Pharmacy Advisor, NHSE London


## 2. Organisational authorisations

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.

NHS England – Midlands authorises this PGD for use by the services or providers listed below:

<b>Authorised for use by the following organisations and/or services</b>
Primary care services and/or all organisations commissioned or contracted by NHS England and NHS Improvement – Midlands to provide immunisation services in: Derbyshire, Nottinghamshire, Leicestershire, Lincolnshire, Northamptonshire, Shropshire, Staffordshire, Birmingham, Coventry, Dudley, Herefordshire, Sandwell, Solihull, Walsall, Warwickshire, Wolverhampton and Worcestershire
<b>Limitations to authorisation</b>
None

<b>Organisational approval (legal requirement)</b>			
<b>Role</b>	<b>Name</b>	<b>Sign</b>	<b>Date</b>
Director of Primary Care and Public Health Commissioning – NHS England - Midlands	Trish Thompson		13.01.2023

<b>Additional signatories according to locally agreed policy</b>			
<b>Role</b>	<b>Name</b>	<b>Sign</b>	<b>Date</b>

Local enquiries regarding the use of this PGD may be directed to The Screening and Immunisation Team, NHS England – Midlands, responsible for your area:

**East** (Derbyshire & Nottinghamshire and Leicester, Leicestershire, Rutland, Lincolnshire & Northamptonshire) [england.emids-imms@nhs.net](mailto:england.emids-imms@nhs.net)

**West** (Shropshire, Staffordshire, Birmingham, Coventry, Dudley, Herefordshire, Sandwell, Solihull, Walsall, Warwickshire, Wolverhampton & Worcestershire) [england.wmid-imms@nhs.net](mailto:england.wmid-imms@nhs.net)

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Section 7 provides a practitioner authorisation sheet. Individual practitioners must be authorised by name to work to this PGD. Alternative practitioner authorisation sheets may be used where appropriate in accordance with local policy but this should be an individual agreement or a multiple practitioner authorisation sheet as included at the end of this PGD.

### 3. Characteristics of staff

<p><b>Qualifications and professional registration</b></p>	<p>Registered professional with one of the following bodies:</p> <ul style="list-style-type: none"> <li>nurses and midwives currently registered with the Nursing and Midwifery Council (NMC)</li> <li>pharmacists currently registered with the General Pharmaceutical Council (GPhC) (Note: This PGD is not relevant to privately provided community pharmacy services)</li> <li>paramedics and physiotherapists currently registered with the Health and Care Professions Council (HCPC)</li> </ul> <p>The practitioners above must also fulfil the <a href="#">Additional requirements</a> detailed below.</p> <p>Check <a href="#">Section 2 Limitations to authorisation</a> to confirm whether all practitioners listed above have organisational authorisation to work under this PGD.</p>
<p><b>Additional requirements</b></p>	<p>Additionally practitioners:</p> <ul style="list-style-type: none"> <li>must be authorised by name as an approved practitioner under the current terms of this PGD before working to it</li> <li>must have undertaken appropriate training for working under PGDs for supply/administration of medicines</li> <li>must be competent in the use of PGDs (see <a href="#">NICE Competency framework</a> for health professionals using PGDs)</li> <li>must be familiar with the vaccine product and alert to changes in the Summary of Product Characteristics (SPC), Immunisation Against Infectious Disease (<a href="#">‘The Green Book’</a>), and national and local immunisation programmes</li> <li>must have undertaken training appropriate to this PGD as required by local policy and in line with the <a href="#">National Minimum Standards and Core Curriculum for Immunisation Training</a></li> <li>must be competent to undertake immunisation and to discuss issues related to immunisation</li> <li>must be competent in the handling and storage of vaccines, and management of the cold chain</li> <li>must be competent in the recognition and management of anaphylaxis</li> <li>must have access to the PGD and associated online resources</li> <li>should fulfil any additional requirements defined by local policy</li> </ul> <p><b>The individual practitioner must be authorised by name, under the current version of this PGD before working according to it.</b></p>
<p><b>Continued training requirements</b></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 should be constantly alert to any subsequent recommendations from the UKHSA and/or NHSE 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>

#### 4. Clinical condition or situation to which this PGD applies

<p><b>Clinical condition or situation to which this PGD applies</b></p>	<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 <a href="#">Chapter 7</a> and <a href="#">Chapter 22</a> of Immunisation Against Infectious Disease: 'The Green Book'.</p>
<p><b>Criteria for inclusion</b></p>	<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>
<p><b>Criteria for exclusion<sup>2</sup></b></p>	<p>Individuals for whom no valid consent has been received</p> <p>Individuals who:</p> <ul style="list-style-type: none"> <li>• are less than 2 years of age</li> <li>• have had a confirmed anaphylactic reaction to a previous dose of the vaccine or to any constituent or excipient of the vaccine including kanamycin</li> <li>• require vaccination for occupational health use, travel or going to reside abroad.</li> <li>• have a history of anaphylactic allergy to latex</li> <li>• are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation)</li> <li>• have completed the routine 2+1 schedule for 4CMenB or received two doses of 4CMenB after their first birthday</li> </ul>
<p><b>Cautions including any relevant action to be taken</b></p>	<p>Facilities for management of anaphylaxis should be available at all vaccination sites (see <a href="#">Chapter 8</a> of the Green Book) and advice issued by the <a href="#">Resuscitation Council UK</a>.</p> <p>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.</p> <p>The immunogenicity of the vaccine could be reduced in individuals who are immunosuppressed and in individuals with HIV. However, vaccination should proceed in accordance with national recommendations (see <a href="#">Chapter 22</a>).</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-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from faints.</p>

<sup>2</sup> 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><b>Action to be taken if the patient is excluded</b></p>	<p>If aged less than 2 years provide 4CMenB in accordance with the national routine immunisation schedule (see <a href="#">Meningococcal Group B Vaccine PGD</a>).</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 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. Refer to appropriate clinician for assessment of risk: benefit – a PSD will be required.</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 <a href="#">Chapter 22</a>.</p> <p>Seek appropriate advice from the local Screening and Immunisation Team, local Health Protection 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>Inform or refer to the individual’s GP or a prescriber as appropriate.</p>
<p><b>Action to be taken if the patient or carer declines treatment</b></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.</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><b>Arrangements for referral for medical advice</b></p>	<p>As per local policy</p>

## 5. Description of treatment

<b>Name, strength and formulation of drug</b>	<p>Meningococcal group B vaccine (rDNA, component, adsorbed), 4CMenB:</p> <p>Bexsero<sup>®</sup> suspension for injection, 0.5ml, in a pre-filled syringe</p> <p>One dose of 0.5ml suspension contains:</p> <table border="0"> <tr> <td>Recombinant Neisseria meningitidis group B NHBA fusion protein</td> <td>50micrograms</td> </tr> <tr> <td>Recombinant Neisseria meningitidis group B NadA protein</td> <td>50micrograms</td> </tr> <tr> <td>Recombinant Neisseria meningitidis group B fHbp fusion protein</td> <td>50micrograms</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
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Recombinant Neisseria meningitidis group B fHbp fusion protein	50micrograms						
<b>Legal category</b>	<p>Prescription only medicine (POM)</p>						
<b>Black triangle ▼</b>	<p>No.</p>						
<b>Off-label use</b>	<p>Administration by deep subcutaneous injection to individuals with a bleeding disorder is off-label administration in line with advice in <a href="#">Chapter 4</a> and <a href="#">Chapter 22</a> of 'The Green Book'.</p> <p>Vaccine should be stored according to the conditions detailed in the <a href="#">Storage section</a> below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to <a href="#">Vaccine Incident Guidance</a>. 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>						
<b>Route and method of administration</b>	<p>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> <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. 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 <a href="#">Chapter 4</a>).</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</p>						

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<b>Route and method of administration</b> (continued)	<p>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 <a href="#">electronic Medicines Compendium website</a>.</p>
<b>Dose and frequency of administration</b>	<p>Individuals over 2 years of age should receive vaccination with 4CMenB in accordance with <a href="#">Chapter 7</a> of 'The Green Book':</p> <p><b>First diagnosed or presenting under 1 year of age</b> Children should be fully immunised according to the national schedule (refer to <a href="#">Meningococcal Group B Vaccine PGD</a>)</p> <p><b>First diagnosed or presenting from 2 years to under 10 years of age</b> Check individuals are immunised according to the national schedule. If they have not received the routine 2+1 schedule for MenB, ensure they have received two doses of MenB 8 weeks apart since first birthday</p> <p><b>First diagnosed at age 10 years and over</b> Older children and adults should receive one dose of Men B, regardless of previous vaccination, and an additional MenB vaccine dose 4 weeks after the first dose</p> <p><b>Individuals who receive eculizumab therapy</b> 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>
<b>Duration of treatment</b>	<p>See dose section above.</p>
<b>Quantity to be supplied and administered</b>	<p>Single dose of 0.5ml per an administration.</p>
<b>Supplies</b>	<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 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 <a href="#">Chapter 3</a>).</p>
<b>Storage</b>	<p>Store between +2°C to +8°C. Store in original packaging in order to protect from light. 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 <a href="#">Vaccine Incident Guidance</a>.</p>
<b>Disposal</b>	<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 <a href="#">technical memorandum 07-01</a>: Safe management of healthcare waste (Department of Health, 2013).</p>

<b>Drug interactions</b>	<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>
<b>Identification and management of adverse reactions</b>	<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 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 (<math>\geq 38\text{ }^{\circ}\text{C}</math>) 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 (<math>\geq 40\text{ }^{\circ}\text{C}</math>) can occur (see <a href="#">Chapter 22</a>).</p> <p>A detailed list of adverse reactions is available in the vaccine's SPC, which is available from the <a href="#">electronic Medicines Compendium website</a>.</p>
<b>Reporting procedure of adverse reactions</b>	<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 <a href="#">Yellow Card</a> reporting scheme or search MHRA Yellow Card in the Google Play or Apple App store.</p> <p>Any adverse reaction to the vaccine should be documented in the individual's record and the individual's GP should be informed.</p>
<b>Written information to be given to patient or carer</b>	<p>Offer marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine.</p> <p>Immunisation promotional material may be provided as appropriate:</p> <ul style="list-style-type: none"> <li>• <a href="#">Splenectomy leaflet</a></li> <li>• <a href="#">Documents relating to the Meningococcal B (MenB) vaccination programme</a></li> <li>• <a href="#">Using paracetamol to prevent and treat fever after MenB vaccination</a> (translated leaflets are also available to download from the <a href="#">health publications website</a>)</li> </ul> <p>Available from: <a href="http://www.gov.uk/government/collections/immunisation">www.gov.uk/government/collections/immunisation</a></p>
<b>Patient advice and follow up treatment</b>	<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 the 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. When applicable, advise individual/parent/carer when the subsequent vaccine dose is due.</p>

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<b>Patient advice and follow up treatment</b> (continued)	When administration is postponed advise the individual/parent/carer when to return for vaccination.
<b>Special considerations and additional information</b>	<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 <a href="#">Chapter 7</a>). 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 <a href="#">MenACWY Risk Groups PGD</a>), 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>
<b>Records</b>	<p>Record:</p> <ul style="list-style-type: none"> <li>• that valid informed consent was given</li> <li>• name of individual, address, date of birth and GP with whom the individual is registered</li> <li>• name of immuniser</li> <li>• name and brand of vaccine</li> <li>• date of administration</li> <li>• dose, form and route of administration of vaccine</li> <li>• quantity administered</li> <li>• batch number and expiry date</li> <li>• anatomical site of vaccination</li> <li>• advice given, including advice given if excluded or declines immunisation</li> <li>• details of any adverse drug reactions and actions taken</li> <li>• supplied via PGD</li> </ul> <p>Records should be signed and dated (or a password controlled immuniser's record on e-records).</p> <p>All records should be clear, legible and contemporaneous.</p> <p>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.</p> <p>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.</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>

## 6. Key references

<b>Key references</b>	<p><b>Meningococcal B Vaccination</b></p> <ul style="list-style-type: none"><li>• Bexsero® Summary of Product Characteristics, GlaxoSmithKline UK. Updated 19 June 2022. <a href="#">Bexsero Meningococcal Group B vaccine for injection in pre-filled syringe - Summary of Product Characteristics (SmPC)</a></li><li>• Immunisation Against Infectious Disease: The Green Book, <a href="#">Chapter 22</a> last updated 17 May 2022 and <a href="#">Chapter 7</a>, last updated 10 January 2020. <a href="http://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book">www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book</a></li><li>• Meningococcal B: vaccine information for healthcare professionals 1 July 2021 <a href="http://www.gov.uk/government/publications/meningococcal-b-vaccine-information-for-healthcare-professionals">www.gov.uk/government/publications/meningococcal-b-vaccine-information-for-healthcare-professionals</a></li></ul> <p><b>General</b></p> <ul style="list-style-type: none"><li>• Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20 March 2013 <a href="http://www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-htm-07-01/">www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-htm-07-01/</a></li><li>• National Minimum Standards and Core Curriculum for Immunisation Training. Published February 2018 <a href="http://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners">www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners</a></li><li>• NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published March 2017 <a href="http://www.nice.org.uk/guidance/mpg2">www.nice.org.uk/guidance/mpg2</a></li><li>• NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. Updated March 2017. <a href="http://www.nice.org.uk/guidance/mpg2/resources">www.nice.org.uk/guidance/mpg2/resources</a></li><li>• UKHSA Immunisation Collection <a href="http://www.gov.uk/government/collections/immunisation">www.gov.uk/government/collections/immunisation</a></li><li>• Vaccine Incident Guidance <a href="http://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors">www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors</a></li></ul>
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## 7. Practitioner authorisation sheet

**MenB Risk Groups PGD v4.00 Valid from: 28 February 2023 Expiry: 28 February 2025**

Before signing this patient group direction (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 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 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 PGD 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 <i>insert name of organisation</i> 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.