



Publications gateway number: GOV-17734

## 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: v5.0  
Valid from: 28 February 2025  
Review date: 1 September 2027  
Expiry date: 28 February 2028

**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'.

Sections 2 and 7 can be edited within the designated editable fields provided, but only for the purposes for which these sections are provided, namely the responsibilities and governance arrangements of the NHS organisation using the PGD. The fields in section 2 and 7 cannot be used to alter, amend to or add to the clinical content. Such action will invalidate the UKHSA clinical content authorisation which is provided in accordance with the regulations.

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:

[Immunisation patient group direction \(PGD\) templates](#)

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

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: see contacts listed on pages 6&7 of this PGD

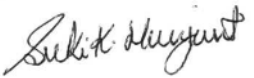
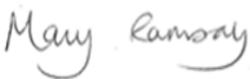

## Change history

Version number	Change details	
V1.0	New MenB Risk Groups Public Health England PGD template	8 December 2016
V2.0	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 Public Health England PGD templates</li> </ul>	21 December 2018
V3.0	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 Public Health England PGD templates</li> </ul>	28 January 2021
V4.0	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

V5.0	<p>MenB Risk Groups PGD amended to:</p> <ul style="list-style-type: none"> <li>• Page 1; updated governance requirements for sections 2 and 7</li> <li>• include minor rewording of standard text, layout and formatting changes for clarity and consistency with organisation change and other UKHSA PGDs</li> <li>• update qualifications and professional registration with reference to clinical scope</li> <li>• update expert panel</li> <li>• add pharmacy technicians in Section 3; qualifications and professional registration</li> <li>• delete allergy to latex as per updated SPC</li> <li>• update the formulation</li> <li>• update references</li> </ul>	11 December 2024
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## 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 Programmes, UKHSA		11 December 2024
<b>Doctor</b>	Mary Ramsay CBE Director of Public Health programmes and Consultant Epidemiologist, Immunisation Programmes, UKHSA		11 December 2024
<b>Registered Nurse</b> (Chair of Expert Panel)	David Green Nurse Consultant for Immunisation Programmes, UKHSA		11 December 2024

This PGD has been peer reviewed by the UKHSA Immunisations PGD Expert Panel in accordance with the UKHSA PGD Policy. It has been ratified by the UKHSA Medicines Governance Committee.

### 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
Lesley McFarlane	Lead Immunisation Nurse Specialist Immunisation Programmes, UKHSA
Tushar Shah	Lead Pharmacy Adviser, 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.

NHSE North East and Yorkshire authorises this PGD for use by the services or providers listed below:

<b>Authorised for use by the following organisations and/or services</b>
NHS England (NHSE) commissioned immunisation services or NHS Trust providing immunisation services.
<b>Limitations to authorisation</b>
Authorisation is limited to those registered practitioners listed in Section 3 who are employed by organisations/providers commissioned by NHSE North East and Yorkshire (NEY) to deliver immunisation programmes within the whole of the NHSE region of North East and Yorkshire

<b>Organisational approval (legal requirement)</b>			
<b>Role</b>	<b>Name</b>	<b>Sign</b>	<b>Date</b>
<b>Deputy Medical Director: System Improvement and Professional Standards</b> NHS England - North East and Yorkshire	<b>Dr James Gossow</b>		<b>28.1.2025</b>

<b>Additional signatories according to locally agreed policy</b>			
<b>Role</b>	<b>Name</b>	<b>Sign</b>	<b>Date</b>
<b>Screening and Immunisation Place Lead</b>  NHS England (NE and Yorkshire)	<b>Laura Brown</b>		<b>24.1.2025</b>
<b>NHSE NEY PGD Governance assurance review</b> (Medicines Optimisation Pharmacist Lead, NHS NECS)	<b>Kurt Ramsden</b>		<b>27.1.2025</b>

Local enquiries regarding the use of this PGD may be directed to your local screening and immunisation teams. See area-specific contacts below:

For North East and North Cumbria Area (i.e. Northumberland, Tyne & Wear, Durham Darlington and Tees and North Cumbria) use the following:

NHS England Screening and Immunisation Team:

email [england.cane.screeningimms@nhs.net](mailto:england.cane.screeningimms@nhs.net)

or NECS Medicine Optimisation Pharmacists: Kurt Ramsden: [kurtramsden@nhs.net](mailto:kurtramsden@nhs.net)

or Sue White: [sue.white14@nhs.net](mailto:sue.white14@nhs.net)

Please note - All North East and North Cumbria PGDs can be found at:

<https://medicines.necsu.nhs.uk/resources/patient-group-directions/>

For Yorkshire and Humber Area use the following:

West Yorkshire - [england.wysit@nhs.net](mailto:england.wysit@nhs.net)

South Yorkshire and Bassetlaw - [england.sybsit@nhs.net](mailto:england.sybsit@nhs.net)

North Yorkshire and Humber [ENGLAND.NYAHSIT@nhs.net](mailto:ENGLAND.NYAHSIT@nhs.net)

or the Health Protection Team Acute Response Centre (ARC): Contact Number: 0113 3860 300.

Please note - All Yorkshire and Humber PGDs can be found at:

<https://www.england.nhs.uk/north-east-yorkshire/our-work/information-for-professionals/pgds/> / [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.

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>All practitioners should only administer vaccination where it is within their clinical scope of practice to do so. Practitioners must also fulfil the <a href="#">additional requirements</a> and <a href="#">continued training requirements</a> 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"> <li>• nurses and midwives currently registered with the Nursing and Midwifery Council (NMC)</li> <li>• pharmacists and pharmacy technicians 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 intramuscular and subcutaneous injection techniques</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>Continued over page</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><b>Continued training requirements</b> (continued)</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>
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#### 4. Clinical condition or situation to which this PGD applies

<b>Clinical condition or situation to which this PGD applies</b>	<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>
<b>Criteria for inclusion</b>	<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>
<b>Criteria for exclusion<sup>2</sup></b>	<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>• 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>
<b>Cautions including any relevant action to be taken</b>	<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>The immunogenicity of the vaccine could be reduced in individuals who are immunosuppressed and in individuals with HIV (see <a href="#">Special Considerations</a> below). 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>
<b>Action to be taken if the patient is excluded</b>	<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>Continued over page</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> (continued)</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 <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> <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>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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<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.</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 <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>								

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<b>Route and method of administration</b> (continued)	<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 <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 4CMenB, 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 4CMen B, regardless of previous vaccination, and an additional 4CMenB 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 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>	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> : Health Technical Memorandum 07-01: Safe and sustainable management of healthcare waste (NHSE) .
<b>Drug interactions</b>	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.
<b>Identification and management of adverse reactions</b>	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 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 ( $\geq 38\text{ }^{\circ}\text{C}$ ) 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 ( $\geq 40\text{ }^{\circ}\text{C}$ ) can occur (see <a href="#">Chapter 22</a> ).  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> .
<b>Reporting procedure of adverse reactions</b>	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.  Any adverse reaction to the vaccine should be documented in the individual's record and the individual's GP should be informed.
<b>Written information to be given to patient or carer</b>	Offer marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine.  For resources in accessible formats and alternative languages, please visit <a href="#">Home – Health Publications</a> . Where applicable, inform the individual/parent/carer that the PIL with large print, Braille or audio CD can be ordered from the manufacturer (see <a href="#">electronic medicines compendium</a> ).  Immunisation promotional material may be provided as appropriate: <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> </ul> Available from: <a href="http://www.gov.uk/government/collections/immunisation">www.gov.uk/government/collections/immunisation</a>
<b>Patient advice and follow up treatment</b>  Continued over page	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

<p><b>Patient advice and follow up treatment</b> (continued)</p>	<p>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.</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><b>Special considerations and additional information</b></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 <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> <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 <a href="#">Chapter 7</a>.</p>
<p><b>Records</b></p> <p>Continued over page</p>	<p>Record:</p> <ul style="list-style-type: none"> <li>• that valid informed consent was given or a decision to vaccinate made in the individual's best interests in accordance with the <a href="#">Mental Capacity Act 2005</a></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> </ul>

<p><b>Records</b> (continued)</p>	<ul style="list-style-type: none"> <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>
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## 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 21 July 2023. <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 <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, NHSE <a href="http://www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-hm-07-01/">www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-hm-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 v5.0 Valid from: 28 February 2025 Expiry: 28 February 2028**

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.