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## Meningococcal Group B (4CMenB) Vaccine for prevention of Gonorrhoea Patient Group Direction (PGD)

This PGD is for the administration of meningococcal group B vaccine (rDNA, component, adsorbed) (4CMenB) to gay, bisexual, and other men who have sex with men (GBMSM) who are at higher risk of gonorrhoea, in accordance with national recommendations.

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: 4CMenB (Gonorrhoea) PGD  
Version no: v1.0a  
Valid from: 1 August 2025  
Review date: 1 February 2027  
Expiry date: 1 August 2027

**The UK Health Security Agency (UKHSA) has developed this PGD to facilitate the delivery of publicly funded immunisations 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 the 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 directions \(PGD\) 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: : Vaccination Team, NHS England – Midlands, responsible for your area:

East: [england.emids-imms@nhs.net](mailto:england.emids-imms@nhs.net)

- Derby and Derbyshire
- Lincolnshire
- Leicester, Leicestershire and Rutland
- Northamptonshire
- Nottingham and Nottinghamshire

West: [england.wmid-imms@nhs.net](mailto:england.wmid-imms@nhs.net)

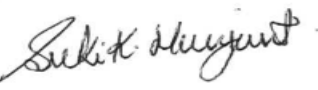
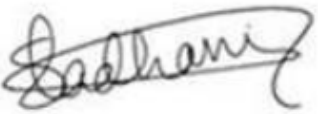

- Herefordshire and Worcestershire
- Birmingham and Solihull
- Staffordshire and Stoke-on-Trent
- Shropshire, Telford and Wrekin
- Black Country
- Coventry and Warwickshire

## Change history

Version number	Change details	Date
V1.0	New UKHSA 4CMenB Gonorrhoea PGD template to support the vaccination of GBMSM individuals who are at higher risk of gonorrhoea in line with recommendations from <a href="#">JCVI</a> and the Green Book, <a href="#">Gonorrhoea Chapter</a> .	9 June 2025
V1.0a	UKHSA 4CMenB Gonorrhoea PGD template amended to <ul style="list-style-type: none"><li>• update the duration of treatment section section to align with updated Green Book, Gonorrhoea Chapter</li></ul>	7 July 2025

## 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 for Immunisation Programmes, UKHSA		7 July 2025
<b>Doctor</b>	Professor Shamez Ladhani Paediatric Infectious Diseases Consultant, St George's Hospital London, Professor of Paediatric Infections and Vaccinology, St George's University London and Consultant Epidemiologist, Immunisation and Vaccine Preventable Diseases Division, UKHSA		7 July 2025
<b>Registered Nurse</b> (Chair of Expert Panel)	David Green Nurse Consultant for Immunisation Programmes, UKHSA		7 July 2025

This PGD has been reviewed by the UKHSA Immunisations PGD Expert Panel in accordance with the UKHSA PGD and Protocol 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, Clinical, NHS England Midlands
Naveen Dosanjh	Senior Clinical Advisor - Vaccinations, NHS England
Helen Fifer	Consultant Microbiologist, Blood Safety, Hepatitis, STI and HIV Division, UKHSA
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, Primary Care Based, Southbourne Surgery
Shilan Ghafoor	Medicines Governance Lead Pharmacist, UKHSA
Briony Mason	Vaccination Manager, Professional Midwifery Advocate, Vaccination and Screening, NHS England, West Midlands
Sema Mandal	Deputy Director, Blood Safety, Hepatitis, STIs and HIV, UKHSA
Hamish Mohammed	Consultant STI Surveillance and Prevention Scientist (and Honorary Associate Professor, University College London), Blood Safety, Hepatitis, Sexually Transmitted Infections (STIs) and HIV Division, UKHSA

Elizabeth Lockett	Senior Screening and Immunisation Manager, NHS England 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, NHS England 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:

Authorised for use by the following organisations and/or services
All Sexual Health Services commissioned or contracted by NHS England – Midlands to provide immunisation services in: <ul style="list-style-type: none"><li>• Derby and Derbyshire</li><li>• Lincolnshire</li><li>• Leicester, Leicestershire, and Rutland</li><li>• Northamptonshire</li><li>• Nottingham and Nottinghamshire</li><li>• Herefordshire and Worcestershire</li><li>• Birmingham and Solihull</li><li>• Staffordshire and Stoke-on-Trent</li><li>• Shropshire, Telford and Wrekin</li><li>• Black Country</li><li>• Coventry and Warwickshire</li></ul>
Limitations to authorisation
None.

Organisational approval (legal requirement)			
Role	Name	Sign	Date
Regional Director of Commissioning Integration, NHS England - Midlands	Roz Lindridge		15/07/2025

Additional signatories according to locally agreed policy			
Role	Name	Sign	Date

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

East: [england.emids-imms@nhs.net](mailto:england.emids-imms@nhs.net)

- Derby and Derbyshire
- Lincolnshire
- Leicester, Leicestershire and Rutland
- Northamptonshire
- Nottingham and Nottinghamshire

West: [england.wmid-imms@nhs.net](mailto:england.wmid-imms@nhs.net)

- Herefordshire and Worcestershire
- Birmingham and Solihull
- Staffordshire and Stoke-on-Trent
- Shropshire, Telford and Wrekin
- Black Country
- Coventry and Warwickshire

[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 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</a> (Limitations to authorisation) 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 for healthcare professionals using PGDs</a>)</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>Practitioners should be constantly alert to any subsequent recommendations from the UKHSA, NHS England and other sources of medicines information.</p>



<b>Continued training requirements</b> (continued)	Note: The most current national recommendations should be followed but a Patient Specific Direction (PSD) or a prescription may be required to administer the vaccine in line with updated recommendations that are outside the criteria specified in this PGD.
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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>	Indicated for GBMSM who are at higher risk of gonorrhoea in accordance with <a href="#">Gonorrhoea Chapter</a> of Immunisation Against Infectious Disease: the Green Book and <a href="#">JCVI</a> recommendations.
<b>Criteria for inclusion</b>	<p>GBMSM who are at higher risk of gonorrhoea include those:</p> <ul style="list-style-type: none"> <li>• who currently have or have had a bacterial sexually transmitted infection (STI) in the previous 12 months (see <a href="#">Special consideration and additional information</a>)</li> <li>OR</li> <li>• who are reporting at least 5 sexual partners in the previous 3 months</li> </ul> <p>NOTE:</p> <p>Whilst gonorrhoea incidence remains the highest in the eligible GBMSM group (as defined above), sexual health clinical professionals may perform individual risk assessment and consider the offer of 4CMenB to the small numbers of individuals with an incidence of gonorrhoea approaching that in the eligible GBMSM group defined above. This may include sex workers practicing condomless sex, and others assessed as having a similar incidence as the eligible GBMSM group. This is outside the scope of the PGD and instead, a Patient Specific Direction (<a href="#">PSD</a>) or a prescription must be used.</p> <p>See Green Book, <a href="#">Gonorrhoea Chapter</a> and <a href="#">JCVI</a> recommendations.</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>• 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>• are not at higher risk of gonorrhoea infection</li> <li>• are not GBMSM</li> <li>• have received two doses of 4CMenB</li> <li>• are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation)</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 individuals with HIV who have a detectable viral load. However, vaccination should proceed in accordance with national recommendations (see <a href="#">Gonorrhoea Chapter</a> and <a href="#">Dose and frequency below</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

<b>Action to be taken if the individual is excluded</b>	<p>Individuals suffering acute severe febrile illness should postpone immunisation until they have recovered; immunisers should advise when the individual can be vaccinated and ensure another appointment is arranged at the earliest opportunity.</p> <p>Vaccination of individuals who are not GBMSM is not covered by this PGD. Sexual health clinical professionals may perform individual risk assessment and consider the offer of 4CMenB to the small numbers of individuals with an incidence of gonorrhoea approaching that in the eligible GBMSM group as defined in <a href="#">Criteria for inclusion</a>; this may include sex workers practicing condomless sex, and others assessed as having a similar incidence as the eligible GBMSM group. This is outside the scope of the PGD and instead a Patient Specific Direction (<a href="#">PSD</a>) or a prescription must be used.</p> <p>Where individuals may already have received two doses of 4CMenB because of their higher risk of meningococcal disease, no further doses are recommended for these individuals.</p> <p>If a confirmed anaphylactic reaction has been experienced after a previous dose of 4CMenB vaccine or any of its components, specialist advice should be sought. If immunisation is recommended do not administer under this PGD; a PSD or a prescription will be required.</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 clinician as appropriate.</p>
<b>Action to be taken if the individual or carer declines treatment</b>	<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/carers, if applicable, 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>
<b>Arrangements for referral for medical advice</b>	<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: Bexsero® 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>Protection against gonorrhoea is not currently a licensed indication for 4CMenB vaccine, however, the off-label use of the vaccine is in accordance with <a href="#">JCVI</a> and <a href="#">Gonorrhoea Chapter</a> recommendations.</p> <p>Administration by deep subcutaneous injection to individuals with a bleeding disorder is off-label administration, however, it is in line with advice in the Green Book, <a href="#">Chapter 4</a> and <a href="#">Gonorrhoea Chapter</a>.</p> <p>Vaccine should be stored according to the conditions detailed in the <a href="#">Storage</a> section 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 or parent or carer as appropriate that the vaccine is being offered outside of product licence but in accordance with national guidance.</p>								
<b>Route and method of administration</b>          Continued over page	<p>4CMenB is given as a 0.5ml dose by intramuscular injection.</p> <p>For individuals with a bleeding disorder, vaccines normally given by an IM route should be given by deep subcutaneous injection to reduce the risk of bleeding (see <a href="#">Chapter 4</a> and <a href="#">Gonorrhoea Chapter</a>).</p> <p>The vaccine is given into the deltoid area of upper arm or anterolateral thigh.</p> <p>4CMenB can be administered before, at the same time as, or after other vaccines (including but not limited to hepatitis A, hepatitis B, human papillomavirus and mpox vaccines) without any restrictions on time intervals between different vaccines.</p> <p>The vaccines should be given at a separate site, preferably in a separate arm. The site at which each vaccine is given should be noted in the patient's clinical record.</p> <p>Vaccinating in a timely manner when an eligible individual is present in the clinic will avoid any delay in protection and reduce the risk of the patient not returning for a later appointment (see <a href="#">Gonorrhoea Chapter</a>)</p>								



<b>Dose and frequency of administration</b> (continued)	<p>For further guidance for the immunisation of HIV-infected individuals see <a href="#">Gonorrhoea Chapter</a>.</p> <p><b>Booster</b></p> <p>There are currently no recommendations for 4CMenB booster doses in eligible adults who have received two doses as part of their primary immunisation.</p>
<b>Duration of treatment</b>	<p>Each dose is 0.5ml. A course of two doses.</p> <p>See <a href="#">dose and frequency section</a> for further details on intervals between the two doses)</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 for delivery of the national immunisation programme can only be ordered via ImmForm. Vaccines for use for the national immunisation programme are provided free of charge.</p> <p>Vaccines for private prescriptions are not provided free of charge or supplied via ImmForm and should be ordered from the manufacturer or 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.</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 <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 NHS England guidance (<a href="#">HTM 07-01: safe and sustainable management of healthcare waste</a> (NHS England).</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 all the other vaccines.</p> <p>For further information see <a href="#">SPC</a>.</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 were pain at the injection site including swelling, induration and erythema, malaise, rash, myalgia, arthralgia, nausea and headache.</p> <p>A detailed list of adverse reactions associated with Bexsero® is available from the vaccine's <a href="#">SPC</a>.</p>

<b>Reporting procedure of adverse reactions</b>	<p>As with all vaccines, healthcare professionals, individuals and carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the <a href="#">Yellow Card reporting scheme</a> or search for 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 clinician should be informed.</p>
<b>Written information to be given to individual or carer</b>	<p>Offer the marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine.</p> <p>For resources in accessible formats and alternative languages, please visit <a href="#">Home - Health Publications</a>. Where applicable, inform the individual/parent/carers that the PIL with large print, Braille or audio CD can be ordered from the manufacturer (see electronic medicines compendium).</p> <ul style="list-style-type: none"> <li>• <a href="#">A guide to the Meningococcal B vaccine for protection against gonorrhoea for gay, bisexual and other men who have sex with men</a></li> <li>• <a href="#">Don't forget your second dose of MenB vaccine to protect against gonorrhoea Meningococcal B (Bexsero) vaccination record card</a></li> <li>• <a href="#">Poster: Have you had your MenB vaccines to protect you against gonorrhoea</a></li> </ul>
<b>Advice and follow up treatment</b>	<p>4CMenB is not expected to provide complete protection against all circulating gonorrhoea infection. Individuals should continue to seek prompt medical attention at the first signs of possible gonorrhoea.</p> <p>Inform individuals who are immunosuppressed or individuals with HIV who have a detectable viral load that the immunogenicity of the vaccine could be reduced.</p> <p>Inform the individual/carers of the possible side effects and their management.</p> <p>The individual/carers should be advised to seek medical advice in the event of an adverse reaction.</p> <p>When applicable, advise the individual/carers when the subsequent vaccine dose is due.</p> <p>When administration is postponed, advise the individual/carers when to return for vaccination.</p>
<b>Special considerations and additional information</b>  Continued over page	<p>Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and easy access to a telephone.</p> <p>Individuals requiring treatment for acute gonorrhoea infection should be managed according to the British Association for Sexual Health and HIV (<a href="#">BASHH</a>) guidelines. There are no data on the immunogenicity or protection offered when 4CMenB is administered during active or recent gonorrhoea infection.</p> <p>Eligible individuals attending sexual health clinics for testing and/or management of bacterial STIs, including gonorrhoea, should be offered 4CMenB at the same clinic attendance, to avoid delay in providing protection.</p> <p>It is possible that acute gonorrhoea may affect immune responses to vaccination since natural infection does not confer protection against reinfection. Even if some attenuation in vaccine response did occur with the</p>

<b>Special considerations and additional information</b> (continued)	<p>first dose, eligible individuals will receive a second dose of the same vaccine after the infection is treated.</p> <p>There is no data on the efficacy of Bexsero® in adults over the age of 50 years. However, administration of the vaccine to individuals over the age of 50 who are identified to be at higher risk of gonorrhoea, is in line with <a href="#">JCVI</a> advice and <a href="#">Gonorrhoea Chapter</a> of the Green Book.</p> <p><b>Immunosuppression and HIV infection</b></p> <p>Individuals with immunosuppression and human immunodeficiency virus (HIV) infection (regardless of CD4 count) should be given 4CMenB vaccine in accordance with the <a href="#">Gonorrhoea Chapter</a> and <a href="#">JCVI</a> recommendations (see <a href="#">dose and frequency</a>).</p>
<b>Records</b>	<p>The practitioner must ensure the following is recorded:</p> <ul style="list-style-type: none"> <li>• that valid informed consent was given or a decision to vaccinate was 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</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 the individual/carer is 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>The offer and uptake of 4CMenB vaccination must be coded in sexual health services' electronic patient records management system and, in accordance with the service specification, reported to UKHSA with routine GUMCAD STI Surveillance returns.</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

<p><b>Key references</b></p>	<p><b>Meningococcal B vaccination and Gonorrhoea</b></p> <ul style="list-style-type: none"> <li>Immunisation Against Infectious Disease: <a href="#">Gonorrhoea: The Green Book Chapter</a> and <a href="#">Chapter 4</a> <a href="http://gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book">gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book</a></li> <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) - (emc) (medicines.org.uk)</a></li> <li>JCVI advice on the use of meningococcal B vaccination for the prevention of gonorrhoea. Published 10 November 2023 <a href="#">JCVI advice on the use of meningococcal B vaccination for the prevention of gonorrhoea - GOV.UK (www.gov.uk)</a></li> <li>Introduction of new routine mpox and 4CMenB for gonorrhoea vaccination programmes, primarily for gay, bisexual and other men who have sex with men (GBMSM) at higher risk of acquiring these infections, delivered by local authority commissioned sexual health services from 1 August 2025. Publication reference: PRN02012 <a href="#">www.gov.uk/government/publications/introduction-of-new-routine-mpox-and-4cmenb-for-gonorrhoea-vaccination-programmes-letter/introduction-of-new-routine-mpox-and-4cmenb-for-gonorrhoea-vaccination-programmes-letter</a></li> </ul> <p><b>General</b></p> <ul style="list-style-type: none"> <li>NHS England Health Technical Memorandum 07-01: safe and sustainable management of healthcare waste, NHS England <a href="#">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="#">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, updated March 2017 <a href="#">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="#">nice.org.uk/guidance/mpg2/resources</a></li> <li>UKHSA Immunisation Collection <a href="#">gov.uk/government/collections/immunisation</a></li> <li>Vaccine Incident Guidance <a href="#">gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors</a></li> </ul>
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## 7. Practitioner authorisation sheet

### 4CMenB (Gonorrhoea) PGD v1.0a Valid from: 1 August 2025 Expiry: 1 August 2027

Before signing this patient group direction (PGD), check that the document has had the necessary authorisations in section 2. 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 Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct.			
Name	Designation	Signature	Date

#### Authorising manager

I confirm that the practitioners named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of <b>INSERT NAME OF ORGANISATION</b> 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.