UK Health Security Agency

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Meningococcal Group B Vaccine Patient Group Direction (PGD)

This PGD is for the administration of meningococcal group B vaccine (rDNA, component, adsorbed) (4CMenB) to individuals from 8 weeks of age eligible for the national routine immunisation programme and to individuals for the prevention of secondary cases of meningococcal group B disease.

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 PGD
Version no:	v7.0
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 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)[1]. **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

[1] This includes any relevant amendments to legislation.

Any concerns regarding the content of this PGD should be addressed to:immunisation@ukhsa.gov.uk

Enquiries relating to the availability of organisationally authorised PGDs and subsequent versions of this PGD should be directed to: your local screening and immunisation team

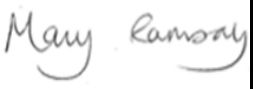
Change history

Version number	Change details	Date
V1.0	New MenB Public Health England PGD template	21 July 2015
V2.0	Public Health England MenB PGD amended to: • include immunisation into the thigh for individuals over 1 year of age • update dosing recommendations for individuals with incomplete vaccination status • reference the protocol for ordering storage and handling of vaccines • update wording regarding authorisation in line with agreed PHE PGD template changes • include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates	3 February 2017
V3.0	Public Health England MenB PGD amended to: • update dosing guidance for the prevention of secondary cases of meningococcal group B disease, see Annex A, in line with revised Public Health England Guidance for Public Health Management of Meningococcal Disease in the UK • include additional healthcare practitioners (pharmacists, paramedics, physiotherapists) in Section 3 • refer to the MenB risk groups PGD in the inclusion criteria section • refer to vaccine incident guidelines in off-label and storage sections • include rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates	24 April 2018
V4.0	Public Health England MenB PGD amended to: • remove the black triangle status • update details regarding permissible use of Immform supplies of 4CMenB • include rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates	21 December 2018
V5.0	Public Health England MenB PGD amended to: • update off-label section because SPC now includes administration of 2+1 schedule starting at 2 months • update adverse drug reactions section • include a caution relating to immunosuppressed individuals • update adverse drug reactions section • include rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates	28 January 2021

V6.0	UKHSA MenB PGD amended to: • include minor rewording of standard text, layout and formatting changes for clarity and consistency with organisation change and other UKHSA PGDs • amend NHS England and Improvement (NHSE) to NHS England (NHSE) following completion of merger on 1 July 2022 • align the management of anaphylaxis with other UKHSA PGDs in cautions section • add the formulation and strength to the name of the drug • update the advice for individuals with unknown or incomplete history of vaccination in dose and frequency section • include in dose and frequency premature infants, HIV and immunosuppressed cohorts • update drug interactions in accordance with SPC update • update adverse reactions in accordance with updated SPC • update advice for administration of paracetamol in adverse reactions section • update references • remove the table for schedule guidance for secondary prevention of MenB disease as linked in references and through the PGD	7 December 2022
V7.0	UKHSA MenB PGD amended to: • Page 1; updated governance requirements for sections 2 and 7 • include minor rewording of standard text, layout and formatting changes for clarity and consistency with organisation change and other UKHSA PGDs • update qualifications and professional registration with reference to clinical scope • update expert panel • add pharmacy technicians in Section 3; qualifications and professional registration • delete allergy to latex as per updated SPC • update off-label use to include interval of 4 weeks for doses in individuals with unknown or incomplete vaccination history • clarify the monitoring requirements for the very premature infants in cautions including any relevant action to be taken • clarify use of paracetamol section in Identification and management of adverse reactions • update the formulation • update dose intervals for individuals with unknown or incomplete vaccination history as per updated Vaccination of individuals with uncertain or incomplete immunisation guidance • update references	11 December 2024

1. PGD development

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

Developed by:	Name	Signature	Date
Pharmacist (Lead Author)	Suki Hunjunt Lead Pharmacist Immunisation Programmes, UKHSA		11 December 2024
Doctor	Mary Ramsay CBE Director of Public Health programmes and Consultant Epidemiologist, Immunisation Programmes, UKHSA		11 December 2024
Registered Nurse (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 Luckett	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.

NHS England (South East) authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisations and/or services
All NHS England commissioned immunisation services within the NHS England South East Region.
Limitations to authorisation
This patient group direction (PGD) must only be used by the registered healthcare practitioners identified in Section 3 who have been named by their organisation to practice under it. The most recent in-date final version authorised by NHS England (South East) must be used. This PGD includes vaccination of individuals across the national immunisation programme. Users of this PGD should note that where they are commissioned to immunise certain groups this PGD does not constitute permission to offer immunisation beyond the groups they are commissioned to immunise.

Organisational approval (legal requirement)			
Role	**Name**	**Sign**	**Date**
South East Medical Director System Improvement and Professional Standards	**Dr Shahed Ahmed**		**06/02/25**

Additional signatories according to locally agreed policy			
Role	**Name**	**Sign**	**Date**

Local enquiries regarding the use of this PGD may be directed to your local screening and immunisation team.

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

Qualifications and professional registration	All practitioners should only administer vaccination where it is within their clinical scope of practice to do so. Practitioners must also fulfil the additional requirements and continued training requirements to ensure their competency is up to date, as outlined in the section below. Registered professional with one of the following bodies: • nurses and midwives currently registered with the Nursing and Midwifery Council (NMC) • pharmacists and pharmacy technicians currently registered with the General Pharmaceutical Council (GPhC) (Note: this PGD is not relevant to privately provided community pharmacy services) • paramedics and physiotherapists currently registered with Health and Care Professions Council (HCPC) The practitioners above must also fulfil the Additional requirements detailed below. Check Section 2 Limitations to authorisation to confirm whether all practitioners listed above have organisational authorisation to work under this PGD.
Additional requirements	Additionally practitioners: • must be authorised by name as an approved practitioner under the current terms of this PGD before working to it • must have undertaken appropriate training for working under PGDs for supply/administration of medicines • must be competent in the use of PGDs (see NICE Competency framework for health professionals using PGDs) • must be familiar with the vaccine product and alert to changes in the Summary of Product Characteristics (SPC), Immunisation Against Infectious Disease ('The Green Book'), and national and local immunisation programmes • must have undertaken training appropriate to this PGD as required by local policy and in line with the National Minimum Standards and Core Curriculum for Immunisation Training • must be competent to undertake immunisation and to discuss issues related to immunisation • must be competent in the handling and storage of vaccines, and management of the cold chain • must be competent in intramuscular and subcutaneous injection techniques • must be competent in the recognition and management of anaphylaxis • must have access to the PGD and associated online resources • should fulfil any additional requirements defined by local policy **The individual practitioner must be authorised by name, under the current version of this PGD before working according to it.**
Continued training requirements Continued over page	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).

Continued training requirements (continued)	Practitioners should be constantly alert to any subsequent recommendations from the UKHSA and/or NHSE and other sources of medicines information. Note: The most current national recommendations should be followed but a Patient Specific Direction (PSD) may be required to administer the vaccine in line with updated recommendations that are outside the criteria specified in this PGD.

4. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	Indicated for the active immunisation of individuals from 8 weeks of age against *Neisseria meningitidis* group B and for the prevention of secondary cases of meningococcal group B disease, in accordance with the recommendations given in Chapter 22 of Immunisation Against Infectious Disease: The Green Book and Guidance for Public Health Management of Meningococcal Disease in the UK.
Criteria for inclusion	Individuals who: • are aged from 8 weeks up to their second birthday and require routine immunisation • require vaccination for the prevention of secondary cases of Men B, following specific advice from UKHSA Health Protection Teams and in accordance with Guidance for Public Health Management of Meningococcal Disease in the UK. Note: Individuals, from 2 years of age, with an underlying medical condition which puts them at increased risk from *Neisseria meningitidis* group B, that is individuals with asplenia, splenic dysfunction or complement disorders (including those on, or due to receive, complement inhibitor treatment such as eculizumab), may require additional 'routine' vaccination outside the inclusion criteria for this PGD - see Meningococcal Group B Vaccine Risk Groups PGD and Chapter 7 of 'The Green Book'.
Criteria for exclusion[2]	Individuals for whom no valid consent has been received. Individuals who: • are less than 8 weeks old • are from 2 years of age, unless advised by the UKHSA for the prevention of secondary cases of MenB infection • have had a confirmed anaphylactic reaction to a previous dose of the vaccine or to any constituent or excipient of the vaccine including kanamycin • require vaccination for occupational health reasons, travel or going to reside abroad • are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation)
Cautions including any relevant action to be taken Continued over page	Facilities for management of anaphylaxis should be available at all vaccination sites (see Chapter 8 of the Green Book) and advice issued by the Resuscitation Council UK. Very premature infants (born ≤28 weeks of gestation) who are in hospital should have respiratory monitoring for 48-72 hours when given their first immunisation, particularly those with a previous history of respiratory immaturity. If the child has apnoea, bradycardia or desaturations after the first immunisation, the second immunisation should also be given in hospital, with respiratory monitoring for 48-72 hours. If the premature infant was stable at discharge and has no history of apnoea/respiratory compromise, further vaccinations can be given in the community setting. As the benefit of immunisation is high in this group of infants, immunisation should not be withheld or delayed.

[2] 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

Cautions including any relevant action to be taken (continued)	The immunogenicity of the vaccine could be reduced in individuals who are immunosuppressed and individuals with HIV. However, vaccination should proceed in accordance with national recommendations see Chapter 22). Syncope (fainting) can occur following, or even before, any vaccination especially in adolescents as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from faints.
Action to be taken if the patient is excluded	If aged less than 8 weeks, 4CMenB is not routinely indicated, advise the parent/carer when the infant can be vaccinated. If aged from 2 years and not in a clinical risk group or requiring vaccination for the prevention of secondary cases of MenB disease, the individual/parent/carer should be advised that 4CMenB is not indicated. Individuals at increased risk of invasive meningococcal infection with asplenia, splenic dysfunction or complement disorders (including those on complement inhibitor treatment such as eculizumab) should be vaccinated in accordance with the recommended schedules in Chapter 7 and Chapter 22 of 'The Green Book' (see Meningococcal Group B Vaccine Risk Groups PGD). Individuals requiring vaccination for occupational health reasons should be referred to their occupational health service provider for vaccination. There are currently no recommendations for 4CMenB vaccination for individuals who are travelling or going to reside abroad. Individuals suffering acute severe febrile illness should postpone immunisation until they have recovered; immunisers should advise when the individual can be vaccinated and ensure another appointment is arranged. Seek appropriate advice from the local Screening and Immunisation Team, local Health Protection Team or the individual's clinician as required. The risk to the individual of not being immunised must be taken into account. Document the reason for exclusion and any action taken in the individual's clinical records. Inform or refer to the GP or a prescriber as appropriate.
Action to be taken if the patient or carer declines treatment	Informed consent, from the individual or a person legally able to act on the person's behalf, must be obtained for each administration. Advise the individual/parent/carer about the protective effects of the vaccine, the risks of infection and potential complications of disease. Document advice given and the decision reached. Inform or refer to the GP or a prescriber as appropriate.
Arrangements for referral for medical advice	As per local policy

5. Description of treatment

Name, strength and formulation of drug	Meningococcal group B Vaccine (rDNA, component, adsorbed), 4CMenB: Bexsero® suspension for injection, 0.5ml, in a pre-filled syringe One dose of 0.5ml suspension contains: Recombinant Neisseria meningitidis group B NHBA fusion protein — 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
Legal category	Prescription only medicine (POM)
Black triangle▼	No
Off-label use	Administration by deep subcutaneous injection to individuals with a bleeding disorder is off-label administration in line with advice in Chapter 4 and Chapter 22 of 'The Green Book'. Doses of MenB should ideally be given 8 weeks apart. However, to complete the primary Men B immunisation schedule in individuals with unknown or incomplete vaccination history, the doses can be given 4 weeks apart as per Guidance Vaccination of individuals with uncertain or incomplete immunisation status. (see Dose and frequency of administration below). Vaccine should be stored according to the conditions detailed in the Storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to Vaccine Incident Guidance. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use this would constitute off-label administration under this PGD. Where a vaccine is recommended off-label consider, as part of the consent process, informing the individual/parent/carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence.
Route and method of administration Continued over page	4CMenB is given as a 0.5ml dose by intramuscular injection. In infants and for the routine booster dose, the UKHSA recommends that all doses of 4CMenB be given in the anterolateral aspect of the left thigh, ideally on their own, so that any local reactions can be monitored more accurately. Vaccine may alternatively be administered in the deltoid muscle region of the upper arm in older subjects (from 1 year of age). If another vaccine needs to be administered in the same limb, they should be given at least 2.5cm apart. The site at which each vaccine was given should be noted in the individual's records. The vaccine must not be injected intravenously or intradermally and must not be mixed with other vaccines in the same syringe. The vaccine must not be given subcutaneously except to individuals with a bleeding disorder when vaccines normally given by an IM route should be

Route and method of administration (continued)	given by deep subcutaneous injection to reduce the risk of bleeding (see Green Book Chapter 4). The vaccine is a white opalescent liquid suspension. Upon storage a fine off-white deposit may be observed in the pre-filled syringe containing the suspension. Before use, the pre-filled syringe should be well shaken in order to form a homogeneous suspension. The vaccine should be visually inspected for particulate matter and discoloration prior to administration. In the event of any foreign particulate matter and/or variation of physical aspect being observed, do not administer the vaccine. The vaccine's SPC provides further guidance on administration and is available from the electronic Medicines Compendium website.
Dose and frequency of administration	**Routine Immunisation Schedule** The national recommendation for infants is a two dose primary course of 4CMenB, routinely starting at 8 weeks of age, to be administered with an 8 week interval and a booster dose to be administered, usually on or after their first birthday, although it may be administered until 2 years of age. 4CMenB 0.5ml should ideally be given as follows: • first primary immunisation visit (usually at age 8 weeks) • third primary immunisation visit (usually at age 16 weeks) • booster on or after the first birthday **Individuals with unknown or incomplete vaccination history** Where there is no reliable history of previous immunisation, it should be assumed that they are unimmunised and the full UK recommendations should be followed (see Chapter 11). Infants younger than 12 months should receive the first dose of 4CMenB and second dose of 4CMenB eight weeks later followed by the 4CMenB booster. Doses of MenB should ideally be given 8 weeks apart. They can be given 4 weeks apart in order for the primary MenB immunisation schedule to be completed before the first birthday if possible (if schedule started after 10 months of age). Children aged one year to less than two years who received less than 2 4CMenB doses in the first year of life should receive two doses of 4CMenB at least 8 weeks apart in the second year of life. Doses of MenB can be given 4 weeks apart if necessary to ensure the 2 dose schedule is completed (if schedule started at 22 months of age). For further information see Guidance Vaccination of individuals with uncertain or incomplete immunisation status. **Prevention of secondary cases of Men B disease** Vaccination for the prevention of secondary cases of MenB disease should be given in accordance with recommendations from the UKHSA Health Protection Team and informed by the Guidance for Public Health Management of Meningococcal Disease in the UK.
Duration of treatment	See dose section above

Quantity to be supplied and administered	Single dose of 0.5ml per administration
Supplies	Centrally purchased vaccines for the national immunisation programme can only be ordered via ImmForm. Vaccines for use for the national immunisation programme or for the prevention of secondary cases of MenB disease are provided free of charge. Vaccines for private prescriptions, occupational health use or travel or for individuals going to reside abroad are NOT provided free of charge and should be ordered from the manufacturer or wholesalers. Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see Green Book Chapter 3).
Storage	Store between +2°C to +8°C. Store in original packaging in order to protect from light. Do not freeze. In the event of an inadvertent or unavoidable deviation of these conditions, vaccine that has been stored outside the conditions stated above should be quarantined and risk assessed for suitability of continued off-label use or appropriate disposal. Refer to Vaccine Incident Guidance.
Disposal	Equipment used for immunisation, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of safely in a UN-approved puncture-resistant 'sharps' box, according to local authority regulations and guidance in the technical memorandum 07-01: Health Technical Memorandum 07-01: Safe and sustainable management of healthcare waste (NHSE).
Drug interactions	Individuals with impaired immune responsiveness, whether due to the use of immunosuppressive therapy, a genetic disorder, or other causes, may have reduced antibody response to active immunisation. Vaccination is recommended even if the antibody response may be limited. 4CMenB can be given at the same time as the other vaccines.
Identification and management of adverse reactions Continued over page	The most common local and systemic adverse reactions observed in 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 (≥ 38 °C) and irritability and the development of a rash. Rarely, in infants and children (up to 10 years of age), seizures (including febrile seizures), pallor, eczema and fever (≥ 40 °C) can occur. In infants and children under two years of age, fever ≥38°C (occasionally ≥39°C) was more common when 4CMenB was administered at the same time as routine vaccines (see Chapter 11) than when 4CMenB was given alone. The fever peaks at around 6 hours and has usually gone by 48 hours after vaccination.

Identification and management of adverse reactions (continued)	Due to the high incidence of fever when primary doses of 4CMenB are administered with other routine immunisations, prophylactic use of paracetamol is recommended by the JCVI for infants under one year of age. Advise the parent/carer that a 2.5ml dose of liquid paracetamol (infant paracetamol 120mg/5ml) should be given orally as soon as possible after the vaccination, followed by a second 2.5 ml dose after 4-6 hours and a third 2.5 ml dose 4-6 hours after the second dose. Should fever persist following the third dose and provided that the child appears otherwise well, additional doses of paracetamol may be administered at intervals of four to six hours for up to 48 hours (see paracetamol SPC for doses and frequencies). Parents should be advised to seek medical advice if their child is noticeably unwell with a fever present, or if the fever occurs at other times. Ibuprofen appears to be less effective than paracetamol at controlling fever following vaccination and is not therefore recommended (see Using paracetamol to prevent and treat fever after MenB vaccination guidance and Written information to be given to patient or carer below). Paracetamol prophylaxis is not required if the immunisation visit does not include 4CMenB (for instance the 3-month routine vaccinations) or with the 4CMenB booster after the first birthday (because 4CMenB does not increase the rates of fever at this age). Fever rates in infants receiving 4CMenB alone are similar to the other routine immunisations so paracetamol prophylaxis is not required. A detailed list of adverse reactions is available in the vaccine's SPC, which is available from the electronic Medicines Compendium website
Reporting procedure of adverse reactions	As with all vaccines, healthcare professionals and individuals/parents/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme or search for MHRA Yellow Card in the Google Play or Apple App Store. Any adverse reaction to a vaccine should be documented in the individual's record and the individual's clinician should be informed.
Written information to be given to patient or carer	Offer marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine. For resources in accessible formats and alternative languages, please visit Home - Health Publications. Where applicable, inform the individual/parent/carer that the PIL with large print, Braille or audio CD can be ordered from the manufacturer (see electronic medicines compendium) Immunisation promotional material may be provided as appropriate: • Documents relating to the Meningococcal B (MenB) vaccination programme. • Protecting your baby against meningitis and septicaemia caused by meningococcal B bacteria • A guide to immunisations for babies up to 13 months of age • A quick guide to childhood immunisation for the parents of premature babies • Using paracetamol to prevent and treat fever after MenB vaccination (translated leaflets are also available to download from the health publications website) Available from: www.gov.uk/government/collections/immunisation

Patient advice and follow up treatment	4CMenB is not expected to provide protection against all circulating meningococcal group B strains. Individuals should continue to seek prompt medical attention at the first signs of possible meningitis or septicaemia. Inform individuals who are immunosuppressed or individuals with HIV that the immunogenicity of the vaccine could be reduced. Inform individual/parent/carer of possible side effects and their management. If appropriate, advise the individual/parent/carer about the use and timing of paracetamol doses to reduce the risk, intensity and duration of fever (see Identification and management of adverse reactions). The individual/parent/carer should be advised to seek medical advice in the event of an adverse reaction or if they are concerned that their child is unwell at any time. When applicable, advise the individual/parent/carer when the subsequent vaccine dose is due. When administration is postponed advise the individual/parent/carer when to return for vaccination.
Special considerations and additional information	It is important that premature infants have their immunisations at the appropriate chronological age, according to the schedule. As the benefit of vaccination is high in premature and very premature infants, vaccination should not be withheld or delayed. The occurrence of apnoea following vaccination is especially increased in infants who were born very prematurely (see Cautions). Meningococcal vaccines may be given to pregnant women when clinically indicated. There is no evidence of risk from vaccinating pregnant women or those who are breast-feeding with inactivated bacterial vaccines. **Immunosuppression and HIV infection** Individuals with immunosuppression and human immunodeficiency virus (HIV) infection (regardless of CD4 count) should be given meningococcal vaccines in accordance with the routine schedule (see Cautions). For further information on preventing secondary cases see the UK Health Security Agency Guidance for Public Health Management of Meningococcal Disease in the UK.
Records Continued over page	Record: • that valid informed consent was given or a decision to vaccinate made in the individual's best interests in accordance with the Mental Capacity Act 2005 • name of individual, address, date of birth and GP with whom the individual is registered • name of immuniser • name and brand of vaccine • date of administration • dose, form and route of administration of vaccine • quantity administered • batch number and expiry date • anatomical site of vaccination • advice given, including advice given if excluded or declines immunisation • details of any adverse drug reactions and actions taken • supplied via PGD

Records (continued)	Records should be signed and dated (or a password controlled immuniser's record on e-records). All records should be clear, legible and contemporaneous. This information should be recorded in the individual's GP record. Where vaccine is administered outside the GP setting appropriate health records should be kept and the individual's GP informed. The local Child Health Information Systems team (Child Health Records Department) must be notified using the appropriate documentation/pathway as required by any local or contractual arrangement. A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.

6. Key references

Key references	Meningococcal B Vaccination • Immunisation Against Infectious Disease: The Green Book, Chapter 4, last updated 20 March 2013, Chapter 7, last updated 10 January 2020 and Chapter 22 last updated 17 May 2022 www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book • Bexsero® Summary of Product Characteristics, GlaxoSmithKline UK. Updated 21 July 2023. Bexsero Meningococcal Group B vaccine for injection in pre-filled syringe - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk) • Meningococcal B (MenB) vaccination programme. Updated 12 July 2021. www.gov.uk/government/collections/meningococcal-b-menb-vaccination-programme • Guidance for Public Health Management of Meningococcal Disease in the UK Health Security Agency, updated November 2024 www.gov.uk/government/publications/meningococcal-disease-guidance-on-public-health-management • Vaccination of individuals with uncertain or incomplete immunisation status. UK Health Security Agency. Updated 30 August 2024 www.gov.uk/government/publications/vaccination-of-individuals-with-uncertain-or-incomplete-immunisation-status • Meningococcal B: vaccine information for healthcare professionals www.gov.uk/government/publications/meningococcal-b-vaccine-information-for-healthcare-professionals • Using paracetamol to prevent and treat fever after MenB vaccination guidance updated 24 November 2022 www.gov.uk/government/publications/menb-vaccine-and-paracetamol/using-paracetamol-to-prevent-and-treat-fever-after-menb-vaccination **General** • Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. NHSE www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-htm-07-01/ • National Minimum Standards and Core Curriculum for Immunisation Training. Published February 2018 www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners • NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published March 2017. www.nice.org.uk/guidance/mpg2 • NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. Updated March 2017

Continued over page

Key references (continued)	www.nice.org.uk/guidance/mpg2/resources • UKHSA Immunisation Collection www.gov.uk/government/collections/immunisation • Vaccine Incident Guidance www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors

7. Practitioner authorisation sheet

MenB PGD v7.0 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 insert name of organisation 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.