Public Health England

NHS

PHE publications gateway number: GW-1914

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:	v03.00
Valid from:	1 March 2021
Review date:	1 September 2022
Expiry date:	28 February 2023

Public Health England has developed this PGD to facilitate the delivery of publicly funded immunisation 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)[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'. Only sections 2 and 7 can be amended within the designated editable fields provided.

Operation of this PGD is the responsibility of commissioners and service providers. The final authorised copy of this PGD should be kept by the authorising organisation completing Section 2 for 8 years after the PGD expires if the PGD relates to adults only and for 25 years after the PGD expires if the PGD relates to children only, or adults and children. Provider organisations adopting authorised versions of this PGD should also retain copies for the periods specified above.

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

Practitioners and organisations must check that they are using the current version of the PGD. Amendments may become necessary prior to the published expiry date. Current versions of PHE PGD templates for authorisation can be found from: https://www.gov.uk/government/collections/immunisation-patient-group-direction-pgd

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

Enquiries relating to the availability of organisationally authorised PGDs and subsequent versions of this PGD should be directed to:

[1] This includes any relevant amendments to legislation (such as 2013 No.235, 2015 No.178 and 2015 No.323).

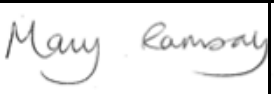
For East Anglia email: England.ea-phsi@nhs.net
For Essex email: England.essexatimms@nhs.net
For Bedfordshire, Hertfordshire, Luton and Milton Keynes email: England.immsqa@nhs.net

Change history

Version number	Change details	Date
V01.00	New MenB Risk Groups PHE PGD Template	08 December 2016
V02.00	MenB Risk Groups PGD amended to: • include additional healthcare practitioners in Section 3 • remove black triangle • refer to vaccine incident guidelines in off-label and storage sections • include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates	21 December 2018
V03.00	MenB Risk Groups PGD amended to: • 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 • exclude those who have completed a course of 4CMenB • include a caution relating to immunosuppressed individuals • update adverse drug reactions section • clarify supplies section • include rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates	28 January 2021

1. PGD development

This PGD has been developed by the following health professionals on behalf of Public Health England:

Developed by:	Name	Signature	Date
Pharmacist (Lead Author)	Elizabeth Graham Lead Pharmacist, Immunisation and Countermeasures, PHE		04/02/2021
Doctor	Mary Ramsay Consultant Epidemiologist and Head of Immunisation and Countermeasures, PHE		04/02/2021
Registered Nurse (Chair of Expert Panel)	David Green Nurse Consultant, Immunisation and Countermeasures, PHE		04/02/2021

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

Expert Panel

Name	Designation
Nicholas Aigbogun	Consultant in Communicable Disease Control, Yorkshire and Humber Health Protection Team, Public Health England
Sarah Dermont	Clinical Project Coordinator and Registered Midwife, NHS Infectious Diseases in Pregnancy Screening Programme, Public Health England
Ed Gardner	Advanced Paramedic Practitioner / Emergency Care Practitioner, Medicines Manager, Proactive Care Lead
Michelle Jones	Senior Medicines Optimisation Pharmacist, NHS Bristol North Somerset & South Gloucestershire CCG
Shamez Ladhani	Paediatric Infectious Disease Consultant, Public Health England
Jacqueline Lamberty	Lead Pharmacist Medicines Management Services, Public Health England
Vanessa MacGregor	Consultant in Communicable Disease Control, Public Health England, East Midlands Health Protection Team
Alison MacKenzie	Consultant in Public Health Medicine, Screening and Immunisation Lead, Public Health England (South West) / NHS England and NHS Improvement South (South West)
Gill Marsh	Senior Screening and Immunisation Manager, Public Health England / NHS England and NHS Improvement (North West)
Lesley McFarlane	Screening and Immunisation Manager: Clinical (COVID-19 and Influenza), Public Health England / NHS England and NHS Improvement (Midlands)
Tushar Shah	Lead Pharmacy Advisor, NHS England and NHS Improvement (London Region)

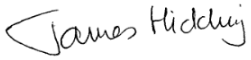
2. Organisational authorisations

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 and NHS Improvement East of England 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 and NHS Improvement East of England commissioned immunisation services or NHS Trust providing immunisation services covering Norfolk, Suffolk, Cambridgeshire, Peterborough, Essex, Southend-on-Sea, Thurrock, Bedfordshire, Hertfordshire, Luton and Milton Keynes local authorities, and Health and Justice facilities where NHS England and NHS Improvement East of England is the commissioner.
Limitations to authorisation
None

Organisational approval (legal requirement)			
Role	**Name**	**Sign**	**Date**
Associate Medical Director	**Dr. James Hickling**		**18/02/2021**

Additional signatories according to locally agreed policy			
Role	**Name**	**Sign**	**Date**
Screening and Immunisation Lead	**Dr. Pam Hall**		**18/02/2021**
Pharmacist	**Dr. Paul Duell**		**16/02/2021**
Screening and Immunisation Coordinator	**Alex Burghelea**		**15/02/2021**

Local enquiries regarding the use of this PGD may be directed to
For East Anglia email: England.ea-phsi@nhs.net
For Essex email: England.essexatimms@nhs.net
For Bedfordshire, Hertfordshire, Luton and Milton Keynes email: England.immsqa@nhs.net

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	Registered professional with one of the following bodies: • nurses and midwives currently registered with the Nursing and Midwifery Council (NMC) • pharmacists currently registered with the General Pharmaceutical Council (GPhC) (Note: This PGD is not relevant to privately provided community pharmacy services) • paramedics and physiotherapists currently registered with the Health and Care Professions Council (HCPC) 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 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	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). Practitioners should be constantly alert to any subsequent recommendations from Public Health England and/or NHS England and NHS Improvement 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 2 years of age, with an underlying medical condition which puts them at increased risk from *Neisseria meningitidis* group B, in accordance with the recommendations given in Chapter 7 and Chapter 22 of Immunisation Against Infectious Disease: 'The Green Book'.
Criteria for inclusion	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). 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.
Criteria for exclusion[2]	Individuals for whom no valid consent has been received Individuals who: • are less than 2 years of age • have had a confirmed anaphylactic reaction to a previous dose of the vaccine or to any constituent or excipient of the vaccine including kanamycin • require vaccination for occupational health reasons, such as laboratory workers working with meningococci • have a history of anaphylactic allergy to latex • are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation) • have completed the routine 2+1 schedule for 4CMenB or received two doses of 4CMenB after their first birthday
Cautions including any relevant action to be taken	Tip cap of the syringe may contain natural rubber latex. For latex allergies other than anaphylactic allergies (such as a history of contact allergy to latex gloves), vaccines supplied in vials or syringes that contain latex can be administered. The immunogenicity of the vaccine could be reduced in immunosuppressed subjects. However, vaccination should proceed in accordance with national recommendations. 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 continued over page	If aged less than 2 years provide 4CMenB in accordance with the national routine immunisation schedule (see MenB PGD). Individuals requiring vaccination for occupational health reasons, such as laboratory workers working with meningococci, should be referred to their occupational health service provider for vaccination.

[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

Action to be taken if the patient is excluded continued	Individuals who have a history of anaphylactic allergy to latex should not be administered 4CMenB unless the benefit of vaccination outweighs the risk of an allergic reaction. Refer to appropriate clinician for assessment of risk:benefit – a PSD will be required. 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. 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 this PGD. 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 individual's 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 individual's GP or a prescriber as appropriate.
Arrangements for referral for medical advice	As per local policy

Continued over page

5. Description of treatment

Name, strength & formulation of drug	Meningococcal group B vaccine (rDNA, component, adsorbed), 4CMenB: • Bexsero® suspension for injection, 0.5ml, in a pre-filled syringe
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'. 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 PHE 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 / method of administration	4CMenB is given as a 0.5ml dose by intramuscular injection usually into the deltoid muscle region of the upper arm in older individuals. When administering at the same time as other vaccines care should be taken to ensure that the appropriate route of injection is used for all the vaccinations. The vaccines should be given at separate sites, preferably in different limbs. If given in the same limb, they should be given at least 2.5cm apart. The site at which each vaccine was given should be noted in the individual's records. The vaccine must not be injected intravenously or intradermally and must not be mixed with other vaccines in the same syringe. The vaccine must not be given subcutaneously except to individuals with a bleeding disorder when vaccines normally given by an IM route should be given by deep subcutaneous injection to reduce the risk of bleeding (see Green Book Chapter 4). 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: www.medicines.org.uk

Dose and frequency of administration	Individuals over 2 years of age should receive two doses of 4CMenB in accordance with Chapter 7 of 'The Green Book' and not less than 1 month apart.
Duration of treatment	See dose section above.
Quantity to be supplied / administered	Single dose of 0.5ml per an administration.
Supplies	Centrally purchased vaccines can be ordered via ImmForm for use under this PGD and are provided free of charge. 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 PHE 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: Safe management of healthcare waste (Department of Health, 2013).
Drug interactions	Immunological response may be diminished in individuals receiving immunosuppressant treatment. Vaccination is recommended even if the antibody response may be limited. 4CMenB can be given at the same time as the other vaccines.
Identification & management of adverse reactions	Diarrhoea and vomiting, eating disorders, sleepiness, unusual crying, headache, arthralgia, injection site reactions (including tenderness, erythema, swelling and induration), fever and irritability and the development of a rash were commonly or very commonly seen in children (up to 10 years of age). In adolescents and adults the most common local and systemic adverse reactions observed were pain at the injection site, malaise and headache. Nausea, myalgia, arthralgia also being commonly or very commonly reported. A detailed list of adverse reactions is available in the vaccine's SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
Reporting procedure of adverse reactions Continued over page	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 at: http://yellowcard.mhra.gov.uk or search MHRA Yellow Card in the Google Play or Apple App store.

Reporting procedure of adverse reactions continued	Any adverse reaction to the vaccine should be documented in the individual's record and the individual's GP 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. Immunisation promotional material may be provided as appropriate: • Splenectomy leaflet • Documents relating to the Meningococcal B (MenB) vaccination programme Available from: www.gov.uk/government/collections/immunisation
Patient advice / 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 the individual/parent/carer of possible side effects and their management. The individual/parent/carer should be advised to seek medical advice in the event of an adverse reaction or if they are concerned that their child is unwell at any time. When applicable, advise individual/parent/carer when the subsequent vaccine dose is due. When administration is postponed advise the individual/parent/carer when to return for vaccination.
Special considerations / additional information	Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a telephone at the time of vaccination. 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. Only those with known splenic dysfunction should be vaccinated in accordance with this PGD. Individuals receiving complement inhibitor therapy (eculizumab) are at heightened risk of meningococcal infection and should be vaccinated with both MenACWY and MenB vaccines (see MenACWY Risk Groups PGD), ideally at least two weeks prior to commencement of therapy. 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. 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.

Records	Record: • that valid informed consent was given • 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 should be signed and dated (or a password controlled immuniser's record on e-records). All records should be clear, legible and contemporaneous. This information should be recorded in the individual's GP record. Where vaccine is administered outside the GP setting appropriate health records should be kept and the individual's GP informed. The local Child Health Information Services team (Child Health Records Department) must be notified using the appropriate documentation/pathway as required by any local or contractual arrangement. 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** • Bexsero® Summary of Product Characteristics, GlaxoSmithKline UK. Updated 13 July 2020.https://www.medicines.org.uk/emc/product/5168 • Immunisation Against Infectious Disease: The Green Book, Chapter 22 last updated 20 September 2016 and Chapter 7, last updated 10 January 2020. https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book **General** • Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20 March 2013 https://www.gov.uk/government/publications/guidance-on-the-safe-management-of-healthcare-waste • National Minimum Standards and Core Curriculum for Immunisation Training. Published February 2018. https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners • NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published March 2017. https://www.nice.org.uk/guidance/mpg2 • NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. Updated March 2017. https://www.nice.org.uk/guidance/mpg2/resources • PHE Immunisation Collection https://www.gov.uk/government/collections/immunisation • PHE Vaccine Incident Guidance https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors

7. Practitioner authorisation sheet

MenB Risk Groups PGD v03.00 Valid from: 01/03/2021 Expiry: 28/02/2023

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.