Public Health England

PHE publications gateway number: GW-100

PATIENT GROUP DIRECTION (PGD)

Administration of meningococcal group B vaccine (rDNA, component, adsorbed) 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 meningococcal group B vaccine (rDNA, component, adsorbed) (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:	v04.00
Valid from:	1 March 2019
Review date:	1 September 2020
Expiry date:	28 February 2021

Public Health England has developed this PGD to facilitate the delivery of publicly funded immunisations 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'. 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.

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

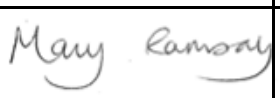
[1] This includes any relevant amendments to legislation (eg 2013 No.235, 2015 No.178 and 2015 No.323).

Change history

Version number	Change details	Date
V01.00	New MenB PHE PGD Template	21 July 2015
V02.00	PHE 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
V03.00	PHE 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
V04.00	PHE 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

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		24/01/2019
Doctor	Mary Ramsay Consultant Epidemiologist and Head of Immunisation and Countermeasures, PHE		24/01/2019
Registered Nurse (Chair of Expert Panel)	David Green Nurse Consultant – Immunisation and Countermeasures, PHE		24/01/2019

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 Management Group and the PHE Quality and Clinical Governance Delivery Board.

Expert Panel

Name	Designation
Ed Gardner	Advanced Paramedic Practitioner / Emergency Care Practitioner, Medicines Manager, Proactive Care Lead
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 / NHS England South (South West)
Gill Marsh	Senior Screening and Immunisation Manager, Public Health England / NHS England Lancashire and South Cumbria
Lesley McFarlane	Screening and Immunisation Co-ordinator, NHS England Leicestershire, Lincolnshire and Northamptonshire
Sally Millership	Consultant in Communicable Disease Control, Public Health England, East of England Health Protection Team
Tushar Shah	Pharmacy Advisor, NHS England London Region
Sharon Webb	Programme Manager / Registered Midwife, NHS Infectious Diseases in Pregnancy Screening Programme, Public Health England
Helen Wilkinson	Principal Pharmacist, Bristol, North Somerset & South Gloucestershire Clinical Commissioning Group

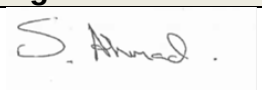
2. Organisational authorisations

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 Hampshire and Thames Valley (HTV) 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 HTV directly commissioned immunisation services. In addition, the PGD may be adopted by provider organisations (providing NHS immunisation and vaccination services) working within the HTV geography. Where this occurs, provider organisations should have this PGD signed off by their governance lead prior to use. Provider organisation staff will be expected to follow local policies and procedures.
Limitations to authorisation
None stated.

Organisational approval (legal requirement)			
Role	**Name**	**Sign**	**Date**
Medical Director	**Shahed Ahmad**		**19/2/19**

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

Local enquiries regarding the use of this PGD may be directed to england.southcentral-pgd@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 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 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 Public Health England Health Protection Teams Note: Individuals, from 2 years of age, with an underlying medical condition which puts them at increased risk from *Neisseria meningitidis* group B, ie individuals with asplenia, splenic dysfunction or complement disorders (including those on, or due to receive, complement inhibitor treatment ie eculizumab), may require additional 'routine' vaccination outside the inclusion criteria for this PGD - see MenB 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 PHE for the prevention of secondary cases of MenB infection • have had a confirmed anaphylactic reaction to a previous dose of the vaccine • have had a confirmed anaphylactic reaction to any constituent or excipient of the vaccine including kanamycin • require vaccination for occupational health reasons e.g. 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)
Cautions including any relevant action to be taken Continued over page	Tip cap of the syringe may contain natural rubber latex. For latex allergies other than anaphylactic allergies (eg a history of contact allergy to latex gloves), vaccines supplied in vials or syringes that contain latex can be administered. 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.

[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)	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 when the individual 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 i.e. eculizumab) should be vaccinated in accordance with the recommended schedules in Chapter 7 and Chapter 22 of 'The Green Book' (see MenB Risk Groups PGD). Individuals requiring vaccination for occupational health reasons, eg laboratory workers working with meningococci, should be referred to their occupational health service provider for vaccination. 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 – A PSD will be required. 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. In a GP practice setting, 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. In a GP practice setting, inform or refer to the GP as appropriate.
Arrangements for referral for medical advice	As per local policy

5. Description of treatment

Name, strength & formulation of drug	Meningococcal group B Vaccine (rDNA, component, adsorbed), 4CMenB, eg: • Bexsero® suspension for injection, 0.5ml, in a pre-filled syringe
Legal category	Prescription only medicine (POM)
Black triangle▼	No
Off-label use	The vaccine schedule differs from the current Bexsero® SPC. However, the national routine schedule is as recommended by the Joint Committee of Vaccination and Immunisation (JCVI) and Public Health England, in line with Chapter 22 of 'The Green Book' and the vaccine schedule for the prevention of secondary cases of MenB disease (Annex A) is in accordance with the Guidance for Public Health Management of Meningococcal Disease in the UK. 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. In infants and for the routine booster dose, PHE recommend 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 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

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Route / method of administration (continued)	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	**Routine Immunisation Schedule** The national recommendation for infants is for 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 **Vaccination of eligible children (born on or after 01/07/2015) with uncertain or incomplete immunisation status** Infants with uncertain or incomplete MenB vaccine history should be vaccinated in accordance with the vaccination of individuals with uncertain or incomplete immunisation status flow chart. Infants under 1 year of age at presentation who have not completed a 4CMenB primary course should complete two doses at least 8 weeks apart and then continue with the routine schedule (ie a booster on or after their first birthday) ensuring at least an 8 week interval between doses. Infants born on or after 1 July 2015, who received less than 2 doses of 4CMenB in the first year of life should receive two doses of 4CMenB at least 8 weeks apart in the second year of life (ie between their first and second birthday). **Prevention of secondary cases of Men B disease** Vaccination for the prevention of secondary cases of MenB disease should be in accordance with recommendations from the local Public Health England Health Protection Team and informed by the Public Health England Guidance for Public Health Management of Meningococcal Disease in the UK. See Annex A for a vaccination schedule based on 4CMenB vaccination status.
Duration of treatment	See dose section above
Quantity to be supplied / administered	Single dose of 0.5ml per an administration
Supplies Continued over page	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 are provided free of charge. Vaccines for private prescriptions, occupational health use or travel, are NOT provided free of charge and should be ordered from the manufacturer/wholesalers.

Supplies (continued)	Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see protocol for ordering storage and handling of vaccines and 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 Continued over page	The most common local and systemic adverse reactions observed in clinical trials after administration of 4CMenB to infants and children (less than 2 years of age) were tenderness and erythema at the injection site, fever and irritability. Diarrhoea and vomiting, eating disorders, sleepiness, unusual crying, headache, arthralgia and the development of a rash were commonly or very commonly seen in this age group. 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 receiving their 4CMenB two dose primary immunisation schedule with other routine immunisations. Paracetamol should be administered at the time or shortly after vaccination to reduce the incidence and severity of fever after vaccination. 2.5ml (60mg) of infant paracetamol 120mg/5ml suspension should be given prophylactically every 4-6 hours for three doses. Recent studies have confirmed that prophylactic paracetamol does not affect the immunogenicity of either 4CMenB or other routine vaccines in the infant immunisation schedule. Paracetamol prophylaxis is not required if the immunisation visit does not include 4CMenB (e.g. 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. See Patient Advice/Follow-up. In adolescents and adults the most common local and systemic adverse reactions observed were pain at the injection site, malaise and headache.

Identification & management of adverse reactions (continued)	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	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
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: • 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 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 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 / additional information Continued over page	Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a telephone at the time of vaccination. Vaccination of preterm infants using Bexsero® is indicated (without correction for prematurity) if the infant is clinically stable. As the benefit of vaccination is high in premature and very premature infants, vaccination should not be withheld or delayed (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. For further information on preventing secondary cases see the Public

Special considerations / additional information (continued)	Health England Guidance for Public Health Management of Meningococcal Disease in the UK.
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 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 June 2012, Chapter 7, last updated 29 September 2016 and Chapter 22 last updated 20 September 2016 https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book • Bexsero® Summary of Product Characteristics, GlaxoSmithKline UK. Updated 7 December 2018. https://www.medicines.org.uk/emc/product/5168 • NHS public health functions agreement 2018-19, Service specification No. 31, Meningococcal group B (MenB) programme. September 2018. https://www.england.nhs.uk/publication/public-health-national-service-specifications/ • Meningococcal B (MenB) vaccination programme. Last updated 19 October 2018. https://www.gov.uk/government/collections/meningococcal-b-menb-vaccination-programme • Guidance for Public Health Management of Meningococcal Disease in the UK, Public Health England, updated February 2018. Published 13 March 2018. https://www.gov.uk/government/publications/meningococcal-disease-guidance-on-public-health-management • Vaccination of individuals with uncertain or incomplete immunisation status. Public Health England. Updated 13 November 2017 https://www.gov.uk/government/publications/vaccination-of-individuals-with-uncertain-or-incomplete-immunisation-status **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-

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Key references (continued)	guidance-responding-to-vaccine-errors • Protocol for ordering storage and handling of vaccines. April 2014. https://www.gov.uk/government/publications/protocol-for-ordering-storing-and-handling-vaccines

7. Practitioner authorisation sheet

MenB PGD v04.00 Valid from: 01/03/2019 Expiry: 28/02/2021

Before signing this 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 patient group direction you are indicating that you agree to its contents and that you will work within it.

Patient group directions 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 **NHS England (HTV)**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.

ANNEX A

Schedule guidance for secondary prevention of MenB disease

Vaccination for the prevention of secondary cases of MenB disease should be in accordance with recommendations from the local Public Health England Health Protection Team and informed by the Public Health England Guidance for Public Health Management of Meningococcal Disease in the UK. The aim of the response is to give protection as early as possible against MenB strains covered by the vaccine.

Age	4CMenB Vaccination Status	Schedule for secondary prevention of MenB disease
< 8 weeks old	Unvaccinated	Vaccinate in accordance with the routine vaccination schedule at the appropriate ages
≥ 8 weeks and < 1 year old	Unvaccinated	Give 2 doses eight weeks apart with a booster at 1 year of age
1-10 year-olds	Unvaccinated	Give 2 doses four weeks apart*
>10 years old and adults	Unvaccinated	Give 2 doses four weeks apart
< 1 year old	Vaccinated	Continue and complete routine vaccination schedule
≥1 year old	Received only a single dose of 4CMenB in infancy	Give a second dose of MenB providing at least four weeks* have elapsed since the last dose. A further dose should be given four weeks* later.
≥1 year old	Completed only primary vaccination with two doses in infancy	Give a single booster dose providing at least four weeks* have elapsed since the last dose.
≥1 year old	Completed only a single dose in infancy and a booster after first birthday	Give a single dose of MenB providing at least four weeks* have elapsed since the last dose.
≥1 year old	Fully vaccinated, have received two or more doses in infancy plus a booster after first birthday.	If the final dose was given more than 12 months previously give a single booster dose of MenB vaccine. If the final dose was given within the past 12 months no further vaccination is needed.
≥1 year old	Partially vaccinated (outside the national programme**), one dose only received after first birthday.	Give a single dose of MenB providing at least four weeks* have elapsed since the last dose.
≥1 year old	Fully vaccinated (outside the national programme**), two doses received after first birthday.	If the final dose was given more than 12 months previously give a single booster dose of MenB vaccine. If the final dose was given within the past 12 months no further vaccination is needed.

*There is no accelerated immunisation schedule for 4CMenB but the interval between doses for 1-10 year olds should be reduced to four weeks for secondary prevention of MenB disease because of the need for rapid protection.

** This may include individuals with asplenia, splenic dysfunction or complement disorder, who have been previously vaccinated due to being at increased risk of meningococcal disease.