Public Health England

NHS

PHE publications gateway number: 2016624

PATIENT GROUP DIRECTION (PGD)

Administration of meningococcal group B vaccine (rDNA, component, adsorbed) 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 meningococcal group B vaccine (rDNA, component, adsorbed) (4CMenB) by currently registered nurses.

Reference no:	MenB Risk Groups PGD
Version no:	v01.00
Valid from:	01 March 2017
Review date:	01 September 2018
Expiry date:	28 February 2019

Public Health England has developed this PGD template to facilitate the delivery of immunisations in the NHS 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.

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

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

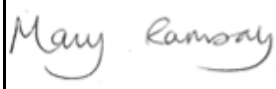
[1] This includes any relevant amendments to legislation (eg 2013 No235, 2015 No.178 and 2015 No.323).

Change history

Version number	Change details	Date
V01.00	New MenB Risk Groups PHE PGD Template	08 December 2016

1. PGD template development

This PGD template 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 Services, PHE		03/02/2017
Doctor	Mary Ramsay Consultant Epidemiologist and Head of Immunisation, Hepatitis & Blood Safety Department, PHE		02/02/2017
Registered Nurse	David Green Nurse Consultant – Immunisations, PHE		06/01/2017

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

Acknowledgements

Name	Designation
Shamez Ladhani	Paediatric Infectious Disease Consultant, Public Health England
Vanessa Saliba	Consultant Epidemiologist , Public Health England
Jacqueline Lamberty	Medicines Management Adviser – Public Health England
Alison Mackenzie	Consultant in Public Health Medicine, Screening and Immunisation Lead, Public Health England / NHS England South (South West)
Gill Marsh	Senior Health Protection Nurse Practitioner, Cheshire & Merseyside Health Protection Team, Public Health England
Lesley McFarlane	Screening and Immunisation Co-ordinator (SIC) NHS England / Public Health England Leicestershire, Lincolnshire and Northamptonshire
Sue Mulvenna	Head of Pharmacy - NHS England South West
Graham Munslow	Clinical Screening and Immunisation Manager, NHS England / Public Health England Greater Manchester Health and Social Care partnership
Matthew Olley	Immunisation Manager, Public Health England / NHS England - London Region

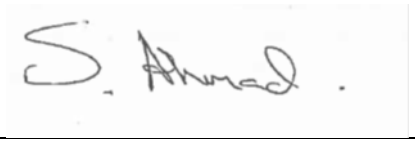
2. Organisational authorisations

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 South (South Central) authorise this PGD for use by the services or providers listed below:

Authorised for use by the following organisations and/or services
All NHS England South (South Central) directly commissioned immunisation services. In addition, PGD adoption by provider organisations (e.g. Sirona) providing this vaccination should have this PGD signed 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**		**27/2/17**

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 currently registered with the Nursing and Midwifery Council (NMC)
Additional requirements	Additionally practitioners: • must be authorised by name as an approved practitioner under the current terms of this Patient Group Direction 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 patient group directions) • must be familiar with the vaccine product and alert to changes in the Summary of Product Characteristics, 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 for Immunisation Training (2005) • 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 Patient Group Direction 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 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 complement inhibitor treatment ie eculizumab). Note: This includes individuals with medical conditions accompanied by functional hyposplenism (eg sickle cell disease) but does not include those with coeliac disease unless concurrent hyposplenism has been diagnosed.
Criteria for exclusion[2]	Patients for whom no valid consent has been received Patients who: • are less than 2 years of age • 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 severe (i.e. 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	Tip cap of the syringe may contain natural rubber latex. For latex allergies other than anaphylactic allergies (e.g. a history of contact allergy to latex gloves), vaccines supplied in vials or syringes that contain latex can be administered. For individuals with a bleeding disorder, vaccines normally given by an intramuscular route should be given by deep subcutaneous injection to reduce the risk of bleeding (see "The Green Book" Chapter 4). 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, eg laboratory workers working with meningococci, should be referred to

[2] Exclusion under this Patient Group Direction 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	their occupational health service provider for vaccination. Individuals who have a history of severe (i.e. 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 Patient Specific Direction (PSD) will be required. In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated and ensure another appointment is arranged. Seek appropriate advice from the local Screening and Immunisation Team, a Consultant in Health Protection or the individual's clinician when a vaccine is indicated outside the remit of this PGD rather than delay immunisation. The risk to the individual of not being immunised must be taken into account. Document 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 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

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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▼	Bexsero®▼is black triangle, *any* suspected adverse reactions should be reported via the National Reporting System and Yellow Card Scheme.
Off-label use	Administration to individuals less than 11 years of age at an interval of not less than 1 month apart is off-label but for individuals from 10 years of age is in accordance with national guidance in Chapter 7 of the Green Book. Administration by deep subcutaneous injection to patients with a bleeding disorder is off-label administration in line with advice in Chapter 4 and Chapter 22 of "The Green Book". Where a vaccine is recommended off-label consider, as part of the consent process, informing the individual/patient/carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence. Off-label vaccine leaflets may be used to support this information.
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) **Handling of vaccine before administration** 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.

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Route / method of administration continued	The vaccine's Summary of Product Characteristics 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 and under 10 years of age should receive two doses of 4CMenB two months apart, unless already received. Individuals from 10 years of age should receive two doses of 4CMenB one month apart, unless already received.
Duration of treatment	See dose section above
Quantity to be supplied / administered	Single dose of 0.5ml per an administration
Supplies	Vaccine for the national immunisation programme should not be used for the vaccination of at risk individuals. Vaccine should be ordered from the manufacturer. 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 at +2°C to +8°C. Store in original packaging in order to protect from light. Do not freeze.
Disposal	Equipment used for immunisation, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of at the end of a session by sealing 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[3]	Immunological response may be diminished in patients receiving immunosuppressant treatment. 4CMenB can be given at the same time as the other vaccines administered as part of the routine childhood immunisation programme.
Identification & management of adverse reactions[3]	The most common local and systemic adverse reactions observed in clinical trials after administration of 4CMenB 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 individuals under 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. A detailed list of adverse reactions is available in the vaccine's Summary of Product Characteristics, which is available from the electronic Medicines Compendium website: www.medicines.org.uk

[3] Refer to British National Formulary (BNF) and Summary of Product Characteristics (SPC) for complete list

Reporting procedure of adverse reactions	As with all vaccines, healthcare professionals and patients/parents/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: http://yellowcard.mhra.gov.uk Bexsero®▼is black triangle. Therefore, *any* suspected adverse reactions should be reported via the National Reporting System and Yellow Card Scheme, documented in the patient's record and the patient'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 patient/parent/carer of possible side effects and their management. The patient/parent/carer should be advised to seek medical advice in the event of an adverse reaction or if they are concerned that their infant is unwell at any time. When applicable, advise patient/parent/carer when the subsequent vaccine dose is due. When administration is postponed advise the patient/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. Minor illnesses without fever or systemic upset are not valid reasons to postpone immunisation. If an individual is acutely unwell, immunisation may be postponed until they have fully recovered. This is to avoid confusing the differential diagnosis of any acute illness by wrongly attributing signs or symptoms to adverse effects of the vaccine. 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 exposure to gluten. Therefore patients 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. 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.

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 Patient Group Direction (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 when vaccine is administered to individuals under 19 years of age. A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.

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6. Key references

Key references	**Meningococcal B Vaccination** • Bexsero® ▼Summary of Product Characteristics, Novartis Vaccines. Updated 11 October 2016 http://www.medicines.org.uk/emc/medicine/28407 • Immunisation Against Infectious Disease: The Green Book, Chapter 22 last updated 20 September 2016 and Chapter 7, last updated 29 September 2016. https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book • Meningococcal B (MenB) vaccination programme. Last updated 26 February 2016. https://www.gov.uk/government/collections/meningococcal-b-menb-vaccination-programme **General** • PHE Immunisation Collection https://www.gov.uk/government/collections/immunisation • British National Formulary (BNF) and British National Formulary for Children (BNF-C) www.BNF.org http://www.evidence.nhs.uk/formulary/bnf/current • National Minimum Standards for Immunisation Training (2005) https://www.gov.uk/government/publications/immunisation-training-national-minimum-standards • NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published August 2013. https://www.nice.org.uk/guidance/mpg2 • NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. January 2014. https://www.nice.org.uk/guidance/mpg2/resources • Immunisation knowledge and skills competence assessment tool. Royal College of Nursing (RCN) 2015. https://www.rcn.org.uk/professional-development/publications/pub-005336 • Protocol for ordering storage and handling of vaccines. April 2014. https://www.gov.uk/government/publications/protocol-for-ordering-storing-and-handling-vaccines • 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

7. Multiple practitioner authorisation sheet

MenB Risk Groups PGD v01.00 Valid from: 01/03/2017 Expiry: 28/02/2019

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 South (South Central)** 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.