This patient group direction (PGD) must only be used by registered health professionals who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used.

Patient Group Direction (PGD)

For the administration or supply of

Meningococcal Group B (rDNA, component, adsorbed) (4CMenB) vaccine

By registered health care professionals for

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.

Throughout the Manx Care and those contracted by the Manx Care where appropriate within practice

PGD NUMBER 78

1. 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
V05.00	PHE 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

2. Medicines practice guideline 2: *Patient group directions*

Refer to the relevant sections of NICE medicines practice guideline 2: *Patient group directions* as stated in the blank template notes. For further information about PGD signatories, see the NHS and Manx Care PGD website FAQs

3. PGD development

Refer to the NICE PGD competency framework for people developing PGDs

Job Title & organisation	Name	Signature	Date
Author of the PGD			
Member of the PGD working group			

4. PGD authorisation

Refer to the NICE PGD competency framework for people authorising PGDs

Job Title	Name	Signature	Date
Medical Director			
Chief Pharmacist/ Pharmaceutical Adviser			
Senior Paramedic			
Director of Nursing			
GP Adviser			
Senior Microbiologist (if PGD contains antimicrobials)			

5. PGD adoption by the provider

Refer to the NICE PGD competency framework for people authorising PGDs

Job title and organisation	Signature	Date	Applicable or not applicable to area

6. Training and competency of registered healthcare professionals, employed or contracted by the Manx Care, GP practice or Hospice

Refer to the NICE PGD competency framework for health professionals using PGDs

	Requirements of registered Healthcare professionals working under the PGD
Qualifications and professional registration	• Registered healthcare professionals, working within or contracted by the Manx Care, GP practice or Hospice who are permitted staff groups outlined within the current PGD policy Additionally practitioners: • 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 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).
Initial training	• Knowledge of current guidelines and the administration of the drug specified in this PGD/BNF and of the inclusion and exclusion criteria • Training which enables the practitioner to make a clinical assessment to establish the need for the medication covered by this PGD • Local training in the use of PGD's

Competency assessment	Staff will be assessed on their knowledge of drugs and clinical assessment as part the competency framework for registered health professionals using PGD's
Ongoing training and competency	The registered health care professionals should make sure they are aware of any changes to the recommendations for this medication; it is the responsibility of the registered health care professionals to keep up to date with continuing professional development. PGD updates will be held every two years

7. Clinical Conditions

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
Inclusion criteria	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, 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 MenB Risk Groups PGD and Chapter 7 of 'The Green Book'
Exclusion criteria[1] *(continued)*	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, for instance laboratory workers working with meningococci • have a history of anaphylactic allergy to latex

[1] 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

Exclusion criteria *(continued)*	• 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 (such as 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. • 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.
Arrangements for referral for medical advice	Patient should be referred to a more experienced clinical practitioner for further assessment
Action to be taken if patient excluded *(continued)*	Patient should be referred to a more experienced clinical practitioner for further assessment • 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 such as 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, such as 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

Action to be taken if patient excluded *(continued)*	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 • Inform or refer to the GP or a prescriber as appropriate
Action to be taken if patient declines treatment	• A verbal explanation should be given to the patient on: the need for the medication and any possible effects or potential risks which may occur as a result of refusing treatment • This information must be documented in the patients' health records • Any patient who declines care must have demonstrated capacity to do so • Where appropriate care should be escalated

8. Details of the medicine

Name, form and strength of medicine	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
Indicate any <u>off-label use</u> (if relevant)	• Administration by deep subcutaneous injection to individuals with a bleeding disorder is off-label administration in line with advice in <u>Chapter 4</u> and <u>Chapter 22</u> of 'The Green Book'. • Vaccine should be stored according to the conditions detailed in the <u>Storage section</u> below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to <u>PHE Vaccine Incident Guidance</u>. 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 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 *(continued)*	**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.

Dose and frequency *(continued)*	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 (that is 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 (that is 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.
Quantity to be administered and/or supplied	Single dose of 0.5ml per an administration
Maximum or minimum treatment period	See dose section above
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
Adverse effects *(continued)*	• 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, 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 infants and children (up to 10 years of age) • 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

Adverse effects *(continued)*	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 (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. 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. 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 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 for MHRA Yellow Card in the Google Play or Apple App Store.
Records to be kept	The administration of any medication given under a PGD must be recorded within the patient's medical records See Appendix C for more information.

9. Patient information

Verbal/Written information to be given to patient or carer	• Verbal information must be given to patients and or carers for all medication being administered under a PGD • Where medication is being supplied under a PGD, written patient information leaflet must also be supplied • A patient information leaflet is available on request 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
Follow-up advice to be given to patient or carer	If symptoms do not improve or worsen or you become unwell, seek medical advice immediately • 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.

10. Appendix A

References

1. British National Formulary (BNF) available online: https://bnf.nice.org.uk
2. Nursing and Midwifery (2018) "The code" available online: https://www.nmc.org.uk
3. Current Health Care Professions Council standards of practice
4. General Pharmaceutical Council standards
5. The General Optical Council
6. Electronic medicines compendium available online: https://www.medicines.org.uk

Meningococcal B Vaccination

- Immunisation Against Infectious Disease: The Green Book, Chapter 4, last updated June 2012, Chapter 7, last updated 10 January 2020 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 13 July 2020. https://www.medicines.org.uk/emc/product/5168
- 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 Updated 6 August 2019. 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 16 December 2019. https://www.gov.uk/government/publications/vaccination-of-individuals-with-uncertain-or-incomplete-immunisation-status

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- 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

11. Appendix B

Health professionals agreed to practice
• Each registered healthcare professional will hold their own Competency framework which will be signed and agreed by their mentor • A mentor is defined within the Manx Care policy as any ward/area managers, sisters, senior nurses, GPs, pharmacists or senior paramedics who has completed the PGD training themselves

12. Appendix C

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. • Vaccination of preterm infants using 4CMenB 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 Health England Guidance for Public Health Management of Meningococcal Disease in the UK.
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.
Records to be kept *(continued)*	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

Records to be kept *(continued)*	• 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.

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 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.