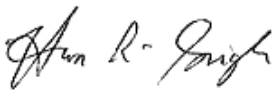
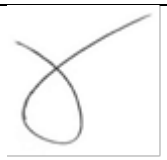
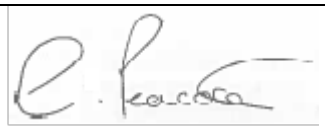
Patient Group Direction (PGD) for the Administration of

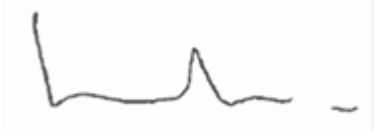
MENINGOCOCCAL B protein Vaccine 4CMenB (Bexsero®▼)

by Registered Professionals to Individuals Accessing NHS Services in Cumbria and North East Sub Region (NHS England North)

YOU MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE YOU ATTEMPT TO WORK ACCORDING TO IT.

Direction Number: - **NECSAT 2019/019**
Valid from: 1st February, 2019
Review date: 1st December, 2020
Expiry date: 31st March, 2021

This patient group direction has been developed & produced by: -			
Title	Name	Signature	Date
Medicines Optimisation Pharmacist (Lead Author) (North of England Commissioning Support)	**Hira Singh** *(Senior Pharmacist)*		31/12/2018
Assistant Medical Director (NHS England, Cumbria and North East)	**Dr James Gossow** *(Senior Doctor)*		24/01/2019
Immunisation and Screening Manager (NHS England, Cumbria and North East)	**Caroline Peacock** *(Senior Nurse)*		02/01/2019

This PGD has been approved for use in Cumbria and North East Sub Region (NHS England) by:			
Title	Name	Signature	Date
Deputy Medical Director (NHS England Cumbria and North East)	**Dr Johnathan Slade** *(Governance Authorisation)*		30/01/2019

1. Clinical Condition or Situation to Which the Direction Applies

Indication (defines situation or condition)

- Patients presenting for immunisation as part of the current NHS immunisation programme

Objectives of care

- To provide active immunisation to patients from 8 weeks old 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 as per Public Health England (PHE) Green Book Guidance

Only use those criteria that are specific to your authorised role & competence.
Ensure appropriate consent has been obtained before commencing any vaccination.

Current PHE immunisation schedule includes anyone falling into the following group: -

- Infants aged from 8 weeks up to their second birthday and require routine immunisation
- Individuals from 2 years of age who are at increased risk of invasive infection with asplenia, splenic dysfunction, or complement disorders (including those receiving complement inhibitor therapy).
  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.
- Those requiring vaccination for the prevention of secondary cases of MenB disease, following specific advice from Public Health England health protection teams (For further information on preventing secondary cases see: https://www.gov.uk/government/publications/meningococcal-disease-guidance-on-public-health-management).

(See PHE Guidance "Immunisation Against Infectious Diseases" Chapter 22 & PHE Guidance for full details).

Exclusion criteria

- No valid consent (as applicable);
- Infants under 2 months of age
- Those who are at increased risk of invasive meningococcal infection with asplenia, splenic dysfunction or complement disorders (including those on complement inhibitor treatment i.e. eculizumab) and are less than 2 years old.
- Individuals from 2 years of age, who do not have an underlying medical condition (i.e. asplenia, splenic dysfunction or complement disorders) which puts them at increased risk from Neisseria meningitidis group B, or for whom additional vaccination has not been advised by PHE for the prevention of secondary cases of MenB infection
- Currently have an acute febrile illness or acute severe systemic illness (NB. Vaccination should only be postponed).
- Infants with confirmed anaphylactic reaction to previously administered dose of the vaccine;
- Infants with confirmed anaphylactic reaction to any component, ingredient or excipient of the vaccine including kanamycin;
- have a history of severe (i.e. anaphylactic) allergy to latex
- require vaccination for occupational health reasons e.g. laboratory workers working with meningococci

Refer to current SPC, Green Book & BNF for full list of details.

Precautions

- Hypersensitivity reactions to previous dose of vaccine or component of vaccine:

  NB. "Local adverse reactions that generally start within a few hours of the injection and are usually mild and self-limiting. Although these are often referred to as 'hypersensitivity reactions', they are not allergic in origin, but may be either due to high titres of antibody or a direct effect of the vaccine product, e.g. endotoxin in whole-cell bacterial vaccines. The occurrence or severity of such local reactions does not contraindicate further doses of immunisation with the same vaccine or vaccines containing the same antigens"
- It is important that premature infants have their immunisations at the appropriate chronological age. Very premature infants (born ≤ 28 weeks of gestation) who are in hospital should have respiratory monitoring for 48-72 hours when given their first immunisations, particularly those with a previous history of respiratory immaturity.
- If the child has apnoea, bradycardia or desaturations after the 1st immunisation, the 2nd immunisation should also be given in hospital, with respiratory monitoring for 48-72hrs. As the benefit of vaccination is high in this group of infants, vaccination should not be withheld or delayed.
- The potential risk of apnoea and the need for respiratory monitoring for 48-72h should be considered when administering the primary immunisation series to very premature infants (born ≤ 28 weeks of gestation) and particularly for those with a previous history of respiratory immaturity.
- 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.
- 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 if excluded

- Discuss with or refer to clinician/doctor. Ensure all actions/decisions are documented.
- The risk to the individual of not being immunised must be taken into account.
- If postponement due to acute illness, arrange a future date for immunisation.
- 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.

Circumstances in which further advice should be sought from a doctor and/or specialist

- Patient meeting the exclusion criteria
- Patient requires additional information in order to decide whether or not to have the vaccination

Action if vaccination refused

- Ensure patient/guardian/carer fully understands the risks of declining vaccination.
- Advise about protective effects of vaccine & the risks of infection and disease complications If postponement due to acute illness, arrange a future date for immunisation
- Document refusal, advice given, actions/decisions in notes (written or electronic). Inform or refer to doctor as appropriate

Special Considerations

- In infants and children under two years of age, fever ≥38°C (occasionally ≥40°C) is more common when 4CMenB is administered at the same time as routine vaccines than when 4CMenB is given alone. Joint Committee of Vaccination and Immunisation (JCVI) recommend administering paracetamol prophylactically when primary doses of 4CMenB are co-administered with other vaccines in infants less than 1 years of age in order to reduce incidence & severity of fever.
- 2.5 ml (60mg) dose of liquid paracetamol should be administered at the time or shortly after vaccination with 4CmenB, followed by a second 2.5 ml (60mg) dose after 4-6hours and a third 2.5 ml (60mg) dose 4-6hours after the second dose. Should fever persist following the third dose and provided that the child appears otherwise well, additional doses of paracetamol may be administered at intervals of four to six hours for up to 48 hours. Parents should be advised to seek medical advice if their child is noticeably unwell with a fever present, or if the fever occurs at other times. Ibuprofen appears to be less effective than paracetamol at controlling fever and other systemic and local symptoms following vaccination and is not therefore recommended.
- Further information is included in the Paracetamol PHE protocol for administration and supply: https://www.gov.uk/government/publications/menb-vaccine-and-paracetamol
- Patients with Asplenia, Splenic dysfunction or complement disorders, (including those receiving complement inhibitor therapy e.g. Eculizumab) should be vaccinated in accordance with the recommended schedules. Please refer to Chapter 7 and 22 of the Green Book (on-line version), as they may require additional doses of 4CMenB.

  (https://www.gov.uk/government/publications/immunisation-of-individuals-with-underlying-medical-conditions-the-green-book-chapter-7)

2. Description of treatment

Name, strength & formulation of drug

Name, strength & formulation of drug:

Bexsero® ▼ [Meningococcal group B Vaccine(rDNA, component, adsorbed) (GlaxoSmithKline UK)

- 1 dose: 0.5 ml suspension in a pre-filled syringe (Type I glass) with a plunger stopper (Type I bromobutyl rubber) and with a protective tip cap (Type I or Type II rubber) with or without needles.
- 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. If two needles of different lengths are provided in the pack, choose the appropriate needle to ensure an intramuscular administration.

Legal Status:

POM –Prescription Only Medicines

Off-Label use:

- The vaccine schedule differs from the current Bexsero®▼ SPC. However, the national routine schedule is as recommended by the JCVI and PHE, 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.
- For individuals who are at increased risk of invasive meningococcal infection with asplenia, splenic dysfunction or complement disorders (including those on complement inhibitor treatment ie eculizumab), administration to those 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".

Dosage / Dose range

0.5ml

Route / Method

Intra-muscular (IM) injection is the preferred route

- Anterolateral left thigh, ideally on its own.

  (Vaccine may alternatively be administered in the deltoid muscle region of the upper arm in older subjects (from 1 year of age)
- Not to be given intravenously.
- Not to be administered in the gluteal muscle or intradermally since this may result in lower immune response.
- For individuals who have a bleeding disorder, vaccines should be given by deep subcutaneous injection (Green Book chapter 4). Manufacturer's SPC states that there is no data on subcutaneous route.
- If given at the same time as other vaccines it should be given at separate sites, preferably in a different limb (anterolateral left thigh). This allows any local reactions to be monitored more accurately. If another vaccine needs to be administered in the same limb, then it must be given at least 2.5cm apart.

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.

The vaccine's SPC provides further guidance on administration and is available from the electronic Medicines Compendium website: www.medicines.org.uk

(Please refer to the manufacturer's SPCs and on line version of the Green Book for detailed information).

Frequency of Administration

The national (Routine Schedule) 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.

Routine Schedule (Born on or after 01/07/2015 and receiving vaccination schedule as planned)

Age	Primary / Booster	Dose
2 months (8 weeks) old	Primary**	1 dose (0.5ml) †
4 months (16 weeks) old	Primary**	1 dose (0.5ml) †
12-13 months old	Booster	1 dose (0.5ml)

† Prophylactic paracetamol is advised where 4CMenB is administered to infants concomitantly with other routine vaccinations at 2 and 4 months – see also 'Adverse Reactions' section.

** NB: Although the summary of product characteristics for 4CMenB states that three doses should be given in those less than one year of age, the Joint Committee on Vaccination and Immunisation have advised that for the routine childhood schedule the provision of two doses of 4CMenB in infancy at two and four months of age with a booster dose at 12-13 months of age would likely be sufficient to provide substantial protection against MenB IMD in infants and toddlers

Frequency of Administration - continued

Vaccination of eligible individuals with unknown or incomplete immunisation status

(Only children born on or after 01/05/15 should be offered MenB)

- **Infants younger than 12 months** at presentation who have not completed a 4CMenB primary course:
  Should receive first dose of 4CMenB and a second 4CMenB dose two months later.
  They should also receive the one year old Hib/MenC dose and 4CMenB booster, ensuring at least a two month (8 week) interval between the 4CMenB doses.

- **Children born after 30th June 2015** (aged 1year to less than 2 years)
  - If received less than 2 doses in first year of life: - give two additional doses of 4CMenB at least 2 months apart in their second year of life (i.e. between their first and second birthday).

Individuals with asplenia, splenic dysfunction or complement disorders
(including those receiving complement inhibitor therapy).

Please refer to page 7, Chapter 7 (Oct. 2016): The Green book (Online) for full details and for details of other vaccines required. (https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/566853/Green_Book_Chapter7.pdf)

Age (when first diagnosed)	**Dosage**
under 1year of age	Children should be fully immunised according to the national schedule
12 - 23 months of age	• If not already administered, give the routine 12-month vaccines (4CMenB, Hib/MenC, PCV13 and MMR). • If not already received, give TWO primary doses of 4CMenB vaccine 2months apart (at the same visit as the other required vaccines).
2 years to under 10yrs of age	Ensure children are immunised according to the national schedule. In addition, • if not already received, give TWO primary doses of 4CMenB vaccine 2 months apart
10 years of age onwards	• If not already received, give TWO primary doses of 4CMenB vaccine 2 months apart

N.B. Children are no longer eligible for routine immunisation with Bexsero®▼ after their 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

Maximum dose / maximum number of vaccinations

- 0.5ml per dose

Maximum number of vaccinations: 3 doses

Follow up treatment

- Follow current DH immunisation schedule (https://www.gov.uk/government/publications/the-complete-routine-immunisation-schedule)

3. Further Aspects of Treatment

Relevant Warnings & Potential Adverse Effects

Relevant Warnings: - See Manufacturers SPC for full details / Green Book chapter 27b

Potential Adverse Effects/Reactions: -

Most common	• Fever (≥ 38°C). Diarrhoea, nausea and vomiting (unusual after booster) • Loss of appetite / Sleepiness, unusual crying. Rash (after Primary) • Injection site tenderness (including severe injection site tenderness defined as crying when injected limb is moved), injection site erythema, injection site swelling, injection site induration, irritability • Headache, Arthralgia
Common & Uncommon	• Rash (after booster) • Pallor (rare after booster)
Rare	• Anaphylaxis,

This list is not exhaustive. Please see current manufacturers Summary of Product Characteristics for details of all potential adverse reactions.

Identification and Management of Adverse Reactions

- Patient/ Carer / Guardian requested to report side effects
- Advice on management including fever and anaphylaxis: - Chapter 8 of the Green Book provides detailed advice on managing adverse drug reactions (ADRs) following immunisation, e.g. Analgesia for pain &/or fever; prevention of dehydration; drinking plenty of clear fluids): https://www.gov.uk/government/publications/vaccine-safety-and-adverse-events-following-immunisation-the-green-book-chapter-8
- Additionally further detailed advice on using paracetamol to prevent and treat fever after MenB vaccination has been provided by PHE; https://www.gov.uk/government/publications/menb-vaccine-and-paracetamol
- Refer to doctor/specialist if appropriate

Reporting Procedure of Adverse Effects

- Report to doctor if appropriate & document in patient's medical records.
- All adverse reactions due to ▼ vaccines should be reported to the MHRA using the yellow card system.
- For established vaccines only report serious adverse reaction. Please refer to www.mhra.gov.uk/yellowcard and the online Green Book - Chapter 9.
- Refer to doctor/specialist if appropriate

  See manufacturers SPC for details of all potential adverse reactions.

Advice to Patient / Carer (verbal or written)

- Explain protection level expected from vaccine.
- Provide a patient information leaflet and discuss as required.
- 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
- Provide advice on & explain potential warnings & side effects and request to report them if they occur.
- Provide advice on management of adverse reactions (see above and manufacturers SPC).
- Should fever persist following the third dose of paracetamol and provided that the child appears otherwise well, additional doses of paracetamol may be administered at intervals of four to six hours for up to 48 hours. Parents should be advised to seek medical advice if their child is noticeably unwell with a fever present, or if the fever occurs at other times. Ibuprofen appears to be less effective than paracetamol at controlling fever and other systemic and local symptoms following vaccination and is not therefore recommended
- Explain procedure for dealing with anaphylaxis /severe allergic reactions.
- Explain the "Out of Hours" procedure.
- Give date of next vaccine if applicable.
- Provide patient with vaccination record card (to include date of next vaccination, completion of course or blood test) if applicable.
- Complete patient-held vaccination record

Arrangements for Referral to Medical Advice

- Doctor/specialist appointment as and when appropriate

Records

In all cases manual records including the Personal Held Child Record, computerised records and data collection for Child Health Information Services (CHIS) should include: -

- Patient's name and date of birth;
- Confirmation that consent has been obtained;
- Reason vaccination required;
- Dose, site and route of injection;
- Date of administration;
- Brand name, batch number and expiry date of vaccine;
- Whom administered by and signature of vaccinator (if not recorded on computer).
- Confirmation that there are no contraindications; That side effects have been discussed;
- Support literature given (where applicable);
- Signature and printed name and designation (in black ink) for paper records. For computer records, ensure data authentication of practitioner delivering care.

Additional Facilities

- Access to updated online Green Book information; the latest SPC and BNF.
- Store in a refrigerator (+2°C to +8°C). Have access to a telephone.
- Stock control & storage of vaccines in accordance with national and local policies / protocols/ guidelines.
- Emergency equipment available including immediate access to Epinephrine (Adrenaline) 1in 1000 injection (as a minimum). (Please refer to PGD for adrenaline as applicable)

Additional Information

- The vaccine is ready to use (no reconstitution or dilution is required) and is to be administered without mixing with any other vaccines or solutions.
- The vaccine should be inspected visually for any foreign particulate matter and/or abnormal physical appearance. In the event of either being observed, discard the vaccine.

References

- 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. January 2014. https://www.nice.org.uk/guidance/mpg2/resources
- 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
- Nursing and Midwifery Council (NMC), 2007: Standards for Medicines Management.
- Nursing and Midwifery Council (NMC), 2007: Record Keeping Advice Sheet.
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- NHS Executive HSC 2000/026 (9th August 2000): Patient Group Directions [England only].
- 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
- 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
- NHS public health functions agreement 2017-18, Service specification No. 31, Meningococcal group B (MenB) programme. April 2017; https://www.england.nhs.uk/publication/public-health-national-service-specifications/
- Immunisation knowledge and skills competence assessment tool. Royal College of Nursing (RCN) 2015. https://www.rcn.org.uk/professional-development/publications/pub-005336
- British National Formulary (BNF), current edition.
- Resuscitation Council (UK), October 2015: Emergency Medical Treatment of anaphylactic reaction by first medical responders and community nurses. www.resus.org.uk/siteindx.htm
- Novartis Bexsero ® vaccine - Summary of Product Characteristics (SPC), 18/09/2017; Accessed on 25/11/18 at https://www.medicines.org.uk/emc/product/5168

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.

4. Characteristics of Healthcare Professional Staff

Only those healthcare professionals that have been specifically authorised by their clinical lead/supervisor/manager may use this PGD for the indications defined within it.

Under current legislation, only the following currently registered healthcare professionals may work under Patient Group Directions (PGDs). These professionals may only supply or administer medicines under a PGD as named individuals. These professionals include -

Pharmacists	Nurses	Chiropodists/Podiatrists
Health Visitors	Physiotherapists	Midwives
Dieticians	Optometrists	Registered Orthoptists
Prosthetists and Orthotists	Radiographers	Occupational Therapists
Speech and Language Therapists	Dental Hygienists	Dental Therapists
State registered paramedics or individuals who hold a certificate of proficiency in ambulance paramedic skills issued by the Secretary of State, or issued with his approval.		

Qualifications required (professional registration applies to specific professions)

Professionals using this PGD must be currently registered with their relevant professional body, e.g.

- For Nurses: - Nursing & Midwifery Council (NMC)
- For Pharmacists: - General Pharmaceutical Council (GPhC)
- For Allied Health Professionals: - Health Professions Council

Additional requirements (applies to all staff)

- Maintain knowledge of vaccinations; either through a recognised course or through in-house training supported by attendance at vaccination study day(s).
- Meeting the requirements of PHE National Minimum Standards and Core Curriculum for Immunisation Training for Registered Healthcare Practitioners. Have up to date resuscitation skills and anaphylaxis training (and competent to recognise & manage anaphylaxis).
- Competent to undertake immunisations and have a current authorised Adrenaline PGD.
- Will have undertaken training in the role, care and administration of the medicine specified in the PGD.
- Have access to a current BNF and *Immunisation Against Infectious Disease* (Green Book online version).
- Any additional training requirements as deemed necessary by your organisation or authorising body.

Continued training requirements (applies to all staff)

- Annual attendance at an update on resuscitation skills and the management of anaphylaxis within the community/primary care (mandatory).
- Maintenance of own level of updating and competence with evidence of continued professional development.
- Annual updates in immunisation (recommended).
- Any continued training requirements as deemed necessary by your organisation or the authorising body.

Individual Healthcare Professional Authorisation

This form can be used for the purpose of managing, monitoring and authorising the use of this Patient Group Direction by the named healthcare professional.

- **This page is to be retained by the individual healthcare professional/practitioner.**
- Each healthcare professional should have access to their own signed copy of the full PGD.
- This PGD is to be read, agreed to and signed by all registered Healthcare Professionals it applies to. Healthcare Professionals must be authorised by the person(s) named below before using the PGD.
- By signing this document, the healthcare professional confirms that they understand the PGD, that they are competent to work under this PGD, that they will practice in accordance with the parameters of the PGD and accept full clinical responsibility for any decisions made with using this PGD).
- Patient Group Directions should be used in conjunction with reference to national or local policies, guidelines or standard text (e.g. manufacturers Summary of Product Characteristics) and DO NOT replace the need to refer to such sources.

Name of Healthcare Professional:-_____

I have read and understood the Patient Group Direction.

Meningococcal B VACCINE (Bexsero®)

I agree to administer Meningococcal B vaccine (Bexsero®) only in accordance with this Patient Group Direction

Signature of Healthcare Professional: - _____

Date signed: - _____

State profession: - _____

Authorisation to use this PGD by: -

This above named healthcare professional has been authorised to work under this PGD by:

Name of Manager/Clinical Lead: - _____

Signature of Manager/Clinical Lead: - _____

Date signed: - _____

PGD Valid from: 1st Feb. 2019	Review Date: - Dec. 2020	**Expiry Date: - 31st March 2021**

Management & Monitoring of Patient Group Direction NECSAT 2019/019

Meningococcal B vaccine (Bexsero®)

Healthcare Professional Authorisation (service/practice list)

This form can be used for the purpose of managing, monitoring and authorising the use of this Patient Group Direction by the named healthcare professionals.

- This page should be signed by all healthcare professionals authorised to use this PGD and retained and kept on file by the service/practice manager as a record of all practitioners authorised to use this PGD.

  NB. Each professional should have access to their own signed copy of the PGD.

The following healthcare professionals are authorised to administer

Meningococcal B vaccine (Bexsero®) under the Patient Group Direction (NECSAT 2019/019)

PGD Valid from date: 1st February 2019 **PGD Expiry Date:** 31st March 2021

Healthcare Professional			**Authorised by:**		
Name	**Signature**	**Date**	**Name**	**Signature**	**Date**

PGD Valid from: 1st Feb. 2019	Review Date: - Dec. 2020	**Expiry Date: - 31st March 2021**