NHS Grampian NHS Highland NHS Orkney NHS Shetland NHS Tayside NHS Eileanan Siar Western Isles

Patient Group Direction for the Administration of Meningococcal Group B Vaccine (Bexsero®) to prevent Gonorrhoea by Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles

Lead Author: Adapted from Public Health Scotland Administration of Meningococcal Group B Vaccine (Bexsero®) to prevent Gonorrhoea Patient Group Direction (PGD) Template Version 1.0 – PHS Publication date 1st of July 2025		**Approver:** NoS PGD Group **Authorisation:** NHS Grampian
Signature:		**Signature:**
NoS Identifier: NoS/PGD_Gonorrhoea/ 1676	**Review Date:** 30 June 2028 **Expiry Date:** 30 June 2028	**Date Approved by NoS:** 22 July 2025

NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles have authorised this Patient Group Direction to help individuals by providing them with more convenient access to an efficient and clearly defined service within the NHS Boards. This Patient Group Direction cannot be used until Appendix 1 and 2 are completed.

Uncontrolled when printed

Version 1.0

Revision History for NoS:

NoS PGD that has been superseded	New PGD from PHS

Most recent changes NoS

Version	Date of change	Summary of Changes	Section heading
1.0	02 July 2025	Reference to NoS Appendix 1 and 2	Authorisation
		Training requirements for NoS	Continuing education and training

PHS recent changes

Version	Date	Summary of changes
1.0	01 July 2025	• New PGD

Review date: The review date for a PGD needs to be decided on a case-by-case basis in the interest of safety. The expiry date should not be more than 3 years, unless a change in national policy or update is required.

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Authorisation

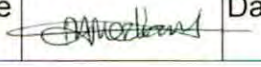
This specimen Patient Group Direction (PGD) template has been produced by Public Health Scotland and adapted by North of Scotland PGD Group (NoS) to assist NHS Boards. NHS Boards should ensure that the final PGD is considered and approved in line with local clinical governance arrangements for PGDs.

The qualified health professionals who may administer vaccine under this PGD can only do so as named individuals. It is the responsibility of each professional to practice within the bounds of their own competence and in accordance with their own Code of Professional Conduct and to ensure familiarity with the manufacturer's product information/Summary of Product Characteristics (SmPC) for all vaccines administered in accordance with this PGD.

NHS Board governance arrangements will indicate how records of staff authorised to operate this PGD will be maintained. Under PGD legislation there can be no delegation. Administration of the vaccine has to be by the same practitioner who has assessed the patient under the PGD.

All authorised staff are required to read the PGD and sign the Agreement to Administer Medicines Under PGD (Appendix 1).

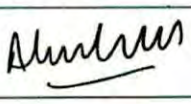
A Certificate of Authorisation (Appendix 2) signed by the authorising professional/manager should be supplied. This should be held in the individual health professional's records, or as agreed within the individual Health Board.

This PGD has been produced for NoS by:					
Doctor	Jenny Wares	Signature		Date Signed	08/07/2025
Pharmacist	Kirsten Smith	Signature		Date Signed	07/07/2025
Nurse	Pauline Merchant	Signature		Date Signed	04/07/2025

Approved for use within NoS by:

NoS Group Chair	**Signature**	**Date Signed**
Lesley Coyle		22/07/2025

Authorised and executively signed for use within NoS by:

NHS Grampian Chief Executive	**Signature**	**Date Signed**
Adam Coldwells – Interim Chief Executive		22/07/2025

Version 1.0 – Approved for NoS from 22 July 2025

1. Clinical situation

1.1. Indication

Immunisation against *Neisseria gonorrhoeae*.

1.2. Inclusion criteria

- Individuals attending sexual health clinics at increased risk of gonorrhoea as recommended in the Gonorrhoea chapter of the Green book and/or Scottish Government communication

Valid consent has been given to receive the vaccine.

1.3. Exclusion criteria

Individuals who:

- have a confirmed anaphylactic reaction to a previous dose of meningococcal group B vaccine.
- have a confirmed anaphylactic reaction to any constituent or excipient of meningococcal group B vaccine. Practitioners must check the marketing authorisation holder's (SmPC) for details of vaccine components.
- have received two doses of 4CMenB as part of their primary immunisation.
- have human immunodeficiency virus (HIV) infection (irrespective of CD4 count), asplenia and complement deficiency (including those on complement inhibitors) who have previously received two doses of 4CMenB because of their higher risk of meningococcal disease.
- have a history of severe (i.e. anaphylactic) reaction to latex where the vaccine is not latex free, including syringe, tip and plunger.
- have acute severe febrile illness – postpone immunisation until patient has fully recovered.

1.4. Cautions/need for further advice/ circumstances when further advice should be sought from a doctor

The Green Book advises that there are very few individuals who cannot receive Meningococcal group B vaccine. Where there is doubt, rather than withholding vaccination, appropriate advice should be sought from the relevant specialist, or from the local immunisation or health protection team.

The presence of a neurological condition is not a contraindication to immunisation but if there is evidence of current neurological deterioration, deferral of vaccination may be considered, to avoid incorrect attribution of any change in the underlying condition. The risk of such deferral should be balanced against the risk of the preventable infection, and vaccination should be promptly given once the diagnosis and/or the expected course of the condition becomes clear.

Individuals with human immunodeficiency virus (HIV) infection (irrespective of CD4 count), asplenia and complement deficiency (including those on complement inhibitors) who have received only one 4CMenB dose can be offered a second dose irrespective of the time interval since the first dose.

Further guidance for the immunisation of HIV-infected individuals is provided by the Royal College of Paediatrics and Child Health (RCPCH), the British HIV Association (BHIVA) and the Children's HIV Association (CHIVA).

Co-administration with other vaccines

There are very limited data for co-administration of 4CMenB with other vaccines that may be administered to individuals attending sexual health clinics. First principles would suggest that any interference between co-administered vaccines with different antigenic content is likely to be limited and any potential interference is most likely to result in a slightly attenuated immune response to one of the vaccines (see Chapter 11). 4CMenB can therefore be administered before, at the same time as, or after other vaccines currently offered in sexual health clinics (including but not limited to hepatitis A, hepatitis B, human papillomavirus and mpox vaccines) without any restrictions on time intervals between different vaccines. Vaccinating in a timely manner when an eligible individual is present in the clinic will avoid any delay in protection and reduce the risk of the individual not returning for a later appointment.

It is recommended that meningococcal B vaccine should be given in a separate limb to other vaccines to enable monitoring of local reactions. If the vaccine is given in the same limb as other vaccines, 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.

Syncope

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.

Pregnancy and breastfeeding

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.

1.5 Action if excluded

Specialist advice must be sought on the vaccine and circumstances under which it could be given. Immunisation using a patient specific direction may be indicated. The risk to the individual of not being immunised must be taken into account.

Document the reason for exclusion and any action taken in accordance with local procedures.

Provide safer sex advice.

Inform or refer to the clinician in charge at the clinic.

Temporary exclusion

In case of postponement due to acute severe febrile illness, arrange a future date for immunisation.

1.6. Action if patient declines

Advise the individual about the protective effects of the vaccine, the risks of infection and potential complications of disease.

Advise how future immunisation may be accessed if they subsequently decide to receive the vaccine.

Provide safer sex advice.

Document advice given and decision reached.

In NHS clinic setting, inform or refer to the clinician in charge.

2. Description of treatment

Meningococcal group B vaccine (Bexsero®).

2.1. Name of medicine/form/strength

Meningococcal group B vaccine (Bexsero®).

Suspension for injection in pre-filled syringe.

2.2. Route of administration

The vaccine is given intramuscularly into the upper arm or anterolateral thigh. This is to reduce the risk of localised reactions, which are more common with subcutaneous injection.

However, for individuals with a bleeding disorder, vaccines should be given by deep subcutaneous injection to reduce the risk of bleeding.

It is recommended the vaccine is given in a separate limb to other vaccines to enable monitoring for local reactions.

Upon storage a fine off-white deposit may be observed in the prefilled 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.

2.3. Dosage

0.5ml

2.4. Frequency

Administer a course of two doses (0.5 ml intramuscular/subcutaneous injection), at least four weeks apart.

There is no maximum time interval limit between the two vaccine doses. Pragmatically and opportunistically, the second dose can be scheduled for the next clinic attendance, which may be after 3, 6 or 12 months. There is no need to recommence the primary immunisation schedule even after a prolonged interval between the two doses.

2.5. Duration of treatment

See Frequency section.

2.6. Maximum or minimum treatment period

See Frequency section.

2.7. Quantity to supply/administer

See Frequency section.

2.8. ▼ black triangle medicines

No.

2.9. Legal category

Prescription only medicine (POM).

2.10. Is the use outwith the SmPC?

Yes.

Administration by deep subcutaneous injection to individuals with a bleeding disorder is off-label administration in line with advice in Chapter 4 and the Gonorrhoea Chapter of the Green Book.

Vaccination for the prevention of gonorrhoea infection is off-label but in line with Gonorrhoea Chapter of the Green Book.

Vaccine should be stored according to the conditions detailed below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to NHS Board guidance on storage and handling of vaccines or National Incident Guidance. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use, administration under this PGD is allowed.

2.11. Storage requirements

Vaccine should be stored at a temperature of +2° to +8°C.

Store in the original packaging to protect from light.

Do not freeze.

NHS Board guidance on Storage and Handling of vaccines should be observed.

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.

2.12. Additional information

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.

Upon storage a fine off-white deposit may be observed in the prefilled 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.

Eligible individuals attending sexual health clinics for testing and/or management of bacterial STIs, including gonorrhoea, should be offered 4CMenB at the same clinic attendance. This is to avoid delay in offering potential protection to those at highest risk of gonorrhoea who may be reinfected before their next visit to the clinic.

Booster

No booster doses are required where previously two doses of 4CMenB are given in eligible individuals.

3. Adverse reactions

3.1. Warnings including possible adverse reactions and management of these

In adolescents and adults the most common local and systemic adverse reactions observed were pain at the injection site, malaise and headache.

For full details/information on possible side effects, refer to the marketing authorisation holder's SmPC.

As with all vaccines there is a very small possibility of anaphylaxis and facilities for its management must be available.

In the event of severe adverse reaction individual should be advised to seek medical advice.

3.2. Reporting procedure for adverse reactions

Healthcare professionals and individuals/carers should report all suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on http://www.mhra.gov.uk/yellowcard

Any adverse reaction to a vaccine should be documented in accordance with locally agreed procedures in the individual's record and the individual's GP should be informed.

3.3. Advice to patient or carer including written information

Manufacturer's patient information leaflet (PIL) provided with vaccine.

Supply immunisation promotional material as appropriate.

Inform of possible side effects and their management.

Give advice regarding normal reaction to the injection e.g. sore limb is possible.

Advise individual to seek medical advice in case of severe adverse reaction.

Provide safer sex advice.

3.4. Observation following vaccination

As syncope (fainting) can occur following vaccination, all vaccinees should either be driven by someone else or should not drive for 15 minutes after vaccination.

Following immunisation, patients remain under observation in line with NHS Board policy.

3.5. Follow up

As above.

3.6. Additional facilities

A protocol for the management of anaphylaxis and an anaphylaxis pack must always be available whenever vaccines are given.

Immediate treatment should include early treatment with intramuscular adrenaline, with an early call for help and further IM adrenaline every 5 minutes.

The health professionals overseeing the immunisation service must be trained to recognise an anaphylactic reaction and be familiar with techniques for resuscitation of a patient with anaphylaxis.

4. Characteristics of staff authorised under the PGD

4.1. Professional qualifications

The following classes of registered healthcare practitioners are permitted to administer this vaccine:

- nurses and midwives currently registered with the Nursing and Midwifery Council (NMC)
- pharmacists currently registered with the General Pharmaceutical Council (GPhC)
- pharmacy technicians currently registered with the General Pharmaceutical Council (GPhC)
- chiropodists/podiatrists, dieticians, occupational therapists, orthoptists, orthotists/prosthetists, paramedics, physiotherapists, radiographers and speech and language therapists currently registered with the Health and Care Professions Council (HCPC)
- dental hygienists and dental therapists registered with the General Dental Council
- optometrists registered with the General Optical Council.

4.2. Specialist competencies or qualifications

Persons must only work under this PGD where they are competent to do so.

All persons operating this PGD

- must be authorised by name by their employer as an approved person under the current terms of this PGD before working to it
- must be familiar with the vaccine product and alert to changes in the manufacturer's product information/summary of product information
- must be competent to undertake immunisation and to discuss issues related to immunisation to assess patients for vaccination and obtain consent
- must be competent in the correct storage of vaccines and management of the cold chain if receiving, responsible for, or handling the vaccine
- must be competent in the recognition and management of anaphylaxis or under the supervision of persons able to respond appropriately to immediate adverse reactions
- must have access to the PGD and associated online resources
- should fulfil any additional requirements defined by local policy

Employer

The employer is responsible for ensuring that persons have the required knowledge and skills to safely deliver the activity they are employed to provide under this PGD

As a minimum, competence requirements stipulated in the PGD must be adhered to.

4.3. Continuing education and training

All practitioners operating under the PGD are responsible for ensuring they remain up to date with the use of vaccines included.

If any training needs are identified these should be discussed with the individuals in the organisation responsible for authorising individuals to act under this PGD.

- Have undertaken NoS PGD module training on TURAS Learn
- Have attended basic life support training either face to face or online and updated in-line with individual Board requirements
- Have undertaken immunisation training where available
- Have undertaken NHS e-anaphylaxis training or equivalent which covers all aspects of the identification and management of anaphylaxis updated in-line with individual Board requirements
- Maintain their skills, knowledge and their own professional level of competence in this area according to their individual Code of Professional Conduct.

5. Audit trail

Record the following information:

- valid informed consent was given
- name of individual, address, date of birth and GP with whom the individual is registered if possible
- name of person that undertook assessment of individual's clinical suitability and subsequently administered the vaccine
- name and brand of vaccine
- date of administration
- dose, form and route of administration of vaccine
- batch number
- where possible 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
- administered under PGD

Records should be kept in line with local procedures.

Local policy should be followed to encourage information sharing with the individual's General Practice.

All records should be clear, legible and contemporaneous and in an easily retrievable format.

6. Additional references

Practitioners operating the PGD must be familiar with:

- Immunisation against Infectious Disease [Green Book]:
- Gonorrhoea Chapter [Green Book]
- Professional Guidance on the Administration of Medicines in Healthcare Settings 2019
- Professional Guidance on the Safe and Secure Handling of Medicines
- All relevant Scottish Government Health Directorate advice including the relevant CMO letter(s)
- Current edition of British National Formulary.
- Marketing authorisation holder's Summary of Product Characteristics
- Educational resources for registered professionals produced by National Education for Scotland

7. PHS Version history

Version	Date	Summary of changes
1.0	01 July 2025	• New PGD

Version history NoS

Version	Date of change	Summary of Changes	Section heading
1.0	02 July 2025	Reference to NoS Appendix 1 and 2	Authorisation
		Training requirements for NoS	Continuing education and training

Appendix 1 - Healthcare Professional Agreement to Administer Medicine(s) Under Patient Group Direction

I: _____ (Insert name)

Working within: _____ e.g. Area, Practice

Agree to administer the medicine(s) contained within the following Patient Group Direction:

Patient Group Direction for the Administration of Meningococcal Group B Vaccine (Bexsero®) to prevent Gonorrhoea by Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles, Version 1.0

I have completed the appropriate training to my professional standards enabling me to administer the medicine(s) under the above direction. I agree not to act beyond my professional competence, nor out with the recommendations of the direction.

Signed: _____

Print Name: _____

Date: _____

Profession: _____

Professional Registration number/PIN: _____

NHS Grampian NHS Highland NHS Orkney NHS Shetland NHS Tayside NHS Eileanan Siar Western Isles

Appendix 2 - Healthcare Professionals Authorisation to Administer Medicine(s) Under Patient Group Direction

The Lead manager/Professional of each clinical area is responsible for maintaining records of all clinical areas where this PGD is in use, and to whom it has been disseminated.
The Senior Nurse/Professional who approves a healthcare professional to administer the medicine(s) under this PGD is responsible for ensuring that they are competent, qualified and trained to do so, and for maintaining an up-to-date record of such approved persons.
The Healthcare Professional that is approved to administer the medicine(s) under this PGD is responsible for ensuring that they understand and are qualified, trained and competent to undertake the duties required. The approved person is also responsible for ensuring that administration is carried out within the terms of the direction, and according to their individual code of professional practice and conduct.
Patient Group Direction for the Administration of Meningococcal Group B Vaccine (Bexsero®) to prevent Gonorrhoea by Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles, Version 1.0
Local clinical area(s) where the listed healthcare professionals will operate under this PGD:

Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date

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Name of Healthcare Professional	**Signature**	**Date**	**Name of Manager**	**Signature**	**Date**