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

VACCINE GROUP DIRECTION (VGD)

For The Administration Of Meningococcal Group B Vaccine (Bexsero®) To Prevent Meningitis B Disease In Young People For Use In NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles

This VGD has been authored by Public Health Scotland (PHS) and authorised by NoS PGD Group on behalf of NoS Boards. PHS Publication date 7th July 2026 Version 1.0		**Approver on behalf of NoS Boards:** NoS PGD Group **Authorisation:** NHS Grampian
		Signature:
NoS Identifier: NoS/VGD/MenBYP/1824	**Review Date:** March 2027 **Expiry Date:** March 2027	**Date Approved by NoS:** 9th July 2026

This VACCINE GROUP DIRECTION (VGD) has been authored by PHS and authorised by NoS PGD Group on behalf of NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles. This VGD is for use, as appropriate, in the time limited vaccination programme to prevent meningitis B disease in young people.

Annex B and C must be completed to comply with the requirements of this VGD.

Uncontrolled when printed

Version 1.0

Public Health Scotland

Vaccine Group Direction: Administration of Meningococcal Group B vaccine (Bexsero®) to prevent meningitis B disease in young people

Publication date: 07 July 2026

Valid From: 07 July 2026

Expiry: 31 March 2027

Version 1.0

Translations and other formats are available on request at:

phs.otherformats@phs.scot

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Most Recent Changes

Version	Date	Summary of changes
1.0	July 2026	New Vaccine Group Direction (VGD) to support time limited meningococcal B vaccination programme.

NoS Document History:

NoS VGD that has been superseded	New PHS Authored VGD. Approved for use by NoS PGD Group on behalf of NoS Boards

Contents

1. About The Vaccine Group Direction (VGD)

This VGD is for the administration of Meningococcal Group B vaccine (Bexsero®) vaccine to prevent meningitis B disease in young people in accordance with the urgent time-limited Meningococcal Group B Vaccination Programme.

This VGD is for the administration of Meningococcal Group B vaccine Bexsero® by appropriately trained persons in accordance with regulation 235A of the Human Medicines Regulations 2012, as amended by the Human Medicines (Amendment) Regulations 2026.

Public Health Scotland, in the capacity of the Scottish public health agency, has produced and authored this VGD, for the purpose of providing protection against an infectious disease, namely meningitis B disease, as part of a vaccination programme which has been approved by Scottish Ministers.

In accordance with regulation 235A, this VGD must be authorised by/on behalf of a senior manager of an NHS Board prior to use in said NHS Board and be in effect at the time at which the medicinal product is administered.

This VGD will facilitate the delivery of the national Meningococcal Group B Vaccination Programme to prevent meningitis B disease in young people by Health Boards in Scotland and any organisation a Health Board makes arrangements with to deliver such services on its behalf, referred to as “the provider”. Please note that in the context of this VGD, “the provider” means:

a. a Health Board,
b. a Health Board working with Armed Forces staff where Armed Forces staff are working in Health Board settings, or
c. an organisation delivering services on behalf of a Health Board.

This VGD may be followed wholly from assessment of an individual through to post-vaccination by a single appropriately specified registered healthcare professional able to operate under Patient Group Directions, as specified in the relevant parts of the Human Medicines Regulations 2012, as amended by the Human Medicines (Amendment) Regulations 2026. **Please note that nursing associates and operating department practitioners are not enabled to consent individuals under VGDs but may carry out non-registrant tasks provided they are supervised by a registered healthcare professional able to operate under Patient Group Directions.** Alternatively, obtaining consent from, and assessment of, an individual may be undertaken by a registered healthcare professional with the processes of vaccine preparation, administration and recording undertaken by a non-registered professional or a non-registered Armed Forces staff member under clinical supervision by a registered healthcare professional.

Where multiple person delivery models are used the provider must ensure that all elements of the VGD are complied with in the provision of the vaccination to each individual. **Please note that only the individual administering a vaccine may undertake reconstitution or dilution and stages 2 and 3 (preparation and administration) must be undertaken by the same individual. Vaccine preparation and administration cannot be separated.**

The provider is responsible for ensuring that persons are trained and competent to safely deliver the activity they are authorised to provide under this VGD. As a minimum, competence requirements stipulated in the VGD under 'Characteristics of staff' must be adhered to.

The provider must identify a clinical supervisor who has overall responsibility for provision of vaccinations under the VGD at all times. This includes overall responsibility for the activities of any Armed Forces staff working under the VGD.

The clinical supervisor must be a registered healthcare professional trained and competent in all aspects of the VGD and provide clinical supervision for the overall provision of clinical care provided under the VGD.

The clinical supervisor must be identifiable to individuals receiving vaccination. Whenever the VGD is used, the name of the clinical supervisor taking responsibility and all of the persons working under different activity stages of the VGD must be recorded for the session using the schedule in Annex C or maintaining an equivalent electronic record.

The clinical supervisor has ultimate responsibility for safe care being provided under the terms of the VGD. Persons working under the VGD may be supported by additional registered healthcare professionals, but the clinical supervisor retains responsibility.

Persons working to the VGD must understand who the clinical supervisor for their practice is at any time and can only work under their authority. The clinical supervisor may withdraw this authority for all persons or individual persons at any time and has authority to stop and start service provision under the VGD as necessary. All members of staff have a responsibility to, and should, report immediately to the clinical supervisor any concerns they have about working under the VGD in general or about a specific individual, process, issue or event.

Individual practitioners must be designated by name to work to this VGD. Persons working in accordance with this VGD must ensure they meet the staff characteristic s for the activity they are undertaking, make a declaration of competence and be authorised in writing by the provider. This can be done by completing Annex B of this VGD or maintaining an equivalent electronic record.

It is a Health Board's responsibility to adhere to this VGD. Where the Health Board is not the provider, it is the Health Board's responsibility to ensure that any organisation they make arrangements with to deliver services on their behalf adheres to this VGD. The final authorised copy of this VGD should be kept by Health Boards for 8 years after the VGD expires. Providers adopting authorised versions of this VGD should also retain copies, along with the details of those authorised to work under it, for 8 years after the VGD expires.

Any provider administering Meningococcal Group B vaccine (Bexsero®) vaccine under VGD must work strictly within the terms of this VGD. **Authorising organisations must not alter, amend or add to the clinical content of this document; such action will invalidate the clinical sign-off with which it is provided in accordance with the regulations. The legal validity of this VGD is**

contingent on those authorising section 2 and Annex B complying with the above.

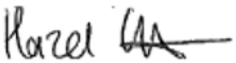
The national Meningococcal Group B Vaccination Programme to prevent meningitis B disease in young people may also be provided under patient group direction, or on a patient specific basis, by or on the directions of an appropriate prescriber. Supply and administration in these instances are not related to this VGD.

Providers must check that they are using the current version of this VGD. Amendments may become necessary prior to the published expiry date. Current versions of VGDs authored by Public Health Scotland in accordance with regulation 235A of the Human Medicines Regulation 2012, as amended by the Human Medicines (Amendment) Regulations 2026, can be requested by emailing phs.vaccination@phs.scot Any concerns regarding the content of this VGD should also be sent to this email address.

2. Approval And Clinical Authorisation

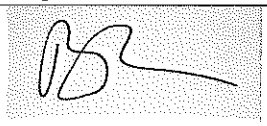
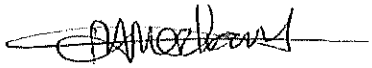
This VGD is not legally valid, in accordance with regulation 235A of the Human Medicines Regulations 2012, as amended by the Human Medicines (Amendment) Regulations 2026, until authored by Public Health Scotland and authorised by NHS Boards in Scotland.

On 07 July 2026 Public Health Scotland approved and authored this VGD in accordance with regulation 235A of the Human Medicines Regulations 2012, as amended by the Human Medicines (Amendment) Regulations 2026. Approval of clinical information in Annex A is via the Clinical Governance and Oversight Group of the Scottish Vaccination and Immunisation Programme on behalf of Public Health Scotland for the delivery of the national Meningococcal Group B Vaccination Programme to prevent meningitis B disease in young people, with defined limitations to authorisation that may be updated from time to time as may be required.

Clinical author signatories – Public Health Scotland			
Role	**Name**	**Signature**	**Date**
Medical	Sam Ghebrehewet		07 July 2026
Pharmacy	Hazel Close		07 July 2026
Nursing	Jill Madden		07 July 2026

Authorised for use by the following organisations and/or services
NoS Boards – authorised by NoS PGD Group on behalf of NoS Boards.
Limitations to authorisation
This authorisation applies to the administration of the Meningococcal Group B vaccine (Bexsero®), only under the conditions set out in the authorisation license set out by the Medicines and Healthcare products Regulatory Agency.

Clinical authorisation acting as a senior manager for/on behalf of the NHS Board or commissioned service

Role	Name	Sign	Date
Medical	Dr Paul Treon		08 July 2026
Pharmacy	Gayle MacDonald		09 July 2026
Nursing	Pauline Merchant		09 July 2026
Chair NoS PGD Group	Lesley Coyle		09 July 2026
Authorised, Executive Approval on behalf of NoS Boards – Chief Executive NHS Grampian	Laura Skaife-Knight		09 July 2026

Approved by NoS PGD Group of behalf of NoS Boards.
Version 1.0 Valid from 9th July 2026.

3. Characteristics Of Staff

Characteristics Of Staff

The provider is responsible for the designation and authorisation of persons within the classes set out below permitted to administer medicinal products under this VGD. In doing so the provider must establish that those persons:

a) demonstrate appropriate knowledge and skills to work under the Vaccine Group Direction for the administration of Meningococcal Group B vaccine (Bexsero®).
b) have met the requirements of the relevant Public Service Delivery (PSD) Scotland, formerly NHS Education for Scotland (NES), Vaccination Proficiency document as appropriate at https://learn.nes.nhs.scot/82079

Classes of persons permitted to administer medicinal products under this VGD		
This VGD may be adhered to wholly from assessment through to post-vaccination by a single appropriately specified registered healthcare professional. Alternatively, multiple persons may undertake specific activity stages in the vaccination pathway in accordance with this VGD under the supervision of the appropriately specified registered healthcare professional[1]. Activity stages of the vaccination pathway under this VGD:		
Stage 1	a) Assessment of the individual presenting for vaccination. b) Provide information and obtain informed consent. c) Provide advice to the individual, including written information.	Registered Healthcare Professionals Only
Stage 2	Vaccine Preparation **Delegation of this stage must be to the same practitioner as stage 3*. Vaccine preparation and administration cannot be separated.**	Registered Healthcare Professionals, non-registered professionals or non-registered Armed Forces staff
Stage 3	Vaccine Administration **Delegation of this stage must be to the same practitioner as stage 2*. Vaccine preparation and administration cannot be separated.**	Registered Healthcare Professionals, non-registered professionals or non-registered Armed Forces staff

Stage 4	Record keeping	Registered Healthcare Professionals, non-registered professionals or non-registered Armed Forces staff

*__From 1 April 2026,__ only the person administering a vaccine may carry out reconstitution or dilution**. Therefore, vaccine preparation and administration must be completed by the same practitioner, where these steps have been delegated by the practitioner working under stage 1.**

Providers are responsible for assessing the competency of, designating and recording the names of, all those persons permitted to administer under this VGD.

[1]The following specified registered healthcare professionals are permitted to operate under the VGD stages 1 to 4, subject to the requirements set out below:

- 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 currently registered with the General Dental Council.
- Optometrists currently registered with the General Optical Council.

The following professionals (who are in the main non-registered) are permitted to administer under the VGD, with appropriate supervision as set out below, subject to the requirements set out below:

- Healthcare support workers
- Pre-registration pharmacists and other pharmacy support practitioners
- Retired clinical practitioners such as doctors, dentists, pharmacists, nurses, optometrists, chiropodists/podiatrists, dieticians, occupational therapists, orthoptists,orthotists/prosthetists, paramedics, pharmacy technicians, physiotherapists, radiographers, speech and language therapists, dental hygienists and dental therapists not currently registered
- Student doctors, dentists, pharmacists, nurses, midwives, optometrists, chiropodists/podiatrists, dieticians, occupational therapists, orthoptists, orthotists/prosthetists, paramedics, physiotherapists, radiographers, speech and language therapists, dental hygienists and dental therapists not currently registered
- Healthcare Scientists
- Dental nurses

- Physician's assistants
- Nursing associates
- Operating department practitioners
- Scottish Ambulance Service Ambulance Technicians

The following non-registered Armed Forces staff are permitted to administer under the VGD with appropriate supervision as set out below, subject to the requirements set out below:

- Combat Medical Technician – Class 1,2 &3 (CMT)
- Royal Navy Medical Assistant (RN MA)
- Royal Air Forces Medic
- Defence Medic
- Healthcare Assistant (HCA)
- Military General Duties Vaccinators

Requirements

All those working under this VGD must have undertaken training, be assessed as competent and receive supervision appropriate to the stage of activity they are undertaking. Where multiple person delivery models are used, the provider must ensure that all elements of the VGD are complied with in the provision of vaccination to each individual. The provider is responsible for ensuring that persons are trained and competent to safely deliver the activity they are employed to provide under this VGD. As a minimum, competence requirements stipulated in the VGD must be adhered to.

All persons must be designated by name by the provider as an approved person under the current terms of this VGD before working to it, and listed on the practitioner authorisation sheet in Annex B. All staff listed on the sheet will be covered by NHS indemnity extended by the Health Board who is responsible for the Meningococcal Group B vaccine (Bexsero®) vaccination programme in that locality. VGDs do not remove inherent obligations or accountability.

All practitioners operating under this VGD must work within their terms of employment at all times; registered healthcare professionals should also abide by their professional code of conduct.

There are three underpinning principles to which every person undertaking activities under the remit of this VGD must adhere.

Training

- They must have undertaken training appropriate to this VGD and relevant to their role, as required by local policy and health board standard operating procedures and in line with the training recommendations for persons vaccinating for Meningococcal Group B disease.
- They must have met the requirements set out in the relevant Public Service Delivery (PSD) Scotland, formerly NHS Education for Scotland (NES) Vaccination Proficiency document.

Competency

- Those providing clinical supervision to those administering the vaccine must be competent to assess individuals for suitability for vaccination, identify any contraindications / exclusions or precautions, discuss issues related to vaccination and obtain informed consent from the individuals being vaccinated. All persons must be one of above noted registered professionals.
- Those that are not registered professionals, and those returning to immunisation after a prolonged interval (more than 12 months), should be assessed and signed off as meeting the requirements of the relevant Public Service Delivery (PSD) Scotland, formerly NHS Education for Scotland (NES) Vaccination Proficiency document. They should be observed preparing and administering the vaccine until both they, and their supervisor or trainer, feel confident that they have the necessary knowledge and skills to prepare and administer vaccines safely and competently.
- Experienced persons should use the relevant PSD Scotland Vaccination Proficiency document to self-assess that they are able to meet all the competencies listed and confirm that they have the knowledge and skills necessary to administer Meningococcal Group B vaccine (Bexsero®). They must have completed local Infection Prevention and Control (IPC) training and comply with the vaccination guidance.

In addition and where indicated as relevant to the role:

- They must be familiar with the vaccine product and alert to any changes in the manufacturers summary of product characteristics (SmPC) and familiar with the national recommendations for the use of this vaccine.
- They must be familiar with, and alert to changes in relevant chapters of The Green Book Chapter.
- They must be familiar with, and alert to changes in the relevant provider's standard operating procedures (SOPs) and provider's arrangements for the national Meningococcal Group B Vaccination Programme to prevent meningitis B disease in young people.
- They must be competent in the correct handling and storage of vaccines and management of the cold chain if receiving, responsible for, or handling the vaccine.
- They must be competent in the recognition and management of anaphylaxis, have completed applicable basic life support training and be able to respond appropriately to immediate adverse reactions.
- They must have access to the provider's VGDs and relevant Meningococcal Group B Vaccination Programme to prevent meningitis B disease in young people online resources.
- For those preparing and administering the vaccine, they must be competent in the handling of the vaccine product and use of the correct technique for preparing the correct dose.
- For those preparing and administering the vaccine, they must be competent in the intramuscular injection technique, this should include a practical element.

- For those in record keeping roles, they must understand the importance of making sure vaccine information is recorded on the vaccination management app.
- They should fulfil any additional requirements defined by local policies developed in accordance with any national guidance.

Supervision

- A period of supervised practice to allow observation of, and development of skills in vaccine administration and application of knowledge to practice is essential.
- Supervision for new immunisers and support for all immunisers is critical to the safe and successful delivery of the Meningococcal Group B Vaccination Programme to prevent meningitis B disease in young people immunisation .
- Non-registered professionals and non-registered Armed Forces staff must be supervised and supported by a registered healthcare professional at all times.
- The clinical supervisor must be a registered healthcare professional trained and competent in all aspects of the VGD and provide clinical supervision for the overall provision of clinical care provided under the VGD.

4. Annex A: Clinical Information

This Annex provides information about the clinical situation or condition and treatment in relation to the Vaccine Group Direction.

4.1 Clinical Condition Or Situation To Which This Vaccine Group Direction Applies

Category	Description
Inclusion Criteria	Immunisation against invasive meningococcal disease caused by Neisseria meningitidis group B. Individuals are eligible for meningococcal B vaccination programme in accordance with the Chief Medical Officer (CMO) letter. Please note this is a time-limited offer (with first doses offered until 31st December 2026 and second doses offered until 31st March 2027), to facilitate provision of two doses for eligible individuals. The eligible groups are the following: • **School-age cohort**: Young people born between 1 March 2008 and 28 February 2009, and others who were in S6 during the academic year 2025/26, regardless of future education plans. • **University entrants:** Any undergraduate under 25 years of age* starting university for the first time in academic year 2026/27, including international students. • **College entrants**: Anyone under 25 years of age* starting college for the first time in academic year 2026/27**, while living away from home in shared student accommodation.** This includes international students. *Individuals who turn 25 years of age between 06/07/2026 and 31/12/26 are eligible. Valid consent has been given to receive the vaccine.
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. • are known to have completed a 2 dose course of Bexsero® within the last 5 years.

	• are known to have completed a 2 dose course (provided those doses were given at least 6 months apart) or 3 dose course of Trumenba® within the last 5 years. • have a history of severe (i.e. anaphylactic) reaction to latex where the vaccine is not latex free, including syringe, tip and plunger. Please note the tip cap of the Bexsero® pre-filled syringe may be made with natural rubber latex. • have acute severe febrile illness – postpone immunisation until patient has fully recovered.
Cautions/need for further advice/ circumstances when further advice should be sought	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 coordinator 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 immunosuppression and human immunodeficiency virus (HIV) infection (regardless of CD4 count) should be given meningococcal vaccines in accordance with national recommendations. These individuals may not make a full antibody response. Re-immunisation should be considered after treatment is finished and recovery has occurred. Specialist advice may be required. Further guidance for the immunisation of HIV-infected individuals is provided by the British HIV Association (BHIVA) Guidelines on the use of vaccines in HIV-positive adults, and the Children's HIV Association (CHIVA) Guidelines on Vaccination of Children Living with HIV. **Co-administration with other vaccines** Meningococcal vaccines can be given at the same time as any other vaccines required including MenACWY, MMR and HPV. The vaccines should be given at a separate site, preferably into a different limb. 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.
Action if excluded	Specialist advice must be sought on the vaccine and circumstances under which it could be given as immunisation using a patient specific direction may be indicated. The risk to the individual not being immunised must be taken into account. Document the reason for exclusion and any action taken in accordance with local procedures. Provide information on meningitis symptoms and advise of need to seek urgent medical attention. Symptoms of meningitis develop suddenly and can include: • a high temperature (fever) over 38°C (100.4°F) • being sick • a headache • a blotchy rash that doesn't fade when a glass is rolled over it (this won't always develop) • a stiff neck • a dislike of bright lights • drowsiness or unresponsiveness • seizures (fits) These symptoms can appear in any order and some may not appear. Inform or refer to the clinician in charge. **Temporary exclusion** In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated and ensure another appointment is arranged.

Action if person 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 information on meningitis symptoms and advise of need to seek urgent medical attention. Symptoms of meningitis develop suddenly and can include: • a high temperature (fever) over 38°C (100.4°F) • being sick • a headache • a blotchy rash that doesn't fade when a glass is rolled over it (this won't always develop) • a stiff neck • a dislike of bright lights • drowsiness or unresponsiveness • **seizures** (fits) These symptoms can appear in any order and some may not appear. Document advice given and decision reached. Inform or refer to the clinician in charge.

4.2 Description Of Treatment

Category	Description
Name of medicine	**Meningococcal group B vaccine (Bexsero®).**
Form	Suspension for injection in pre-filled syringe.
Route of administration	**Meningococcal group B vaccine (Bexsero®)** is given intramuscularly preferably into the deltoid muscle region of the upper arm. The intramuscular route is routinely used because localised reactions are more common when vaccines are given subcutaneously. However, for individuals with a bleeding disorder, vaccines may alternatively be given by deep subcutaneous injection to reduce the risk of bleeding. 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.
Dosage	0.5mL
Frequency	Administer a course of two doses of Bexsero (0.5 mL), at least four weeks apart. There is no maximum time interval limit between the two vaccine doses. There is no need to recommence the immunisation schedule even after a prolonged interval between the two doses. Table 1 below summarises recommendations regarding administration of vaccination to individuals with incomplete or previous meningococcal B vaccination, depending on the number of prior doses received, and of which specific vaccine product. Where an eligible individual is uncertain about their vaccination history and is unable to produce any evidence of prior vaccination when they present, a two dose course of Bexsero should commence rather than risk leaving them unprotected. In clinical trials, no increase in the incidence or severity of the adverse reactions to Bexsero vaccine (commonly pain at the injection site, malaise and headache) was seen with the administration of further doses.

Table 1: Summary of recommendations regarding administration of vaccination to individuals with incomplete or previous meningococcal B vaccination

Meningococcal B vaccination status	Schedule	Additional detail
One dose of Bexsero® (irrespective of timing of that prior dose)	One dose of Bexsero®	Where individuals have received one prior dose of Bexsero®, a further dose should be given, a minimum of 28 days after the first dose, to complete the full course of two Bexsero® doses.
Two doses of Bexsero® less than 5 years ago	No further doses	Where individuals have previously completed a two dose course of Bexsero® within the last 5 years, no further vaccination is required.
Two doses of Bexsero® 5 or more years ago	One dose of Bexsero®	Where individuals have previously completed a two dose course of Bexsero® 5 or more years ago then a single dose should be offered.
Two or three doses of Trumenba® (complete course) 5 or more years ago	A course of two doses of Bexsero® administered at least 4 weeks apart	Two doses of Trumenba® at least 6 months apart are considered equivalent to receipt of three doses. Trumenba® and Bexsero® MenB vaccines are **not** interchangeable. Where individuals have previously completed a course of Trumenba® 5 or more years ago, they should be offered to restart a two dose course with Bexsero®. There is no specific information on the best interval between Trumenba® and Bexsero®, however from first principles an interval of at least 4 weeks is advised.
Two or three doses of Trumenba® (complete course) less than 5 years ago	No further doses	Where individuals have previously completed a course of Trumenba® within the last 5 years, no further vaccination is required.
One dose of Trumenba®, or two doses delivered less than 6 months apart (partial course)	A course of two doses of Bexsero® administered at least 4 weeks apart (or they can choose to complete the Trumenba® schedule but not via the national programme)	Where individuals have had a partial course of Trumenba® (defined as one prior dose, or two doses delivered less than 6 months apart), they may complete their vaccination course of that vaccination. Alternatively, they can be offered a two dose course of Bexsero®.

Duration of treatment	See frequency section.
Maximum or minimum treatment period	See frequency section.
Quantity to administer	See frequency section.
▼ black triangle medicines	No.
Legal category	Prescription Only Medicine (POM)
Is the use outwith the SPC?	Yes. Administration by deep subcutaneous injection to individuals with a bleeding disorder is off-label administration in line with advice in The Green Book Chapter 4. There is no specific information on the best interval between Trumenba® and Bexsero®. Based on official recommendations, an interval of at least 4 weeks is advised, as specified in the CMO letter. 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 VGD is allowed. 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.
Storage requirements	**General 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 use or appropriate disposal.
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.

4.3 Adverse Reactions

Category	Description
Warnings including possible adverse reactions	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 adverse reaction, refer to manufacturer's product literature or 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 a severe adverse reaction individuals should be advised to seek medical advice.
Management of adverse reactions	Anaphylaxis is a very rare, recognised side effect of most vaccines and suspected cases should be reported via the MHRA Yellow Card Scheme. The Green Book Vaccine safety and adverse events following immunisation chapter (8) gives detailed guidance on distinguishing between faints, panic attacks and the signs and symptoms of anaphylaxis. If a case of suspected anaphylaxis meets the clinical features described in The Green Book Vaccine safety and adverse events following immunisation chapter (8) , this should be reported via the Yellow Card Scheme as a case of 'anaphylaxis' (or if appropriate 'anaphylactoid reaction'). Cases of less severe allergic reactions (i.e. not including the clinical features of anaphylaxis) should not be reported as anaphylaxis but as 'allergic reaction'.
Reporting procedure for adverse reactions	Healthcare professionals and individuals/carers should report 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'srecord and the individual's GP should be informed.
Advice to patient or carerincluding written information	**Written information to be given to individual** • Provide manufacturer's consumer information leaflet/patient information leaflet (PIL) provided with the vaccine. • Supply immunisation promotional material as appropriate. **Individual advice/follow up treatment:** • Inform the individual/carer of possible side effects and their management. • Give advice regarding normal reaction to the injection e.g. sore limb is possible. • The individual should be advised to seek medical advice in the event of a severe adverse reaction. • Two doses are essential to protect against most types of meningitis and sepsis caused by meningococcal group B bacteria, as a single dose does not provide protection. • Protective immunity develops around two weeks after the second dose. • The second dose should be offered a minimum of 28 days after the first dose, with first doses offered as early as possible to ensure completion of the course prior to the start of the 2026/27 academic year, where possible. • Recipients must be made aware of the importance of the second dose and supported to return for it. Provide information on meningitis symptoms and advise of need to seek urgent medical attention. Symptoms of meningitis develop suddenly and can include: • a high temperature (fever) over 38°C (100.4°F) • being sick • a headache • a blotchy rash that doesn't fade when a glass is rolled over it (this won't always develop) • a stiff neck • a dislike of bright lights • drowsiness or unresponsiveness • seizures (fits) These symptoms can appear in any order and some may not appear.

Observation following vaccination	As syncope (fainting) can occur following vaccination, where relevant, all vaccinees should either be driven by someone else or should not drive for 15 minutes after vaccination. Following immunisation individuals remain under observation in line with NHS Board policy.
Follow up	As above.
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 professional overseeing the immunisation service must be trained to recognise an anaphylactic reaction and be familiar with techniques for resuscitation of an individual with anaphylaxis.

5. Audit Trail/Records

Name	Description
Record/ audit trail	Record: • that valid informed consent was given • name of individual, address, date of birth and GP with whom the individual is registered • name of person that undertook assessment of individual's clinical suitability • name of person that 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 vaccine group direction. • Records should be kept 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. References

Name	Description
Additionalreferences	• Immunisation against Infectious Disease [Green Book] • Immunisation against Infectious Disease [Green Book] Meningococcal chapter • Prescribing and dispensing / supply / administration by the same healthcare professional - Royal College of Pharmacy • Professional guidance to support prescribing and dispensing / supply / administration by the same healthcare professional - Royal College of Pharmacy • All relevant JCVI statements • 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 Public Services Delivery Scotland, formerly NES • Meningitis | NHS inform. • Meningococcal B (MenB) vaccine for young people | NHS inform

7. Annex B: Practitioner Authorisation Sheet

Meningococcal Group B Vaccination Programme To Prevent Meningitis B Disease In Young People Vaccine Group Direction Version 1.0

Valid from: **9th July 2026**

Expiry: **31st March 2027**

Before signing this VGD, check that the document has had the necessary **authorisations. Without these, this VGD is not lawfully valid.**

Practitioner

By signing this VGD you are indicating that you agree to its contents and that **you will work within it.**

VGDs do not remove inherent professional obligations or accountability.

It is the responsibility of each practitioner to practice only within the bounds of their own competence and any appropriate professional code of conduct.

I confirm that I have read and understood the content of this VGD and that I am willing and competent to work to it within my professional code of conduct.			
Name	Designation	Signature	Date

Person authorising on behalf of the Provider

I confirm that the practitioners named above have declared themselves suitably trained and competent to work under this VGD. I give authorisation on behalf of **insert name of organisation** for the above named health care professionals who have signed the VGD to work under it.			
Name	Designation	Signature	Date

Note to person authorising on behalf of Provider

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 VGD.

8. Annex C: Clinical Supervision Sheet

Meningococcal Group B Vaccination Programme To Prevent Meningitis B Disease In Young People Vaccine Group Direction Version 1.0

Valid from: **9th July 2026**

Expiry: **31st March 2027**

This sheet must record the name of the clinical supervisor taking responsibility and all of the people working under different activity stages of the VGD.

Activity stages of the vaccination pathway under this VGD:

Stage 1	a) Assessment of the individual presenting for vaccination b) Provide information and obtain informed consent c) Provide advice to the individual, including written information	Registered Healthcare Professionals Only
Stage 2	Vaccine Preparation **Delegation of this stage must be to the same practitioner as stage 3*. Vaccine preparation and administration cannot be separated.**	Registered Healthcare Professionals, non-registered professionals or non-registered Armed Forces staff
Stage 3	Vaccine Administration **Delegation of this stage must be to the same practitioner as stage 2*. Vaccine preparation and administration cannot be separated.**	Registered Healthcare Professionals, non-registered professionals or non-registered Armed Forces staff
Stage 4	Record Keeping	Registered Healthcare Professionals, non-registered professionals or non-registered Armed Forces staff

***From 1 April 2026, only the person administering a vaccine may carry out reconstitution or dilution. Therefore, vaccine preparation and administration must be completed by the same practitioner, where these steps have been delegated by the practitioner working under stage 1.**

The clinical supervisor has ultimate responsibility for safe care being provided under the terms of the VGD. Persons working under the VGD may be supported by additional registered healthcare professionals, but the clinical supervisor retains responsibility.

Before signing this VGD, check that the document has had the necessary authorisations. Without these, this VGD is not lawfully valid.

Clinical Supervisor

Name	Designation	Signature	Date

Practitioner(s) and Activity Stages

Name	Activity Stage(s)	Signature	Date	Clinical Supervisor Initials

Note to Clinical Supervisor

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 clinical supervision arrangements for those working under this VGD.

9. Version History

Version	Date	Summary of changes
1.0	July 2026	New Vaccine Group Direction (VGD) to support time limited meningococcal B vaccination programme.