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 Conjugate Vaccine (Bexsero®) By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles

Lead Author: Adapted from PHS National PGD by the Medicines Management Specialist Nurse NHSG	**Consultation Group:** See relevant page in the PGD	**Approver:** NoS PGD Group **Authorisation:** NHS Grampian
Signature: 		**Signature:** 
NoS Identifier: NoS/PGD/Bexsero/ MGPG1213	**Review Date:** November 2023 **Expiry Date:** November 2024	**Date Approved:** November 2021

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 2.2 (Amended July 2022)

Revision History:

Reference and approval date of PGD that has been adapted and/or superseded	PGD adapted from PHS national template and supersedes NoS/PGD/Bexsero/MGPG1213 Version 2.1.1

Date of change	**Summary of Changes**	**Section heading**
September 2021	Yearly updated PGD adapted from PHS PGD template. This PGD has undergone minor rewording, layout, formatting changes.	
September 2021	Cautions sectioned updated with additional wording about latex allergy.	Precautions and special warnings
September 2021	Action if excluded section wording updated to indicate that vaccination under a patient specific direction may be indicated when excluded.	Action if excluded from treatment
March 2022	Wording changed to include all healthcare professionals approved in current legislation that can operate under a PGD.	Professional qualifications and Authorisation of administration
April 2022	Minor amendment to Authorisation of Administration section due to omission of occupational therapist, orthoptist/prosthetists, radiographers and speech and language therapists to include all registered healthcare professionals that may be authorised to operate under this PGD.	Authorisation of Administration
July 2022	PGD transferred onto new NoS vaccine PGD template following an update to the PHS National PGD template.	Throughout
July 2022	Inclusion criteria expanded to include other patient groups out with the Scottish childhood immunisation programme.	Inclusion criteria
July 2022	Section updated to include dosing information for the other patient groups out with the Scottish childhood immunisation programme.	Frequency of dose/Duration of treatment
July 2022	Information on individuals with asplenia, splenic dysfunction or complement disorders and individuals receiving complement inhibitor therapy included.	Additional information
July 2022	Section updated to include information on administration of paracetamol to be age or weight based.	Identifying and managing possible adverse reactions

NoS Identifier:	NoS/PGD/Bexsero/MGPG1213 Version 2.2
Keyword(s):	PGD Patient Group Direction Meningococcal Group B Conjugate Vaccine Bexsero Nurses Health Visitors

Policy Statement:
It is the responsibility of the individual healthcare professional and their line managers to ensure that they work within the terms laid down in this PGD and to ensure that staff are working to the most up to date PGD. By doing so, the quality of the services offered will be maintained, and the chances of staff making erroneous decisions which may affect individual, staff or visitor safety and comfort will be reduced. Supervisory staff at all levels must ensure that staff using this PGD act within their own level of competence.

The lead author is responsible for the review of this PGD and for ensuring the PGD is updated in line with any changes in clinical practice, relevant guidelines, or new research evidence.

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.

Document:	Drafted:	September 2021
	Completed:	November 2021
	Approved:	November 2021 (published – December 2021, August 2022)
	Amended and reauthorised:	March 2022, April 2022, July 2022

Organisational Authorisations

This PGD is not legally valid until it has had the relevant organisational authorisation.

PGD Developed/Reviewed by;

Medical practitioner	**Name:** Dr Jenny Wares **Health Board:** NHSH **Title:** Public Health Consultant **Contact email:** jenny.wares@nhs.scot **Signature:** ..... **Date signed:** 23/08/2022
Senior representative of the professional group who will provide care under the direction	**Name:** Fiona Browning **Health Board:** NHSG **Title:** Health Protection Nurse Specialist **Contact email:** fiona.browning@nhs.scot **Signature:** ..... **Date signed:** 09/08/2022
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Approved for use within NoS Boards by;

North of Scotland (NoS) PGD Group Chair	Signature	Date Signed
Lesley Coyle		19/07/2022

Authorised and executively signed for use within NoS Boards by;

NHS Grampian Chief Executive	Signature	Date Signed
Professor Caroline Hiscox		23/08/2022

Management and Monitoring of Patient Group Direction

PGD Consultative Group

The consultative group is legally required to include a medical practitioner, a pharmacist and a representative of the professional group who will provide care under the direction.

Name:	Title:
Frances Adamson	**Lead Author:** Medicines Management Specialist Nurse NHSG
Alison Jane Smith	**Pharmacist:** Medicines Management Pharmacist NHSG
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Clinical indication to which this PGD applies

Definition of situation/Condition	This Patient Group Direction (PGD) will authorise approved healthcare professionals as detailed in the characteristics of staff authorised to work under this PGD to administer Meningococcal group B vaccine (Bexsero®) for vaccination against meningococcal group B disease. This PGD should be used in conjunction with the recommendations in the current British National Formulary (BNF), British National Formulary for Children (BNFC), The Green Book and the individual Summary of Product Characteristics (SmPC).
Inclusion criteria	• Individuals from six weeks of age as part of the Scottish childhood immunisation programme. • Individuals with uncertain or incomplete immunisation status in accordance with the vaccination of individuals with uncertain or incomplete immunisation status flow chart • Individuals requiring vaccination for the prevention of secondary cases of Meningitis B, following specific advice from NHS Board Health Protection Teams • Individuals who are at increased risk of invasive meningococcal infection due to underlying medical conditions or medicinal treatment as described in The Green Book Chapter 7 and Chapter 22 • Revaccination of individuals who have received a haemopoietic stem cell transplant. Prior to the administration of the vaccine, valid consent to receiving treatment under this PGD must be obtained. Consent must be in line with current individual NHS Boards consent policy.
Exclusion criteria	Individuals who: • Are less than 6 weeks of age • 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 summary of product characteristics (SmPC) for details of vaccine components.

	• Have a confirmed anaphylactic reaction to latex. The tip-cap of the syringe may contain natural rubber latex. For latex allergies other than anaphylactic allergies (such as a history of contact allergy to latex gloves), vaccines supplied in vials or syringes that contain latex can be administered. • Acute severe febrile illness –postpone immunisation until the individual has fully recovered. Individuals for whom no valid consent has been received.
Precautions and special warnings	Minor illness without fever or systemic upset is not a valid reason to postpone immunisation. If an individual is acutely unwell, immunisation may be postponed until they have fully recovered. 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.
Action if excluded from treatment	Medical advice must be sought – refer to relevant medical practitioner for advice on the vaccine and circumstances under which it could be given using a patient specific direction. The risk to the individual of not being immunised must be taken into account. Discussion of the risk and benefits of vaccination should take place. Discussions and decisions taken should be documented in clinical records. In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated at a later date and ensure another appointment is arranged. If aged less than 6 weeks advise to return for routine immunisation when the child is eight weeks of age or over and give an appropriate appointment. Immunisation can be administered from six weeks of age if required e.g. if

	travelling to an endemic country or given early with the first dose of the Hexavalent vaccine to provide protection against hepatitis B infection. Document the reason for exclusion under the PGD and any action taken in the individual's appropriate clinical records.
Action if treatment is declined	Advise about the protective effects of the vaccine and the risk of infection and disease complications. Ensure they have additional reading material e.g. the Patient Information Leaflet (PIL) available to print here. Document advice given and decision reached. Advise how future immunisation may be accessed if they subsequently decide to receive the vaccine. Inform/refer to the relevant medical practitioner if individual/parent/carer declines treatment. Document that the administration of the vaccine was declined, the reason and advice given in appropriate clinical records.

Description of vaccine available under the PGD

Name form and strength of vaccine	Meningococcal group B vaccine (Bexsero®) suspension for injection in pre-filled syringe.
Legal status	Bexsero® is a Prescription-only Medicine (POM).
Is the use out with the SmPC?	The administration of this vaccine by subcutaneous injection to individuals with a bleeding disorder is outside the terms of the marketing authorisation and constitutes an off-label use of the vaccine. However, the use of the vaccine in this way is in-line with recommendations in The Green Book Chapter 4. The individual or the person with parental responsibility should be informed prior to the administration that the use is off-label. In certain circumstances, the first set of primary immunisations (including Meningococcal B) can be administered from 6 weeks of age, for example for infants that are due to travel to another country before they reach 8 weeks of age when the primary immunisations are usually given. However, Meningococcal B vaccine is licensed from 8 weeks of age so if it is administered earlier than this it is treated as 'off label' use of a licensed medicine.

	There may also be circumstances where the second Meningococcal B vaccine dose may be given seven weeks after the first. However, the recommended interval between doses is eight weeks. Accordingly, if the second dose is given seven weeks after the first dose this it is treated as 'off label' use of a licensed medicine. The individual or the person with parental responsibility should be informed prior to the administration that the use is off-label, however the vaccine is being offered in accordance with national guidance. 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 guidance. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use, administration under this PGD is allowed.
Dosage/Maximum total dose	0.5mL
Frequency of dose/Duration of treatment	**Routine Immunisation Programme:** The routine infant immunisation schedule for 4CMenB is a two dose primary course followed by a booster dose, ideally given as follows: • First primary dose usually at age 8***** weeks • Second primary dose usually at age 16 weeks • Booster dose on or after the first birthday (although it may be administered until 2 years of age) *****The first dose of primary immunisations can be given at 6 weeks of age if required in certain circumstances e.g. travel to an endemic country or given early with the first dose of the Hexavalent vaccine to provide protection against hepatitis B infection. There are no clinical data on whether the interval between the first and second doses can be reduced below two months. Where other primary immunisations are being given before the scheduled date e.g. due to impending travel to an endemic country or if, for practical reasons, it is not possible to schedule the second dose at the recommended interval of eight weeks after the first, or there is a high likelihood that the individual will not return for a second dose eight weeks after the first, then the second dose can be given seven weeks after the first dose in order to complete primary immunisation.

	If the primary course is interrupted, it should be resumed and not repeated, allowing an interval of two months between the doses. Those individuals with uncertain or incomplete immunisation status should be vaccinated in accordance with the vaccination of individuals with uncertain or incomplete immunisation status flow chart. **Prevention of secondary cases of Meningococcal B disease:** Vaccination for the prevention of secondary cases of Meninigococcal B disease should be in accordance with recommendations from the local Public Health Protection Team and informed by the Public Health England Guidance for Public Health Management of Meningococcal Disease in the UK. **Meningococcal vaccination schedule for children and adults at risk of invasive meningococcal disease:** In accordance with the schedule for immunising individuals at increased risk of meningococcal disease summarised in the Green Book, Chapter 7, depending on the age at which their at-risk condition is diagnosed. **Revaccination of individuals who have received a haemopoietic stem cell transplant:** In accordance with the schedule recommended by the Scottish Haematology Society vaccination policy (Post HSC Transplantation):
Maximum or minimum treatment period	See Frequency of dose/Duration of treatment section above.
Route/Method of administration	Intramuscular injection into the deltoid region of the upper arm or anterolateral aspect of the thigh. 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.

	Meningococcal Group B vaccine can be given at the same time as other vaccines such as rotavirus, pneumococcal, measles, mumps and rubella (MMR), diphtheria, tetanus, pertussis, polio, Hib and MenC. When administering at the same time as other vaccines care should be taken to ensure that the appropriate route of injection is used for each of the vaccinations. The vaccines should be given when possible in different limbs to allow monitoring of local reactions to Bexsero® vaccine. If given in the same limb they should be given at different sites at least 2.5cm apart (American Academy of Paediatrics 2003). The site at which each vaccine was administered should be noted in the individual's records.
Quantity to be administered	0.5mL
Storage requirements	Vaccine will be stored in a temperature controlled refrigerator between +2°C and +8°C. Refrigerators should have maximum and minimum temperatures recorded daily. Store in original packaging in order to protect from light. Do not freeze. Individual NHS Board guidance on the storage, handling and cold chain in relation to vaccines must be observed. Likewise, individual NHS Board guidance in relation to waste management and the disposal of all spent, partially spent or unused vaccines must also 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.
Additional Information	Very premature infants (born less than or equal to 28 weeks of gestation) who are in hospital should have respiratory monitoring for 48 to 72 hrs when given their first immunisation, particularly those with a previous history of respiratory immaturity. If the child has apnoea, bradycardia or desaturations after the first immunisation, the second immunisation should also be given in hospital, with respiratory monitoring for 48 to 72 hrs. The immunogenicity of the vaccine could be reduced in immunosuppressed individuals. However, vaccination should proceed in accordance with national recommendations.

	Medical conditions such as coeliac disease, sickle cell disease and other haemoglobinopathies may be accompanied by functional hyposplenism. However, hyposplenism in coeliac disease is uncommon in children, and the prevalence correlates with the duration of exposure to gluten. Therefore, individuals diagnosed with coeliac disease early in life and well managed are unlikely to require additional Meninigococcal B vaccine. Only those with known splenic dysfunction should be vaccinated in accordance with this PGD. Individuals receiving complement inhibitor therapy (eculizumab) are at heightened risk of meningococcal infection and should be vaccinated with both Meninigococcal B and MenACWY vaccines (see MenACWY PGD), ideally at least two weeks prior to commencement of therapy. Prophylactic paracetamol is not indicated when 4CMenB is given to children from 2 years of age but may be used to manage a fever should one occur. 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
Follow-up (if applicable)	Following immunisation patients should remain under observation in line with individual NHS Board policy. The Individual/parent/carer should not leave if they are feeling unwell/they have any concerns that the vaccine recipient is unwell without speaking to the healthcare professional who administered the vaccine first. If necessary a doctor or the individuals GP should be contacted for advice.
Advice (Verbal)	• Advise individual/parent/carer what to expect and of the possible side effects and their management. • Advise parent/carer that paracetamol can be obtained from a community pharmacy and administer a dose of paracetamol in accordance with the NoS Patient Group Direction For The Administration Of Paracetamol 120mg/5mL Oral Suspension, At The Time Of Administration Of Meningococcal Group B Conjugate (Bexsero®) Vaccine, By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles. • Inform parent/carer that where Bexsero® is given at the same time as other vaccines in infancy three doses of paracetamol (age or weight appropriate) should be given orally, with the first dose provided at the time of vaccination as per PGD above, or as soon as possible after vaccination

	and that two subsequent doses should be administered at intervals of 4 to 6 hours. • If serious adverse or persistent effects occur, the individual/parent/carer should be advised to contact their GP/Accident and Emergency Department/NHS24. • Individuals/carers should be advised to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme. • When administration is postponed advise the individual/parent/carer when to return for vaccination. If appropriate, advise when subsequent doses are due and if any follow up is required.
Advice (Written)	The PIL contained in the medicine(s) should be made available to the individual/parent/carer. Where this is unavailable, or unsuitable, sufficient information should be given in a language that they can understand. More information regarding this vaccine can be found at: https://www.nhsinform.scot/healthy-living/immunisation
Identifying and managing possible adverse reactions	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. The most commonly seen reactions are minor local injection site reactions such as hardening of the skin, oedema, pain and redness. A small painless nodule may form at the injection site. Diarrhoea and vomiting, eating disorders, sleepiness, unusual crying, headache, arthralgia, injection site reactions (including tenderness, erythema, swelling and induration), fever and irritability and the development of a rash were commonly or very commonly seen in children (up to 10 years of age). In infants and children under two years of age, fever greater than or equal to 38°C (occasionally greater than or equal to 40°C) was more common when Bexsero® was administered at the same time as routine vaccines than when Bexsero® was given alone.

	Prophylactic paracetamol around the time of vaccination is not routinely recommended for preventing post-vaccination fever because of concerns that it may lower antibody responses to some vaccines. Where such vaccines are co-administered with Bexsero®, however, giving paracetamol at the time of vaccination reduces the fever associated with vaccination but does not affect the immunogenicity of either Bexsero® or routine vaccines in infants. Paracetamol should, therefore, be offered prophylactically when Bexsero® is given with the routine vaccines in infants under one year of age. Paracetamol is not routinely recommended when Bexsero® is not given with 6:1 routine infant vaccine in children over the age of 12 months. Where Bexsero® is given at the same time as other vaccines in infancy, three doses of paracetamol (age or weight appropriate) should be given orally, with the first dose provided as soon as possible after vaccination and two subsequent doses at intervals of 4 to 6 hours. Parent/carer's should be advised to seek medical advice if their child is noticeably unwell with a fever present. In adolescents and adults the most common local and systemic adverse reactions observed were pain at the injection site, malaise and headache. Nausea, myalgia, arthralgia also being commonly or very commonly reported. As with all vaccines there is a very small possibility of anaphylaxis and facilities for its management must be available. **This list is not exhaustive. Please also refer to current BNF/BNFC and manufacturers SmPC for details of all potential adverse reactions.** **BNF/BNFC**: BNF British National Formulary - NICE BNF for Children British National Formulary - NICE **SmPC/PIL/Risk Minimisation Material:** Home - electronic medicines compendium (emc) MHRA Products | Home RMM Directory - (emc) If an adverse reaction does occur give immediate treatment and inform relevant medical practitioner as soon as possible. Document in accordance with locally agreed procedures in the individual's record.

	Report any suspected adverse reactions using the Yellow Card System. Yellow Card Scheme - MHRA
Facilities and supplies required	The following are to be available at sites where the vaccine is to be administered: • Pharmaceutical refrigerator (or a validated cool box for storing vaccine if mobile unit) • An acceptable level of privacy to respect individual's right to confidentiality and safety • Basic airway resuscitation equipment (e.g. bag valve mask) • Immediate access to Epinephrine (Adrenaline) 1 in 1000 injection • Access to a working telephone • Another competent adult, who can summon urgent emergency support if required should ideally be present • Access to medical support (this may be via the telephone) • Approved equipment for the disposal of used materials • Clean and tidy work areas, including access to hand washing facilities or alcohol hand gel • A copy of this PGD in print or electronically

Characteristics of staff authorised to administer vaccine under PGD

Professional qualifications	The following classes of registered healthcare practitioners are permitted to administer vaccines as identified and included in individual Board immunisation delivery plans: • Nurses and midwives currently registered with the Nursing and Midwifery Council (NMC) • Pharmacists 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.
Specialist competencies	**Approved by the organisation as:** • Competent to assess the individual/parent/carer's capacity to understand the nature and purpose of vaccination in order to give or refuse consent

	• Familiar with the vaccine product and alert to changes in the product information. • Competent to undertake administration of the vaccine and discuss issues related to vaccination • Competent in the recognition and management of anaphylaxis or under the supervision of persons able to respond appropriately to immediate adverse reactions • Competent in the handling and storage of vaccines, and management of the "cold chain" • Competent to work under this PGD and authorised by name as an approved person to work under the terms of the PGD.

Ongoing training and competency	**All professionals working under this PGD must:**
	• 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
	• 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. **Note:** All practitioners operating under the PGD are responsible for ensuring they remain up to date with the use of the vaccine. If any training needs are identified these should be discussed with those responsible for authorisation to act under the PGD.
	• Have knowledge and familiarity of the following;
	  ○ Current edition of the Green Book
	  ○ SmPC for the vaccine to be administered in accordance with this PGD
	  ○ Relevant policy relating to vaccine storage and immunisation procedures for use within their Health Board
	  ○ Relevant Scottish Government Health Directorate advice including the relevant CMO letter(s).

Responsibilities of professional manager(s)	**Professional manager(s) will be responsible for;** Ensuring that the current PGD is available to all staff providing care under this direction. Ensuring that staff have received adequate training in all areas relevant to this PGD and meet the requirements above.

	Maintain up to date record of all staff authorised to administer the vaccine specified in this direction.

Documentation

Authorisation of administration	Qualified registered healthcare professionals working within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles listed and approved in legislation as able to operate under PGD can be authorised to administer the vaccine specified in this PGD in accordance with local delivery plans and by agreement at individual Board level as per the following: Nurses, midwives and health visitors can be authorised by their line manager. Pharmacists working within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles can be authorised to administer the medicine(s) specified in this PGD when they have completed local Board requirements for service registration. The following list of healthcare professionals can be authorised by their Line Manager, Head of Service or Vaccine Coordinator: Chiropodists, dental hygienists, dental therapists, dieticians, occupational therapists, optometrists, orthoptists, orthotist/prosthetists, paramedics, physiotherapists, podiatrists, radiographers and speech and language therapists. 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.
Record of administration	An electronic or paper record for recording the screening of individuals and the subsequent administration, or not of the vaccine specified in this PGD must be completed in order to allow audit of practice. This should include as a minimum: • Date and time of vaccine administration • Individuals name, address and CHI • GP with whom the individual is registered • Exclusion criteria, record why the vaccine was not administered (if applicable) • Record that valid consent to treatment under this PGD was obtained

	• The name, brand, dose, form, batch number, expiry date, route/and anatomical site of the vaccination administered • Advice given, including advice given if excluded or declined vaccination under this PGD • Signature and name in capital letters of the healthcare professional who administered the vaccine, and who undertook the assessment of the individual's clinical suitability for the vaccine • Where childhood immunisations are given information of the administration must be provided to the GP Practice and Practitioner Services Division (PSD) for inclusion on the Scottish Immunisation Recall System (SIRS). • Record of any adverse effects and the actions taken (advise individuals' GP/relevant medical practitioner). Depending on the clinical setting where administration is undertaken, the information should be recorded manually or electronically on the individual service specific system, as appropriate. • Child Health Information Services if appropriate • Hand–held records such as red book if appropriate • Individual's GP records if appropriate • Individual service specific systems. Local policy should be followed with respect to sharing information with the individual's General Practitioner. All records should be clear, legible and contemporaneous and in an easily retrievable format.
Audit	All records of the vaccine specified in this PGD will be filed with the normal records of medicines in each practice/service. A designated person within each practice/service where the PGD will be used will be responsible for annual audit to ensure a system of recording medicines administered under a PGD.
References	Electronic Medicines Compendium http://www.medicines.org.uk Bexsero® – Date of revision of text 01/01/21, accessed 19/07/2022. British National Formulary for Children and the British National Formulary accessed 19/07/2022. Department of Health (2006): Immunisation against Infectious Disease [Green Book] Meningococcal: the green book, chapter 22 - GOV.UK (www.gov.uk)

	American Academy of Pediatrics (2003) Active immunisation. In: Pickering LK (ed.) Red Book: 2003 Report of the Committee on Infectious Diseases, 26th edition. Elk Grove Village, IL: American Academy of Pediatrics, p 33.

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

Appendix 1

Healthcare Professional Agreement to Administer Vaccine Under Patient Group Direction

I: _____ (Insert name)

Working within: _____ e.g. Area, Practice

Agree to administer the vaccine contained within the following Patient Group Direction:

Patient Group Direction For The Administration Of Meningococcal Group B Conjugate Vaccine (Bexsero®) By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles

I have completed the appropriate training to my professional standards enabling me to administer the vaccine 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 Vaccine 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 vaccine 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 vaccine 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 Conjugate Vaccine (Bexsero®) By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles
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**