Patient Group Direction template

Administration of Meningococcal Group B vaccine (Bexsero®)

Version 3.0 updated after expiry of version 2.2
Removal of dates of birth from inclusion criteria and frequency sections
Change of recommended age to eight and 16 weeks from two and four months

This specimen patient group direction (PGD) template has been produced by Health Protection Scotland to assist NHS Boards

NHS Boards should amend/adapt this PGD template and must ensure that the PGD is considered and approved in line with local clinical governance arrangements for PGDs

PGD Meningococcal Group B vaccine

Authorisation

This specimen Patient Group Direction (PGD) template has been produced by Health Protection Scotland 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 Meningococcal Group B 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 marketing authorisation holder's summary of product characteristics (SPC) 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.

This PGD has been produced for NHS (*insert details*) by

Doctor	_____	Signature	_____
Pharmacist	_____	Signature	_____
Nurse	_____	Signature	_____

Approved on behalf of NHS (*insert details*) by

Medical Director	_____	Signature	_____
Director of Pharmacy/Senior Pharmacist	_____	Signature	_____
Clinical Governance Lead	_____	Signature	_____

Date Approved _____

Effective from	01/07/2018	Review Date	31/07/2020

Clinical Situation

Indication	Vaccination against meningococcal group B disease
Inclusion Criteria	Individuals from age eight weeks requiring primary vaccination as part of the routine immunisation schedule. Valid consent has been given to receive the vaccine.
Exclusion Criteria	Aged greater than 24 months Confirmed anaphylactic reaction to a previous dose of meningococcal group B vaccine. 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 (SPC) for details of vaccine components. Confirmed anaphylactic reaction to latex. Acute severe febrile illness –postpone immunisation until patient has fully recovered.
Cautions /Need for further advice/ Circumstances when further advice should be sought from a doctor	Patients with known bleeding disorders should receive the vaccine by deep subcutaneous route to reduce the risk of bleeding.
Action if Excluded	Specialist advice must be sought on the vaccine and circumstances under which it could be given. The risk to the individual of not being immunised must be taken into account. Document in clinical records**.** Temporary exclusion: In case of postponement due to acute severe febrile illness, arrange a future date for immunisation.
Action if Patient Declines	Advise about the protective effects of the vaccine, the risks of infection and complications. Document advice given and decision reached. In GP practice setting, inform or refer to GP.

Description of Treatment

Name of Medicine	Meningococcal group B vaccine Bexsero®
Form/Strength	Suspension for injection in pre-filled syringe
Route of administration	Intramuscular injection. Preferred site is the anterolateral left thigh**.** It is recommended the vaccine is given in a separate limb to other vaccines to enable monitoring for local reactions.

	Patients with known bleeding disorders should receive the vaccine by deep subcutaneous route to reduce the risk of bleeding.
Dosage	0.5ml.
Frequency	The primary course consists of two doses with an interval of two months between the doses. If the primary course is interrupted it should be resumed and not repeated, allowing an interval of two months between the doses. The recommended age for immunisation is a dose at eight weeks followed by a dose at 16 weeks. All children who have previously received a primary course before 12 months should be offered a reinforcing/booster dose. The recommended age for the booster is between 12 and 13 months (i.e. within one month of first birthday) but can be given up to the child's second birthday.
Duration of treatment	See frequency section.
Maximum or minimum treatment period	See frequency section.
Quantity to supply/administer	See frequency section.
▼ black triangle medicines	Bexsero® is subject to additional monitoring by MHRA
Legal Category	POM – prescription only medicine.
Is the use outwith the SPC	The SPC states that three doses should be given in those aged two-five months. This is superseded by the Green Book recommendation to give two doses of Meningococcal group B vaccine in infancy followed by a booster at age 12 months.
Storage requirements	Vaccine should be stored at a temperature of +2° to +8°C. If the vaccine has been frozen, it should be discarded. NHS board guidance on Storage and Handling of vaccines should be observed.
Additional Information	Upon storage a fine off-white deposit may be observed in the pre-filled syringe containing the suspension. Before use, the pre-filled syringe should be well shaken in order to form a homogeneous suspension. The vaccine should be visually inspected for particulate matter and discoloration prior to administration. In the event of any foreign particulate matter and/or variation of physical aspect being observed, do not administer the vaccine. Very premature infants (born ≤ 28 weeks of gestation) who are in hospital should have respiratory monitoring for 48-72 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 48-72 hrs. 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. It is recommended that MenB 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.
Warnings including possible adverse reactions and management of these	In infants and children up to 10 years of age, injection site reactions, fever (≥38°C) and irritability were very commonly seen. Diarrhoea and vomiting, eating disorders, sleepiness, unusual crying and the development of a rash were commonly or very commonly seen in this age group. In infants and children under two years of age, fever ≥38°C (occasionally ≥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 5:1 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 (60mg) doses of paracetamol should be given orally, with the first dose provided as soon as possible after vaccination and two subsequent doses at intervals of 4-6 hours. For full details/information on possible side effects, refer to the marketing authorisation holder's SPC. 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.

Reporting procedure for adverse reactions	Any adverse events that may be attributable to Meningococcal group B vaccine should be reported using the yellow card system on http://yellowcard.mhra.gov.uk/

	Any serious adverse reaction to the vaccine should be documented in an individual's record. GP should also be informed.
Advice to Patient/carer including written information	Manufacturer's patient information leaflet (PIL) provided with vaccine. Inform of possible side effects and their management. Provide prescription for supply of paracetamol 120mg/5ml suspension if required. Inform parent/carer that further doses (60mg) of paracetamol should be given 4-6 hours after the first dose and 4-6 hours after the second dose. 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.
Monitoring	Following immunisation patients remain under observation in line with NHS Board policy.
Follow-up	Not applicable.
Additional Facilities	Immediate access to Epinephrine (Adrenaline) 1 in 1000 injection. Access to a telephone.

Characteristics of staff authorised under the PGD

Professional qualifications	Those registered health care professionals that are listed and approved in legislation as able to operate under patient group directions.
Specialist competencies or qualifications	Approved by the organisation as competent: • to undertake immunisation and discuss issues related to immunisation, • to assess the person's capacity to understand the nature and purpose of the immunisation in order to give or refuse consent, • to work with this patient group direction, • in the recognition and management of anaphylaxis,
Continuing education and training	The practitioner must be familiar with the SPC for all vaccines administered in accordance with this PGD. It is the responsibility of the individual to keep up to date with all aspects of immunisation and in the recognition and management of anaphylaxis.

Audit Trail

Record/Audit Trail	The approved practitioner must ensure maintenance of records for each vaccine administered and may be required to share information with appropriate parties in line with confidentiality protocols.The information relating to immunisation of each individual must include as a minimum:

	• Patient's name and date of birth, • Dose, • Site and route of injection, • Brand, batch number and expiry date of vaccine, • Date given and by whom (name/signature). All records must be clear and legible and, ideally, in an easily retrievable format. Depending on the clinical setting where immunisation is undertaken, the information should be recorded manually or electronically, in one (or more) of the following systems, as appropriate: • GP practice computer, • Individuals GP records, • Child Health Systems (e.g. SIRS) • Personal Held Child Record (red book)
Additional references	Practitioners operating the PGD must be familiar with: Department of Health (2006): Immunisation against Infectious Disease [Green Book] Immunisation against Infectious Disease [Green Book] chapter 22 Meningococcal Current edition of British National Formulary Marketing authorisation holder's Summary of Product Characteristics All relevant Scottish Government Health Directorate advice including the relevant CMO letter(s) NMC (2015) Code of Professional Conduct. NMC (2010) Standards for Medicines Management

PGD for administration of Meningococcal group B vaccine– Authorisation

This PGD does not remove professional obligations and accountability. It is the responsibility of each professional to practice within the bounds of their own competence and in accordance with their Code of Professional Conduct and to ensure familiarity with the manufacturer's summary of product characteristics for all vaccines administered in accordance with this PGD.

Note to Authorising Managers

Authorised staff should be provided with an individual copy of the clinical content of the PGD and a photocopy of the document showing their authorisation.

I have read and understood the Patient Group Direction. I agree to administer meningococcal group B vaccine only in accordance with this PGD.

Name of Professional	**Signature**	**Date**

I agree that the professionals listed above are authorised to supply/administer medicines in accordance with this PGD to patients cared for in this service area.

Lead Clinician for the service area (Doctor)		
Name:	Signature:	Date: