NHS Greater Glasgow and Clyde

Administration of Meningococcal Group B vaccine (Bexsero®)

Patient group direction (PGD)

Publication date: 1 March 2024

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Version 6.1

Translations and other formats are available on request at:

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Most recent changes

Version	Date	Summary of changes
6.1	1 March 2024	The following changes to version 6.0 of the PGD have been made: • Inclusion criteria, frequency, is the use outwith the SmPC and additional reference sections updated to include reference to the Scottish Haematology Society schedule for the revaccination of individuals following haematopoietic stem cell transplant or CAR-T treatment. • Inclusion criteria amended to include individuals invited, or eligible in accordance with the recommendations in Green Book and/or in line with subsequent correspondence/publications from Scottish Government. • Observation following vaccination section updated to include advice on driving post-immunisation

Contents

Authorisation

PGD Meningococcal Group B Vaccine

This Patient Group Direction (PGD) has been produced by Public Health Scotland to assist NHS Boards.

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 manufacturer's product information/Summary of Product Characteristics (SmPC) for all vaccines administered in accordance with this PGD.

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

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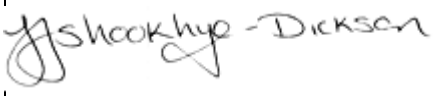
Name: Jacqui Shookhye-Dickson  Signature: Date: 04/03/2024	Designation: Health Protection Nurse Specialist E-mail address: **jacqui.shookhye-dickson@ggc.scot.nhs.uk**
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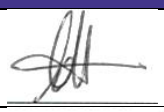
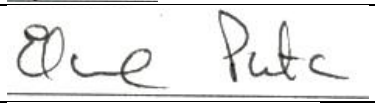
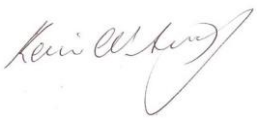
Chair	Dr Craig Harrow	
Senior Pharmacist	Elaine Paton, Senior Prescribing Adviser	
Nurse Director Representative	Kevin McAuley, Lead Nurse North Sector	

Effective from: 1 March 2024 Expires: 28 February 2026

1. Clinical situation

1.1. Indication

Immunisation against Neisseria meningitidis group B.

1.2. 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 and are invited, or eligible in accordance with the recommendations in Green Book **Chapter 7** and **22**, and/or in line with subsequent correspondence/publications from Scottish Government.
- Individuals who have received a haematopoietic stem cell transplant or CAR-T therapy and who require revaccination, in accordance with the **Scottish Haematology Society Revaccination Schedule.**

Valid consent has been given to receive the vaccine.

1.3. Exclusion criteria

Age less than 6 weeks.

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 (SmPC) for details of vaccine components.

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 patient has fully recovered.

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

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

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

Co-administration with other vaccines

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 meningococcal B vaccine should be given in a separate limb to other vaccines to enable monitoring of local reactions. If the vaccine is given in the

same limb as other vaccines, they should be given at least 2.5cm apart. The site at which each vaccine was given should be noted in the individual's records.

Syncope

Syncope (fainting) can occur following, or even before, any vaccination especially in adolescents as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from faints.

Pregnancy and breastfeeding

Meningococcal vaccines may be given to pregnant women when clinically indicated. There is no evidence of risk from vaccinating pregnant women or those who are breast-feeding with inactivated bacterial vaccines.

1.5 Action if excluded

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

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

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

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.

Temporary exclusion

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

1.6. Action if patient declines

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

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

Document advice given and decision reached.

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

2. Description of treatment

Meningococcal group B vaccine (Bexsero®).

2.1. Name of medicine/form/strength

Meningococcal group B vaccine (Bexsero®).

Suspension for injection in pre-filled syringe.

2.2. Route of administration

Intramuscular injection into the deltoid region of the upper arm or anterolateral aspect of the thigh.

Patients with known bleeding disorders should receive the vaccine by deep subcutaneous route to reduce the risk of bleeding.

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

Upon storage a fine off-white deposit may be observed in the prefilled syringe containing the suspension. Before use, the pre-filled syringe should be well shaken in order to form a homogeneous suspension.

The vaccine should be visually inspected for particulate matter and discoloration prior to administration. In the event of any foreign particulate matter and/or variation of physical aspect being observed, do not administer the vaccine.

2.3. Dosage

0.5ml

2.4. Frequency

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 Meningococcal 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 **Revaccination of patients following haematopoietic stem cell transplant or CAR-T treatment.**

2.5. Duration of treatment

See Frequency section.

2.6. Maximum or minimum treatment period

See Frequency section.

2.7. Quantity to supply/administer

See Frequency section.

2.8. ▼ black triangle medicines

No.

2.9. Legal category

Prescription only medicine (POM).

2.10. Is the use out with the SmPC?

Yes.

Administration by deep subcutaneous injection to individuals with a bleeding disorder is off-label administration in line with advice in Chapter 4 and Chapter 22 of the Green Book.

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.

Revaccination of individuals following haematopoietic stem cell transplant of CAR-T treatment is considered off-label but is in accordance with the **Scottish Haematology Society schedule.**

Vaccine should be stored according to the conditions detailed below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to NHS board guidance on storage and handling of vaccines or National Incident Guidance.

Where vaccine is assessed in accordance with these guidelines as appropriate for continued use, administration under this PGD is allowed.

2.11. Storage requirements

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

Store in the original packaging to protect from light.

Do not freeze.

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

In the event of an inadvertent or unavoidable deviation of these conditions, vaccine that has been stored outside the conditions stated above should be quarantined and risk assessed for suitability of continued off-label use or appropriate disposal.

2.12. Additional information

Minor illnesses without fever or systemic upset are not valid reasons to postpone immunisation.

If an individual is acutely unwell, immunisation may be postponed until they have fully recovered.

Upon storage a fine off-white deposit may be observed in the prefilled syringe containing the suspension. Before use, the pre-filled syringe should be well shaken in order to form a homogeneous suspension.

The vaccine should be visually inspected for particulate matter and discoloration prior to administration. In the event of any foreign particulate matter and/or variation of physical aspect being observed, do not administer the vaccine.

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.

3. Adverse reactions

3.1. Warnings including possible adverse reactions and management of these

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.

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.

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

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

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

3.2. Reporting procedure for adverse reactions

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

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

3.3. Advice to patient or carer including written information

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

Supply immunisation promotional material as appropriate.

Inform of possible side effects and their management.

Advise that paracetamol can be obtained from a community pharmacy or provide prescription for supply of paracetamol 120mg/5ml suspension if required.

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 as soon as possible after vaccination and two subsequent doses at intervals of 4 to 6 hours.

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.

3.4. Observation following vaccination

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

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

3.5. Follow up

As above.

3.6. Additional facilities

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

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

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

4. Characteristics of staff authorised under the PGD

4.1. Professional qualifications

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

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

4.2. Specialist competencies or qualifications

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

All persons operating this PGD

- must be authorised by name by their employer as an approved person under the current terms of this PGD before working to it
- must be familiar with the vaccine product and alert to changes in the manufacturer's product information/summary of product information

- must be competent to undertake immunisation and to discuss issues related to immunisation to assess patients for vaccination and obtain consent
- must be competent in the correct storage of vaccines and management of the cold chain if receiving, responsible for, or handling the vaccine
- must be competent in the recognition and management of anaphylaxis or under the supervision of persons able to respond appropriately to immediate adverse reactions
- must have access to the PGD and associated online resources
- should fulfil any additional requirements defined by local policy

Employer

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

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

4.3. Continuing education and training

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

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

5. Audit trail

Record the following information:

- valid informed consent was given
- name of individual, address, date of birth and GP with whom the individual is registered if possible
- name of person that undertook assessment of individual's clinical suitability and subsequently administered the vaccine
- name and brand of vaccine
- date of administration
- dose, form and route of administration of vaccine
- batch number
- where possible expiry date
- anatomical site of vaccination
- advice given, including advice given if excluded or declines immunisation
- details of any adverse drug reactions and actions taken
- administered under PGD

Records should be kept in line with local procedures.

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

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

6. Additional references

Practitioners operating the PGD must be familiar with:

- **Immunisation against Infectious Disease [Green Book]**:
- **Immunisation against Infectious Disease [Green Book] chapter 22**
- **Immunisation against Infectious Disease (Green Book) chapter 7**
- **Scottish Haematology Society advice on the revaccination of patients following haematopoietic stem cell transplant or CAR-T treatment**
- **Guidance for Public Health Management of Meningococcal Disease in the UK**
- **Professional Guidance on the Administration of Medicines in Healthcare Settings 2019**
- **Professional Guidance on the Safe and Secure Handling of Medicines**
- All relevant Scottish Government Health Directorate advice including the relevant CMO letter(s)
- Current edition of British National Formulary.
- Marketing authorisation holder's Summary of Product Characteristics

7. PGD for administration of Meningococcal Group B vaccine V6.1 (valid from 1 March 2024 and expires 28 February 2026): authorisation

Practitioner

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 marketing authorisation holder's summary of product characteristics for all vaccines administered in accordance with this PGD.

By signing this Patient Group Direction, you are indicating that you agree to its contents and that you will work within it. I agree to administer Meningococcal Group B vaccine only in accordance with this PGD.

Name of professional	Signature	Date

Authorising manager

I confirm that the practitioners named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of **[insert name of organisation]** for the above-named health care professionals who have signed the PGD to work under it.

Lead clinician for the service area:

Name …….

Signature ……..

Date ……

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.

This authorisation sheet should be retained to serve as a record of those practitioners authorised to work under this PGD.

8. Version history

Version	Date	Summary of changes
4.0	March 2019	• Version 4.0 produced • Inclusion criteria section updated to enable first dose to be given at six weeks. • Action if excluded section updated with information for those aged under six weeks. • Frequency section updated to state that first dose can be given from 6 weeks and that the second dose may be given up to a week early when required if primary immunisation are being given before the scheduled date e.g. due to impending travel to an endemic country. • Use out with SmPC section updated to highlight that administration at six weeks is off label use of a licensed medicine. • Use out with SmPC section updated to highlight that administration of the second dose given up to a week early when required if primary immunisation are being given before the scheduled date is off label use of a licensed medicine. • Use out with SmPC section updated to recommend assessment following inadvertent or unavoidable deviation from recommended storage conditions. • Storage section updated to include additional information on action required following inadvertent or unavoidable deviation from recommended storage conditions. • Warnings including possible adverse reactions section updated to reflect the change in infant vaccine from 5 in 1 to 6 in 1.
5.0	1 September 2021	• Version 5.0 produced • This PGD has undergone minor rewording, layout, formatting changes for clarity and consistency with other PHS national specimen PGDs • The following changes have been made:

Version	Date	Summary of changes
		• Cautions sectioned updated with additional wording about latex allergy. • Action if excluded section wording updated to indicate that vaccination under a patient specific direction may be indicated when excluded. • Black triangle section updated to indicated the vaccine is no longer under additional monitoring by MHRA. • Use outwith SmPC section updated to state administration by deep subcutaneous injection to individuals with a bleeding disorder is off-label administration in line with advice in Chapter 4 and Chapter 22 of the Green Book and following update to SmPC to remove previous wording that two doses followed by a booster at age 12 months as not in accordance with SmPC. • Additional information section updated to include information on use in those with immunosuppression. References have been updated.
6.0	1 June 2022	• Inclusion criteria expanded to include other patient groups out with the Scottish childhood immunisation programme. • Frequency section updated to include dosing information for the other patient groups out with the Scottish childhood immunisation programme. • Additional information section updated to include further information on individuals with asplenia, splenic dysfunction or complement disorders and individuals receiving complement inhibitor therapy. • Warnings/adverse reactions section updated to include information on administration of paracetamol to be age or weight based.
6.1	1 March 2024	The following changes to version 6.0 of the PGD have been made: • Inclusion criteria, frequency, is the use outwith the SmPC and additional reference sections updated to include reference to the Scottish Haematology Society schedule for the revaccination of individuals

Version	Date	Summary of changes
		following haematopoietic stem cell transplant or CAR-T treatment. • Inclusion criteria amended to include individuals invited, or eligible in accordance with the recommendations in Green Book and/or in line with subsequent correspondence/publications from Scottish Government. • Observation following vaccination section updated to include advice on driving post-immunisation