Administration of Meningococcal ACWY conjugate vaccine [Non-Travel]

Patient group direction (PGD)

Date: 14TH December 2022

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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 December 2022	• Additional information section updated with minor amendments for those individuals diagnosed with coeliac disease early in life and well managed and for individuals receiving complement inhibitor therapy.

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Authorisation

PGD Meningococcal ACWY conjugate vaccine

This Patient Group Direction (PGD) has been produced by Public Health 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 ACWY conjugate 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 (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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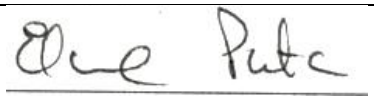
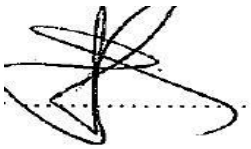
Senior Pharmacist	Elaine Paton, Senior Prescribing Adviser	
Nurse Director Representative	John Carson, Lead Nurse North Sector	

Effective from: 1 June 2022 Expires: 31 May 2024

Authorised on 14th December 2022

1. Clinical situation

1.1. Indication

Immunisation against *Neisseria meningitidis* groups A, C, W and Y.

1.2. Inclusion criteria

- Adolescents aged 13 years to 18 years in line with 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 ACWY, following specific advice from NHS Board Health Protection Team.
- 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 **22**.
- Revaccination of individuals who have received a haemopoietic stem cell transplant

Valid consent has been given to receive the vaccine.

1.3. Exclusion criteria

Individuals who:

- have had a confirmed anaphylactic reaction to a previous dose of meningococcal ACWY conjugate vaccine.
- have confirmed anaphylactic reaction to any constituent or excipient of the vaccine including meningococcal polysaccharide, diphtheria toxoid or the CRM197 carrier protein or tetanus toxoid. Practitioners must check the marketing authorisation holder's SmPC for details of vaccine components.
- have a history of severe reaction (i.e. anaphylactic reaction) to latex where vaccine is not latex free. As circumstances change you should check each time latex-sensitive individual presents.
- require vaccination for the purpose of travel (see separate travel PGD).
- are suffering from acute severe febrile illness (the presence of a minor illness without fever or systemic upset is not a contraindication for immunisation).

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 ACWY 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.

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.

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.

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.

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.

Inform or refer to the clinician in charge.

2. Description of treatment

2.1. Name of medicine/form/strength

Meningococcal ACWY conjugate vaccine.

Menveo® powder and solution for solution for injection.

Nimenrix® powder and solvent for solution for injection in pre-filled syringe.

2.2. Route of administration

Intramuscular injection.

Preferred site is deltoid area of 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.

The MenACWY vaccines must be reconstituted in accordance with the manufacturers' instructions prior to administration.

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.

It is recommended that the vaccine be administered immediately after reconstitution, to minimize loss of potency. Discard reconstituted vaccine if it is not used within 8 hours.

2.3. Dosage

0.5ml.

2.4. Frequency

Adolescents aged 13 years to 18 years in line with the Scottish childhood immunisation programme

Single dose.

Prevention of secondary cases of Meningococcal ACWY disease

Vaccination for the prevention of secondary cases of Meningococcal ACWY 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): **http://scothaem.org/vaccination-policy-post-hsc-transplantation.asp**

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?

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

Menveo® is off-label for children under 2 years of age and Nimenrix® is licensed from 6 weeks of age, for a schedule with a minimum 2 month interval between doses, but either vaccine is recommended in accordance with advice in Green Book **Chapter 7** and **Chapter 22**.

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 Vaccine 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.

After reconstitution, the vaccine should be used immediately. However, stability after reconstitution has been demonstrated for 8 hours below 25°C (below 30°C for Nimenrix®). Discard any reconstituted vaccine not used within 8 hours.

NHS GGC Vaccine Ordering, Storage and Handling Guidelines should be observed.

https://clinicalguidelines.nhsggc.org.uk/vaccines-blood-and-immunological-products/

Vaccine storage history e.g. temperature charts must be checked and deemed satisfactory before administration to patient. 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.

Meningococcal ACWY conjugate vaccine can be given at the same time as other vaccines such as pneumococcal, measles, mumps and rubella (MMR), diphtheria, tetanus, pertussis, polio, Hib and HPV.

The vaccines should be given at a separate site, preferably a separate limb. If given in the same limb, 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.

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 MenACWY vaccine. Only those with known splenic dysfunction should be vaccinated in accordance with this PGD.

Individuals receiving complement inhibitor therapy (such as eculizumab or ravulizumab) are at heightened risk of meningococcal infection and should be vaccinated with both MenACWY and MenB vaccines (see MenB PGD), ideally at least two weeks prior to commencement of therapy.

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 virus or bacterial vaccines or toxoids.

3. Adverse reactions

3.1. Warnings including possible adverse reactions and management of these

For Menveo®, very common or common reported reactions include injection site reactions including pain, erythema, induration and pruritus. Other very common or common reactions include headache, nausea, rash and malaise.

For Nimenrix®, very common or common reported reactions include injection site reactions including pain, erythema, and swelling. Other very common or common reactions include irritability, drowsiness, headache, nausea and loss of appetite.

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 suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme **http://yellowcard.mhra.gov.uk**

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

Written information to be given to individuals:

- 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.
- The individual should be advised to seek medical advice in the event of a severe adverse reaction.
- Inform the individual that they can report suspected adverse reactions to the MHRA using the Yellow Card reporting scheme on: **http://www.mhra.gov.uk/yellowcard**
- When administration is postponed advise the individual how future vaccination may be accessed.
- When applicable, advise individual/parent/carer when the subsequent dose is due.

3.4. Observation following vaccination

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

3.5. Follow up

Not applicable.

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.
- 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 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 Meningococcal.**
- **Immunisation against Infectious Disease (Green Book) chapter 7.**
- **Scottish Haematology Society vaccination policy (Post HSC Transplantation)**.
- **Guidance for Public Health Management of Meningococcal Disease in the UK.**
- Current edition of British National Formulary (BNF) and BNF for children.
- Marketing authorisation holder's Summary of Product Characteristics.
- All relevant Scottish Government advice including the relevant CMO letter(s).
- **Professional Guidance on the Administration of Medicines in Healthcare Settings 2019.**
- **Professional Guidance on the Safe and Secure Handling of Medicines.**

7. PGD for administration of Meningococcal ACWY conjugate vaccine V6.0 (valid from 1 June 2022 and expires 31 May 2024): 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 ACWY conjugate 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 ……Fiona Kinnon…….

Signature ……  ……..

Date ……22/12/2022……

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
5.0	July 2020	Version 5.0 produced (now branded as Public Health Scotland national specimen PGD). The following changes from version 4.0 of the PGD have been made: • Use outwith SmPC section updated to recommend assessment following inadvertent or unavoidable deviation from recommended storage conditions. • Use outwith SmPC section updated to highlight administration by deep subcutaneous injection to individuals with a bleeding disorder is off-label administration in line with advice in Chapter 4 of 'The Green Book'. • Storage section updated to include additional information on action required following inadvertent or unavoidable deviation from recommended storage conditions. • References section 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. • This PGD has undergone minor rewording, layout, formatting changes for clarity and consistency with other PHS national specimen PGDs.
6.1	1 December 2022	• Additional information section updated with minor amendments for those individuals diagnosed with coeliac disease early in life and well managed and for individuals receiving complement inhibitor therapy.