Patient Group Direction template

Administration of Meningococcal ACWY conjugate vaccine

Version 4.0 Updated following expiry of version 3.0
Removal of black triangle status for Nimenrix®

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 ACWY conjugate 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 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 (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	01/08/2018	Review Date	31/08/2020

Clinical Situation

Indication	Vaccination of adolescents against group ACWY meningococcal disease in line Scottish Government Health Directorate MenACWY immunisation programme.
Inclusion Criteria	Adolescents aged 13 years to 18 years Valid consent has been given to receive the vaccine.
Exclusion Criteria	Confirmed anaphylactic reaction to a previous dose of meningococcal ACWY conjugate vaccine. 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 summary of product characteristics (SPC) for details of vaccine components. 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 ACWY conjugate vaccine. Menveo® Nimenrix®
Form/Strength	Menveo® powder and solution for solution for injection. Nimenrix® powder and solvent for solution for injection in pre-filled syringe.
Route of administration	Intramuscular injection. Preferred site is deltoid area of upper arm. Patients with known bleeding disorders should receive the vaccine by deep subcutaneous route to reduce the risk of bleeding.
Dosage	0.5ml.

Frequency	Single dose.
Duration of treatment	See frequency section.
Maximum or minimum treatment period	See frequency section.
Quantity to supply/administer	See frequency section.
▼ black triangle medicines	No
Legal Category	POM – prescription only medicine.
Is the use outwith the SPC	No.
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	Nimenrix®: After reconstitution, the vaccine should be used promptly. Although delay is not recommended, stability has been demonstrated for 8 hours at 30°C after reconstitution. If not used within 8 hours, do not administer the vaccine. Menveo®: After reconstitution, the medicinal product should be used immediately. However, chemical and physical stability after reconstitution was demonstrated for 8 hours below 25°C. 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.
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 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 ACWY conjugate 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. 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, • Batch number and where appropriate brand 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 Information Services • Consent forms.
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 ACWY Conjugate 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 ACWY conjugate 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: