Patient Group Direction template

Administration of

Gardasil® Vaccine
Human Papillomavirus Vaccine [Types 6, 11, 16, 18] (Recombinant, adsorbed).

Version 3.0 Updated following expiry of version 2.0

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 PGD.

PGD Gardasil® Vaccine
(Human Papillomavirus Vaccine [Types 6, 11, 16, 18] (Recombinant, adsorbed))

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 Patient Group Directions.

The qualified health professionals who may administer Gardasil® 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 31.07.2020

Clinical Situation

Indication	Active immunisation against disease caused by Human Papillomavirus (HPV) types 6, 11, 16 and 18 in line with Scottish Government Health Directorate HPV immunisation programme.
Inclusion Criteria	Females aged 11 to under 18 years. Gardasil® is recommended in females from school year S1, aged around 11-12 years, including those not in school. Females who do not commence HPV immunisation in S1 remain eligible until they reach 18 years of age. Valid consent has been given to receive the vaccine.
Exclusion Criteria	Confirmed anaphylactic reaction to a previous dose of HPV vaccine. Confirmed anaphylactic reaction to any component of the vaccine. Practitioners must check the marketing authorisation holder's summary of product characteristics (SPC) for details of vaccine components. Known pregnancy. No valid consent. Acute systemic or febrile illness –postpone immunisation until the individual has fully recovered.
Cautions /Need for further advice/ Circumstances when further advice should be sought from doctor	Individuals 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. Temporary exclusion: In case of postponement due to acute severe illness, arrange a future date for immunisation. Document in clinical records.
Action if Patient Declines	Advise individual about the protective effects of the vaccine, the risks of infection, diseases and complications. Document advice given and decision reached. In GP practice setting, inform or refer to GP.

Description of Treatment

Name of Medicine	Gardasil® Vaccine (Human Papillomavirus Vaccine [Types 6, 11, 16, 18] (Recombinant, adsorbed))
Form/Strength	Suspension for injection ~~in a pre-filled syringe~~. During storage, a white precipitate may develop and the vaccine should be shaken before use to form a white cloudy liquid.
Route of administration	Intramuscular injection Preferred site is deltoid area of upper arm. It can also be administered in the anterolateral area of the thigh. Individuals with known bleeding disorders should receive the vaccine by deep subcutaneous route to reduce the risk of bleeding.
Dosage	0.5ml
Frequency	The frequency depends on the age the individual receives their first dose and whether the individual is immunocompromised at the time of vaccination. **Individuals aged below 15 years when receiving the first dose** The course consists of two doses; • First dose. • Second dose at least six months after the first dose. Both doses should ideally be given with a 24 month period. If the course is interrupted, it should be resumed but not repeated. **Individuals aged 15 years or above receiving the first dose or individuals of any age who are known to be HIV positive (including those on antiretroviral therapy) or are immunocompromised at the time of vaccination** The course consists of three doses; • First dose. • Second dose at least one month after the first dose. • Third dose at least three months after the second dose. All three doses should be ideally given within a 12-month period. If the course is interrupted, it should be resumed but not repeated, ideally allowing the appropriate interval between the remaining doses. There are no clinical data on whether the interval between doses two and three can be reduced below three months. Where the second dose is given late and there is a high likelihood that the

	individual will not return for a third dose after three months or if, for practical reasons, it is not possible to schedule a third dose within this time-frame, then a third dose of HPV vaccine can be given at least one month after the second dose.
Duration of treatment	See frequency section.
Maximum or minimum treatment period	See frequency section.
Quantity to supply/administer	Maximum three doses.
▼ black triangle medicines	No
Legal Category	POM – prescription only medicine.
Is the use outwith the SPC	Yes, the SPC for Gardasil® states the two dose schedule should be used in girls up to age 14 years. This is superseded by Scottish Government policy based on JCVI recommendation/advice in Green Book.
Storage requirements	Vaccine should be stored in the original packaging 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	During storage, a white precipitate may develop and the vaccine should be shaken before use to form a white cloudy liquid. Gardasil® vaccine can be given at the same time as other vaccines such as Td/IPV, MMR, influenza, MenC, Men ACWY and hepatitis B. The vaccines should be given at a separate site, preferably in a different 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	The most common adverse reaction observed after HPV vaccine administration is mild to moderate short-lasting pain at the injection site. An immediate localised stinging sensation has also been reported. Redness has also been reported at the injection site. Other reactions commonly reported are headache, myalgia, fatigue and low grade fever. 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. Syncope (vasovagal reaction) or fainting can occur during any vaccination, most commonly amongst adolescents. Some individuals may also experience panic attacks before vaccination.

	The clinical features of fainting and panic attacks are described in Chapter 8 of the Green Book. Fainting and panic attacks before or very shortly after vaccination are not usually direct side effects (adverse reactions) of the vaccine but events associated with the injection process itself.
Reporting procedure for adverse reactions	As with all vaccines, healthcare professionals and parents/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme 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	Supply marketing authorisation holder'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 arm is possible. Give advice on the management if individual becomes feverish. Advise individual to seek medical advice in case of severe adverse reaction. Advise individual when subsequent doses are due when applicable.
Monitoring	Following immunisation individual to remain under observation in line with NHS Board policy.
Follow-up	Advise individual when subsequent doses are due when applicable.
Additional Facilities	Immediate access to Epinephrine (Adrenaline) 1 in 1000 injection Access to 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 marketing authorisation holder's 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: • Individual'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. 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: • Consent forms, • Child Health Information Services, • Individual's GP records.
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 18a HPV 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 Gardasil® vaccine – Authorisation

This PGD does not remove professional obligations and accountability. It is the responsibility of each professional to practice with 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 Gardasil® 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: