Administration of Human Papillomavirus vaccine

Patient group direction (PGD)

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Translations and other formats are available on request at:

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Most recent changes

Version	Date	Summary of changes
9.1	1 March 2024	The following changes to version 9.0 of the PGD have been made: • minor rewording, layout and formatting changes for clarity and consistency with other PHS PGDs • 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. • Observation following vaccination section updated to include advice on driving post-immunisation

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Authorisation

PGD Human Papillomavirus Vaccine

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

The qualified health professionals who may administer Human papillomavirus 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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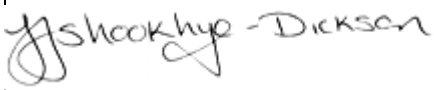
Name: Jacqui Shookhye-Dickson  Signature: Date: 04/03/2024	Designation: Health Protection Nurse Specialist E-mail address: **jacqui.shookhye-dickson@ggc.scot.nhs.uk**

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Effective from: 1 March 2024 Expiry date 28 February 2026

1. Clinical situation

1.1. Indication

Active immunisation against disease caused by Human papillomavirus (HPV) in line with Scottish Government immunisation programme and JCVI advice/recommendations as set out in **Green Book Chapter 18a** and subsequent correspondence/publications from Scottish Government

1.2. Inclusion criteria

- Individuals from school year S1, aged around 11-13 years, including those not in school.
- Individuals in eligible cohorts aged under 25 years (that is, boys who became eligible from academic year 2019/20 and girls who would have been eligible under routine, and catch up programme introduced in 2008.Individuals up to 25 years of age with uncertain or incomplete immunisation status in accordance with the **vaccination of individuals with uncertain or incomplete immunisation status** flow chart.
- Men who have sex with men (MSM) aged up to and including 45 years of age attending sexual health or HIV clinic.
- Transgender individuals attending sexual health or HIV clinic.
- Sex workers attending sexual health or HIV clinic.
- Men and women living with HIV infection attending sexual health or HIV clinic.
- Prisoners up to and including 45 years of age who identify as MSM.
- 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

Individuals who:

- Have had a confirmed anaphylactic reaction to a previous dose of HPV vaccine.
- Have had a confirmed anaphylactic reaction to any component of the vaccine. Practitioners must check the marketing authorisation holder's SmPC for details of vaccine components.
- Are less than 9 years of age.
- Have a history of severe (i.e. anaphylactic reaction) to latex where the vaccine is not latex free.
- Are known to be pregnant.
- Are suffering from an acute severe febrile illness (the presence of a minor infection 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 HPV 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

HPV vaccines can be given at the same time as other vaccines including Td/ IPV, MMR, Influenza, MenACWY and hepatitis B.

When administering at the same time as other vaccines care should be taken to ensure that the appropriate route of injection is used for all the vaccinations. The vaccines should be given at separate sites, preferably in different limbs. 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.

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

Individuals known to be pregnant should complete immunisation after their pregnancy. If high-risk sexual activity continues during pregnancy, and the opportunity for vaccination after pregnancy is uncertain, the benefit of vaccination during pregnancy is likely to outweigh any potential risk. Vaccination during pregnancy is not covered by this PGD so in such instances the individual may need to be referred and/or a PSD may be required.

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.

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

Gardasil® 9 Vaccine (Human papillomavirus 9 valent Vaccine [Types 6, 11, 16, 18, 31, 33, 45, 52, 58] (Recombinant, adsorbed).

Suspension for injection in a prefilled syringe or vial.

2.2. Route of administration

Administer by intramuscular injection.

The preferred site is the deltoid region of the upper arm. It can also be administered in the anterolateral area of the thigh.

Individuals with bleeding disorders may be vaccinated intramuscularly if, in the opinion of a doctor familiar with the individual's bleeding risk, vaccines or similar small volume intramuscular injections can be administered with reasonable safety by this route. If the individual receives medication/treatment to reduce bleeding, for example treatment for haemophilia, intramuscular vaccination can be scheduled shortly after such medication/ treatment is administered. Individuals on stable anticoagulation therapy, including individuals on warfarin who are up to date with their scheduled INR testing and whose latest INR was below the upper threshold of their therapeutic range, can receive intramuscular vaccination. A fine needle (equal to 23 gauge or finer calibre such as 25 gauge) should be used for the vaccination, followed by firm pressure applied to the site (without rubbing) for at least 2 minutes. If in any doubt, consult with the clinician responsible for prescribing or monitoring the individual's anticoagulant therapy.

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.

During storage, a white precipitate may develop and the vaccine should be shaken before use to form a white cloudy liquid.

2.3. Dosage

0.5ml

2.4. Frequency

As the HPV vaccination programme transitions to Gardasil® 9, some individuals may receive a mixed schedule during the switch. Gardasil® and Gardasil® 9 vaccines are considered interchangeable and vaccination should not be delayed due to preference for either vaccine.

Immunocompetent individuals in routine adolescent programme and MSM programme before their 25th birthday who are not known to be HIV positive.

The vaccination schedule is one dose.

If an eligible individual has started a three or two-dose course under 25 years of age, their vaccination schedule should now be regarded as complete regardless of whether Gardasil® or Gardasil® 9 was used.

Immunocompetent individuals from age of 25 years in the MSM programme who are not known to be HIV positive.

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 even if more than 24 months have elapsed since the first dose.

Where two doses of Gardasil® 9 Vaccine have been administered less than 5 months apart a third dose should be given at least 3 months after the second dose.

Those individuals who commenced vaccination prior to August 2022 whose schedule is interrupted/delayed such that they had an interval of six months or more between their first and second dose only need a two dose schedule (do not require a third dose).

Individuals who are immunosuppressed or known to be HIV positive

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.

Vaccination of individuals with unknown or incomplete vaccination status

Unimmunised individuals who enter an eligible cohort for HPV vaccination (see **Criteria for inclusion**) will retain their eligibility until their 25th birthday or in case of MSM aged up to and including 45 years of age attending sexual health or HIV clinic and should be vaccinated in accordance with the schedules above. For an individual who has started but not completed an HPV immunisation schedule at an eligible age, it is reasonable to complete their vaccination course, with Gardasil® 9, in accordance with the schedules above.

Revaccination of individuals who have received a haemopoietic stem cell transplant or CAR-T treatment

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 of a one dose schedule for all those eligible in the programme up to their 25th birthday is off-label but is in accordance with the **JCVI statement on a one-dose schedule for the routine HPV immunisation programme.**

Additionally in those from the age of 25 years in the MSM programme administration of a two-dose schedule of Gardasil® 9 is off-label but is in accordance with the **JCVI statement on a one-dose schedule for the routine HPV immunisation programme.**

Administration of a two-dose course with a 0, 6-24 month schedule differs slightly from schedules in the SmPC but is in accordance with Green Book **Chapter 18a**.

Completion of a HPV vaccine course using Gardasil® 9 when it was not commenced with the same HPV vaccine product is off-label but is in accordance with Green Book **Chapter 18a**.

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.**

The HPV vaccine SmPCs state that ‘vaccinees should be observed for approximately 15 minutes after vaccine administration’. In line with advice in the Green Book **Chapter 4**, recipients of any vaccine should be observed for immediate adverse drug reactions. There is no evidence to support the practice of keeping individuals under longer observation.

Where a vaccine is recommended off-label consider, as part of the consent process, informing the individual/parent/carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence.

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

Store at between +2°C to +8°C.

Store in original packaging in order to protect from light.

Do not freeze.

HPV vaccine should be administered as soon as possible after being removed from the cold chain.

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

Data from stability studies demonstrate the Gardasil® 9 vaccine components are stable for 96 hours when stored at temperatures from 8°C to 40°C or for 72 hours when stored at temperatures from 0°C to 2°C. These data are intended to guide healthcare professionals in case of temporary temperature excursion only. This PGD may be used to administer vaccine that has not exceeded these stability data parameters.

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.

3. Adverse reactions

3.1. 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 at the injection site has also been reported.

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 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

Written information to be given to individual:

- 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.
- 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 when subsequent doses are due when applicable.
- 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: **yellowcard.mhra.gov.uk**

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 18a**
- **JCVI statement on a one-dose schedule for the routine HPV immunisation programme**
- Current edition of British National Formulary (BNF) and BNF for children
- Marketing authorisation holder's Summary of Product Characteristics
- **Educational resources for registered professionals produced by National Education for Scotland**
- 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**
- **Scottish Haematology Society advice on the revaccination of patients following haematopoietic stem cell transplant or CAR-T treatment**

7. PGD for administration of Human Papillomavirus (HPV) vaccine V9.1 (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 Human Papillomavirus (HPV) 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	July 2019	• Inclusion criteria updated to reflect inclusion of males in immunisation programme in schools. • Inclusion criteria updated to reflect the policy change to include individuals up to age 25 years. • Inclusion criteria updated to include MSM in same PGD as individuals at school. • Quantity section wording updated. • Use out with SmPC section updated to highlight at administration by deep subcutaneous injection is off label but in line with Green Book advice. • Use out with SmPC section updated to recommend assessment following inadvertent of unavoidable deviation from recommended storage conditions. • Storage section updated to include additional information on data from stability studies and action required following inadvertent of unavoidable deviation from recommended storage conditions. • Record/audit trail section updated to add NaSH as record of vaccination in MSM.
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.
6.0	1 April 2022	Version 6.0 produced • Frequency section updated to reflect updated recommendations that those commencing vaccination from 15 years of age should commence a 2-dose schedule with a minimum 6-month interval. • Use out with SmPC section updated. • Minor rewording, layout, formatting changes for clarity and consistency with other PHS national specimen PGDs.

Version	Date	Summary of changes
7.0	1 August 2022	Version 7.0 produced. Changes from version 6.0 include: • Change of name from Gardasil® vaccine to Human papillomavirus (HPV) vaccine. • PGD amended to include nine valent vaccine (Gardasil® 9) • Action if excluded section updated with information for individuals known to be pregnant. • Frequency section updated to include details for Gardasil® 9 vaccine, interchangeability of HPV vaccines, vaccination of individuals with unknown or incomplete vaccination status. • Out with the SmPC section updated with details for Gardasil® 9 vaccine. • Storage section updated with details for Gardasil® 9 vaccine.
8.0	1 December 2022	Version 8.0 produced. Changes from version 7.0 include: • Frequency section updated to align with JCVI advice on one dose schedule. • Use outwith SmPC updated to align with JCVI advice on one dose schedule. • References updated to include JCVI advice on one dose schedule.
9.0	1 August 2023	Version 9.0 produced following publication of updated Green Book chapter. This PGD has undergone minor rewording, layout, formatting changes for clarity and consistency with other PHS national specimen PGDs. Key changes from version 8.0 include: • Removal of Gardasil® Vaccine (Human papillomavirus Vaccine [Types 6, 11, 16, 18] as no longer available. • Inclusion criteria updated to include other groups attending Sexual Health or HIV clinics. Route of administration section updated to align with Green Book chapter (subcutaneous injection removed).

Version	Date	Summary of changes
9.1	1 March 2024	The following changes to version 9.0 of the PGD have been made: • minor rewording, layout and formatting changes for clarity and consistency with other PHS PGDs • 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. • Observation following vaccination section updated to include advice on driving post-immunisation