

Publications gateway number: GOV-18920

## Human papillomavirus (HPV) vaccine Patient Group Direction (PGD)

This PGD is for the administration of human papillomavirus (HPV) vaccine to individuals from 12 years of age or from school year 8 and aged less than 25 years in accordance with the national immunisation programme.

This PGD is for the administration of HPV vaccine by registered healthcare practitioners identified in [Section 3](#), subject to any limitations to authorisation detailed in [Section 2](#).

Reference no: HPV Vaccine PGD  
Version no: v7.0  
Valid from: 1 September 2025  
Review date: 1 April 2028  
Expiry date: 1 September 2028

**The UK Health Security Agency (UKHSA) has developed this PGD to facilitate the delivery of publicly funded immunisation in England in line with national recommendations.**

Those using this PGD must ensure that it is organisationally authorised and signed in Section 2 by an appropriate authorising person, relating to the class of person by whom the product is to be supplied, in accordance with Human Medicines Regulations 2012 (HMR2012)<sup>1</sup>. **The PGD is not legal or valid without signed authorisation in accordance with [HMR2012 Schedule 16 Part 2](#).**

Authorising organisations must not alter, amend or add to the clinical content of this document (sections 4, 5 and 6); such action will invalidate the clinical sign-off with which it is provided. In addition, authorising organisations must not alter section 3 'Characteristics of staff'.

**Sections 2 and 7 can be edited within the designated editable fields provided, but only for the purposes for which these sections are provided, namely the responsibilities and governance arrangements of the NHS organisation using the PGD. The fields in section 2 and 7 cannot be used to alter, amend to or add to the clinical content. Such action will invalidate the UKHSA clinical content authorisation which is provided in accordance with the regulations. The legal validity of this PGD is contingent on those authorising sections 2 and 7 complying with the above.**

Operation of this PGD is the responsibility of commissioners and service providers. The final authorised copy of this PGD should be kept by the authorising organisation completing Section 2 for 8 years after the PGD expires if the PGD relates to adults only and for 25 years after the PGD expires if the PGD relates to children only, or adults and children. Provider organisations adopting authorised versions of this PGD should also retain copies for the periods specified above.

**Individual practitioners must be authorised by name, under the current version of this PGD before working according to it.**

Practitioners and organisations must check that they are using the current version of the PGD. Amendments may become necessary prior to the published expiry date.

Current versions of UKHSA PGD templates for authorisation can be found from:

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<sup>1</sup> This includes any relevant amendments to legislation  
HPV Vaccine PGD v7.0 Valid from: 1 September 2025 Expiry: 1 September 2028

[Immunisation patient group direction \(PGD\) templates](#)

Any concerns regarding the content of this PGD should be addressed to:  
[immunisation@ukhsa.gov.uk](mailto:immunisation@ukhsa.gov.uk).

Enquiries relating to the availability of organisationally authorised PGDs and subsequent versions of this PGD should be directed to: [england.londonimms@nhs.net](mailto:england.londonimms@nhs.net)

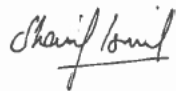
## Change history

| Version number | Change details                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Date          |
|----------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|
| V1.0           | New PHE PGD template                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | 6 April 2016  |
| V2.0           | <p>PHE HPV PGD amended to:</p> <ul style="list-style-type: none"> <li>• include immunisation of transgender boys and transgender girls as appropriate</li> <li>• provide additional information on capacity to consent with link to the DH 'Reference guide to consent for examination or treatment'</li> <li>• include additional healthcare practitioners (midwives, pharmacists, paramedics, physiotherapists) in Section 3</li> <li>• reference the protocol for ordering storage and handling of vaccines</li> <li>• add additional paragraphs to the off-label section on storage and consent</li> <li>• refer to vaccine incident guidelines</li> <li>• refer to upload of records onto National Health Application Infrastructure Services</li> <li>• include rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates</li> </ul> | 21 March 2018 |
| V3.0           | <p>PHE HPV PGD amended to:</p> <ul style="list-style-type: none"> <li>• update inclusion criteria to include boys from September 2019</li> <li>• include retention of eligibility until the individuals 25<sup>th</sup> birthday</li> <li>• update off-label section</li> <li>• include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 17 April 2019 |
| V4.0           | <p>PHE HPV PGD amended to:</p> <ul style="list-style-type: none"> <li>• include the nine valent vaccine (Gardasil® 9)</li> <li>• include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 21 July 2021  |
| V5.0           | <p>HPV PGD amended to:</p> <ul style="list-style-type: none"> <li>• update dose and frequency section to reflect updated recommendations that, from 1 April 2022, those commencing vaccination from 15 years of age should commence a 2-dose schedule with a minimum 6-month interval</li> <li>• refer to Chapter 2 of the Green Book for further information on consent</li> <li>• update off-label section to reflect the revised schedule</li> <li>• reflect updated storage details for Gardasil 9</li> <li>• update organisation from PHE to the UKHSA</li> <li>• include minor rewording, layout and formatting changes for clarity and consistency with other UKHSA PGDs</li> </ul>                                                                                                                                                                                         | 4 March 2022  |

|      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |              |
|------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|
| V6.0 | <p>HPV PGD amended to:</p> <ul style="list-style-type: none"> <li>• change to one-dose schedule for the routine HPV immunisation programme</li> <li>• update the eligible cohorts on Page 1, clinical condition and criteria for inclusion</li> <li>• add use of Gardasil® 9 in pregnancy in off-label and special consideration sections and amend exclusion and actions to be taken sections accordingly</li> <li>• add one dose schedule in off-label section</li> <li>• add use of mixed schedule in off-label section</li> <li>• update criteria for exclusion</li> <li>• remove 2 doses schedule from dose and frequency</li> <li>• remove Gardasil® throughout the document as it has been discontinued and has not been used since July 2022 in the programme</li> <li>• include facilities for management for anaphylaxis statement in cautions section for consistency</li> <li>• add statement for separate order lines for gay, bisexual, and other men who have sex with men (GBMSM) and adolescent HPV programmes on ImmForm</li> <li>• add advice to be given if fainting occurs in patient advice</li> <li>• add accessible information in written information section</li> <li>• update reference section</li> <li>• include minor rewording of standard text, layout and formatting changes for clarity and consistency with organisation change, gateway requirements and other UKHSA PGDs</li> <li>• amend NHS England and NHS Improvement (NHSEI) to NHSE following completion of merger on 1 July 2022</li> </ul> | 28 June 2023 |
| V7.0 | <p>HPV PGD amended to:</p> <ul style="list-style-type: none"> <li>• update the schedule for routine immunisation in the dose and frequency of administration section</li> <li>• Page 1; updated governance requirements for sections 2 and 7</li> <li>• include minor rewording of standard text, layout and formatting changes for clarity and consistency with organisation change and other UKHSA PGDs</li> <li>• update qualifications and professional registration with reference to clinical scope</li> <li>• update expert panel</li> <li>• add pharmacy technicians in Section 3; qualifications and professional registration</li> <li>• update qualifications and professional registration section to include dietitians, podiatrists, and occupational therapists</li> <li>• add statement in dose and frequency section with reference to where vaccines have been given inadvertently</li> <li>• add statement in dose and frequency section with reference to using a mixed schedule for vaccination of individuals with unknown or incomplete vaccination status</li> <li>• delete the statement for post-marketing surveillance in the identification and management of adverse reactions section</li> </ul>                                                                                                                                                                                                                                                                                                          | 16 July 2025 |

## 1. PGD development

This PGD has been developed by the following health professionals on behalf of the UKHSA:

| Developed by:                                      | Name                                                                                     | Signature                                                                           | Date         |
|----------------------------------------------------|------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|--------------|
| <b>Pharmacist</b><br>(Lead Author)                 | Suki Hunjunt<br>Lead Pharmacist Immunisation Programmes,<br>UKHSA                        |   | 17 July 2025 |
| <b>Doctor</b>                                      | Sharif Ismail<br>Consultant Epidemiologist, Public Health<br>Infection Programmes, UKHSA |  | 17 July 2025 |
| <b>Registered Nurse</b><br>(Chair of Expert Panel) | David Green<br>Nurse Consultant for Immunisation<br>Programmes, UKHSA                    |  | 17 July 2025 |

This PGD has been peer reviewed by the UKHSA Immunisations PGD Expert Panel in accordance with the UKHSA PGD and Protocol Policy. It has been ratified by the UKHSA Medicines Governance Committee.

## Expert Panel

|                       |                                                                                                             |
|-----------------------|-------------------------------------------------------------------------------------------------------------|
| Nicholas Aigbogun     | Consultant in Communicable Disease Control, Yorkshire and Humber Health Protection Team, UKHSA              |
| Gayatri Amrithalingam | Consultant Epidemiologist, Immunisation Programmes, UKHSA                                                   |
| Jessica Baldasera     | Health Protection Practitioner, North East Health Protection Team Regions Directorate, UKHSA                |
| Alison Campbell       | Screening and Immunisation Coordinator, Public Health Commissioning NHS England (NHS England) Midlands      |
| Jodie Crossman        | Clinical Nurse Specialist GUM - Brighton SHAC, Co-Chair - STI Foundation                                    |
| Jane Freeguard        | Deputy Director of Vaccination – Medicines and Pharmacy NHS England                                         |
| Rosie Furner          | Advanced Specialist Pharmacist - Medicines Governance, Specialist Pharmacist Services (SPS)                 |
| Ed Gardner            | Advanced Paramedic Practitioner/Emergency Care Practitioner, Medicines Manager, Proactive Care Lead         |
| Shilan Ghafoor        | Medicines Governance Lead Pharmacist, UKHSA                                                                 |
| Greta Hayward         | Consultant Midwife – Immunisation Programmes, UKHSA                                                         |
| Naveen Dosanjh        | Senior Clinical Advisor - Vaccinations, NHS England                                                         |
| Elizabeth Luckett     | Senior Screening and Immunisation Manager, NHS England South West                                           |
| Briony Mason          | Vaccination Manager, Professional Midwifery Advocate, Vaccination and Screening, NHS England, West Midlands |
| Vanessa MacGregor     | Consultant in Communicable Disease Control, East Midlands Health Protection Team, UKHSA                     |
| Laura Craig           | Lead Immunisation Nurse Specialist, Immunisation and Vaccine Preventable Diseases Division, UKHSA           |
| Tushar Shah           | Lead Pharmacy Adviser, NHS England London                                                                   |

## 2. Organisational authorisations

The PGD is not legally valid until it has had the relevant organisational authorisation.

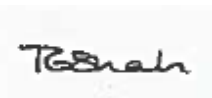
**The fields in this section cannot be used to alter, amend or add to the clinical or other PGD content (sections 3 to 6 inclusive). Such action will invalidate the UKHSA clinical content authorisation which is provided in accordance with the regulations. See page 1 for full details.**

It is the responsibility of the organisation that has legal authority to authorise the PGD, to ensure that all legal and governance requirements are met. The authorising body accepts governance responsibility for the appropriate use of the PGD.

NHS England – London authorises this PGD for use by the services or providers listed below:

| Authorised for use by the following organisations and/or services                                                                                                                                                                                                                                          |  |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
| This PGD must only be used by specified registered healthcare professionals working for providers that are directly commissioned by NHS England - London, or who are administering vaccinations as part of a national immunisation programme, and who have been named and authorised to practice under it. |  |
| Limitations to authorisation                                                                                                                                                                                                                                                                               |  |
| None                                                                                                                                                                                                                                                                                                       |  |

| Organisational approval (legal requirement) |              |                                                                                      |            |
|---------------------------------------------|--------------|--------------------------------------------------------------------------------------|------------|
| Role                                        | Name         | Sign                                                                                 | Date       |
| Chief Nurse,<br>NHS England – London        | Karen Bonner |  | 31/07/2025 |

| Additional signatories according to locally agreed policy |              |                                                                                      |            |
|-----------------------------------------------------------|--------------|--------------------------------------------------------------------------------------|------------|
| Role                                                      | Name         | Sign                                                                                 | Date       |
| Director of Nursing,<br>NHS England – London              | Gwen Kennedy |  | 31/07/2025 |
| Lead Pharmacy Adviser,<br>NHS England – London            | Tushar Shah  |  | 30/07/2025 |

Local enquiries regarding the use of this PGD may be directed to [england.londonimms@nhs.net](mailto:england.londonimms@nhs.net)

Section 7 provides a practitioner authorisation sheet. Individual practitioners must be authorised by name to work to this PGD. Alternative practitioner authorisation sheets may be used where appropriate in accordance with local policy but this should be an individual agreement or a multiple practitioner authorisation sheet as included at the end of this PGD.

### 3. Characteristics of staff

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|-----------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Qualifications and professional registration</b> | <p>All practitioners should only administer vaccination where it is within their clinical scope of practice to do so. Practitioners must also fulfil the <a href="#">additional requirements</a> and <a href="#">continued training requirements</a> to ensure their competency is up to date, as outlined in the section below:</p> <p>Practitioners working to this PGD must also be one of the following registered professionals who can legally supply and administer under a PGD:</p> <ul style="list-style-type: none"> <li>• nurses and midwives currently registered with the Nursing and Midwifery Council (NMC)</li> <li>• pharmacists and pharmacy technicians currently registered with the General Pharmaceutical Council (GPhC) (Note: this PGD is not relevant to privately provided community pharmacy services)</li> <li>• paramedics, physiotherapists, dieticians, podiatrists, and occupational therapists currently registered with the Health and Care Professions Council (HCPC)</li> </ul> <p>The practitioners above must also fulfil the <a href="#">Additional requirements</a> detailed below.</p> <p>Check <a href="#">Section 2 Limitations to authorisation</a> to confirm whether all practitioners listed above have organisational authorisation to work under this PGD.</p>                                                                                                                                                                                                                                                                              |
| <b>Additional requirements</b>                      | <p>Additionally, practitioners:</p> <ul style="list-style-type: none"> <li>• must be authorised by name as an approved practitioner under the current terms of this PGD before working to it</li> <li>• must have undertaken appropriate training for working under PGDs for supply/administration of medicines</li> <li>• must be competent in the use of PGDs (see <a href="#">NICE Competency framework</a> for health professionals using PGDs)</li> <li>• must be familiar with the vaccine product and alert to changes in the Summary of Product Characteristics (SPC), Immunisation Against Infectious Disease (the '<a href="#">Green Book</a>'), and national and local immunisation programmes</li> <li>• must have undertaken training appropriate to this PGD as required by local policy and in line with the <a href="#">National Minimum Standards and Core Curriculum for Immunisation Training</a></li> <li>• must be competent to undertake immunisation and to discuss issues related to immunisation</li> <li>• must be competent in intramuscular injection techniques</li> <li>• must be competent in the handling and storage of vaccines, and management of the cold chain</li> <li>• must be competent in the recognition and management of anaphylaxis</li> <li>• must have access to the PGD and associated online resources</li> <li>• should fulfil any additional requirements defined by local policy</li> </ul> <p><b>The individual practitioner must be authorised by name, under the current version of this PGD before working according to it.</b></p> |
| <b>Continued training requirements</b>              | <p>Practitioners must ensure they are up to date with relevant issues and clinical skills relating to immunisation and management of anaphylaxis, with evidence of appropriate Continued Professional Development (CPD).</p> <p>Practitioners should be constantly alert to any subsequent recommendations from the UKHSA and/or NHS England (NHSE) and other sources of medicines information.</p> <p>Note: The most current national recommendations should be followed but a Patient Specific Direction (PSD) or a prescription may be required to administer the vaccine in line with updated recommendations that are outside the criteria specified in this PGD.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |

#### 4. Clinical condition or situation to which this PGD applies

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|------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Clinical condition or situation to which this PGD applies</b> | Indicated for the active immunisation of individuals from 12 years of age or from school year 8 and aged less than 25 years (see <a href="#">Criteria for Inclusion</a> ), for the prevention of human papillomavirus infection in accordance with the national immunisation programme and recommendations given in <a href="#">Chapter 18a</a> of Immunisation Against Infectious Disease: The 'Green Book'.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Criteria for inclusion</b>                                    | <p>Individuals who:</p> <ul style="list-style-type: none"> <li>are aged 12 to 13 years in the birth cohort for school year 8<sup>2</sup>.</li> <li>are females born on or after 1 September 1991 and males born on or after 1 September 2006 and are less than 25 years old</li> <li>Transgender females and transgender males, in birth cohorts eligible for the girls' programme from 1 September 2008, may be vaccinated in accordance with this PGD as appropriate</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Criteria for exclusion<sup>3</sup></b>                        | <p>Individuals for whom no valid consent has been received (or for whom a best-interests decision in accordance with the <a href="#">Mental Capacity Act 2005</a>, has not been obtained). For further information on consent, see <a href="#">Chapter 2</a> of the Green Book). Several resources are available to inform consent (see <a href="#">written information to be given to individual or carer section</a>).</p> <p>Individuals who:</p> <ul style="list-style-type: none"> <li>are less than 12 years of age and in school year 7 or lower</li> <li>are less than 9 years of age</li> <li>are aged 25 years and over, except those who have received a partial course of HPV immunisation<sup>4</sup></li> <li>have had a confirmed anaphylactic reaction to a previous dose of HPV vaccine or to any components of the vaccine</li> <li>have completed a course of HPV vaccine</li> <li>are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation)</li> </ul> |
| <b>Cautions including any relevant action to be taken</b>        | <p>Facilities for management of anaphylaxis should be available at all vaccination sites (see <a href="#">Chapter 8</a> of the Green Book) and advice issued by the <a href="#">Resuscitation Council</a> UK.</p> <p>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.</p> <p>The immunogenicity of the vaccine could be reduced in immunosuppressed subjects. Vaccination should proceed in accordance with the national recommendations. However, re-immunisation may need to be considered (see Green Book <a href="#">Chapter 7</a>). Seek medical advice as appropriate.</p>                                                                                                                        |
| <b>Action to be taken if the patient is excluded</b>             | If aged less than 12 years and in a school year below year 8, advise the individual when the national routine immunisation is indicated.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |

<sup>2</sup> Individuals in school year 8 who are aged outside the designated birth cohort for the school year may be immunised with their peers

<sup>3</sup> Exclusion under this PGD does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation will be required.

<sup>4</sup> It is clinically appropriate to complete the course but vaccination of individuals who have attained 25 years of age will not attract a payment.

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|----------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                      | <p>If aged less than 9 years HPV vaccination is off-label. Immunisation is not indicated unless in school year 8 or above and a PSD or a prescription would be required.</p> <p>If aged 25 years and over advise that vaccination against HPV is not provided under the routine NHS HPV immunisation programme.</p> <p>GBMSM and are 25 years and over can be advised that HPV vaccination may be accessed through specialist sexual health services (see <a href="#">Chapter 18A</a>).</p> <p>If a confirmed anaphylactic reaction has been experienced after a previous dose of HPV vaccine, or any of its components, specialist advice should be sought. If immunisation is recommended do not administer under this PGD; a PSD or a prescription will be required.</p> <p>Individuals suffering acute severe febrile illness should postpone immunisation until they have recovered; immunisers should advise when the individual can be vaccinated and ensure another appointment is arranged at the earliest opportunity.</p> <p>Seek appropriate advice from the local Screening and Immunisation Team, local Health Protection Team or the individual's clinician as required.</p> <p>The risk to the individual of not being immunised must be taken into account.</p> <p>Document the reason for exclusion and any action taken in the individual's clinical records.</p> <p>Inform or refer to the GP or a prescriber as appropriate.</p> |
| <b>Action to be taken if the patient or carer declines treatment</b> | <p>Informed consent, from the individual or a person legally able to act on the individual's behalf, must be obtained for each administration (see <a href="#">Additional Information</a>).</p> <p>Advise the individual/parent/carers about the protective effects of the vaccine, the risks of infection and potential complications.</p> <p>Document the advice given and the decision reached.</p> <p>Inform or refer to the GP or a prescriber as appropriate.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Arrangements for referral for medical advice</b>                  | As per local policy                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |

## 5. Description of treatment

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|-----------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Name, strength and formulation of drug</b> | Human papillomavirus 9-valent vaccine [types 6, 11, 16, 18, 31, 33, 45, 52, 58] (recombinant, adsorbed): <ul style="list-style-type: none"> <li>Gardasil® 9, suspension for injection in a pre-filled syringe or vial</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Legal category</b>                         | Prescription only medicine (POM)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Black triangle▼</b>                        | No                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Off-label use</b>                          | <p>The use of a one-dose schedule of Gardasil® 9 is off-label, however, it is in accordance with national recommendations by <a href="#">JCVI</a> and <a href="#">Chapter 18a</a> of the 'Green Book'.</p> <p>The SPC does not recommend the use of Gardasil® 9 during pregnancy and advises to postpone the vaccination until completion of pregnancy. However, vaccination in pregnancy can be given in accordance with the Green Book, <a href="#">Chapter 18A</a> (see <a href="#">Special considerations</a>).</p> <p>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 official recommendations and <a href="#">Chapter 18a</a> of the Green Book.</p> <p>The HPV vaccine SPC states that 'vaccinees should be observed for approximately 15 minutes after vaccine administration'. In line with advice in <a href="#">Chapter 4</a> of the 'Green Book', 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.</p> <p>Vaccine should be stored according to the conditions detailed in the <a href="#">Storage section</a> below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to <a href="#">Vaccine Incident Guidance</a>. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use this would constitute off-label administration under this PGD.</p> <p>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.</p> |
| <b>Route and method of administration</b>     | <p>Administer by intramuscular injection. The preferred site is the deltoid region of the upper arm.</p> <p>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.</p> <p>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</p>                                                                                                                                                                                                                                                                                                                                                                                          |

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|                                                 | <p>it is reasonable to complete their vaccination course, with Gardasil® 9, in accordance with the schedules above.<sup>5</sup></p> <p>For individuals who are immunocompetent and are not HIV positive, and present with an inadequate vaccination history, every effort should be made to clarify what doses they have had and when they received them. Individuals who have received one HPV vaccine dose before reaching the age of 25 years, do not require any further doses.</p> <p>Individuals who started their schedule with a product not available in the UK, and require additional doses to complete their course, (see <a href="#">Chapter 18a</a>) will follow a mixed schedule.</p>                                                                                                                                                                                                                                                                                                     |
| <b>Duration of treatment</b>                    | A one or three dose course (see <a href="#">Dose and Frequency</a> section above)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Quantity to be supplied and administered</b> | Single 0.5ml dose per administration.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Supplies</b>                                 | <p>Centrally purchased vaccines for the national immunisation programme can only be ordered via ImmForm. Vaccines for use for the national immunisation programme are provided free of charge.</p> <p>There are separate order lines for the GBMSM and adolescent HPV programmes on Immform. The correct one must be used to order vaccine for each programme, even where an ImmForm account holder is ordering for both.</p> <p>Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see the 'Green Book' <a href="#">Chapter 3</a>).</p>                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Storage</b>                                  | <p>Store at +2°C to +8°C.<br/>Store in original packaging in order to protect from light.<br/>Do not freeze.</p> <p>Gardasil® 9 should be administered as soon as possible after being removed from the refrigerator.</p> <p>Data from stability studies demonstrate that 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.</p> <p>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 on a case-by-case for suitability of continued off-label use or appropriate disposal. Refer to <a href="#">Vaccine Incident Guidance</a>.</p> |
| <b>Disposal</b>                                 | Equipment used for immunisation, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of safely in a UN-approved puncture-resistant 'sharps' box, according to local waste disposal arrangements and NHS England guidance in the <a href="#">technical memorandum 07-01: Safe management of healthcare waste</a> (NHS England).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Drug interactions</b>                        | Immunological response may be diminished in those receiving immunosuppressive treatment. Vaccination is recommended even if the antibody response may be limited.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |

<sup>5</sup> It is clinically appropriate to complete the course but vaccination of individuals who have attained 25 years of age will not attract a payment.

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|                                                                                                              | <p>May be given at the same time as other vaccines.</p> <p>Gardasil® 9 may be administered concomitantly with dTaP, dT/IPV or dTaP/IPV with no significant interference with antibody response to any of the components of either vaccine. See the Green Book <a href="#">Chapter 18a</a> for full details of vaccines that can be given at the same time as Gardasil®9.</p> <p>A detailed list of drug interactions is available in the SPC, which is available from the <a href="#">electronic Medicines Compendium website</a>.</p>                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Identification and management of adverse reactions</b>                                                    | <p>Local reactions following vaccination are very common, such as pain, swelling or redness at the injection site and headache.</p> <p>Mild side effects such as, nausea, dizziness, fatigue, fever, injection-site haematoma and injection-site pruritus are reported as common.</p> <p>Hypersensitivity reactions and anaphylaxis can occur but are very rare.</p> <p>A detailed list of adverse reactions is available in the SPC which is available from the <a href="#">electronic Medicines Compendium website</a>.</p>                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Reporting procedure of adverse reactions</b>                                                              | <p>Healthcare professionals and individuals/parents/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the <a href="#">Yellow Card reporting scheme</a> or search for MHRA Yellow Card in the Google Play or Apple App Store.</p> <p>Any adverse reaction to a vaccine should be documented in the individual's record and the individual's GP should be informed.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Written information to be given to patient or carer</b>                                                   | <p>Offer the marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine.</p> <p>For resources in accessible formats and alternative languages, please visit <a href="#">Home - Health Publications</a>.</p> <p>Where applicable, inform the individual/parent/carer that the PIL with large print, Braille or audio CD can be ordered from the manufacturer (see <a href="#">electronic medicines compendium</a>).</p> <p>Immunisation promotional material may be provided as appropriate:</p> <ul style="list-style-type: none"> <li>• <a href="#">Immunisations for teenagers and young people</a></li> <li>• <a href="#">HPV universal vaccination: leaflet - GOV.UK (www.gov.uk)</a></li> <li>• <a href="#">Human papillomavirus (HPV): vaccination record card - GOV.UK (www.gov.uk)</a></li> </ul> <p>Available via the <a href="#">UKHSA Immunisation Collection</a> webpage.</p> |
| <b>Patient advice and follow up treatment</b><br><br><br><br><br><br><br><br><br><br>Continued over the page | <p>Inform the individual/parent/carer of possible side effects and their management. The individual/parent/carer should be advised to seek medical advice in the event of an adverse reaction.</p> <p>If relevant, advise the individual/parent/carer when the next dose is due.</p> <p>Advise that individuals should continue to take appropriate precautions to protect themselves from sexually transmitted diseases and unwanted pregnancy.</p> <p>Advise that HPV vaccination is not a replacement for the national cervical screening programme which should be accessed by individuals with a cervix at the appropriate age.</p> <p>As fainting can occur following vaccination, individuals, where appropriate, should be advised not to drive or use machinery until symptoms have cleared (see <a href="#">Cautions</a>).</p>                                                                                    |



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| <b>Records</b><br>(continued) | <p>Records should be signed and dated (or a password-controlled immuniser's record on e-records).</p> <p>All records should be clear, legible and contemporaneous.</p> <p>This information should be recorded in the individual's GP record. Where vaccine is administered outside the GP setting appropriate health records should be kept and the individual's GP informed.</p> <p>When vaccine is administered to individuals under 19 years of age, notify the local Child Health Information Systems team (Child Health Records Department) using the appropriate documentation/pathway as required by any local or contractual arrangement.</p> <p>Systems should be in place to ensure that the HPV vaccination record is uploaded onto the National Health Application Infrastructure Services (NHAIS) system (also known as Open Exeter) for NHS cervical screening programme call-recall purposes.</p> <p>A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.</p> |
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## 6. Key references

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|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Key references</b> | <b>Human papillomavirus (HPV) vaccine</b> <ul style="list-style-type: none"><li>• Immunisation Against Infectious Disease: The Green Book <a href="#">Chapter 18a</a>, last updated 20 June 2023.<br/><a href="http://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book">www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book</a></li><li>• Summary of Product Characteristic for Gardasil®9, MSD Ltd. Last updated 13 September 2024.<br/><a href="http://www.medicines.org.uk/emc/product/7330">www.medicines.org.uk/emc/product/7330</a></li><li>• HPV Vaccination Consent Form last updated 28 June 2023.<br/><a href="http://www.gov.uk/government/publications/human-papillomavirus-hpv-vaccination-consent-form">www.gov.uk/government/publications/human-papillomavirus-hpv-vaccination-consent-form</a></li><li>• JCVI statement on a one-dose schedule for the routine HPV immunisation programme 5 August 2022.<br/><a href="http://www.gov.uk/government/publications/single-dose-of-hpv-vaccine-jcvi-concluding-advice/jcvi-statement-on-a-one-dose-schedule-for-the-routine-hpv-immunisation-programme">www.gov.uk/government/publications/single-dose-of-hpv-vaccine-jcvi-concluding-advice/jcvi-statement-on-a-one-dose-schedule-for-the-routine-hpv-immunisation-programme</a></li><li>• HPV vaccination programme: changes from September 2023 bi-partite letter.<br/><a href="http://www.gov.uk/government/publications/hpv-vaccination-programme-changes-from-september-2023-letter">www.gov.uk/government/publications/hpv-vaccination-programme-changes-from-september-2023-letter</a></li></ul> <b>General</b> <ul style="list-style-type: none"><li>• Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. NHS England, 2024.<br/><a href="http://www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-hm-07-01/">www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-hm-07-01/</a></li><li>• National Minimum Standards and Core Curriculum for Immunisation Training. Published June 2023.<br/><a href="http://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners">www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners</a></li><li>• NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published March 2017.<br/><a href="http://www.nice.org.uk/guidance/mpg2">www.nice.org.uk/guidance/mpg2</a></li><li>• NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. Updated March 2017.<br/><a href="http://www.nice.org.uk/guidance/mpg2/resources">www.nice.org.uk/guidance/mpg2/resources</a></li><li>• UKHSA Immunisation Collection.<br/><a href="http://www.gov.uk/government/collections/immunisation">www.gov.uk/government/collections/immunisation</a></li><li>• Vaccine Incident Guidance.<br/><a href="http://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors">www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors</a></li></ul> |
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## 7. Practitioner authorisation sheet

**HPV vaccine PGD v7.00 Valid from: 1 September 2025 Expiry: 1 September 2028**

Before signing this patient group direction (PGD), check that the document has had the necessary authorisations in section two. Without these, this PGD is not lawfully valid.

### Practitioner

By signing this PGD you are indicating that you agree to its contents and that you will work within it.

PGDs do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

| I confirm that I have read and understood the content of this PGD and that I am willing and competent to work to it within my professional code of conduct. |             |           |      |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|-----------|------|
| Name                                                                                                                                                        | Designation | Signature | Date |
|                                                                                                                                                             |             |           |      |
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### 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 the following named organisation .....<br>for the above named healthcare professionals who have signed the PGD to work under it. |             |           |      |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|-----------|------|
| Name                                                                                                                                                                                                                                                                                            | Designation | Signature | Date |
|                                                                                                                                                                                                                                                                                                 |             |           |      |

### Note to authorising manager

Score through unused rows in the list of practitioners to prevent practitioner additions post managerial authorisation.

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