Administration
PATIENT GROUP DIRECTION (PGD) FOR

Human Papillomavirus (Gardasil)

YOU MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE YOU ATTEMPT TO WORK ACCORDING TO IT

Clinical Condition	
Indication	Active immunisation of males for the prevention of future cases of human papilloma virus (types 6, 11, 16, 18) infection (prophylactic).
Inclusion criteria	Men who have sex with men (MSM) attending a Level 3 Sexual health / HIV clinic. Age between 16 years and 45 years The above are in accordance with the NHS commissioned service
Exclusion criteria If any of the following apply the PGD CANNOT be used and the patient must be referred to a prescriber	Females Age under 16 years (even if they are part way through a course they will a need a PSD) Over 45 years (a PSD will be needed and vaccine purchased direct from wholesaler). Individuals for whom no valid consent has been received Individuals with bleeding disorders (use PSD for sub cut route) Men who do not have sex with men Confirmed anaphylactic reaction to a previous dose of HPV vaccine or to any components of the vaccine Current acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation), arrange another appt.
Action to be taken if the patient is excluded	This PGD does not apply to females. Transgender individuals should be considered on a case by case basis and offered vaccination if their risk of HPV infection is similar to MSM, however this is not covered by this PGD so a PSD would be required. Document the reason for exclusion and any action taken in the individual's clinical records. Inform or refer to the patient's clinician as appropriate.
Action to be taken if the patient or carer declines treatment	Advise the individual about the protective effects of the vaccine, the risks of infection and potential complications.Document advice given and the decision reached. Inform or refer to the patient's clinician as appropriate.
Cautions including any relevant action to be taken	It is important that procedures are in place to avoid injury from faints. The immunogenicity of the vaccine could be reduced in immunosuppressed subjects.
Drug Details	
Name, form & strength of medicine	Human papillomavirus vaccine types 6, 11, 16 & 18 (recombinant, adsorbed), eg:Gardasil®, suspension for injection in a prefilled syringe or vial

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	This PGD does not cover the administration of the Human Papillomavirus 9-valent Vaccine, Gardasil® 9.
Storage	Store in original packaging in order to protect from light. Do not freeze. Gardasil® should be administered as soon as possible after being removed from the cold chain. Store at between +2°C to +8°C. In the event of an inadvertent or unavoidable deviation of these conditions refer to PHE Vaccine Incident Guidance. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use this would constitute off-label administration under this PGD. The vaccine's normal appearance is a white cloudy liquid which may settle to a clear liquid and white precipitate. Shake well before use. 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.
Legal Status	Prescription Only Medicine (POM)
Route/Method	Administer by intramuscular injection. The preferred site is the deltoid region of the upper arm. Other routes are not covered by this PGD.
Dose and Frequency	Single 0.5ml dose per administration. Vaccination should be aligned with other routine SSHS or HIV clinic re-attendance where possible to reduce additional visits for vaccination. **MSM aged 15 years to 45 years and MSM aged 45 years and under who are immunosuppressed or HIV positive** Administer a course of three doses: • first dose of 0.5ml of HPV vaccine, then • second dose of 0.5ml at least one month after the first dose, then • a third dose of 0.5ml at least three months after the second dose All three doses should ideally be given within a 12-month period. The programme will aim to deliver three doses within 12 months where possible, using existing appointments where possible to limit additional appointments, and up to 24 months where this is not possible. If the course is interrupted, it should be resumed but not repeated, ideally allowing the appropriate interval between the remaining doses. Whenever possible, immunisations for all individuals on the three dose schedule should follow the recommended 0, 1, 4-6 month schedule. There is no clinical data on whether the interval

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	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 can be given at least one month after the second dose. **Immunocompetent MSM aged under 15 years at time of first dose** Administer a course of two doses to MSM aged under 15 years with a 6 month to 24 month interval between doses ie: • first dose of 0.5ml of HPV vaccine, then • second dose 6 to 24 months after the first dose 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 have been administered less than 6 months apart a third dose should be given at least 3 months after the second dose.
Side effects	Local reactions are very common pain, swelling & redness at the injection site. Hypersensitivity reactions and anaphylaxis can occur but are very rare. Report suspected adverse reactions to the MHRA using the Yellow Card reporting scheme on: http://yellowcard.mhra.gov.uk
Patient advice / follow up treatment	When next dose is due. What to do if in the event of an adverse reaction. Continued protective action eg condom
Staff Characteristics	
Professional qualifications	Nurses on the NMC Register
Specialist competencies or qualifications	A specialist sexual health nurse who after discussion with service or departmental lead has undertaken appropriate documented training to work under PGDs for the administration of medicines and manage anaphylaxis.Must be competent to undertake vaccination and to discuss related issues
Continuing education & training	It is the responsibility of the individual to keep up-to-date with clinical developments as part of their CPD.
Referral Arrangements and Audit Trail	
Records/audit trail	All records should be clear, legible and contemporaneous. Consent details. Patient's name, address, date of birth, Contact details of GP (if registered), Site of injection. Advice given to patient (including side effects), Records should be signed and dated (or a password controlled immunisers record on e-records). Details of any adverse drug reaction and actions taken including documentation in the patient's medical record, Referral arrangements (including self-care). Vaccination records for each eligible MSM should be coded on

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	GUMCADv2 and/or HARS in accordance with the service specification. A searchable record of all individuals receiving treatment under this PGD must be kept for audit purposes
References/Resources and comments	Current versions of the SPC (Summary of Product Characteristics) BNF(British National Formulary) and BASH guidelines

Clinical Authorisation	
Lead Doctor	Dr.W.M.Spice, Clinical Director for the Sexual Health Service Signature: WM Spice Date: 15/08/18
Lead Pharmacist	Dr Alex Johnson, Prescribing Support Pharmacist Signature: Date: 14.8.18
Lead Nurse	Carolyn Gosling, GUM Specialist Nurse Signature: Date: 7.9.18
Organisational Authorisation	
On behalf of Worcestershire Health & Care NHS Trust	Michelle Clarke, Director of Nursing & Quality Signature: Date: 14/8/18

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Individual Authorisation

PGDs DO NOT REMOVE INHERENT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY.

It is the responsibility of each professional to practice only within the bounds of their own competence and in accordance with their own Code of Professional Conduct.

Note to Authorising Managers: authorised staff should be provided with an individual copy of the clinical content of the PGD and a photocopy of the document showing their authorisation. Authorising managers should be sure that staff signed up to use the PGD have the necessary competence, training and knowledge to apply it.

I have read and understood the Patient Group Direction and agree to supply/administer this medicine only in accordance with this PGD. I confirm that I have the necessary competence, training and knowledge to apply it.

Name of Professional	Signature	Authorising Manager	Date