

## **HUMAN PAPILLOMA VIRUS (HPV) IMMUNISATION PROGRAMME FOR MEN THAT HAVE SEX WITH MEN (MSM) 2018/19**

The following document covers NHS England's response to the DHSC announcement on 5 February 2018, and FAQs for the HPV s7a programme. The FAQ section will be updated on a regular basis.

### **DHSC FORMAL ANNOUNCEMENT:**

*“Government confirms HPV vaccination for men who have sex with men”*

The government has confirmed that it will be introducing a nationwide HPV vaccination programme for men who have sex with men aged 45 or younger attending level 3 specialist sexual health services (SSHS) / genitourinary medicine (GUM) and HIV clinics in England. NHS England and Public Health England will work together to agree a programme for implementation starting from April 2018

Since 2008 girls aged 11 to 13 have been vaccinated against the HPV virus, and this provides indirect protection to boys. HPV is a virus transmitted through sexual contact, with over 100 different types of HPV. It is most commonly associated with causing cervical cancer in women.

The Joint Committee on Vaccination and Immunisation (JCVI) have recognised the increasing evidence of the association between HPV infection and non-cervical cancers, as well as the burden from genital warts on Men who have sex with Men (MSM), who do not benefit from indirect protection from the girls programme.

As a result, a vaccination pilot started in 42 specialist sexual health services clinics from June 2016, to assess the feasibility and cost-effectiveness of a national HPV vaccination programme for MSM delivered through this setting. This pilot was a success: [www.gov.uk/government/publications/hpv-vaccination-for-men-who-have-sex-with-men-year-1-pilot](http://www.gov.uk/government/publications/hpv-vaccination-for-men-who-have-sex-with-men-year-1-pilot)

The Government has therefore decided to proceed with a phased, nationwide rollout to protect men who have sex with men from some cancers which are caused by HPV as well as genital warts.

Given the phased approach to the rollout, patients should not contact their clinics to request the vaccine. Instead if the vaccine is available patients will be offered it as part of their routine sexual health check-up.

Dr Michael Edelstein, Consultant Epidemiologist at PHE, said:

*“Our evidence shows that men who have sex with men are welcoming a HPV vaccination programme, and it can be delivered successfully through sexual health services. MSM are a group who receive little indirect protection from the adolescent girls vaccination programme. We expect the new programme to reduce the number of cancers that are directly caused by HPV.”*

## **FREQUENTLY ASKED QUESTIONS (FAQS):**

### **Health Care Professionals – Providers and Commissioners:**

#### **What is the expected uptake rate for the HPV vaccination service in the level 3 SSSHS/ GUM and HIV clinics?**

NHS England will not have a set target uptake rate in 2018/19, as part of the public health functions agreement (section 7a) reporting. However, for service development and planning, we are expecting an uptake of 60% for the first dose, (which the findings from the pilots suggest is achievable), 55% for the second and 50% for the third.

#### **Where can I find more information about the expected service specification?**

The service specification for HPV-MSM can be found here:

<https://www.england.nhs.uk/wp-content/uploads/2017/04/Gateway-ref-08441-180913-Service-specification-No.-32-HPV-MSM.pdf>

PHE have also provided comprehensive clinical and operational guidance for health care professionals here: <https://www.gov.uk/government/publications/hpv-vaccination-for-msm-guidance-for-health-professionals>

#### **Which MSM are eligible?**

All MSM 45 years and under attending SSSHS/ HIV clinics are eligible, (3 doses for 15 years and over and 2 doses under 15 years). Providers should be aware that normal safeguarding procedures will apply.

#### **Why is the cut off for those aged under 46 years old?**

JCVI advised to vaccinate MSM aged up to 45 years because this is the population for which evidence of the benefit of HPV infection is available. JCVI considered an analysis indicating that it is highly likely a programme to vaccinate MSM up to 40 years of age attending GUM and HIV clinics would be cost-effective, as long as the vaccine is procured, and the programme is delivered at a cost-effective price. JCVI considered it reasonable to extrapolate the findings to those MSM aged 45 years,

although there is too much uncertainty in the data to extrapolate further. The policy of not offering the vaccine routinely, through the national programme, to an older MSM population is therefore based on expert advice that there is less evidence of the benefits of vaccination.

**Will there be consideration to provide to those who are HIV positive, regardless of age or gender?**

The JCVI considers that there may be considerable benefit in offering the HPV vaccine to other individuals who have a similar risk profile to that seen in the MSM population attending GUM and HIV clinics, including some MSM over 45, sex workers, HIV+ve women, and HIV+ve men. Clinicians may exercise their clinical judgement to offer vaccinations outside of the national programme and so HPV vaccination can therefore be considered for such individuals on a case-by-case basis.

**What are the plans for roll-out?**

NHS England will be introducing a nationwide HPV vaccination programme for men who have sex with men aged 45 or younger attending level 3 SSHS/ GUM and HIV clinics in England via a phased rollout from April 2018. The service will be offered in all other Level 3 Sexual Health and HIV Services sites and rolled out as soon as reasonably practicable. All the former PHE pilot sites have continued delivery, with full roll-out of the programme across England to be completed by April 2019.

**Can my clinic apply to be a HPV MSM vaccination site?**

NHS England are rolling out the programme across England, in HIV and Level 3 SSHS/ GUM clinics, and in the first instance NHS England will prioritise the commissioning of the HPV MSM immunisation service from the current PHE led pilot sites from 1 April 2018. The detailed planning for the delivery of the HPV-MSM immunisation programme will be completed at local level, so any proposals will be considered by your local NHS England public health commissioning team. Existing providers of sexual health services who wish to offer the programme to their clients should contact their local public health commissioning teams. If Providers do not have contact details for NHS England public health commissioners, their local authority public health commissioners and/or NHS England specialised commissioners should be able to signpost them.

**Is there any scope for it also to be offered in Level 2 settings?**

Currently only level 3 settings can offer the programme.

**Will eligible MSM be signposted if accessing sexual health services online?**

Yes. Some Local Authorities commission on-line services, and MSM using such services should be signposted to a physical clinic for vaccination if eligible.

**Will the service be available in the prison settings?**

NHS England will work with PHE to begin a pilot within prison settings in 2018/19, to ensure the method of delivery is acceptable and sustainable in places of detention

**What is the administration fee for the vaccination or cost per dose?**

The administration fee for the 3-dose regimen is £10 per dose in 2018/19.

**Is there any capital funding to go alongside the cost per dose – for example to fund fridges?**

No.

**Will Commissioning for Quality and Innovation (CQUIN) goals apply?**

Yes, if relevant to your overall contract with the provider and will be calculated on top of the agreed £10 per dose administration fee. It is not anticipated that providers will be expected to deliver a programme specific CQUIN in 2018/19.

**Where can I find the Patient Group Directions?**

The Patient Group Directions for services in SSHS/ GUM and HIV clinics can be found at the following link: <https://www.gov.uk/government/publications/human-papillomavirus-hpv-vaccine-for-msm-pgd-template>

**Where can I find posters and leaflets?**

Leaflets and posters for the programme can be found here:

<https://www.gov.uk/government/publications/hpv-vaccination-for-msm-posters-and-leaflets>

**What is the Sexual Orientation Monitoring (SOM) Information Standard?**

The Lesbian Gay Bisexual and Trans (LGBT) Foundation worked with key stakeholders including NHS Digital, to develop a [Sexual Orientation Monitoring Information Standard](#) on behalf of NHS England. The SOM information standard provides a consistent mechanism for recording the sexual orientation of all patients/service users aged 16 years across all health services in England. It will

## **Publications Gateway Reference: 08766**

also cover local authorities with responsibilities for adult social care in all service areas where it may be relevant to record this data using a standardised format.

This standard provides the categories for recording sexual orientation but does not mandate a collection.

More information can be found here:

<https://www.england.nhs.uk/about/equality/equality-hub/sexual-orientation-monitoring-information-standard/>

### **What is the vaccine licenced for?**

HPV vaccine (Gardasil) is licenced for use from the age of 9 years for the prevention of:

- premalignant genital lesions (cervical, vulvar and vaginal), premalignant anal lesions, cervical cancers and anal cancers causally related to certain oncogenic Human Papillomavirus (HPV) types
- genital warts (condyloma acuminata) causally related to specific HPV types.

### **Is there any plan to consider procurement of the 9 valent vaccine to be used in national programmes?**

Gardasil9<sup>®</sup> can be considered in the next round of tendering for the HPV programme. The current contract for Gardasil<sup>®</sup> was awarded in 2016 with a commitment to purchase until 2020. Gardasil9<sup>®</sup> was not licenced in time under a two dose schedule to be considered for the current contract.

### **How can I order the vaccine?**

The HPV vaccine Gardasil<sup>®</sup> is available to order by authorised level 3 GUM and HIV clinics in England through ImmForm (<https://portal.immform.dh.gov.uk/>), for use in the national HPV vaccination programme for men who have sex with men (MSM) aged 45 years or younger.

Most GUM clinics already have an ImmForm account (due to arrangements put in place for the Hepatitis A outbreak response). You will be able to use the same account to access Gardasil<sup>®</sup> for the purposes of the MSM programme, although clinics who have not been commissioned to deliver the programme should not be ordering the vaccine. Providers will not be paid a fee for administration of the vaccine without explicit agreement having been reached with their local NHS England public health commissioning team.

If you are a GUM clinic that is not yet able to access centrally supplied vaccines through ImmForm, please see the instructions below.

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HIV clinics are likely to have links with hospital pharmacies that will be able to order Gardasil® for the purposes of the MSM programme on your behalf through existing ImmForm accounts. However, these accounts will first need to be identified by PHE in order to give the correct-access to the Gardasil® product line for the MSM programme.

**Please be aware that there is a separate product line for Gardasil® for the MSM programme on the vaccine ordering page of ImmForm, and the Gardasil® product line for use in the girls' programme should not be used to order vaccine for the MSM programme.**

### **Instructions for HIV clinics and GUM clinics that do not have access to ImmForm**

To order Gardasil® vaccine for the purposes of the MSM HPV programme you will need to:

1. Identify whether your clinic has access to an active ImmForm account – most likely through a hospital pharmacy. If it does, move to 3.
2. If your clinic does not have access to an active ImmForm account then a new ImmForm account will need to be set up. You can open an account via [Helpdesk@immform.org.uk](mailto:Helpdesk@immform.org.uk), stating that it is for the purposes of the National MSM HPV programme.
3. Once you have an active account, please provide the following details of your ImmForm account to [vaccinesupply@phe.gov.uk](mailto:vaccinesupply@phe.gov.uk)
  - Clinic name, code and postcode
  - ImmForm /Movianto account number of the pharmacy who will be supplying your clinic
  - Pharmacy location including delivery postcode
  - Contact details for ImmForm account holder
4. You should begin this process at least one month in advance of your projected programme start date. This will allow time for accounts to be set up and given the correct access. You should bear in mind that your account will have a fixed weekly delivery day.

If you have any further questions, please send them to: [england.phs7apmo@nhs.net](mailto:england.phs7apmo@nhs.net)