

# **Yukon Immunization Program Manual**

## **Section 8 - Biological Products**

### **HPV vaccine**



## SECTION 8 – BIOLOGICAL PRODUCTS

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2021 January	
<b>Human Papillomavirus Vaccine (GARDASIL®9)</b> <b>[NONVALENT (Types 6, 11, 16, 18, 31, 33, 45, 52, and 58)]</b> <p style="text-align: right;"><b>Supplier: Merck Canada Inc.</b></p>	
INDICATIONS	INITIAL SERIES ③④⑤⑥⑦⑧⑨
<u>Recommended and provided free to:</u>  <b>(1)</b> Females and Males in grade 6 school year ①②  <b>(2)</b> Females and Males age 9-14 years initiating series prior to their 15 <sup>th</sup> birthday outside of the school based program. ①②	<b>2 doses</b> in grade 6 (or before 15 years of age): <b>Dose1:</b> 0.5 ml IM (minimum of 24 weeks after dose one)* <b>Dose 2:</b> 0.5 ml IM  <b>*If the interval between dose 1 &amp; 2 is shorter than 150 days (5 months), follow 3 dose schedule – 3<sup>rd</sup> dose should be given at least 24 weeks after 1<sup>st</sup> dose and 12 weeks after the 2<sup>nd</sup> dose.</b>
<b>(3)</b> Females and Males <b>15 years of age to 26 years.</b> <b>(4)</b> Females and Males HIV+ (9 – 45 years of age). <b>(5)</b> Males high risk (9 – 26 years of age at time of 1 <sup>st</sup> dose) – MSM; Street involved; <b>(6)</b> People who are Transgender (9 – 26 years of age at time of 1 <sup>st</sup> dose).	<b>3 doses:</b>  0.5 ml IM 0.5 ml IM at 8 weeks 0.5 ml IM at 24 weeks
<u>Recommended but NOT provided free to:</u>  <b>(7)</b> Females 27 years – 45 years of age at initiation of immunization series. <b>See Special Considerations.</b>	<b>3 doses:</b>  0.5 ml IM 0.5 ml IM at 8 weeks 0.5 ml IM at 24 weeks
REINFORCEMENTS	No booster doses are recommended at this time.
VACCINE COMPONENTS	Potential allergens: polysorbate 80, yeast protein. Other components: amorphous aluminum hydroxyphosphate sulfate, L-histidine, sodium borate.

2020 September	
<b>Human Papillomavirus Vaccine (GARDASIL®9)</b> <b>[NONVALENT (Types 6, 11, 16, 18, 31, 33, 45, 52, and 58)]</b>	
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<b>ADVERSE EVENTS</b>	Local: mild to moderate pain, redness, swelling Systemic: headache.
<b>CONTRAINDICATIONS</b>	<ol style="list-style-type: none"> <li>1. History of anaphylactic reaction to a previous dose of HPV vaccine, or to any component of GARDASIL®9</li> <li>2. Pregnancy. Although the vaccine has not been causally associated with adverse outcomes of pregnancy or adverse events to the developing fetus, the data on vaccination in pregnancy are limited. Administer vaccine series after completion of the pregnancy. If a woman is found to be pregnant after initiating the vaccine series, delay completion of the series until after pregnancy. If a vaccine dose has been administered during pregnancy, there is no indication for any intervention.</li> </ol>
<b>SPECIAL CONSIDERATIONS</b>	<ul style="list-style-type: none"> <li>• Individuals for whom HPV vaccine is recommended may be immunized even if already sexually active or have had a known HPV infection. The likelihood that they have been infected with all types of HPV contained in the vaccine is low and they stand to benefit from immunization. ⑦</li> <li>• Provision of HPV9 vaccine for individuals at no charge, referred to YCDC or rural health centers by Yukon OB/GYN specialists, for individuals with CIN2+ with a demonstrated financial need, as determined by specialist. All other indications for immunization apply (age, dosing and spacing). Document high risk in Panorama under the Reason for Immunization Tab.</li> </ul>

2020 September

**Human Papillomavirus Vaccine (GARDASIL®9)**  
**[NONVALENT (Types 6, 11, 16, 18, 31, 33, 45, 52, and 58)]**

**Supplier: Merck Canada Inc.**

- ❶ Those individuals receiving this series outside of the school based program, should be offered the series on the 2 dose schedule of 0 and 24 weeks if initiating before 15th birthday. Those initiating series on or after 15th birthday should be immunized with the 3 dose schedule of 0, 8 weeks and 24 weeks.
- ❷ Individuals who are known to have immune system defects associated with solid organ transplant, stem cell transplant, or HIV infection should receive HPV vaccine in the three dose schedule at 0, 8 weeks and 24 weeks. The immunosuppressed state results in a less robust immune response, and those with such conditions are at risk of persistent HPV infection and associated HPV disease if they become infected.
- ❸ Currently, routine HPV testing is not recommended before or after immunization. In addition, serologic tests are not routinely available in Canada.
- ❹ Individuals who are immunocompromised, either from disease or medication, can receive this vaccine; however, the immune response to vaccination and vaccine efficacy might be less than in immunocompetent individuals.
- ❺ Gardasil®/Gardasil®9 vaccine can be administered at the same visit as other age-appropriate vaccines, using a separate needle and syringe for each injection.
- ❻ If the schedule is interrupted, the vaccine series does not need to be restarted. If the series is interrupted after any dose, the subsequent dose should be given as soon as possible. The minimum interval schedule between dose one and dose two is 4 weeks, and between dose two and dose three is 12 weeks. The minimum interval schedule should not be followed on a routine basis; it should only be used at the client – specific level based on health care provider assessment. The preferred schedule is 0, 8 weeks and 24 weeks.
- ❼ Advise vaccine recipients that there are no data to suggest the vaccine will have any therapeutic effect on existing cervical lesions (i.e., vaccine does not prevent the consequences of current HPV infection). Although there is some emerging evidence that there is some reduction in recurrence of anal and cervical intraepithelial neoplasia when the HPV vaccine is used for clients in the endoscopy and colposcopy setting, these benefits are still to be confirmed, and there are no therapeutic indications for the use of the vaccine.
- ❽ Individuals who started an HPV series with Gardasil® and complete the series with Gardasil®9 are considered up to date for program purposes. Clients can be reassured that although a complete series of Gardasil®9 is currently recommended to ensure protection against the five additional HPV types in the vaccine, there is already substantial cross-protection against other strains not included in the Gardasil® vaccine, and even one dose of Gardasil®9 is likely to offer significant additional protection against these strains.
- ❾ While there are no supporting data at this time, a minimum interval of 6 months is recommended between completion of a Gardasil® series and initiation of a Gardasil®9 series.