

## Transition to Gardasil® 9 from Gardasil® for Publicly Funded Immunization Programs

**Attention:** Physicians, Nurse Practitioners, Walk-in Clinics/Urgent Care Clinics, Family Health Teams, NSM LHIN, Central LHIN, Hospitals, Correctional Facilities, Beausoliel Health Centre, Rama Mnjikaning Health Centre

**Date:** March 21, 2019

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**Merck Canada Inc. has confirmed that the HPV4 (Gardasil®) vaccine is no longer available. Ontario's publicly funded stock expired on March 14, 2019. Therefore, effective March 15, 2019, Ontario fully transitioned to the HPV9 vaccine for its publicly funded immunization program.**

HPV9 (Gardasil® 9 - manufactured by Merck Canada Inc.) protects against the original 4 strains that were included in HPV4 (6, 11, 16 & 18) plus 5 additional strains (31, 33, 45, 52 & 58).

HPV9 started being offered to Grade 7 students in the School Immunization Program in addition, it was provided to Men who have sex with Men (MSM) as a High Risk vaccine program in September 2017. At that time, students and MSM were to have their series completed with HPV4. Now that HPV4 is no longer available, those who remain eligible to start or complete their HPV vaccine series will do so with HPV9.

### **Eligibility Criteria for Publicly-Funded HPV9 Vaccine**

As of March 15, 2019 the following individuals are eligible to receive HPV9 publicly funded vaccine in Ontario:

- All students in grades 7 and 8
- Males in grade 9 who have either not started or have an incomplete HPV4 series
- Females in grade 9 to 12 who have either not started or have an incomplete HPV4 series
- Those who identify as MSM as per the HPV high-risk program, including those who have an incomplete HPV4 series

Individuals who have completed their HPV4 series as of March 14, 2019 will be considered up-to-date with their HPV immunization and will not be eligible for publicly funded HPV9 vaccine. NACI states that there is insufficient evidence at this time to recommend, at a population level, re-immunization with HPV9 vaccine in individuals who have completed an immunization series with another HPV vaccine.

**The product monograph for HPV9 states it is indicated for females through 45 years and males through 26 years of age. However, the National Advisory Committee on Immunization (NACI) guidelines state that HPV vaccine may be administered to anyone (male or female) at ongoing risk of exposure to HPV with no upper age limit. Non-publicly funded HPV vaccine can be accessed via a prescription from HCPs, and is also a vaccine that trained pharmacists can administer as well, and many do so for a fee.**

### **Immunization Schedule for the HPV9 Vaccine**

- Immunocompetent individuals who are 9 through 14 years of age (until their 15<sup>th</sup> birthday) when receiving their 1<sup>st</sup> dose, should receive 2 doses given as 0.5 mL IM injections, separated by at least 6 months.
- Those 15 years of age and older when receiving their 1<sup>st</sup> dose and those who are immunocompromised (including those with HIV infection) should receive 3 doses given as 0.5 mL IM injections at 0, 2 and 6 months.



## **Effectiveness**

High risk HPV types 16 and 18 are included in both vaccines. These strains have been shown to cause about 70% of cervical cancers and the majority of other HPV-associated cancers in both females and males in Canada. In addition, HPV4 and HPV9 contain HPV types 6 and 11 that are associated with anogenital warts.

HPV9 also contains additional HPV types 31, 33, 45, 52 & 58 which have been shown to cause approximately 15% to 19% of cervical cancers in females. A smaller percentage of HPV-associated cancers in males are caused by the five additional strains in the HPV9 vaccine.

Immunization with HPV4 prevents:

- 80% cervical cancers
- 60% high-risk precancerous cervical lesions
- 70% anogenital cancers
- 90% anogenital warts

**Immunization with HPV9 prevents an additional:**

- 17% cervical cancers
- 30% high-risk precancerous cervical lesions
- 14% anogenital cancers

## **Safety**

Gardasil<sup>®</sup> 9 was authorized for use in Canada in February 2015. The safety profile of the HPV9 vaccine is comparable to the HPV4 vaccine. Both HPV vaccines are very safe and effective. They have been carefully tested and evaluated before receiving approval by Health Canada. Extensive, ongoing monitoring done in Canada and globally continues to show that the HPV vaccines are very safe.

Gardasil<sup>®</sup> 9 has been shown to be generally well tolerated. However, as with all vaccines, there may be some side effects. Syncope can occur after immunization and is most common among adolescents and young adults. Serious side effects such as anaphylaxis may occur but is extremely rare.

## **Who Should Not Get The HPV9 Vaccine**

Individuals who have had a life-threatening allergic reaction (also known as anaphylaxis) to a previous dose of the HPV vaccine should not receive the HPV4 or HPV9 vaccine.

HPV vaccine is not recommended for use in pregnancy because data on HPV vaccination in pregnancy is limited. HPV vaccine, however, has not been causally associated with adverse outcomes of pregnancy or adverse events to the fetus.

For more information about HPV vaccine, refer to the Canadian Immunization Guide:

<https://www.canada.ca/en/public-health/services/canadian-immunization-guide.html>

If you have any questions, please contact the Simcoe Muskoka District Health Unit's Immunization Program at 705-721-7520 or toll free at 1-877-721-7520 ext. 8806.