

<b>Section 7:</b>	<b>Biological Product Information</b>	<b>Standard #: 07.241</b>
<b>Created by:</b>	Province-wide Immunization Program Standards and Quality	
<b>Approved by:</b>	Province-wide Immunization Program, Standards and Quality	
<b>Approval Date:</b>	September 1, 2016	<b>Revised:</b> January 1, 2021

Gardasil®9	
<b>Manufacturer</b>	Merck Canada Inc.
<b>Biological Classification</b>	Inactivated: Recombinant
<b>Indications for Provincially Funded Vaccine</b>	<p><b>Grade 6 students – routine immunization program</b></p> <ul style="list-style-type: none"> <li>• For students in ungraded classes, vaccine can be provided on a case by case basis, generally at 11 to 12 years up to and including 26 years of age. <ul style="list-style-type: none"> <li>○ The guiding principle should be to offer protection to students prior to them leaving the school system.</li> </ul> </li> </ul> <p><b>Notes:</b></p> <ul style="list-style-type: none"> <li>• Public health will screen all students in grades 6 through 9 to ensure they are up to date for HPV-9.</li> <li>• Students eligible for vaccine in Grade 6 continue to be eligible to receive the vaccine up to and including 26 years of age if they present to public health.</li> </ul> <p><b>Males and females 17 years up to and including 26 years of age.</b></p> <ul style="list-style-type: none"> <li>• Males and females initiating the HPV vaccine series at 26 years of age who will be 27 years of age by the time they complete the series are eligible for provincially funded vaccine. Males and females who do not complete the series in their 27<sup>th</sup> year will not be eligible for provincially funded vaccine to complete their series.</li> </ul> <p><b>Hematopoietic Stem Cell Transplantation (HSCT) Recipients:</b></p> <ul style="list-style-type: none"> <li>• All HSCT recipients 9 years up to and including 26 years of age. See Standard for Immunizing Transplant Candidates and Recipients (#08.304).</li> </ul> <p><b>Solid Organ Transplant (SOT) Candidates and Recipients:</b></p> <ul style="list-style-type: none"> <li>• All SOT candidates and recipients 9 years up to and including 26 years of age. See Standard for Immunizing Transplant Candidates and Recipients (#08.304).</li> </ul>
<b>Schedule</b>	<p><b>Immunocompetent and non HIV infected individuals ages 9 to 14 years of age inclusive (2-dose series):</b></p> <ul style="list-style-type: none"> <li>• Dose 1 – day 0</li> <li>• Dose 2 – 6 months after dose 1</li> </ul> <p><b>Immunocompromised and/or HIV infected individuals age 9 to 14 years of age inclusive (3-dose series):</b></p> <ul style="list-style-type: none"> <li>• Dose 1 – day 0</li> <li>• Dose 2 – 2 months after dose 1</li> <li>• Dose 3 – 6 months after dose 1</li> </ul> <p><b>Individuals 15 years of age and older (3 dose series):</b></p> <ul style="list-style-type: none"> <li>• Dose 1 – day 0</li> <li>• Dose 2 – 2 months after dose 1</li> <li>• Dose 3 – 6 months after dose 1</li> </ul>

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	<p><b>Notes:</b></p> <ul style="list-style-type: none"> <li>• The number of recommended doses in a series is based on the age at administration of the first dose. In immunocompetent individuals 15 years of age and older who received the first dose between 9 to less than 15 years of age, a two dose schedule can be used, with the second dose administered at least 6 months after the first dose.</li> <li>• In a two dose schedule the minimum interval is 24 weeks between the first and second dose.</li> <li>• In a three dose schedule the minimum interval between the first and second doses of vaccine is 4 weeks, the minimum interval between the second and third doses of vaccine is 12 weeks, and the minimum interval between the first and last dose is 24 weeks. <ul style="list-style-type: none"> <li>○ When reviewing immunization records, for HPV4 vaccine, if the third dose was administered at less than the interval outlined above, the dose can be considered valid and vaccine would not need to be repeated if there is a minimum interval of at least 4 months (16 weeks) between the first and third dose. This spacing <b>must not</b> be used to schedule immunization rounds/appointments. This direction does not apply to HPV9.</li> </ul> </li> <li>• An interrupted schedule does not require restarting.</li> <li>• When reviewing immunization records, individuals who are immunocompetent and started a HPV series between 9 to 14 years of age prior to September 1, 2018 can be considered complete if they received two doses of vaccine a minimum of 24 weeks apart.</li> <li>• Immunization started in another province or territory as part of a funded program can be completed as they present to public health using the current schedule and dose recommended in Alberta.</li> <li>• Eligible individuals who began their series with Gardasil® (HPV4) can complete the series using Gardasil® 9. However, they should be advised that protection against HPV types 31, 33, 45, 52 and 58 cannot be ensured.</li> <li>• There is insufficient evidence at this time to recommend the re-immunization with HPV-9 of individuals who have completed an immunization series with another HPV vaccine.</li> </ul>
<b>Preferred Use</b>	N/A
<b>Dose</b>	0.5 mL
<b>Route</b>	IM
<b>Contraindications/ Precautions</b>	<p><b>Contraindications:</b></p> <ul style="list-style-type: none"> <li>• Known severe hypersensitivity to any component of the vaccine.</li> <li>• Anaphylactic or other allergic reaction to previous dose of vaccine containing similar components.</li> </ul> <p><b>Precautions:</b></p> <ul style="list-style-type: none"> <li>• None identified</li> </ul>
<b>Possible Reactions</b>	<p><b>Common:</b></p> <ul style="list-style-type: none"> <li>• Pain, swelling, redness, itching, bruising, mass, hemorrhage, hematoma and redness at injection site.</li> <li>• Headache, fever, nausea, dizziness, fatigue, diarrhea, myalgia, oropharyngeal pain, upper abdominal pain.</li> </ul> <p><b>Rare:</b></p> <ul style="list-style-type: none"> <li>• Anaphylaxis, allergic reactions</li> <li>• Asthmatic crisis, tonsillitis</li> <li>• Serious adverse events are rare and in most cases data are insufficient to determine a causal association. Clinical trials have found no increase in the number or type of serious adverse events in recipients of HPV vaccine compared with those who received placebo.</li> </ul>

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	<ul style="list-style-type: none"> <li>• There has been no published evidence to support an association between HPV vaccine and any of the following conditions: Guillain-Barre Syndrome, transverse myelitis, acute disseminated encephalomyelitis, multiple sclerosis, brachial neuritis, chronic inflammatory disseminated polyneuropathy, amyotrophic lateral sclerosis, neuromyelitis optica, pancreatitis, transient arthralgia or thromboembolic events.</li> <li>• As with any immunization, unexpected or unusual side effects can occur. Refer to the product monograph for more detailed information.</li> </ul>
<b>Pregnancy</b>	<ul style="list-style-type: none"> <li>• Gardasil® should not be given to pregnant women or women who become pregnant before the completion of the series. If pregnant, immunization with the remaining doses of vaccine should be deferred until after delivery.</li> <li>• If a vaccine dose has been administered during pregnancy, no intervention is indicated. Merck Canada should be contacted by the client to report incident.</li> </ul>
<b>Lactation</b>	Can be safely administered to eligible breastfeeding women.
<b>Composition</b>	<p><b>Each 0.5 mL dose contains:</b></p> <ul style="list-style-type: none"> <li>• 30 mcg of HPV 6 L1 protein</li> <li>• 40 mcg of HPV 11 L1 protein</li> <li>• 60 mcg of HPV 16 L1 protein</li> <li>• 40 mcg of HPV 18 L1 protein</li> <li>• 20 mcg of HPV 31 L1 protein</li> <li>• 20 mcg of HPV 33 L1 protein</li> <li>• 20 mcg of HPV 45 L1 protein</li> <li>• 20 mcg of HPV 52 L1 protein</li> <li>• 20 mcg of HPV 58 L1 protein</li> <li>• 500 mcg aluminum (amorphous aluminum hydroxyphosphate sulphate adjuvant)</li> <li>• 9.56 mg sodium chloride</li> <li>• 0.78 mg L-histidine</li> <li>• 50 mcg polysorbate 80</li> <li>• 35 mcg sodium borate</li> <li>• water for injection</li> <li>• <i>Saccharomyces cerevisiae</i> (yeast) is used to produce L1 proteins</li> </ul>
<b>Blood/Blood Products</b>	Contains no human blood/blood products.
<b>Bovine/Porcine Products</b>	Contains no bovine or porcine products.
<b>Latex</b>	There is no latex in the vaccine or vaccine packaging.
<b>Interchangeability</b>	<ul style="list-style-type: none"> <li>• HPV vaccines produced by different manufacturers can be used interchangeably. Eligible individuals, who began their immunization series with CERVARIX™ or Gardasil®, can complete the series using GARDASIL®9. All 3 vaccines provide protection against HPV types 16 and 18. If less than the recommended number of doses of Gardasil®9 vaccine are provided, protection against the additional HPV types cannot be ensured. Counseling on this issue must be provided to the client at the time of immunization. For situations deemed to be high risk, consideration for a Gardasil®9 series must include consultation with the MOH.</li> <li>• The dose administered should be that recommended by the manufacturer for the specific product being used.</li> </ul>
<b>Administration with Other Products</b>	<ul style="list-style-type: none"> <li>• May be given at the same time as other inactivated and live vaccines using a separate needle and syringe for each vaccine.</li> <li>• The same limb may be used if necessary, but different sites on the limb must be chosen.</li> </ul>
<b>Appearance</b>	After agitation, the vaccine appears as a white, cloudy liquid.
<b>Storage</b>	<ul style="list-style-type: none"> <li>• Store at +2°C to +8°C</li> <li>• Do not freeze</li> </ul>

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	<ul style="list-style-type: none"> <li>Do not use beyond the labeled expiry date</li> <li>Must be stored in original package to protect from light</li> </ul>
<b>Vaccine Code</b>	HPV-9
<b>Antigen Code</b>	HPV
<b>Licensed for</b>	<ul style="list-style-type: none"> <li>Females 9 years of age up to and including 45 years of age.</li> <li>Males 9 years up to and including 26 years of age.</li> </ul>
<b>Program Notes:</b>	
<ul style="list-style-type: none"> <li>2008/2009 School Year: HPV vaccine became part of the routine Alberta Immunization Program for grade 5 girls.</li> <li>2009/2010 School Year: HPV vaccine was made available to grade 9 girls for a 3 year catch up program.</li> <li>November 2012: HPV vaccine eligibility expanded to include: <ul style="list-style-type: none"> <li>females who were eligible in grade 5 would remain eligible to the end of grade 12</li> <li>male and female recipients of HSCT 9 years up to and including 17 years of age.</li> </ul> </li> <li>July 2014: HPV vaccine eligibility expanded to include male recipients of HSCT 9 years up to the end of grade 12.</li> <li>September 2014: HPV vaccine was included in the routine school immunization program for boys in grade 5. In addition, a catch-up program was offered to grade 9 boys for a 4 year time period, ending in June 2018.</li> <li>September 1, 2016: Gardasil® 9 vaccine replaced Gardasil® vaccine for all eligible individuals.</li> <li>February 2018: HPV eligibility was expanded to include MSM.</li> <li>September 2018: HPV schedule was changed to a two dose series for immunocompetent and non HIV infected individuals ages 9 to 14 years of age inclusive. In addition, the routine school immunization program for HPV vaccine changed from being offered in grade 5 to grade 6.</li> <li>April 2020: Expanded eligibility to include males and females 17 years up to and including 26 years of age starting July 1, 2020. Students remain eligible up to and including 26 years of age.</li> </ul>	
<b>Related Resources:</b>	
<ul style="list-style-type: none"> <li>Human Papillomavirus Vaccine Information Sheet (104506).</li> </ul>	
<b>References:</b>	
<ol style="list-style-type: none"> <li>Alberta Health, Public Health and Compliance Division, Alberta Immunization Policy (2020, July 1). <i>Human Papillomavirus 9-valent Vaccine: GARDASIL®9</i>.</li> <li>Alberta Health (2019, April) Adverse Events Following immunization (AEFI) Policy for Alberta Immunization Providers <a href="https://open.alberta.ca/publications/ae-fi-policy-for-alberta-immunization-providers">https://open.alberta.ca/publications/ae-fi-policy-for-alberta-immunization-providers</a></li> <li>American Academy of Pediatrics. Summaries of Infectious Diseases. In: Pickering LK, Baker CJ, Kimberlin DW, Long SS, eds. <i>Red Book: 2012 Report of the Committee on Infectious Diseases</i>. 28th ed. Elk Grove Village, IL: American Academy of Pediatrics: pp. 524-530.</li> <li>Centers for Disease Control and Prevention. (2011, January). General Recommendations on Immunization: Recommendations of the Advisory Committee on Immunization Practices (ACIP). <i>Morbidity and Mortality Weekly Report</i>, 60(2).</li> <li>Centers for Disease Control and Prevention. (2015). <i>Epidemiology and Prevention of Vaccine-Preventable Diseases 13<sup>th</sup> Edition (Pink Book)</i>.</li> <li>Merck Canada Inc. (2016 Dec 15). GARDASIL®9: Human Papillomavirus 9-valent vaccine. Product monograph.</li> <li>National Advisory Committee on Immunization, (2007, February 15). Statement on human papillomavirus vaccine. <i>Canada Communicable Disease Report</i>, 33.</li> <li>National Advisory Committee on Immunization, (2012, January). Update on human papillomavirus vaccines. <i>Canada Communicable Disease Report</i>, 37.</li> <li>National Advisory Committee on Immunization. (2016 July 7). Updated Recommendations on Human Papillomavirus (HPV) Vaccines: 9-valent HPV vaccine and clarification of minimum intervals between doses in the HPV immunization schedule.</li> <li>National Advisory Committee on Immunization. (2018). <i>Canadian immunization guide (Evergreen Edition)</i>. Ottawa, ON: Public Health Agency of Canada. <a href="http://www.phac-aspc.gc.ca/publicat/cig-gci/">http://www.phac-aspc.gc.ca/publicat/cig-gci/</a></li> </ol>	