

Varicella Vaccine

Revision Date: October 31, 2018

Rationale for Update:

- Updated NACI Recommendations for varicella proof of immunity. Verbal history is not a reliable indicator of immunity in populations where varicella vaccine has been introduced.
- Clarified immunization recommendations for HCWs.

Please consult the Product Monograph ^{1,2} for further information about the vaccine.		
	VARILRIX®	VARIVAX® III
Manufacturer	GlaxoSmithKline Inc.	Merck Canada Inc.
Licensed use	All individuals 12 months of age and older as per the indications section.	All individuals 12 months of age and older as per the indications section.
Off-license use	Children starting at 6 months of age to less than 12 months of age expecting solid organ transplant.	Children less than 12 months of age expecting solid organ transplant. Second dose for children 4 – 6 years of age and susceptible adults with HIV meeting clinical criteria.
Indications for use of provincially funded vaccine	<p>Children 12 months up to and including 6 years of age born August 1, 2012 or later.</p> <p>Notes:</p> <ul style="list-style-type: none"> • Verbal history of disease in the varicella vaccine era is not a reliable indicator of immunity.^{3,4} • Children born August 1, 2012 or later with a history of chicken pox disease should be offered varicella vaccine as they present in child health clinic. Note: These children will not be offered varicella vaccine as part of the school immunization program until record review in grade 6. • When both MMR vaccine and varicella vaccine are indicated for children 12 months up to and including 6 years of age, measles, mumps, rubella and varicella combined vaccine should be considered. <p>Children 7 years up to and including 12 years of age</p> <p>Notes:</p> <ul style="list-style-type: none"> • Children born prior to August 1, 2012 who have a history of chickenpox disease occurring at one year of age and older will not be offered varicella vaccine at this time. • When both MMR vaccine and varicella vaccine are indicated for children 7 years up to and including 12 years of age, measles, mumps, rubella and varicella combined vaccine should be considered. <p>Individuals 13 years of age and older (with unknown/uncertain or no history of chickenpox disease and negative serology). See exceptions related to pregnant females and health care workers below.</p> <ul style="list-style-type: none"> • Individuals 13 years of age and older who have a history of chickenpox disease occurring at one year of age and older will not be offered varicella vaccine at this time. 	

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	<ul style="list-style-type: none"> Serology to determine susceptibility is required for individuals 13 years of age and older with unknown/uncertain or no history of chickenpox disease except for students in the school immunization program (grades 1 to 9). <p>Note: Susceptibility of students in the school immunization program will be based on history of disease or documented varicella immunization. Serological testing for this cohort will not be required.</p> <p>Exceptions: Pregnant Females and Health care workers (HCWs)</p> <ol style="list-style-type: none"> Pregnant Females - Women identified through routine prenatal screening should be offered up to a maximum of two doses of varicella vaccine as they present post-partum regardless of disease history unless presenting with laboratory confirmation of immunity (varicella IgG positive).³ HCWs and Post-secondary HCW Students without evidence of immunity should be offered two doses of varicella vaccine as they present. <ul style="list-style-type: none"> Those presenting with documentation of one dose of varicella vaccine should be offered a second dose of varicella vaccine. Zostavax® may be considered a valid first dose in a 2-dose varicella vaccine series on a case-by-case basis. (Shingrix® doses cannot be counted in a varicella vaccine series).⁵ <p>Evidence of immunity for non-pregnant HCWs and post-secondary HCW students includes:</p> <ul style="list-style-type: none"> Documentation of two valid doses of varicella containing vaccine⁴; or Laboratory evidence of immunity⁴; or Laboratory confirmation of varicella disease⁴; or Physician diagnosed shingles disease⁴; or Self reported history or physician diagnosed varicella disease in Canada prior to a routine immunization program: <ul style="list-style-type: none"> In Alberta, prior to January 2001. For start dates of other Canadian jurisdictions see the NACI Varicella Proof of Immunity - 2015 Update. 						
<p>Considerations for Immuno-compromised Individuals</p>	<p>Considerations for Immuno-compromised Individuals</p> <p>Varicella vaccine can be used with caution for select groups of immunocompromised persons as listed below.³ Medical consultation with the individual's physician(s) should be sought before immunizing immunocompromised persons.</p> <table border="1" data-bbox="402 1285 1469 1829"> <tr> <td data-bbox="402 1285 667 1503"> <p>Children with acute lymphocytic leukemia (ALL):³ (can receive Varilrix® only)</p> </td> <td data-bbox="667 1285 1469 1503"> <ul style="list-style-type: none"> Must be in remission for 12 months or longer³ AND Total lymphocyte count of 1.2 x 10⁹/L or greater³ AND Not be receiving radiation therapy^{1,3} AND Maintenance chemotherapy can be withheld for at least 1 week before to 1 week after immunization.^{1,3} <p>Note: Two doses of vaccine are recommended for all children that meet the above conditions for ALL.^{3,6}</p> </td> </tr> <tr> <td data-bbox="402 1503 667 1661"> <p>Cured of ALL (can receive Varilrix® or Varivax®)</p> </td> <td data-bbox="667 1503 1469 1661"> <ul style="list-style-type: none"> Susceptible persons who have been cured of ALL may be immunized with up to 2 doses starting at least 1 week after completing chemotherapy.³ </td> </tr> <tr> <td data-bbox="402 1661 667 1829"> <p>HIV infected individuals (can receive Varilrix® or Varivax®)</p> </td> <td data-bbox="667 1661 1469 1829"> <ul style="list-style-type: none"> Children 12 months of age and older who are varicella non-immune and with CDC clinical category N, A or B and immunologic category 1 or 2 (i.e., CD4 counts greater than or equal to 15%) may be immunized with 2 doses of univalent vaccine with a 3 – 6 month interval between doses.^{3,7} </td> </tr> </table>	<p>Children with acute lymphocytic leukemia (ALL):³ (can receive Varilrix® only)</p>	<ul style="list-style-type: none"> Must be in remission for 12 months or longer³ AND Total lymphocyte count of 1.2 x 10⁹/L or greater³ AND Not be receiving radiation therapy^{1,3} AND Maintenance chemotherapy can be withheld for at least 1 week before to 1 week after immunization.^{1,3} <p>Note: Two doses of vaccine are recommended for all children that meet the above conditions for ALL.^{3,6}</p>	<p>Cured of ALL (can receive Varilrix® or Varivax®)</p>	<ul style="list-style-type: none"> Susceptible persons who have been cured of ALL may be immunized with up to 2 doses starting at least 1 week after completing chemotherapy.³ 	<p>HIV infected individuals (can receive Varilrix® or Varivax®)</p>	<ul style="list-style-type: none"> Children 12 months of age and older who are varicella non-immune and with CDC clinical category N, A or B and immunologic category 1 or 2 (i.e., CD4 counts greater than or equal to 15%) may be immunized with 2 doses of univalent vaccine with a 3 – 6 month interval between doses.^{3,7}
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<p>HIV infected individuals (cont.)</p>	<ul style="list-style-type: none"> Susceptible adolescents and adults (no previous history of varicella illness or previous varicella immunization and a negative varicella antibody test) with CD4 cell count greater or equal to $200 \times 10^6/L$ and greater or equal to 15 % may be considered for varicella immunization.⁸ <p>Note: It is essential to ascertain with the specialist that the individual conforms to the appropriate clinical and immunologic categories before making the decision to immunize with varicella vaccine.⁷</p>
<p>Planned solid organ transplant (can receive Varilrix® or Varivax®)</p>	<ul style="list-style-type: none"> Persons with planned solid organ transplant, at least 4 weeks prior to the initiation of immunosuppressant treatment and/or transplant and only following consultation with the attending transplant physician. See: <ul style="list-style-type: none"> <u>Immunization for Children Expecting Solid Organ Transplant before 18 Months of Age (Accelerated)</u>, <u>Immunization for Children Expecting Solid Organ Transplant after 18 Months of Age or Older (Catch-up Schedule)</u> and <u>Immunization for Adult Solid Organ Transplant Candidates and Recipients</u>
<p>Hematopoietic stem cell transplants (HSCT) (can receive Varilrix® or Varivax®)</p>	<ul style="list-style-type: none"> Child and adult recipients of hematopoietic stem cell transplants (HSCT) if there is no graft versus host disease. Consultation with the attending transplant physician is recommended. See: <ul style="list-style-type: none"> <u>Immunization for Child Hematopoietic Stem Cell Transplant Recipients</u> and <u>Immunization for Adult Hematopoietic Stem Cell Transplant Recipients.</u> <p>Note: Varicella immunization is not indicated for persons awaiting HSCT.</p>
<p>Isolated immunodeficiency diseases (can receive Varilrix® or Varivax®)</p>	<ul style="list-style-type: none"> People with isolated immunodeficiency diseases and known intact T-cell systems may be immunized using the same age-appropriate schedule for healthy persons.³ <ul style="list-style-type: none"> B cell deficiencies: Isolated humoral (immunoglobulin) deficiency diseases. Phagocytic and neutrophil deficiency disorders. Complement deficiency diseases.
<p>Cured of malignancies other than ALL (can receive Varilrix® or Varivax®)</p>	<ul style="list-style-type: none"> Susceptible persons cured of malignancies other than ALL may be immunized 3 months or more after completion of immunosuppressive therapy.³
<p>Low-dose steroid therapy (can receive Varilrix® or Varivax®)</p>	<ul style="list-style-type: none"> Susceptible children and adults on low-dose steroid therapy (less than 2 mg prednisone/kg daily or less than 20 mg/day if weight is greater than 10 kg for less than 2 weeks) or who are taking inhaled or topical steroids may be safely immunized using the age-appropriate schedule for healthy persons.³
<p>Other immunosuppressive treatment (can receive Varilrix® only)</p>	<ul style="list-style-type: none"> Persons receiving immunosuppressive treatment (e.g. high-dose steroids or treatment for renal failure or auto-immune diseases causing immunosuppression) may be considered for varicella immunization if the total lymphocyte count is at least $1,200 \text{ per mm}^3$ ($1.2 \times 10^9/L$) or there is no other evidence of lack of cellular immune competence.¹

Post-exposure	<p>Post-exposure immunization could be considered for susceptible contacts of varicella or disseminated zoster cases.</p> <ul style="list-style-type: none"> • When given within 5 days of first exposure, it may prevent or modify varicella disease.⁹ • If more than 5 days after first exposure, the vaccine could still be offered as this will provide protection for future exposures.¹⁰ <p>Refer to <i>Public Health Notifiable Disease Management Guidelines – Varicella (Chickenpox)</i>.⁸</p>
Dose	0.5 mL
Route	Subcutaneous
Schedule	<p>Individuals who have never been immunized are eligible for two doses according to the following schedules:</p> <p>Children 12 months up to and including 6 years of age:</p> <ul style="list-style-type: none"> ❖ Dose 1: 12 months of age ❖ Dose 2: 4 – 6 years of age <p>Notes:</p> <ul style="list-style-type: none"> • Most young children in Alberta routinely receive MMR-Varicella combined vaccine at 12 months of age with the second dose at 4 – 6 years of age. See Measles, mumps, rubella and varicella combined vaccine. • After the start of second dose varicella vaccine program August 1, 2012, children born on August 1, 2005 or later, up to 12 years of age inclusively will continue to be eligible for two doses of varicella vaccine. • If the first dose is given at 4 years of age or later, the second dose can be given 3 months after the first dose.⁵ • If a univalent vaccine is given as the first or second dose, MMR-varicella combined vaccine (if MMR also required) can be administered for the other dose to complete the series but the interval between the 2 vaccines should be at least 3 months.⁵ • The minimum interval between live vaccines is 4 weeks if rapid protection is required.³ • Children who have received a single dose of varicella-containing vaccine and develop laboratory-confirmed varicella disease, do not require the second dose of a varicella-containing vaccine.³ <p>Refer to <i>Public Health Notifiable Disease Management Guidelines – Varicella (Chickenpox)</i>.⁷</p> <p>Children 7 years up to and including 12 years of age:</p> <ul style="list-style-type: none"> ❖ Dose 1: day 0 ❖ Dose 2: 3 months after dose 1⁵ <p>Individuals 13 years of age and older:</p> <ul style="list-style-type: none"> ❖ Dose 1: day 0 ❖ Dose 2: 6 weeks after dose 1^{1,2,5} <p>Note: Individuals who received one dose under the age of 13 years AND whose birthdate is prior to August 1, 2005 are considered COMPLETE at this time.</p>

	<p><u>Exceptions:</u></p> <ul style="list-style-type: none"> ➤ Women identified through routine prenatal screening are eligible for a maximum of two doses of varicella containing vaccine. ➤ HCWs upon hire and Post-secondary HCW Students are eligible for a maximum of two doses of varicella containing vaccine. ➤ Zostavax® vaccine may be considered a valid first dose in a 2-dose varicella vaccine series on a case-by-case basis. (Shingrix® doses cannot be counted in a vaccine series).⁵ <p>Additional Notes:</p> <ul style="list-style-type: none"> • Individuals infected with HIV, who meet the clinical and immunologic categories under Indications above, should receive 2 doses of varicella vaccine with an interval of at least 3 months between doses.⁷ MMR vaccine, if needed, may be administered at the same time.⁷ • Post-immunization serology is usually not indicated for healthy children and adults as commercial laboratory tests are not sensitive enough to detect vaccine-induced antibodies.³
<p>Contraindications</p>	<ul style="list-style-type: none"> • Known severe hypersensitivity to any component of varicella vaccine.³ • Anaphylactic reaction to a previous dose of vaccine containing varicella antigen.³ • Pregnancy³ • Individuals with a suspicious medical history for immunodeficiency disorders until they have been investigated and T-cell dysfunction is ruled out.³ • Children and adults with T-cell or combined T-and B-cell immunodeficiencies.³ • Children and adults with advanced HIV.³ • Children and adults with solid tumors.³ • Individuals undergoing radiotherapy.³ • Individuals with chronic inflammatory diseases (e.g., inflammatory bowel disease, collagen-vascular disease, nephrotic syndrome) taking long-term immunosuppressive therapy or whose immunosuppressive therapy was stopped less than 6 –12 weeks previously.³ • Active, untreated tuberculosis.³ • Solid organ transplant recipients.¹¹ • Immune globulins and blood products within the previous 3 – 11 months. Refer to Assessment Expected Prior to Vaccine Administration – Guidelines for Interval between Blood Products and Live Vaccines. See also Canadian Immunization Guide³ – Blood products, human immune globulin and timing of immunization. <p>Note:</p> <ul style="list-style-type: none"> • Varicella immunization of susceptible post-partum women should be delayed for 2 months after receipt of Rh immune globulin (Rh IG).³ <p>For Varilrix® only:</p> <ul style="list-style-type: none"> • Individuals undergoing immunosuppressive treatment for acute myelogenous leukemia, adults undergoing treatment for ALL³ and children with ALL that is not in remission³ (See ‘Considerations for Immunocompromised Individuals’ above).

	<ul style="list-style-type: none"> Individuals with primary or acquired immunodeficiency states with a total lymphocyte count of less than 1,200 per mm³ or presenting other evidence of lack of cellular immune competence, such as individuals with active leukemias, lymphomas, blood dyscrasias, clinically manifest HIV infection or patients receiving immunosuppressive therapy (including high-dose corticosteroids).¹ <p>Note: Varilrix® should not be administered to high-risk patients at the same time as other live attenuated vaccines¹ (exception HIV infection see note above in Schedule).</p> <p><u>For Varivax® III:</u></p> <ul style="list-style-type: none"> Children and adults with leukemia (ALL or acute myelogenous leukemia.)³ Individuals with blood dyscrasias, leukemia, lymphomas of any type or other malignant neoplasms affecting the bone marrow or lymphatic systems.² Individuals receiving immunosuppressive therapy.² Individuals with primary and acquired immunodeficiency states including HIV infection except as outlined in Indications above.
Precautions	<ul style="list-style-type: none"> Avoid use of salicylates for 6 weeks after vaccination,^{1,2} if possible due to association of varicella and Reye's syndrome. However, children and adolescents on long-term salicylate therapy should be considered for immunization with close subsequent monitoring.³ Medical consultation is recommended before proceeding with immunization for children on salicylate therapy. Individuals taking long-term antiviral therapy should discontinue these drugs (e.g., acyclovir, valacyclovir or famciclovir) if possible from at least 24 hours before administration of varicella vaccine and up to 14 days after immunization.³ Medical consultation is recommended before proceeding with immunization. See 'Considerations for Immunocompromised Individuals' above for precautions and considerations. If the vaccine recipient develops a varicella-like rash, the rash should be covered when possible; when not possible, direct contact with susceptible high-risk individuals should be avoided for the duration of the rash.³
Possible reactions	<p>Common:</p> <ul style="list-style-type: none"> Local pain, redness and swelling^{1,2} Fever and rash, pruritis^{1,2} Varicella-like rash^{1,2} <p>Uncommon:</p> <ul style="list-style-type: none"> Lymphadenopathy, irritability, headache, somnolence, cough, rhinitis, nausea, vomiting, loss of appetite, arthralgia, myalgia, fatigue, malaise, and pharyngitis.^{1,2} <p>Rare:</p> <ul style="list-style-type: none"> Conjunctivitis, abdominal pain, diarrhea and urticaria.^{1,2} Anaphylaxis³ <p>Post-immunization varicella-like rash: Transmission from post-varicella rash to susceptible individuals is rare. HCWs who develop a rash post-immunization should be individually evaluated. Generally, if the post-vaccine rash at the injection site can be covered, the individual can continue to work. Those with varicella-like rash not confined to the injection site should be excluded from work in high-risk patient care areas (e.g., where there are premature infants and immunocompromised patients) until the lesions are crusted.^{3,12}</p>

	<p><u>For Varilrix® only:</u></p> <ul style="list-style-type: none"> The following additional adverse events have been reported from post-marketing surveillance: Herpes zoster, hypersensitivity, anaphylaxis, convulsions, cerebellitis, cerebellitis- type symptoms (including transient gait disturbance and transient ataxia), encephalitis, cerebrovascular accident, thrombocytopenia, erythema multiforme, and vasculitis.¹ <p><u>For Varivax® III:</u></p> <ul style="list-style-type: none"> The following additional adverse events have been reported from post-marketing surveillance: aplastic anemia, thrombocytopenia, encephalitis, transverse myelitis, GBS, Bell's palsy, cerebral vascular accident, ataxia, febrile and non-febrile seizures, aseptic meningitis, paraesthesia, Stevens-Johnson syndrome, erythema multiforme, Henoch-Schönlein purpura, secondary bacterial infection of skin and soft tissue, anaphylaxis, pharyngitis, and herpes zoster.² <p>Refer to <i>Adverse Events Following Immunization (AEFI), Policy for Alberta Immunization Providers</i>.¹³</p>
Pregnancy	Contraindicated for pregnant women. Pregnancy should be avoided for 1 month following completion of the appropriate number of doses. ³
Lactation	Breastfeeding is not a contraindication to immunization. ³ If post-vaccination rash develops, breastfeeding should not be discontinued. The rash should be covered if possible. ³
Program Notes	<ul style="list-style-type: none"> March 2001 - Varicella vaccine for non-immune special groups (household contacts of immunocompromised individuals, HCWs known to be susceptible and women identified through routine pre-natal care). April 2001 - Varicella vaccine for susceptible students in Grade 5. July 2001 - Routine program for children 12 months of age (born January 1, 2000 or after). Spring 2002 - Catch-up program was offered during the preschool immunization visit. April 2003 - Varicella vaccine for all susceptible individuals. August 2012 - All children born on or after August 1, 2005 eligible to receive 2 doses of varicella vaccine. September 2018 - Verbal history of disease is no longer considered a reliable indicator of immunity after introduction of routine varicella vaccine programs (phased in approach) and immunization recommendation for 2 doses of varicella containing vaccine. (phased in approach). Priority groups: children born August 1, 2012 or later, women identified through routine prenatal screening, and HCWs/HCW students.

References

- ¹ GlaxoSmithKline Inc. (2017, August 11). Varilix®: Varicella virus vaccine, live, attenuated (Oka-strain). *Product Monograph*.
- ² Merck Canada Inc. (2018, July 4). Varivax® III: Varicella virus vaccine, live, attenuated (Oka/Merck). *Product Monograph*.
- ³ National Advisory Committee on Immunization. (2018). *Canadian Immunization Guide*. (Evergreen ed.) Ottawa, ON: Public Health Agency of Canada. www.canada.ca/en/public-health/services/canadian-immunization-guide.html
- ⁴ National Advisory Committee on Immunization . (2015 Update). Varicella Proof of Immunity. An Advisory Committee Statement (ACS). <http://www.healthycanadians.gc.ca/publications/healthy-living-vie-saine/varicella-proof-immunity-2015-varicelle-preuve-immunite/alt/varicella-proof-immunity-2015-varicelle-preuve-immunite-eng.pdf>
- ⁵ Immunization Action Coalition. (2018, October 5). Ask the Experts. Retrieved October 30, 2018 from http://www.immunize.org/askexperts/experts_var.asp
- ⁶ National Advisory Committee on Immunization. (2010). Varicella vaccination two-dose recommendations. *Canada Communicable Disease Report*, 36(ACS-8).
- ⁷ National Advisory Committee on Immunization. (2010). Updated recommendations for the use of varicella and MMR vaccines in HIV-infected individuals. *Canada Communicable Disease Report*, 36(ACS-7).
- ⁸ Alberta Health and Wellness. Varicella (chickenpox). In *Public Health Notifiable Disease Management Guidelines*. www.health.alberta.ca/professionals/notifiable-diseases-guide.html
- ⁹ American Academy of Pediatrics. (2018) *Red book: 2018 Report of the Committee on Infectious Diseases (31st ed.)*. Elk Grove Village, IL.
- ¹⁰ Centers for Disease Control and Prevention. (2016) Routine Varicella Vaccination. In *Vaccines and Preventable Diseases*. Retrieved October 30, 2018 from, <https://www.cdc.gov/vaccines/vpd/varicella/hcp/recommendations.html>
- ¹¹ Expert opinion of Alberta Infectious Disease, physicians November 2017.
- ¹² Centers for Disease Control and Prevention. (2011). Immunization of Health-Care Personnel: Recommendations of the Advisory Committee on Immunization Practices (ACIP). *Morbidity and Mortality Weekly Report (MMWR)*, 60(RR07);1-45. <https://www.cdc.gov/mmwr/preview/mmwrhtml/rr6007a1.htm>
- ¹³ Alberta Health. (2018, December). *Adverse Events Following Immunization (AEFI), Policy for Alberta Immunization Providers*. <https://open.alberta.ca/dataset/d86b52a9-45f4-4948-8a06-53b2c045135e/resource/f2da2a7a-e350-4bab-b2c2-77677beeb22b/download/aip-adverse-events-following-immunization-policy.pdf>.