# Varicella Vaccine

Revision Date: April 8, 2024

# Rationale for Update:

Varilrix® product available in Alberta.

Please consult the Product Monograph for further information about the vaccine.			
	VARILRIX® <sup>(1)</sup>	VARIVAX® III <sup>(2)</sup>	
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	<ul> <li>Children starting at 6 months of age to less than 12 months of age expecting solid organ transplant.</li> <li>Third dose for solid organ transplant candidates if VZ IgG is negative after the second dose. (Only at the request of the transplant physician).<sup>(3)</sup></li> </ul>	<ul> <li>Children starting at 6 months of age to less than 12 months of age expecting solid organ transplant.</li> <li>Susceptible adults with HIV meeting clinical criteria (see below).</li> <li>Children with acute lymphocytic leukemia (ALL) (see below).</li> <li>Individuals receiving other immunosuppressive treatment (see below).</li> <li>Third dose for solid organ transplant candidates if VZ IgG is negative after the second dose. (Only at the request of the transplant physician).</li> </ul>	
Indications for use of provincially funded vaccine	Children 12 months up to and including 6 years of age.  Notes:  • Verbal history of disease in the varicella vaccine era is not a reliable indicator of		
	<ul> <li>immunity.<sup>(5,6)</sup></li> <li>Children with a verbal history of chicken pox disease should be offered varicella vaccine.</li> </ul>		
	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.		
	Children 7 years up to and including 12 years of age		
	Notes:		
	<ul> <li>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.</li> </ul>		
		ella vaccine are indicated for children 7 years , measles, mumps, rubella and varicella lered.	



**Individuals 13 years of age and older** (with unknown/uncertain or no history of chickenpox disease and negative serology). See **exceptions** related to pregnant individuals and health care workers below.

- 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.
- 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) and Ukrainian evacuees.

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.

# **Exceptions**: Pregnant individuals and Health care workers (HCWs)

- 1. Pregnant individuals Women identified through routine prenatal screening with negative serology 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). (5)
- 2. HCWs and Post-secondary HCW Students without evidence of immunity should be offered two doses of varicella vaccine as they present.
  - Those presenting with documentation of one dose of varicella vaccine should be offered a second dose of varicella vaccine.
  - Shingrix® doses cannot be counted in a varicella vaccine series.<sup>(7)</sup>

**Evidence of immunity** for non-pregnant HCWs and post-secondary HCW students includes:

- Documentation of two valid doses of varicella containing vaccine<sup>(5,6)</sup>; or
- Laboratory evidence of immunity<sup>(5,6)</sup>; or
- Laboratory confirmation of varicella disease<sup>(5,6)</sup>; or
- Physician diagnosed shingles disease<sup>(5,6)</sup>; or
- Self reported history or physician diagnosed varicella disease in Canada prior to a routine immunization program:
  - o In Alberta, prior to January 2001.
  - For start dates of other Canadian jurisdictions see the NACI Varicella Proof of Immunity - 2015 Update.

# Considerations for Immuno-compromised Individuals

## **Considerations for Immuno-compromised Individuals**

- Varicella vaccine can be used with caution for select groups of immunocompromised persons as listed below.<sup>(5)</sup>
- Although the use of VARIVAX® III is off license for children with acute lymphocytic leukemia (ALL) and for individuals receiving other immunosuppressive treatment, either VARILRIX® or VARIVAX® III can be offered.<sup>(4)</sup>

#### Note:

Medical consultation with the individual's physician(s) should be sought before immunizing immunocompromised persons.

# Children with acute lymphocytic leukemia (ALL):(4,5)

- Must be in remission for 12 months or longer AND
- Total lymphocyte count of 1.2 x 10<sup>9</sup>/L or greater<sup>(3)</sup> AND
- Not be receiving radiation therapy<sup>(1,3)</sup> AND
- Maintenance chemotherapy can be withheld for at least 1 week before to 1 week after immunization. (1,3)



		Note: Two doses of vaccine are recommended for all children
		that meet the above conditions for ALL. (1,3,8)
	Cured of ALL	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)
	HIV infected individuals	<ul> <li>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. (5,9,10)</li> <li>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 200x10<sup>6</sup>/L and greater or equal to 15 % may be considered for varicella immunization. (10)</li> <li>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. (5,10)</li> </ul>
	Planned solid organ transplant	<ul> <li>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.</li> <li>In addition, solid organ transplant candidates may be provided a third dose of varicella vaccine if VZ IgG is negative after the second dose and it is requested by the transplant physician. (9,11–13)</li> <li>See:         <ul> <li>Immunization for Children Expecting Solid Organ Transplant before 18 Months of Age (Accelerated),</li> <li>Immunization for Children Expecting Solid Organ Transplant after 18 Months of Age or Older (Catch-up Schedule) and</li> <li>Immunization for Adult Solid Organ Transplant Candidates and Recipients</li> </ul> </li> </ul>
	Hematopoietic stem cell transplants (HSCT)	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:      Immunization for Child Hematopoietic Stem Cell Transplant Recipients and     Immunization for Adult Hematopoietic Stem Cell Transplant Recipients.  Note: Varicella immunization is not indicated for persons awaiting HSCT.
	Isolated immune- deficiency diseases	<ul> <li>People with isolated immunodeficiency diseases and known intact T-cell systems may be immunized using the same age-appropriate schedule for healthy persons.<sup>(3,5)</sup></li> <li>B cell deficiencies: Isolated humoral (immunoglobulin) deficiency diseases.</li> <li>Phagocytic and neutrophil deficiency disorders.</li> <li>Complement deficiency diseases.</li> </ul>
	Cured of malignancies other than ALL	Susceptible persons cured of malignancies other than ALL may be immunized 3 months or more after completion of immunosuppressive therapy. <sup>(5,9)</sup>



	<ul> <li>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. (5,9)</li> <li>Other 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</li> </ul>	
	1,200 per mm³ (1.2 x 10 <sup>9</sup> /L) or there is no other evidence of lack of cellular immune competence. <sup>(1)</sup>	
Post-exposure	Post-exposure immunization could be considered for susceptible contacts of varicella or disseminated zoster cases.	
	When given within 5 days of first exposure, it may prevent or modify varicella disease.  (14)	
	<ul> <li>If more than 5 days after first exposure, the vaccine could still be offered as this will provide protection for future exposures.<sup>(14)</sup></li> </ul>	
	<ul> <li>For disease investigation, contact assessment and reporting requirements, refer to https://open.alberta.ca/publications/varicella-chickenpox.</li> </ul>	
Dose	0.5 mL <sup>(1,2)</sup>	
Route	Subcutaneous <sup>(1,2)</sup>	
Schedule	Individuals who have never been immunized are eligible for two doses according to the following schedules:	
	Children 12 months up to and including 6 years of age:	
	❖ Dose 1: 12 months of age	
	❖ Dose 2: 18 months of age	
	Notes:	
	<ul> <li>Most children in Alberta routinely receive measles, mumps, rubella and varicella combined vaccine (MMR-Var) at 12 months and 18 months of age. See <u>Measles</u> <u>mumps, rubella and varicella</u> combined vaccine.</li> </ul>	
	<ul> <li>After the start of second dose varicella vaccine program August 1, 2012, children born on August 1, 2005 or later are eligible for two doses of varicella vaccine.</li> </ul>	
	<ul> <li>The recommended spacing between the first and the second dose is 3 months. (1,5,7,9)</li> </ul>	
	<ul> <li>If Varicella vaccine is given as the first dose, MMR-Var vaccine can be administered for the other dose to complete the series if MMR is also required. The recommended interval between the two vaccines is 3 months. (5,7,9)</li> </ul>	
	<ul> <li>The minimum interval between live vaccines is 4 weeks if rapid protection is required.<sup>(5,9)</sup></li> </ul>	
	<ul> <li>Children who have received a single dose of varicella-containing vaccine and develop laboratory-confirmed varicella disease, do not require the second dos of a varicella-containing vaccine.<sup>(5,9)</sup></li> </ul>	
	Children 7 years up to and including 12 years of age:	
	❖ Dose 1: day 0	
	❖ Dose 2: 3 months after dose 1 <sup>(5)</sup>	



**Note:** The minimum interval between live vaccines is 4 weeks if rapid protection is required. (5,9)

# Individuals 13 years of age and older:

❖ Dose 1: day 0

❖ Dose 2: 6 weeks after dose 1<sup>(1,2,5,9)</sup>

#### Notes:

- The minimum interval between live vaccines is 4 weeks if rapid protection is required.
- 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. See exceptions.

## Exceptions:

- 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.
- Shingrix® doses cannot be counted in a vaccine series.<sup>(7)</sup>

#### **Additional Notes:**

- 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. (10) MMR vaccine, if needed, may be administered at the same time. (10)
- 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. (5,9)

## **Contraindications**

- Known severe hypersensitivity to any component of varicella vaccine, (1,2) including gelatin (in Varivax).
- Individuals with a history of anaphylactic/anaphylactoid reaction to neomycin. (1,2)
- Individuals with blood dyscrasias, leukemia, lymphomas of any type or other malignant neoplasms affecting the bone marrow or lymphatic systems, except as outlined in Indications above.<sup>(1,2)</sup>
- Individuals receiving immunosuppressive therapy, except as outlined in Indications above. (1,2)
- Individuals with primary and acquired immunodeficiency states including HIV infection except as outlined in Indications above.
- Family history of congenital or hereditary immunodeficiency, unless the immune competence of the potential vaccine recipient is demonstrated. (2,5,9)
- Active, untreated tuberculosis. (2,5,9)
- Anaphylactic reaction to a previous dose of vaccine containing varicella antigen. (5,9)
- Pregnancy. (1,2,5,9)
- Individuals with a suspicious medical history for immunodeficiency disorders until they have been investigated and T-cell dysfunction is ruled out.<sup>(5,9)</sup>
- Children and adults with T-cell or combined T-and B-cell immunodeficiencies. (5,9)
- Children and adults with advanced HIV. (5,9)
- Children and adults with solid tumors undergoing immunosuppressive therapy. (5,9)



	(5.0)
	Individuals undergoing radiotherapy. <sup>(5,9)</sup>
	<ul> <li>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.<sup>(5,9)</sup></li> </ul>
	Solid organ transplant recipients. <sup>(9)</sup>
	Refer to SOT recommendations for exceptions:
	Child SOT (before 18 months of age)
	Child SOT (after 18 months of age)
	Immune globulins and blood products within the previous 3 – 11 months. Refer to <u>Assessment Expected Prior to Vaccine Administration</u> – Guidelines for Interval between Blood Products and Live Vaccines. See also Canadian Immunization Guide <sup>(5,9)</sup> – <u>Blood products</u> , <u>human immune globulin and timing of immunization</u> .
	Varicella immunization of susceptible post-partum women should be delayed for 3 months after receipt of Rh immune globulin (Rh IG). (5,9)
Precautions	Avoid use of salicylates for 6 weeks after immunization <sup>(1,2)</sup> , 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. (5,9) 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.       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. <sup>(5,9)</sup>
Possible reactions	See Product Monograph.
Pregnancy	Contraindicated for pregnant individuals. <sup>(1,2)</sup> Pregnancy should be avoided for at least 1 month following completion of the appropriate number of doses. <sup>(1,5,9)</sup>
Lactation	<ul> <li>It is not known whether varicella vaccine virus is secreted in human milk. (1,2)</li> <li>Breastfeeding is not a contraindication to immunization. (5,9) If post-vaccination rash develops, breastfeeding should not be discontinued. The rash should be covered if possible. (5,9)</li> </ul>
Program Notes	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 two doses of varicella containing vaccine (phased in approach). Priority groups: children born August 1, 2012 or later, women identified through routine prenatal screening.
  - Specifically for <u>HCWs/HCW students</u>, evidence of immunity includes: documentation of two valid doses of varicella containing vaccine; or laboratory evidence of immunity; or laboratory confirmation of varicella disease; or physician diagnosed shingles disease; or self reported history or physician diagnosed varicella disease in Canada prior to a routine immunization program (In Alberta prior to January 2001. See the <u>NACI Varicella Proof of Immunity 2015 Update</u> for other Canadian jurisdictions.)
- April 2020 Univalent varicella vaccine has been shown to be safe and effective in carefully selected pediatric renal and liver transplant recipients >1 year posttransplant receiving minimal immune suppression. In consultation with the transplant team (transplant/infectious disease physician), univalent varicella vaccine may be administered to those who were not optimally immunized prior to transplant
- January 1, 2021 Varicella second dose offered at 18 months instead of 4 years of age.
- April 20, 2022 Included Ukrainian evacuees 13 years of age and older under exception for serology requirement to determine susceptibility.
- September 1, 2023 Removal of Varilrix® as product no longer available in Alberta.
   Included expert advice allowing off-license use of VARIVAX® III in children with acute lymphocytic leukemia (ALL) and persons receiving other immunosuppressive treatment.
- January 29, 2024 Third dose provincially funded for solid organ transplant candidates if VZ IgG negative after second dose at the request of the transplant physician.
- April 8, 2024 Varilrix® product available in Alberta.



#### References

- 1. GlaxoSmithKline Inc. VARILRIX ® Varicella virus vaccine, live, attenuated (Oka strain). Product. 2019.
- 2. Merck Canada Inc. VARIVAX ® III. Product Monograph. 2023.
- 3. Expert opinion of Alberta Infectious Disease and Solid Organ Transplant physicians. (November 2023).
- 4. Expert opinion of Alberta Infectious Disease physicians. (July 2023).
- 5. National Advisory Committee on Immunization. Canadian Immunization Guide (Evergreen ed.). Ottawa, Public Heal Agency Canada [Internet]. Available from: <a href="https://www.canada.ca/en/public-health/services/canadian-immunization-guide.html">https://www.canada.ca/en/public-health/services/canadian-immunization-guide.html</a>.
- 6. National Advisory Committee on Immunization (NACI). Varicella Proof of Immunity-2015 Update. An Advisory Committee Statement (ACS) [Internet]. 2015. Available from: <a href="https://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">https://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</a>.
- 7. Immunization Action Coalition. Ask The Experts Archive | Immunize.org [Internet]. 2022 [cited 2023 Dec 19]. Available from: https://www.immunize.org/ask-experts/?q=Varicella+and+Zostavax.
- 8. National Advisory Committee on Immunization. Varicella Vaccination Two-Dose Recommendations. Canada Commun Dis Rep [Internet]. Infectious Disease and Control Branch (IDPCB) Public Health Agency of Canada; 2010;36(ACS-8). Available from: <a href="https://www.canada.ca/en/public-health/services/reports-publications/canada-communicable-disease-report-ccdr/monthly-issue/2010-36/canada-communicable-disease-report-13.html">https://www.canada.ca/en/public-health/services/reports-publications/canada-communicable-disease-report-13.html</a>.
- 9. Expert opinion of Alberta Solid Organ Transplant Program physicians. (November 2017, November 2019, and November 2023).
- 10. National Advisory Committee on Immunization. Updated Recommendations for the Use of Varicella and MMR Vaccines In HIV-Infected Individuals. Canada Commun Dis Rep [Internet]. Infectious Disease and Control Branch (IDPCB) Public Health Agency of Canada; 2010;36(ACS-7). Available from: <a href="https://www.canada.ca/en/public-health/services/reports-publications/canada-communicable-disease-report-ccdr/monthly-issue/2010-36/canada-communicable-disease-report-12.html">https://www.canada.ca/en/public-health/services/reports-publications/canada-communicable-disease-report-ccdr/monthly-issue/2010-36/canada-communicable-disease-report-12.html</a>.
- 11. Pittet LF, Danziger-Isakov L, Allen UD, Ardura MI, Chaudhuri A, Goddard E, et al. Management and prevention of varicella and measles infections in pediatric solid organ transplant candidates and recipients: An IPTA survey of current practice. Pediatr Transplant. 2020;24(8):1–8.
- 12. Pergam SA, Limaye AP. Varicella zoster virus in solid organ transplantation: Guidelines from the American Society of Transplantation Infectious Diseases Community of Practice. Clin Transplant. 2019;33(9).
- 13. American Academy of Pediatrics. Red Book: 2021-2024 Report of the Committee on Infectious Diseases (32nd ed.). Elk Grove Village, IL. 2015.
- 14. Centers for Disease Control and Prevention. Varicella Vaccine Recommendations [Internet]. Vaccines and Preventable Diseases. 2023 [cited 2023 Dec 19]. Available from: https://www.cdc.gov/vaccines/vpd/varicella/hcp/recommendations.html.

