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- Refer to SIM, Chapter 5, *Immunization Schedules,* Section 2.1, *Minimum Intervals for Specific Vaccine Series*.
- Product monographs can be found in Health Canada's Drug Product Database.
- For post-exposure immunoprophylaxis, refer to the Saskatchewan Communicable Disease Control manual.

1.0 ACTIVE IMMUNIZING AGENTS

- **Cholera – *E. coli* Vaccine (Chol-Ecol-O)**
  - DUKORAL®
- **COVID-19 Vaccine Q &A for Immunizers**
- **XBB.1.5 COVID-19 Vaccination Schedules**
- **Additional XBB.1.5 COVID-19 Vaccine Dose Eligibility**
- **COVID – 19 Vaccines**
  - MODERNA Spikevax™ 6+ months **XBB.1.5** (Royal Blue Cap/Coral Blue Label)
  - Novavax Nuvaxovid™ 12 + **XBB.1.5**
  - Pfizer BioNTech Comirnaty® 12 + **XBB.1.5** (Gray cap/label border)
  - Pfizer BioNTech Comirnaty® 5-11 years **XBB.1.5** (Blue cap/label border)
  - Pfizer BioNTech Comirnaty® 6 month – 4 years **XBB.1.5** (Maroon cap/label border)
- **Diphtheria-Tetanus-acellular Pertussis-Polio-*Haemophilus influenzae* type b Adsorbed Vaccine (DTaP-IPV-Hib)**
  - INFANRIX™-IPV/Hib
  - PENTACEL®
  - PEDIACEL®
- **Diphtheria-Tetanus-acellular Pertussis-Hepatitis B-Polio-*Haemophilus influenzae* type b Adsorbed Vaccine (DTaP-HB-IPV-Hib)**
  - INFANRIX™-hexa
- ***Haemophilus influenzae* type b Conjugate Vaccine (Hib)**
  - Act-HIB ®
- **Hepatitis A Vaccine (HA) Indications**
- **Hepatitis A Vaccine (HA)**
  - Avaxim™ and Avaxim™ Pediatric
  - Havrix® 1440 and Havrix® 720 Junior
  - Vaqta®
- **Hepatitis A and B Vaccine Combined Vaccine (HAHB)**
  - Twinrix™ and Twinrix Junior™
- **Hepatitis B (HB) Vaccine Indications**
- **Publicly Funded Hepatitis B Vaccine Eligibility for Students of Health Care Professions**
- **Hepatitis B Vaccine - Immigrant Populations Ineligibility List**
- **Hepatitis B Re-Vaccination Assessment Algorithm**
- **Hepatitis B Series Completion Recommendations for Children 11-15 Years Old**
- **Hepatitis B Completion Scenarios**
- **Hepatitis B Vaccine (HB)**
  - ENGERIX®-B
  - RECOMBIVAX HB®
  - PREHEVBRIO™

- **Herpes Zoster Vaccine**
  Shingrix™ **(RZV)**
- **Human Papillomavirus Vaccine**
  - CERVARIX™ **(HPV-2**)
  - GARDASIL®9 **(HPV-9)**
- **Influenza Vaccine** (Non Publicly Funded)
  - FLUAD Pediatric and FLUAD
  - FLUMIST QUADRIVALENT
  - SUPEMTAK
- **Influenza Vaccine**
  - AFLURIA TETRA
  - FLULAVAL TETRA
  - FLUZONE® QUADRIVALENT
  - FLUZONE® HIGH DOSE QUADRIVALENT
- **Japanese Encephalitis Vaccine (JE)**
  - IXIARO™
- **Measles-Mumps-Rubella Vaccine (MMR)**
  - MMRII™
  - PRIORIX™
- **Measles-Mumps-Rubella-Varicella Vaccine (MMRV)**
  - PRIORIX-Tetra™
  - ProQuad™
- **Meningococcal Conjugate C Vaccine** (**Men-C-C**)
  - MENJUGATE™ Liquid
  - Neis Vac-C®
- **Meningococcal Conjugate ACYW-135 Vaccine** (**Men-C-ACYW-135**)
  - Menactra®
  - MenQuadfi™
  - Menveo™
  - NIMENRIX™
- **Multicomponent Meningococcal B Vaccine**
  - BEXSERO® **(MenB 4C)**
  - Trumenba™ **(MenB bivalent)**
- **Pneumococcal Conjugate Vaccine**
  - SYNFLORIX™ **(Pneu-C-10)**
  - Prevnar® 13® **(Pneu-C-13)**
  - VAXNEUVANCE® **(Pneu-C-15)**
  - PREVNAR 20 ™ **(Pneu-C-20)**
- **Pneumococcal Polysaccharide Vaccine (Pneu-P-23**)
  - PNEUMOVAX® 23
  - Pneu-P-23 recommendations for adults 18+ immunized with only Pneu-C-15 or Pneu-C-20
- **Poliomyelitis Vaccine (Inactivated) (IPV)**
  - IMOVAX® Polio

- **Rabies Vaccine (Rab) (Post-exposure prophylaxis)**
  - IMOVAX® Rabies
  - RabAvert®
- **Respiratory Syncytial Virus Vaccine (RSV)**
  - ABRYSVO
  - AREXVY
- **Rotavirus Vaccine**
  - Rotarix™ **(Rot-1**)
  - RotaTeq® **(Rot-5)**
- **Smallpox and Mpox Vaccine (SMV)**
  - IMVAMUNE
- **Tetanus-Diphtheria Vaccine (Td)**
  - Td Adsorbed™
- **Tetanus-Diphtheria-acellular Pertussis Vaccine (Tdap)**
  - ADACEL®
  - BOOSTRIX™
- **Tetanus-Diphtheria-acellular Pertussis-Inactivated Poliomyelitis Vaccine (Tdap-IPV)**
  - ADACEL®-Polio
  - BOOSTRIX®-Polio™
- **Typhoid Vaccine (Typh-I) (Salmonella Typhi Vi Capsular Polysaccharide)**
  - Typhim Vi®
- **Typhoid Vaccine (Typh-O) (Live Oral Attenuated Ty 21a)**
  - Vivotif®
- **Varicella Vaccine (Var)**
  - VARILRIX®
  - Varivax III™
- **Yellow Fever Vaccine (YF)**
  - YF-Vax™

2.0 DIAGNOSTIC, PASSIVE IMMUNIZING AND ANTITOXIN AGENTS

- **Purified (tuberculosis) Protein Derivative (PPD) (Mantoux)**
  - Tubersol®
- Immune Globulin Preparation Injection Site, Needle Length and Daily Total Site Volume per Age Group
- **Botulism Immune Globulin**
  - BabyBIG
- **Hepatitis B Immune Globulin (HBIg)**
  - HepaGam B ™
  - HyperHEP B™
- **Immune Globulin (Ig - Intramuscular)**
  - GamaSTAN™
- **Rabies Immune Globulin (RabIg)**
  - HYPERRAB™
  - KamRAB™
- **Tetanus Immune Globulin (TIg)**
  - HYPERTET™

- **Varicella Zoster Immune Globulin (VarIg)**
  - VariZIG™
- **Botulism Antitoxin (BAT)**
  - Botulism Antitoxin
- **Diphtheria Antitoxin (DAT)**
  - Diphtheria Antitoxin

THIS CHAPTER MEETS THE FOLLOWING IMMUNIZATION COMPETENCIES FOR HEALTH PROFESSIONALS (PHAC, 2008): http://www.phac-aspc.gc.ca/im/pdf/ichp-cips-eng.pdf

#4: The Types of Immunizing Agents and Their Composition

- Competency: Applies the knowledge of the components and properties of immunizing agents as needed for safe and effective practice.

#8: Administration of Immunizing Agents

- Competency: Prepares and administers immunization agents correctly.

#11: Populations Requiring Special Considerations

- **Competency**: Recognizes and responds to the unique immunization needs of certain population groups

Cholera - E. coli (Chol-Ecol-O)

[Non-publicly funded]

DUKORAL®

(Valneva Canada. 2023 product monograph available at: https://www.valneva.ca)

COVID-19 Vaccine Q &A for Immunizers

1) **How many XBB.1.5 COVID-19 vaccine doses are recommended for immune competent or immunocompromised individuals?**
Response: Refer to SIM Chapter 10 XBB.1.5 COVID-19 Vaccination Schedules and Additional XBB.1.5 COVID-19 Vaccine Dose Eligibility for current recommendations. Future COVID-19 vaccine dose eligibility will be determined based on future epidemiology, data on waning immunity, new emerging variants, and/or new vaccines.

2) **Are any individuals able to get additional XBB.1.5 vaccine doses?**
Response: Consult the Additional XBB.1.5 COVID-19 Vaccine Dose Eligibility for current recommendations. Future COVID-19 vaccine dose eligibility will be determined based on future epidemiology, data on waning immunity, new emerging variants, and/or new vaccines.

3) **For previously immunized clients, what is the minimum interval after their last NON-XBB.1.5 COVID-19 vaccine dose before getting an XBB.1.5 COVID-19 vaccine dose?**
Response:
   A. For individuals presenting at 5 years of age and older, a 6-month interval is recommended between their last non-XBB.1.5 dose and an XBB.1.5 dose. More time between infection and vaccination promotes a strong immune response. **3 months is the minimum interval in SK.**
   B. **For the purposes of vaccinating long term care facility, assisted living, or personal care home residents,** XBB.1.5 vaccine can be administered **less than 3** months (**NO MINIMUM INTERVAL**) after the last non-XBB.1.5 dose.
   C. For children presenting at 6 months to 4 years of age, the interval between XBB.1.5 vaccine doses depends on the client's vaccination history. Refer to SIM Chapter 10 XBB.1.5 COVID-19 Vaccination Schedules.

4) **How long should a client (previously immunized or not) wait before getting an XBB.1.5 COVID-19 vaccine dose after recovering from COVID-19 infection?**
Response:
   A. For individuals all ages, a 6-month interval is recommended between infection and an XBB.1.5 dose. More time between infection and vaccination ensures a stronger immune response. **3 months is the minimum interval in SK.**
   B. **For the purposes of vaccinating** a **long-term care facility, personal care home, or senior congregate living (i.e., assisted living facility) resident,** their first XBB.1.5 vaccine can be administered **less than 3** months after infection.

5) **Is there a preferred mRNA XBB.1.5 vaccine brand to be offered to immunocompromised or immune competent individuals of any age.**
Response: No.

6) **Are XBB.1.5 vaccine dosages for all children based on age at presentation?**
Response: Yes. Refer to SIM Chapter 10 XBB.1.5 COVID-19 Vaccination Schedules.

7) **Is there a preferred XBB.1.5 vaccine brand that should be offered to those 12 years to 29 years to decrease the possible risk of myocarditis or pericarditis?**
Response: No.

8) **Are there any instances where mRNA vaccines are preferable or recommended instead of Novavax's NUVAXOVID?**
Response: No, as more safety evidence emerges for currently licensed COVID-19 vaccines.

XBB.1.5 COVID-19 Vaccination Schedules

***For a list of immunocompromising conditions, refer Canadian Immunization Guide: canada.ca/CIG - COVID19 Immunocompromised**

IMPORTANT NOTE: **3** Pfizer Comirnaty® XBB.1.5 vaccines are available:

- **12+ Years of Age**: **Gray Cap/Label Border** - **DO NOT DILUTE**, multidose vial containing 6 doses of 0.3 mL.
- **5 Years to 11 Years**: **Blue Cap/Label Border** – **DO NOT DILUTE**, multidose vial containing 6 doses of 0.3 mL.
- **6 Months to 4 Years**: **Maroon Cap/Label Border** – **MUST DILUTE PRIOR TO USE**, multiple dose vial containing 10 doses of 0.2 mL after dilution.

Table 1: Schedules for individuals presenting at 12 years and older who are NOT immunocompromised

Vaccination History (non-XBB.1.5)	XBB.1.5 Vaccine Dosage [2]	XBB.1.5 doses required	Interval between last (non-XBB) dose and XBB.1.5 dose [1]
0 doses	Moderna = 0.5 ml (50 mcg)	1	N/A
	Pfizer 12+ = 0.3 ml (30 mcg) (Grey cap/label)		
	Novavax 12+ = 0.5 ml (5 mcg)	1[4] or 2 [3]	
1 or more doses	Moderna = 0.5 ml (50 mcg)	1	6 months (min. 3 months)
	Pfizer 12+ = 0.3 ml (30 mcg) (Grey cap/label)		
	Novavax 12+ = 0.5 ml (5 mcg)		

[1] For those who had previous SARS-CoV-2 infection, an interval of 6 months (min. 3 months) is required. For the purposes of vaccinating long term care facility, personal care home, or senior congregate living (i.e. assisted living facility) residents, XBB.1.5 vaccine can be administered less than 3 months after infection.

[2] **The following dosages are considered invalid:**

- Pfizer: 3 or 10 mcg administered at 12+ years of age.
- Moderna: 25 mcg administered at 12+ years of age.
- **Administer an appropriate vaccine dosage based on age at presentation at a minimum interval of 4 weeks after an invalid (lower dosage for age) dose.**

[3] A 3-week (21 days) interval between Novavax doses 1 and 2 is acceptable, as per the Novavax XBB.1.5 product monograph.

[4] 1 dose is acceptable as noted in Updated guidance on the use of protein subunit COVID-19 vaccine (Novavax Nuvaxovid), NACI 2024-03-08.

Table 2: Schedules for individuals presenting at 12 years and older WHO ARE moderately to severely immunocompromised*

Vaccination History (non-XBB.1.5)	XBB.1.5 Vaccine Dosage [2]	XBB.1.5 doses required	Interval between last dose and first XBB.1.5 dose [1]	Interval between XBB.1.5 doses [1]
0 doses	Moderna = 0.5 ml (50 mcg)	3	N/A	4-8 weeks [3]
	Pfizer 12+ = 0.3 ml (30 mcg) (Grey cap/label)			
	Novavax 12+ = 0.5 ml (5 mcg) [3]	2		
1 dose	Moderna = 0.5 ml (50 mcg)	2	4-8 weeks	4-8 weeks [3]
	Pfizer 12+ = 0.3 ml (30 mcg) (Grey cap/label)			
	Novavax 12+ = 0.5 ml (5 mcg) [3]			
2 doses	Moderna = 0.5 ml (50 mcg)	1	4-8 weeks	N/A
	Pfizer 12+ = 0.3 ml (30 mcg) (Grey cap/label)			
	Novavax 12+ = 0.5 ml (5 mcg)			
3 or more doses	Moderna = 0.5 ml (50 mcg)	1	6 months (min. 3 months)	N/A
	Pfizer 12+ = 0.3 ml (30 mcg) (Grey cap/label)			
	Novavax 12+ = 0.5 ml (5 mcg)			

[1] For those who had previous SARS-CoV-2 infection, an interval of 6 months (min. 3 months) is required.

[2] **The following dosages are considered invalid:**

- Pfizer: 3 or 10 mcg administered at 12+ years of age.
- Moderna: 25 mcg administered at 12+ years of age.
- **Administer an appropriate vaccine dosage based on age at presentation at a minimum interval of 4 weeks after an invalid (lower dosage for age) dose**

[3] NACI recommended 8 weeks, but 3-week (21 days) interval between Novavax doses 1 and 2 is acceptable in the Novavax XBB.1.5 product monograph.

Table 3: mRNA Schedules for individuals presenting at 5-11 years who are NOT immunocompromised

Vaccination History	XBB.1.5 Dosage [2]	XBB.1.5 doses required	Interval between last dose and XBB.1.5 dose [1]
0 or more doses	Moderna = 0.25 ml (25 mcg) Pfizer 5-11 = 0.3 ml (10 mcg) (Blue cap/label)	1 [3]	6 months [3] (min. 3 months)

[1] For those who had previous SARS-CoV-2 infection, an interval of 6 months (min. 3 months) is required. **See footnote 3 for children who transitioned to age 5 during a primary series.**

[2] **The following dosages are considered invalid:**
- Pfizer: 3 mcg administered at 5-11 years of age.
- **Administer an appropriate vaccine dosage based on age at presentation at a minimum interval of 4 weeks after an invalid (lower dosage for age) dose.**

[3] Children who started a primary series with a **non-XBB.1.5 or XBB.1.5** vaccine when they were less than 5 years of age are recommended to receive 1 more dose of an XBB vaccine given **4 to 8 weeks** after their last dose.

Table 4: Schedule for individuals presenting at 5 to 11 years WHO ARE moderately to severely immunocompromised*

Vaccination History	XBB.1.5 Dosage [2]	XBB.1.5 doses required	Interval between last dose and first XBB.1.5 dose [1]	Interval between XBB.1.5 doses [1]
0 doses	Moderna = 0.25 ml (25 mcg) Pfizer 5-11= 0.3 ml (10 mcg) (blue cap/label)	3	N/A	4-8 weeks
1 dose	Moderna = 0.25 ml (25 mcg) Pfizer 5-11= 0.3 ml (10 mcg) (blue cap/label)	2 [3a]	4-8 weeks	4-8 weeks
2 doses	Moderna = 0.25 ml (25 mcg) Pfizer 5-11 = 0.3 ml (10 mcg) (blue cap/label)	1 [3b or 4] OR 2 [3c or 4]	4-8 weeks [3 or 4]	4-8 weeks [3 or 4]
3 or more doses	Moderna= 0.25 ml (25 mcg) Pfizer 5-11 = 0.3 ml (10 mcg) (blue cap/label)	1 [3d or 4]	6 months [3 or 4] (min. 3 months)	N/A

[1] For those who had previous SARS-CoV-2 infection, an interval of 6 months (min. 3 months) is required.

[2] **The following dosages are considered invalid:**
- Pfizer: 3 mcg administered at 5-11 years of age.
- **Administer an appropriate vaccine dosage based on age at presentation at a minimum interval of 4 weeks after an invalid (lower dosage for age) dose.**

[3] Children who started a primary series with an XBB.1.5 vaccine when they were less than 5 years of age should complete the primary series with 4 to 8 weeks between doses and from their last dose as follows: **NOTE:** the number of doses they receive after turning 5 years of age should not exceed 2 doses.

a. 2 more doses of XBB.1.5 vaccine (if had 1 previous dose of Pfizer or Moderna XBB.1.5 between 6 mo-4 years) **OR**
b. 1 more dose of XBB.1.5 (if 2 doses of Moderna XBB.1.5 were received between 6 mo-4 yrs) **OR**
c. 2 more doses of XBB.1.5 vaccine (if any of the 2 previous doses were Pfizer XBB.1.5 between 6 mo-4 years) **OR**
d. 1 more dose of XBB.1.5 (if any of the 3 previous doses were Pfizer XBB.1.5 between 6 mo-4 years)

[4] Children who started their primary series with 2 or 3 doses of a **non-XBB.1.5 Pfizer** vaccine when they were less than 5 years of age are recommended to receive a total of 4 doses of COVID-19 vaccine in their primary series with **4 to 8 weeks** between doses and after their last dose.

Table 5: MODERNA SPIKEVAX™ XBB.1.5 schedules for children presenting at age 6 months to 4 years who are NOT immunocompromised

Vaccination History (non-XBB.1.5)	Moderna XBB.1.5 6 mo-4 yr Dosage	Number of doses required [2]	Interval between last dose and first XBB.1.5 dose [1]	Interval between XBB.1.5 doses [1]
0 doses	0.25 ml (25 mcg)	2	N/A	4-8 weeks
1 dose Pfizer	0.25 ml (25 mcg)	2	4-8 weeks	4-8 weeks
2 doses Pfizer	0.25 ml (25 mcg)	1	4-8 weeks	N/A
1 dose Pfizer **and** 1 dose Moderna				
1 dose Moderna				
3 doses Pfizer	0.25 ml (25 mcg)	1	6 months (min. 3 months)	N/A
2 doses Moderna				
2 doses Pfizer **and** 1 dose Moderna				
1 dose Pfizer **and** 2 doses Moderna				

[1] For those who had previous SARS-CoV-2 infection, an interval of 6 months (min. 3 months) is required.

[2] For mixed schedules consisting of at least one dose of Pfizer 3 mcg, 3 doses are recommended as per the Pfizer XBB.1.5 schedule in **Table 6**. Either Pfizer or Moderna Spikevax can be used to complete the remaining doses.

Table 6: PFIZER COMIRNATY® XBB.1.5 schedules for children presenting at age 6 months to 4 years who are NOT immunocompromised

Vaccination History (non-XBB.1.5)	Pfizer 6mo-4yr XBB.1.5 Dosage (Maroon cap/label) DILUTE PRIOR TO USE	Number of doses required	Interval between last dose and first XBB.1.5 dose [1]	Interval between XBB.1.5 doses [1]
0 doses	0.2 ml (3 mcg)	3	N/A	4-8 weeks
1 dose Pfizer	0.2 ml (3 mcg)	2	4-8 weeks	4-8 weeks
1 dose Moderna				
2 doses Pfizer	0.2 ml (3 mcg)	1	4-8 weeks	N/A
1 dose Pfizer **and** 1 dose Moderna				
3 doses Pfizer	0.2 ml (3 mcg)	1	6 months (min. 3 months)	N/A
2 doses Moderna				
2 doses Pfizer **and** 1 dose Moderna				
1 dose Pfizer **and** 2 doses Moderna				

[1] For those who had previous SARS-CoV-2 infection, an interval of 6 months (min. 3 months) is required.

Table 7: MODERNA SPIKEVAX™ XBB.1.5 schedules for children presenting at age 6 months to 4 years WHO ARE moderately to severely immunocompromised*

Vaccination History (non-XBB.1.5)	Moderna XBB.1.5 6 mo-4 yr Dosage	Number of doses required [2]	Interval between last dose and first XBB.1.5 dose [1]	Interval between XBB.1.5 doses [1]
0 doses	0.25 ml (25 mcg)	3	N/A	4-8 weeks
1 dose Pfizer	0.25 ml (25 mcg)	3	4-8 weeks	4-8 weeks
1 dose Moderna	0.25 ml (25 mcg)	2	4-8 weeks	4-8 weeks
2 doses Pfizer				
1 dose Pfizer **and** 1 dose Moderna				
2 doses Moderna	0.25 ml (25 mcg)	1	4-8 weeks	N/A
3 doses Pfizer				
2 doses Pfizer **and** 1 dose Moderna				
1 dose Pfizer **and** 2 doses Moderna				
4 doses Pfizer	0.25 ml (25 mcg)	1	6 months (min. 3 months)	N/A
3 doses Moderna				
3 doses Pfizer **and** 1 dose Moderna				
2 doses of Pfizer **and** 2 doses of Moderna				
1 dose of Pfizer **and** 3 doses of Moderna				

[1] For those who had previous SARS-CoV-2 infection, an interval of 6 months (min. 3 months) is required.

[2] For mixed schedules consisting of at least one dose of Pfizer 3 mcg, 4 total doses are recommended as per the Pfizer Comirnaty XBB.1.5 schedule in **Table 8**. Either Pfizer or Moderna Spikevax can be used to complete the remaining doses.

Table 8: PFIZER COMIRNATY® XBB.1.5 schedules for children presenting at age 6 months to 4 years WHO ARE moderately to severely immunocompromised*

Vaccination History (non-XBB.1.5)	Pfizer 6 mo -4 yr XBB.1.5 Dosage (Maroon cap /label) DILUTE PRIOR TO USE	Number of doses	Interval between last dose and first XBB.1.5 dose [1]	Interval between XBB.1.5 doses [1]
0 doses	0.2 ml (3 mcg)	4	N/A	4-8 weeks
1 dose Pfizer 1 dose Moderna	0.2 ml (3 mcg)	3	4-8 weeks	4-8 weeks
2 doses Moderna 2 doses Pfizer 1 dose Pfizer **and** 1 dose Moderna	0.2 ml (3 mcg)	2	4-8 weeks	N/A
3 doses Pfizer 2 doses Pfizer **and** 1 dose Moderna 1 dose Pfizer **and** 2 doses Moderna	0.2 ml (3 mcg)	1		
4 doses Pfizer 3 doses Moderna 3 doses Pfizer **and** 1 dose Moderna 2 doses of Pfizer **and** 2 doses of Moderna 1 dose of Pfizer **and** 3 doses of Moderna	0.2 ml (3 mcg)	1	6 months (min. 3 months)	N/A

[1] For those who had previous SARS-CoV-2 infection, an interval of 6 months (min. 3 months) is required.

Additional XBB.1.5 COVID-19 Vaccine Dose Eligibility

- From April 1 to June 30, 2024, the following individuals are recommended to receive an additional XBB.1.5 COVID-19 vaccine dose given at least **6 months** (min. 3 months) from their last COVID-19 XBB.1.5 dose or COVID-19 infection (whichever interval is longer as applicable):
    - Adults 65 years of age and older.
    - Adults 18 to 64 years old residing in long-term care facilities, personal care homes, and congregate living settings (i.e., assisted living settings) that have senior residents 65+ years ([correctional institutions excluded]).
    - Individuals six months of age and older who are moderately to severely immunocompromised with medical conditions described at https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-4-active-vaccines/page-26-covid-19-vaccine.html#a6.4.considerations.

Age	XBB.1.5 COVID-19 Vaccine and Dosage
12+ years	Moderna = 0.5 ml (50 mcg)
	Pfizer 12+ = 0.3 ml (30 mcg) (Grey cap/label)
	Novavax 12+ = 0.5 ml (5 mcg)
5-11 years	Moderna = 0.25 ml (25 mcg)
	Pfizer 5-11 = 0.3 ml (10 mcg) (Blue cap/label)
6 mo-4 yrs	Moderna = 0.25 ml (25 mcg)
	Pfizer 6 mo-4 years = 0.2 ml (3 mcg) (Maroon cap/label)

- Reference: NACI (2024-01-12) Guidance on an additional dose of COVID-19 vaccines in the spring for individuals at high risk of severe illness due to COVID-19.

COVID-19 Vaccine

Moderna Spikevax™ 6+ months XBB.1.5 (Royal Blue Cap/Coral Blue Label)

0.1 mcg/mL DO NOT DILUTE VACCINE

	COVID-19 monovalent XBB.1.5 mRNA Vaccine (Frozen Vaccine)
Composition/Platform Vaccine Type	• Andusomeran mRNA vaccine. • Formulated in lipid nanoparticles (LNPs). • Does not contain any preservatives, antibiotics, adjuvants, or human- or animal-derived materials.
Route	Intramuscular injection (IM). Do not administer this vaccine intravenously or subcutaneously.
Schedule & Dosage	Refer to the XBB.1.5 COVID-19 Vaccination Schedules document in SIM chapter 10.
Contraindications	**Known severe hypersensitivity to any component of the vaccine.** • Two non-medicinal ingredients in the vaccine that have been associated with allergic reactions in other products: • Polyethylene glycol (PEG). The potential allergen may be found in bowel preparation products for colonoscopy, laxatives, cough syrup, cosmetics, contact lens care solutions, skin products and some food and drinks. • Tromethamine (trometamol or Tris) – component found in contrast media, oral and parenteral medications. • **Anaphylaxis to previous dose of mRNA or other COVID-19 vaccine.** • For further details, refer to the Ministry of Health's COVID – 19 Vaccine Contraindications and Precautions Background Document found in the COVID-19 Immunization Manual.
Precautions	For further details on the following precautions, refer to the Ministry of Health's COVID – 19 Vaccine Contraindications and Precautions Background Document found in the COVID-19 Immunization Manual. • Concurrent Illness • SARS-CoV-2 (COVID-19) Infection—current or previous • Treatment with COVID-19 Monoclonal Antibodies or Convalescent Plasma for SARS-CoV-2 Infection • Thrombocytopenia and bleeding disorders • Multisystem Inflammatory Syndrome in Children • Immunocompromised individuals • Auto-immune conditions • History of myocarditis and/or pericarditis
Pregnancy & Lactation	• It is recommended that an mRNA COVID-19 vaccine should be offered to individuals in the authorized age group who are pregnant or breastfeeding. • An mRNA vaccine is preferred due to reassuring data on the safety of these vaccines during pregnancy and lactation. • Pregnant or breastfeeding individuals were excluded from COVID-19 vaccine clinical trials. However, analysis of data collected through international COVID-19 immunization registries to date have not revealed any maternal or neonatal safety signals. • There is a pregnancy exposure registry that monitors pregnancy outcomes in those exposed to SPIKEVAX XBB.1.5 vaccine during pregnancy. Individuals who are vaccinated during pregnancy are encouraged to enroll in the registry by calling 1-866-MODERNA (1-866-663-3762).
Possible reactions	**Commonly or very commonly reported:** • Pain at injection site, fatigue, headache, myalgia, arthralgia, axillary swelling or tenderness, erythema, nausea, vomiting, fever and chills. • A local delayed reaction (onset at least 7 days) known as 'COVID arm' is associated with Moderna COVID-19 vaccines as an expected reaction that resolves on its own

	within 7-10 days. • Local and systemic adverse reactions last an average of 2 days. **Rare** • Anaphylaxis • Non-severe allergic reactions (such as rash, itching, hives or swelling of the face), severe allergic reactions, erythema multiforme (red round patches on the skin) and facial paralysis / Bell's palsy have been reported with the administration of Original SPIKEVAX vaccine formulation. • One case of facial paralysis / Bell's palsy was reported in the bivalent vaccine study but a causal relationship was not established. • Very rare cases of myocarditis and/or pericarditis following vaccination with the original SPIKEVAX vaccine have been reported during post-authorization use. These cases occurred more commonly after the second primary series dose or first booster dose in adolescents and young adults. There were no vaccine-related cases of myocarditis or pericarditis reported during Moderna bivalent vaccine studies in adults. Health Canada will monitor for reports of myocarditis and pericarditis as more people get this XBB.1.5 vaccine. • Vaccinated individuals (including parents or caregivers) should be instructed to seek immediate medical attention if they develop symptoms indicative of myocarditis or pericarditis such as (acute and persisting) chest pain, shortness of breath, or palpitations following vaccination. • NACI recommends that prophylactic oral analgesics or antipyretics (e.g., acetaminophen or ibuprofen) should not be routinely used before or at the time of vaccination, but their use is not a contraindication to vaccination. Oral analgesics or antipyretics may be considered for the management of adverse events (e.g., pain or fever, respectively), if they occur after vaccination.
Administration with Other Products	• Can be given concomitantly with non-COVID-19 vaccines; no intervals are required before or after COVID-19 vaccine administration. • NACI recommends that Imvamune® smallpox/mpox vaccine be given at least 4 weeks after or before an mRNA vaccine for COVID-19 as a precaution in order to prevent erroneous attribution of myocarditis or pericarditis to one particular vaccine or the other. Protection from mpox exposure should be prioritized and recent mRNA vaccine receipt should not delay Imvamune® PEP or PrEP if protection is urgent.
Appearance	• Vaccine is a white to off-white dispersion. It may contain white or translucent product-related particulates. Visually inspect vials for foreign particulate matter and/or discoloration prior to administration. If either of these conditions exists, the vaccine should not be administered.
Preparation & Administration	• Each vial must be thawed prior to administration. • For thawing instructions, refer to COVID-19 Immunization Manual *Vaccine Storage and Handling and Cold Chain Break Procedure for COVID-19 Vaccines* work standard. • **DO NOT DILUTE THIS VACCINE!** • Swirl the vial gently after thawing and between each withdrawal. Do not shake. • Thawed vials and filled syringes can be handled in room light conditions during preparation. • **Use aseptic technique for preparation and administration.**
Storage and Handling	• Store frozen between -50°C to -15°C up to expiry date. Do not store below -50°C. • Store in original carton to protect from light. • After thawing, store closed vials between +2°C to +8°C for up to 30 days. **Do not refreeze after thawing.** • Thawed, punctured vials (first dose is withdrawn) can be stored at +2°C to +25°C for 24 hours. The vaccine must be discarded after this time. • For additional storage and handling details, refer to the COVID-19 Immunization Manual:

	○ *Vaccine Storage and Handling and Cold Chain Break Procedure for COVID-19 Vaccines* work standard ○ Appendix A- Moderna Spikevax™ XBB.1.5 mRNA COVID-19 Vaccine Storage & Handling Summary Table
Transportation	Refer to *Transportation of Moderna COVID-19 Vaccine in a Frozen and Thawed State* work standard found on the COVID-19 Immunization Manual website: https://www.ehealthsask.ca/services/Manuals/Pages/COVID-19.aspx
Packaging	• 2.5 ml per vial • 10 vials per carton/box
Ingredients	Andusomeran (mRNA) encoding the pre-fusion stabilized conformation variant (K982P and V983P) of the SARS-CoV-2 Spike glycoprotein (Omicron subvariant XBB.1.5), acetic acid, cholesterol, DSPC (1,2-distearoyl-sn-glycero-3- phosphocholine), Lipid SM-102, PEG2000-DMG (1,2-dimyristoyl-racglycerol, methoxy-polyethyleneglycol), sodium acetate trihydrate , sucrose, trometamol, trometamol hydrochloride, water for injection

References

- Moderna SPIKEVAX™ XBB.1.5 Product Monograph (2023-09-12). https://covid-vaccine.canada.ca/info/pdf/spikevax-xbb-1-5-pm-en.pdf
- *Canadian Immunization Guide*: COVID-19 Vaccines: https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-4-active-vaccines/page-26-covid-19-vaccine.html
- National Advisory Committee on Immunization. National Advisory Committee on Immunization. (2022-09-01). NACI Rapid Response: Interim guidance on the use of Imvamune® in the context of mpox outbreaks in Canada https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/guidance-imvamune-mpox.html
- National Advisory Committee on Immunization. (January 14, 2022). Summary of NACI advice on vaccination with COVID-19 vaccines following myocarditis (with or without pericarditis) https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/summary-advice-vaccination-covid-19-vaccines-following-myocarditis

COVID-19 Vaccine

Novavax NUVAXOVID™ 12+ XBB.1.5

Composition/Platform Vaccine Type	• Recombinant protein subunit, adjuvanted COVID-19 vaccine • No preservatives
Route	0.5 ml IM. Do not administer this vaccine intradermally, intravenously or subcutaneously
Schedule & Dosage	Refer to the XBB.1.5 COVID-19 Vaccination Schedules document in SIM chapter 10.
Contraindications	• NUVAXOVID XBB.1.5 is contraindicated in individuals who are hypersensitive to the active ingredient or to any ingredients in the formulation, including any non-medicinal ingredient, or component of the container. • One non-medicinal ingredient in the vaccine known to cause type 1 hypersensitivity reactions is polysorbate 80. Polysorbate 80 can be found in medical preparations such as vitamin oils, tablets, anticancer agents, vaccines and cosmetics. • Anaphylaxis to previous dose of this vaccine. The product monograph states, "*A second dose of the vaccine should not be given to those who have experienced anaphylaxis to the first dose of NUVAXOVID*". However, NACI notes: In individuals with a history of a severe, immediate (≤4h following vaccination) allergic reaction (e.g., anaphylaxis) after previous administration of COVID-19 vaccine, re-vaccination (i.e. administration of a subsequent dose in the series when indicated) may be offered with the same vaccine or an mRNA vaccine if a risk assessment deems that the benefits outweigh the potential risks for the individual and if informed consent is provided. • If re-vaccinated, vaccine administration should be done in a controlled setting with expertise and equipment to manage anaphylaxis. Individuals should be observed for at least 30 minutes after re-vaccination.
Precautions	For further details on the following precautions, refer to the Ministry of Health's COVID – 19 Vaccine Contraindications and Precautions Background Document found in the COVID-19 Immunization Manual. • Concurrent illness • SARS-CoV-2 (COVID-19) Infection—current or previous • Treatment with COVID-19 Monoclonal Antibodies or Convalescent Plasma for SARS-CoV-2 Infection • Thrombocytopenia and bleeding disorders • Immunocompromised individuals • Auto-immune conditions • History of myocarditis or pericarditis following COVID-19 vaccination.
Pregnancy & Lactation	• Due to lower overall usage to date, there is less data available about the protein subunit platform compared to the mRNA platform for COVID-19 vaccines, particularly for people who are pregnant. Additional evidence on the use of protein subunit COVID-19 vaccines is expected to accumulate over time. • There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to NUVAXOVID during pregnancy. Women who are vaccinated with NUVAXOVID during pregnancy are encouraged to enroll in the registry by visiting https://c-viper.pregistry.com/. • For further details, refer to the Ministry of Health's COVID – 19 Vaccine Contraindications and Precautions Background Document found in the COVID-19 Immunization Manual.
Possible reactions	• The most frequent adverse reactions were injection site tenderness, injection site pain fatigue, myalgia, headache, malaise, arthralgia, and nausea or vomiting. Adverse reactions were usually mild to moderate in severity with a median duration of ≤ 2 days for local events and ≤ 1 day for systemic events following vaccination. • Hypoesthesia and paresthesia have been reported as post-market adverse reactions. • Vaccinated individuals (including parents or caregivers) should be instructed to seek immediate medical attention if they develop symptoms indicative of myocarditis or pericarditis such as (acute and persisting) chest pain, shortness of breath, or

	palpitations following vaccination. • NACI recommends that prophylactic oral analgesics or antipyretics (e.g., acetaminophen or ibuprofen) should not be routinely used before or at the time of vaccination, but their use is not a contraindication to vaccination. Oral analgesics or antipyretics may be considered for the management of adverse events (e.g., pain or fever, respectively), if they occur after vaccination.
Administration with Other Products	• Can be given concomitantly with non-COVID-19 vaccines; no intervals are required before or after COVID-19 vaccine administration.
Appearance	• NUVAXOVID XBB.1.5 is colourless to slightly yellow, clear to mildly opalescent suspension, free of particles.
Preparation & Administration	• **Must not be diluted or mixed with other vaccines or medicinal products.** • Gently swirl the multidose vial before and in between each dose withdrawal. Do not shake. • Prior to administration, visually inspect the contents of the vial for visible particulate matter and/or discolouration prior to administration. Also, visually inspect the vial for cracks or any abnormalities, such as evidence of tampering. If any of these conditions exists, the vaccine should not be administered. • **Use aseptic technique for preparation and administration.**
Storage & Handling	Unopened MDV: • +2°C to +8°C up to the end of its expiry date, kept in the original packaging and protected from light. Do not freeze. Opened MDV: • After first vial puncture, the vaccine is stable at +2°C to +8°C for 12 hours **OR** at room temperature (up to +25°C) for 6 hours, then must be discarded. • Ensure that the vial is clearly labeled with the date and time of first vial entry. • Time out of Refrigeration (ToR) limits for the storage of Nuvaxovid withdrawn into a sterile syringe, support temperature excursions for up to 12 hours at temperatures between 2°C and 25°C. • Refer to the *Vaccine Storage and Handling and Cold Chain Break Procedure for COVID-19 Vaccines* work standard and Appendix B in the COVID-19 Immunization Manual for additional storage and handling details.
Transportation	• Refer to Transportation of Fridge Stable COVID-19 Vaccines work standard found COVID-19 Immunization Manual.
Packaging	• 5 doses per vial (total 2.5 mL). ● 2 MDVs per carton (10 doses)
Vaccine non-medicinal Ingredients	Disodium hydrogen phosphate heptahydrate, Hydrochloric acid (for adjustment of pH), Polysorbate 80, Sodium chloride, Sodium dihydrogen phosphate monohydrate, Sodium hydroxide (for adjustment of pH), Water for Injection. Matrix-M adjuvant (*Quillaja saponaria* saponins fraction-A and fraction-C), Cholesterol, Disodium hydrogen phosphate dihydrate, Phosphatidylcholine, Potassium chloride, Potassium dihydrogen phosphate, Sodium chloride.

References

- Novavax NUVAXOVID COVID-19 Vaccine *Product Monograph* (2023-12-05) https://covid-vaccine.canada.ca/info/pdf/nuvaxovid-xbb-1-5-pm-en.pdf
- *Canadian Immunization Guide*: COVID-19 Vaccines: https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-4-active-vaccines/page-26-covid-19-vaccine.html
- NACI (2024-03-08). Updated guidance on the use of protein subunit COVID-19 vaccine (Novavax Nuvaxovid).
- NACI (2022-02-17). Recommendations on the use of Novavax Nuvaxovid COVID-19 vaccine. https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-novavax-nuvaxovid-covid-19-vaccine.html
- NACI (January 14, 2022). Summary of NACI advice on vaccination with COVID-19 vaccines following myocarditis (with or without pericarditis) https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/summary-advice-vaccination-covid-19-vaccines-following-myocarditis-with-without-pericarditis.html

COVID-19 Vaccine

Pfizer BioNTech Comirnaty® 12+ XBB.1.5 (Grey cap/ label border)

DO NOT DILUTE THIS VACCINE PRIOR TO USE!

	COVID-19 XBB.1.5 mRNA Vaccine (Ultra-frozen Vaccine)
Composition/Platform Vaccine Type	• Each dose contains contains 30 mcg of a nucleoside modified messenger RNA (modRNA) encoding the viral spike (S) protein of SARS-CoV-2 Omicron variant lineage XBB.1.5. • Formulated in lipid nanoparticles (LNPs). • Does not contain any preservatives.
Route	0.3 ml IM. Do not administer this vaccine intravenously or subcutaneously
Schedule & Dosage	• Refer to the XBB.1.5 COVID-19 Vaccination Schedules document in SIM chapter 10.
Contraindications	**Known severe hypersensitivity to any component of the vaccine.** • Two non-medicinal ingredients in the vaccine that have been associated with allergic reactions in other products: • Polyethylene glycol (PEG). The potential allergen may be found in bowel preparation products for colonoscopy, laxatives, cough syrup, cosmetics, contact lens care solutions, skin products and some food and drinks. • Tromethamine (trometamol or Tris) – component found in contrast media, oral and parenteral medications. • **Anaphylaxis to previous dose of mRNA or other COVID-19 vaccine.** • For further details, refer to the Ministry of Health's COVID – 19 Vaccine Contraindications and Precautions Background Document found in the COVID-19 Immunization Manual.
Precautions	For further details on the following precautions, refer to the Ministry of Health's COVID – 19 Vaccine Contraindications and Precautions Background Document found in the COVID-19 Immunization Manual. • Concurrent Illness • SARS-CoV-2 (COVID-19) Infection—current or previous • Treatment with COVID-19 Monoclonal Antibodies or Convalescent Plasma for SARS-CoV-2 Infection • Thrombocytopenia and bleeding disorders • Immunocompromised individuals • Auto-immune conditions • History of myocarditis or pericarditis following COVID-19 vaccination.
Pregnancy & Lactation	• It is recommended that an mRNA COVID-19 vaccine should be offered to individuals in the authorized age group who are pregnant or breastfeeding. • An mRNA vaccine is preferred due to reassuring data on the safety of these vaccines during pregnancy and lactation. • No data are available yet regarding the use of COMIRNATY Omicron XBB.1.5 during pregnancy or lactation. • Pregnant or breastfeeding individuals were excluded from COVID-19 vaccine clinical trials. However, analysis of data collected through international COVID-19 immunization registries to date have not revealed any maternal or neonatal safety signals.
Possible reactions	• Expected reactions may include pain, fatigue, headache, myalgia, arthralgia and axillary swelling or tenderness. ▪ A local delayed reaction with these symptoms (onset at least 7 days) is known as 'COVID arm' and is associated with mRNA COVID-19 vaccines as an expected reaction that resolves on its own within 7-10 days. • Rare reactions: Anaphylaxis • Non-severe allergic reactions (such as rash, itching, hives or swelling of the face), severe allergic reactions, erythema multiforme (red round patches on the skin) and facial

	paralysis/Bell's palsy, hypoesthesia and paresthesia have been reported with the administration of Original Comirnaty vaccine formulation. • Very rare cases of myocarditis and/or pericarditis following vaccination with original COMIRNATY vaccines were been reported during post-authorization use. These cases occurred more commonly after the second dose and in adolescents and young adults. Typically, the onset of symptoms has been within a few days following receipt of COMIRNATY. Available short-term follow-up data suggest that the symptoms resolve in most individuals, but information on long-term sequelae is lacking. The decision to administer COMIRNATY vaccine to an individual with a history of myocarditis or pericarditis should take into account the individual's clinical circumstances. Health Canada will monitor for reports of myocarditis and pericarditis as more people get this vaccine. • Vaccinated individuals (including parents or caregivers) should be instructed to seek immediate medical attention if they develop symptoms indicative of myocarditis or pericarditis such as (acute and persisting) chest pain, shortness of breath, or palpitations following vaccination. • NACI recommends that prophylactic oral analgesics or antipyretics (e.g., acetaminophen or ibuprofen) should not be routinely used before or at the time of vaccination, but their use is not a contraindication to vaccination. Oral analgesics or antipyretics may be considered for the management of adverse events (e.g., pain or fever, respectively), if they occur after vaccination.
Administration with Other Products	• Can be given concomitantly with most non-COVID-19 vaccines; no intervals are required before or after COVID-19 vaccine administration. • However, NACI recommends that Imvamune® smallpox/mpox vaccine be given at least 4 weeks after or before an mRNA vaccine for COVID-19 as a precaution in order to prevent erroneous attribution of myocarditis or pericarditis to one particular vaccine or the other. Protection from mpox exposure should be prioritized and recent mRNA vaccine receipt should not delay Imvamune® PEP or PrEP if protection is urgent.
Appearance	• Vaccine is a white to off-white dispersion. It may contain white or translucent product-related particulates. Visually inspect vials for foreign particulate matter and/or discoloration prior to administration. If either of these conditions exists, the vaccine should not be administered.
Preparation & Administration	• Each vial must be thawed prior to administration. • For thawing instructions, refer to COVID-19 Immunization Manual *Vaccine Storage and Handling and Cold Chain Break Procedure for COVID-19 Vaccines* work standard. • **DO NOT DILUTE THIS VACCINE!** • Before use, mix by inverting vaccine vial gently 10 times. Do not shake. • Thawed vials and filled syringes can be handled in room light conditions during preparation. • **Use aseptic technique for preparation and administration.**
Storage and Handling	• Store ultra-frozen at -90°C to -60°C for up to 18 months from the date of manufacture (printed on the vial). • **Do not store vials at -25°C to -15°C.** • Thawed vials can be stored between +2°C to +8°C for up to 10 weeks within the expiry date. • Store in original carton to minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light. • **Do not refreeze after thawing.** • After first vial puncture, the vaccine must be used within 12 hours. • Thawed vials may be stored at room temperature [up to 25°C (77°F)] for up to 12 hours prior to use. • For additional storage and handling details, refer to the COVID-19 Immunization Manual: a. *Vaccine Storage and Handling and Cold Chain Break Procedure for COVID-19*

	Vaccines work standard b. Appendix A XBB.1.5 COVID-19 Vaccine Storage and Handling Summary.
Transportation	• Refer to *Transportation of Pfizer COVID-19 Vaccine in a Frozen and Thawed State* work standard found on the COVID-19 Immunization Manual website: https://www.ehealthsask.ca/services/Manuals/Pages/COVID-19.aspx.
Packaging	• 6 doses per vial. • 60 doses per carton
Ingredients	Raxtozinameran (mRNA) encodes for the viral spike (S) protein of SARS-CoV-2 Omicron XBB.1.5 strain, ALC-0315 = ((4-hydroxybutyl) azanediyl)bis (hexane-6,1-diyl)bis(2-hexyldecanoate), ALC-0159 = 2-[(polyethylene glycol)- 2000]-N,N-ditetradecylacetamide, cholesterol, DSPC = 1,2-distearoyl-sn-glycero-3- phosphocholine, sucrose, tromethamine, tromethamine hydrochloride, water for injection.

References

- Pfizer Comirnaty™ XBB.1.5 Product Monograph (2023-09-28). https://covid-vaccine.canada.ca/info/pdf/comirnaty-omicron-xbb-1-5-pm-en.pdf
- *Canadian Immunization Guide*: COVID-19 Vaccines: https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-4-active-vaccines/page-26-covid-19-vaccine.html
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COVID-19 Vaccine

Pfizer BioNTech Comirnaty® 5-11 years XBB.1.5 (Blue cap/ label border)

DO NOT DILUTE THIS VACCINE PRIOR TO USE!

	COVID-19 bivalent mRNA Vaccine (Ultra-frozen Vaccine)
Composition/Platform Vaccine Type	• Each dose contains 10 mcg of a nucleoside modified messenger RNA (modRNA) encoding the viral spike (S) protein of SARS-CoV-2 Omicron variant lineage. • Formulated in lipid nanoparticles (LNPs). • Does not contain any preservatives.
Route	0.3 ml IM. Do not administer this vaccine intravenously or subcutaneously.
Schedule & Dosage	• Refer to the XBB.1.5 COVID-19 Vaccination Schedules document in SIM chapter 10.
Contraindications	**Known severe hypersensitivity to any component of the vaccine.** • Two non-medicinal ingredients in the vaccine that have been associated with allergic reactions in other products: • Polyethylene glycol (PEG). The potential allergen may be found in bowel preparation products for colonoscopy, laxatives, cough syrup, cosmetics, contact lens care solutions, skin products and some food and drinks. • Tromethamine (trometamol or Tris) – component found in contrast media, oral and parenteral medications. • **Anaphylaxis to previous dose of mRNA or other COVID-19 vaccine.** • For further details, refer to the Ministry of Health's COVID – 19 Vaccine Contraindications and Precautions Background Document found in the COVID-19 Immunization Manual.
Precautions	For further details on the following precautions, refer to the Ministry of Health's COVID – 19 Vaccine Contraindications and Precautions Background Document found in the COVID-19 Immunization Manual. • Concurrent Illness • SARS-CoV-2 (COVID-19) Infection—current or previous • Treatment with COVID-19 Monoclonal Antibodies or Convalescent Plasma for SARS-CoV-2 Infection • Thrombocytopenia and bleeding disorders • Multisystem Inflammatory Syndrome in Children • Immunocompromised individuals • Auto-immune conditions • History of myocarditis and/or pericarditis
Possible reactions	• **Expected reactions may include** Pain, fatigue, headache, myalgia, arthralgia and axillary swelling or tenderness. A local delayed reaction with these symptoms (onset at least 7 days) is known as 'COVID arm' and is associated with mRNA COVID-19 vaccines as an expected reaction that resolves on its own within 7-10 days. • **Rare reactions may include** Anaphylaxis • Non-severe allergic reactions (such as rash, itching, hives or swelling of the face), severe allergic reactions, erythema multiforme (red round patches on the skin) and facial paralysis/Bell's palsy, hypoesthesia and paresthesia have been reported with the administration of Original Comirnaty vaccine formulation. • Very rare cases of myocarditis and/or pericarditis following vaccination with original COMIRNATY vaccines were reported during post-authorization use. These cases occurred more commonly after the second dose and in adolescents and young adults. Typically, the onset of symptoms has been within a few days following receipt of COMIRNATY. Available short-term follow-up data suggest that the symptoms resolve in most individuals, but information on long-term sequelae is lacking. The decision to administer COMIRNATY vaccine to an individual with a history of myocarditis or pericarditis should take into account the individual's clinical circumstances. Health Canada will monitor for reports of myocarditis and pericarditis as more people get this bivalent vaccine. • Vaccinated individuals (including parents or caregivers) should be instructed to seek immediate

	medical attention if they develop symptoms indicative of myocarditis or pericarditis such as (acute and persisting) chest pain, shortness of breath, or palpitations following vaccination. • NACI recommends that prophylactic oral analgesics or antipyretics (e.g., acetaminophen or ibuprofen) should not be routinely used before or at the time of vaccination, but their use is not a contraindication to vaccination. Oral analgesics or antipyretics may be considered for the management of adverse events (e.g., pain or fever, respectively), if they occur after vaccination.
Administration with Other Products	• Can be given concomitantly with most non-COVID-19 vaccines; no intervals are required before or after COVID-19 vaccine administration. • However, NACI recommends that Imvamune® smallpox/mpox vaccine be given at least 4 weeks after or before an mRNA vaccine for COVID-19 as a precaution in order to prevent erroneous attribution of myocarditis or pericarditis to one particular vaccine or the other. Protection from mpox exposure should be prioritized and recent mRNA vaccine receipt should not delay Imvamune® PEP or PrEP if protection is urgent.
Appearance	• Vaccine is a white to off-white dispersion. It may contain white or translucent product-related particulates. Visually inspect vials for foreign particulate matter and/or discoloration prior to administration. If either of these conditions exists, the vaccine should not be administered.
Preparation & Administration	• Each vial must be thawed prior to administration. • For thawing instructions, refer to COVID-19 Immunization Manual *Vaccine Storage and Handling and Cold Chain Break Procedure for COVID-19 Vaccines* work standard. • **DO NOT DILUTE THIS VACCINE!** • Before use, mix by inverting vaccine vial gently 10 times. Do not shake. • Thawed vials and filled syringes can be handled in room light conditions during preparation. • **Use aseptic technique for preparation and administration.**
Storage & Handling	• Store ultra-frozen at -90°C to -60°C (-130°F to -76°F) for up to 18 months from the date of manufacture (printed on the vial). • **Do not store vials at -25°C to -15°C.** • Store thawed vials between +2°C to +8°C for up to 10 weeks within the expiry date. • Store in original carton to minimize exposure to room light and avoid exposure to direct sunlight and ultraviolet light. • **Do not refreeze after thawing.** • Upon first vial puncture, the vaccine must be used within 12 hours. • Thawed vials may be stored at room temperature [up to 25°C (77°F)] for up to 12 hours prior to use. • For additional storage and handling details, refer to the COVID-19 Immunization Manual: a. *Vaccine Storage and Handling and Cold Chain Break Procedure for COVID-19 Vaccines* work standard b. Appendix A XBB.1.5 COVID-19 Vaccine Storage and Handling Summary.
Transportation	Refer to *Transportation of Pfizer COVID-19 Vaccine in a Frozen and Thawed State* work standard found on the COVID-19 Immunization Manual website: https://www.ehealthsask.ca/services/Manuals/Pages/COVID-19.aspx.
Packaging	• 6 doses per vial • 60 doses per carton
Ingredients	10 mcg Raxtozinameran (mRNA) encodes for the viral spike (S) protein of SARS-CoV-2 Omicron XBB.1.5 strain, ALC-0315 = ((4-hydroxybutyl) azanediyl)bis (hexane-6,1-diyl)bis(2- hexyldecanoate), ALC-0159 = 2-[(polyethylene glycol)- 2000]-N,N-ditetradecylacetamide, cholesterol, DSPC = 1,2-distearoyl-sn-glycero-3- phosphocholine, sucrose, tromethamine, tromethamine hydrochloride, water for injection

References

- Pfizer Comirnaty™ XBB.1.5 Product Monograph (2023-09-28). https://covid-vaccine.canada.ca/info/pdf/comirnaty-omicron-xbb-1-5-pm-en.pdf
- *Canadian Immunization Guide*: COVID-19 Vaccines: https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-4-active-vaccines/page-26-covid-19-vaccine.html
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COVID-19 Vaccine

Pfizer BioNTech Comirnaty® 6 months to 4 years XBB.1.5 (Maroon cap/ label border)

Vaccine must be diluted prior to administration!

	COVID-19 bivalent mRNA Vaccine (Ultra-frozen Vaccine)
Composition/Platform Vaccine Type	• Each dose contains 3 mcg of a nucleoside modified messenger RNA (modRNA) encoding the viral spike (S) protein of SARS-CoV-2 Omicron variant lineage XBB.1.5. • Formulated in lipid nanoparticles (LNPs). • Does not contain any preservatives.
Route	• 0.2 ml IM. Do not administer this vaccine intravenously or subcutaneously.
Schedule & Dosage	• Refer to the XBB.1.5 COVID-19 Vaccination Schedules document in SIM chapter 10.
Contraindications	**Known severe hypersensitivity to any component of the vaccine.** • Two non-medicinal ingredients in the vaccine that have been associated with allergic reactions in other products: • Polyethylene glycol (PEG). The potential allergen may be found in bowel preparation products for colonoscopy, laxatives, cough syrup, cosmetics, contact lens care solutions, skin products and some food and drinks. • Tromethamine (trometamol or Tris) – component found in contrast media, oral and parenteral medications. • **Anaphylaxis to previous dose of mRNA or other COVID-19 vaccine.** • For further details, refer to the Ministry of Health's COVID – 19 Vaccine Contraindications and Precautions Background Document found in the COVID-19 Immunization Manual.
Precautions	For further details on the following precautions, refer to the Ministry of Health's COVID – 19 Vaccine Contraindications and Precautions Background Document found in the COVID-19 Immunization Manual. • Concurrent Illness • SARS-CoV-2 (COVID-19) Infection—current or previous • Treatment with COVID-19 Monoclonal Antibodies or Convalescent Plasma for SARS-CoV-2 Infection • Thrombocytopenia and bleeding disorders • Multisystem Inflammatory Syndrome in Children • Immunocompromised individuals • Auto-immune conditions • History of myocarditis and/or pericarditis
Possible reactions	• **Expected reactions may include p**ain, fatigue, irritability, headache, myalgia, arthralgia and axillary swelling or tenderness. A local delayed reaction with these symptoms (onset at least 7 days) is known as 'COVID arm' and is associated with mRNA COVID-19 vaccines as an expected reaction that resolves on its own within 7-10 days. • **Rare reactions may include** Anaphylaxis • Non-severe allergic reactions (such as rash, itching, hives or swelling of the face), severe allergic reactions, erythema multiforme (red round patches on the skin) and facial paralysis/Bell's palsy, hypoesthesia and paresthesia have been reported with the administration of Original Comirnaty vaccine formulation. • NACI recommends that prophylactic oral analgesics or antipyretics (e.g., acetaminophen or ibuprofen) should not be routinely used before or at the time of vaccination, but their use is not a contraindication to vaccination. Oral analgesics or antipyretics may be considered for the management of adverse events (e.g., pain or fever, respectively), if they occur after vaccination.
Administration with Other Products	• Can be given concomitantly with most non-COVID-19 vaccines; no intervals are required before or after COVID-19 vaccine administration.

Appearance	• Vaccine is a white to off-white dispersion. It may contain white or translucent product-related particulates. Visually inspect vials for foreign particulate matter and/or discoloration prior to administration. If either of these conditions exists, the vaccine should not be administered.
Preparation & Administration	**The multiple dose vial contains a frozen suspension that must be thawed and diluted prior to administration.** • Before dilution, let vial stand at room temperature for 15 minutes. • When at room temperature, mix by inverting vaccine vial gently 10 times. **Do not shake.** • Dilution with 2.2 ml sterile 0.9% Sodium Chloride Injection is required. (Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent.) • Cleanse the vial stopper with a single-use antiseptic swab. • Add 2.2 mL of 0.9% Sodium Chloride Injection, into the vaccine vial using a needle 21-gauge or narrower. Diluent is **single** use. Once the 2.2 ml required is drawn from the diluent vial and added to the antigen vial, the diluent vial MUST be discarded. It **cannot** be used to dilute multiple vials of vaccine. • Equalize vial pressure before removing the needle from the vial by withdrawing 2.2 ml air into the empty diluent syringe. This is to prevent any vaccine loss through spraying out due to higher pressure. • Gently invert the diluted vial 10 times to mix. **Do not shake.** • Inspect the vial to confirm there are no particulates and no discoloration is observed. • Record the date and time of dilution on the vaccine vial label. • Store between +2°C to +25°C. **Do not refreeze.** • Discard any unused vaccine **12 hours** after dilution. **Vials After Dilution** • After dilution, store vials between +2°C to +25°C and use within 12 hours from the time of dilution. • Any vaccine remaining in vials must be discarded after 12 hours.
Storage & Handling	• To be stored ultra-frozen between -90°C to -60°C storage until the expiry date (18 months from date of manufacture printed on the vial). • **Do not store between -25°C to -15°C.** • Store closed, thawed vials between +2°C to +8°C for up to 10 weeks within the 18-month shelf-life. • Store in original carton to minimize exposure to room ligh, and avoid exposure to direct sunlight and ultraviolet light. • **Do not refreeze after thawing.** • After first vial puncture, the vaccine must be used within 12 hours. • For additional storage and handling details, refer to the COVID-19 Immunization Manual: a. *Vaccine Storage and Handling and Cold Chain Break Procedure for COVID-19 Vaccines* work standard b. Appendix A XBB.1.5 COVID-19 Vaccine Storage and Handling Summary.
Packaging	Vaccine • 10 doses per vial • 100 doses per carton Diluent • Diluent is provided in 10 mL plastic vials (latex-free, preservative-free). • Packaged in cartons of 25 vials and can be stored at room temperature. • Diluent is **single use**. Once the required 2.2 mL is withdrawn from the diluent vial and added to the antigen vial, the diluent vial MUST be discarded. It **cannot** be used to dilute multiple vials of vaccine.

Ingredients	Raxtozinameran (mRNA) encodes for the viral spike (S) protein of SARS-CoV-2, ALC-0315 = ((4-hydroxybutyl) azanediyl)bis (hexane-6,1-diyl)bis(2-hexyldecanoate), ALC-0159 = 2-[(polyethylene glycol)-2000]- N,N-ditetradecylacetamide, cholesterol, DSPC = 1,2-distearoyl-sn-glycero-3- phosphocholine, sodium chloride, sucrose, tromethamine, tromethamine hydrochloride, water for injection
Transportation	Refer to *Transportation of Pfizer COVID-19 Vaccine in a Frozen and Thawed State* work standard found on the COVID-19 Immunization Manual website: https://www.ehealthsask.ca/services/Manuals/Pages/COVID-19.aspx.

References

- Pfizer Comirnaty™ XBB.1.5 Product Monograph (2023-09-28). https://covid-vaccine.canada.ca/info/pdf/comirnaty-omicron-xbb-1-5-pm-en.pdf
- *Canadian Immunization Guide*: COVID-19 Vaccines: https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-4-active-vaccines/page-26-covid-19-vaccine.html
- National Advisory Committee on Immunization. (January 14, 2022). Summary of NACI advice on vaccination with COVID-19 vaccines following myocarditis (with or without pericarditis) https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/summary-advice-vaccination-covid-19-vaccines-following-myocarditis-with-without-pericarditis.html

Diphtheria-Tetanus-acellular Pertussis-Polio-Haemophilus influenzae type b Adsorbed Vaccine (DTaP-IPV-Hib)

INFANRIX™-IPV/Hib

(GlaxoSmithKline 2018 monograph available at: https://ca.gsk.com/media/6248/infanrix-ipv-hib.pdf)

DOSE / PRIMARY SERIES [1, 2, 5]	**Dose 1**: 0.5 mL IM at 2 months old **Dose 2**: 0.5 mL IM at 4 months old **Dose 3**: 0.5 mL IM at 6 months old **Dose 4**: 0.5 mL IM at 18 months old [3]
REINFORCEMENT [4]	Tdap-IPV at age 4-6 years (school entry)
PRECAUTION	Acellular pertussis-containing vaccines may be administered to clients with the following conditions once a treatment regimen has been established and their condition has stabilized: • Progressive or unstable neurologic disorder (including infantile spasms for DTaP) • Uncontrolled seizures • Progressive encephalopathy
CONTRAINDICATIONS	• History of anaphylactic reaction to a previous dose of DPT, DTaP, IPV or Hib-containing vaccine or to any INFANRIX™-IPV/Hib vaccine component. • History of Guillain-Barré syndrome (GBS) within 6 weeks of receipt of a tetanus-containing vaccine. • Individuals who have experienced transient thrombocytopenia or other neurological complications following an earlier immunization against diphtheria and/or tetanus. • Encephalopathy (e.g., coma, decreased level of consciousness, prolonged seizures) not attributable to another identifiable cause within 7 days after receiving a dose of a pertussis-containing vaccine.
VACCINE COMPONENTS	Sterile suspension for injection/ not less than 25 limit of flocculation (Lf) [30 International Units (IU)] of diphtheria toxoid; 10 Lf (40 IU) of tetanus toxoid; 25 mc of pertussis toxoid; 25 mcg of filamentous haemagglutinin; 8 mcg of pertactin; 40 D-antigen units (DU) of type 1 poliovirus; 8 DU type 2 poliovirus; 32 DU type 3 poliovirus; 10 mcg of purified polyribosyl-ribitol-phosphate capsular polysaccharide of *Haemophilus Influenzae* type B covalently bound to 25 mcg of tetanus toxoid per 0.5 mL dose. **Clinically Relevant Nonmedicinal Ingredients:** lactose, sodium chloride, aluminum adjuvant (as aluminum salts), Medium 199 (as stabilizer including amino acids, mineral salts and vitamins) and water for injection, residual formaldehyde, polysorbate 80, potassium chloride, disodium phosphate, monopotassium phosphate, glycine and trace amounts of neomycin sulphate and polymyxin B sulphate. Thimerosal and latex-free. The vial is sealed with a butyl rubber stopper. The syringes are fitted with butyl rubber plunger stoppers and tip caps.
EXPECTED REACTIONS	**Local**: Redness, tenderness, and swelling. **Systemic**: Irritability, crying, fever, drowsiness, decreased activity and decreased appetite, vomiting and diarrhea.

Diphtheria-Tetanus-acellular Pertussis-Polio-*Haemophilus influenzae* type b Adsorbed Vaccine (DTaP-IPV-Hib)

INFANRIX™-IPV/Hib

(GlaxoSmithKline 2018 monograph available at: https://ca.gsk.com/media/590970/infanrix-ipv-hib.pdf)

EFFECTIVENESS	Following administration of the 4th dose in the second year of life, more than 99.5% of infants had tetanus and diphtheria antibody titres of > 0.1 IU/mL. Following administration of the 4th dose in the second year of life, a booster response was seen in 98.6%, 97.6% and 97.9% of vaccinated infants against pertussis antigens. Following administration of the 4th dose in the second year of life, 100% of infants were seroprotected for the three polio serotypes. One month after the 4th dose was administered in the second year of life, a Hib titre of ≥ 0.15 mcg/mL was obtained in 99.7% of all infants, and in > 98.3% of infants, a Hib titre of 1 mcg/mL was reached.

[1] Minimum age is 6 weeks.

[2] If a child's immunization schedule is delayed, the child may require fewer doses of Hib vaccine. Refer to SIM, Chapter 5, *Immunization Schedules* Section 1.2, *Hib Schedule for Children Delayed by 1 Month or More* .

[3] If required, this dose can be given as early as 24 weeks following dose number 3. For protection against Hib, do not give the 4th dose before 12 months of age.

[4] The 5th dose is not necessary if the 4th dose was given after the 4th birthday.

[5] May be administered off label to HSCT and solid organ transplant recipients (whose age is beyond the vaccine's licensed age range) to reduce the number of injections they require to meet the antigen requirements as noted in Appendix 7.6 or 7.10 immunization schedules.

Diphtheria-Tetanus-acellular Pertussis-Polio-*Haemophilus influenzae* type b Adsorbed Vaccine (DTaP-IPV-Hib)

PENTACEL®
(Sanofi Pasteur 2023 monograph available at https://pdf.hres.ca/dpd_pm/00069309.PDF)

DOSE / PRIMARY SERIES [1, 2, 5]	**Dose 1**: 0.5 mL IM at 2 months old **Dose 2**: 0.5 mL IM at 4 months old **Dose 3**: 0.5 mL IM at 6 months old **Dose 4**: 0.5 mL IM at 18 months old [3]
REINFORCEMENT [4]	Tdap-IPV at age 4-6 years (school entry)
PRECAUTION	Acellular pertussis-containing vaccines may be administered to clients with the following conditions once a treatment regimen has been established and their condition has stabilized: • Progressive or unstable neurologic disorder (including infantile spasms for DTaP) • Uncontrolled seizures • Progressive encephalopathy
CONTRAINDICATIONS	• History of anaphylactic reaction to a previous dose of DPT, DTaP, IPV or Hib--containing vaccine or to any PEDIACEL® vaccine component. • History of Guillain-Barré syndrome (GBS) within 6 weeks of receipt of a tetanus-containing vaccine. • Individuals who have experienced transient thrombocytopenia or other neurological complications following an earlier immunization against diphtheria and/or tetanus. • Encephalopathy (e.g., coma, decreased level of consciousness, prolonged seizures) not attributable to another identifiable cause within 7 days after receiving a dose of a pertussis-containing vaccine.
VACCINE COMPONENTS	Diphtheria toxoid, tetanus toxoid, acellular pertussis [pertussis toxoid (PT), filamentous haemagglutinin (FHA), pertactin (PRN), fimbriae types 2 and 3 (FIM)], inactivated poliomyelitis vaccine [type 1 (Mahoney), type 2 (MEF1), type 3 (Saukett)], purified polyribosylribitol phosphate capsular polysaccharide (PRP) of *Haemophilus influenzae* type b covalently bound to tetanus protein, water for injection, Tris (hydroxymethyl) aminomethane, sucrose. **Excipients**: aluminum phosphate (adjuvant), 2-phenoxyethanol, polysorbate 80. **Manufacturing process residuals**: formaldehyde, glutaraldehyde, .bovine serum albumin, neomycin, polymyxin B , streptomycin sulfate. Latex and thimerosal free.
EXPECTED REACTIONS	**Local**: Redness, tenderness, and swelling. **Systemic**: Irritability, crying, fevers greater than 38.3°C, drowsiness, decreased activity and decreased appetite, vomiting and diarrhea.

https://products.sanofi.ca/en/pediacel.pdf).

Diphtheria-Tetanus-acellular Pertussis-Polio-*Haemophilus influenzae* type b Adsorbed Vaccine (DTaP-IPV-Hib) **PENTACEL®** (Sanofi Pasteur 2023 monograph available at: https://products.sanofi.ca/en/pediacel.pdf).	
EFFECTIVENESS	One month after the third and fourth doses, no clinically significant differences were observed between the antibody responses to each of the vaccine antigens in children receiving PEDIACEL®. After the third and fourth doses, at least 97.9% of the PEDIACEL® vaccinees achieved seroprotective levels against Hib disease (anti-PRP antibody ≥ 0.15 mcg/mL), diphtheria (diphtheria antitoxin ≥ 0.01 IU/mL), tetanus (tetanus antitoxin ≥ 0.01 EU/mL) and poliomyelitis types 1, 2, and 3 (poliovirus neutralizing antibody titre ≥ 1:8). Seroconversion rates (≥ 4-fold rise) were high for each of the pertussis antibodies after the primary series. A robust booster response was observed after the fourth dose.

[1] Minimum age is 6 weeks.

[2] If a child's immunization schedule is delayed, the child may require fewer doses of Hib vaccine. Refer to SIM, Chapter 5, *Immunization Schedules* Section 1.2, *Hib Schedule for Children Delayed by 1 Month or More* .

[3] If required, this dose can be given as early as 24 weeks following dose number 3. For protection against Hib, do not give the 4th dose before 12 months of age.

[4] The 5th dose is not necessary if the 4th dose was given after the 4th birthday.

[5] May be administered off label to HSCT and solid organ transplant recipients (whose age is beyond the vaccine's licensed age range) to reduce the number of injections they require to meet the antigen requirements as noted in Appendix 7.6 or 7. 10 immunization schedules.

Diphtheria-Tetanus-acellular Pertussis-Polio-*Haemophilus influenzae* type b Adsorbed Vaccine (DTaP-IPV-Hib)

PEDIACEL®
(Sanofi Pasteur 2023 monograph available at: https://products.sanofi.ca/en/pediacel.pdf).

DOSE / PRIMARY SERIES [1, 2, 5]	**Dose 1**: 0.5 mL IM at 2 months old **Dose 2**: 0.5 mL IM at 4 months old **Dose 3**: 0.5 mL IM at 6 months old **Dose 4**: 0.5 mL IM at 18 months old [3]
REINFORCEMENT [4]	Tdap-IPV at age 4-6 years (school entry)
PRECAUTION	Acellular pertussis-containing vaccines may be administered to clients with the following conditions once a treatment regimen has been established and their condition has stabilized: • Progressive or unstable neurologic disorder (including infantile spasms for DTaP) • Uncontrolled seizures • Progressive encephalopathy
CONTRAINDICATIONS	• History of anaphylactic reaction to a previous dose of DPT, DTaP, IPV or Hib--containing vaccine or to any PEDIACEL® vaccine component. • History of Guillain-Barré syndrome (GBS) within 6 weeks of receipt of a tetanus-containing vaccine. • Individuals who have experienced transient thrombocytopenia or other neurological complications following an earlier immunization against diphtheria and/or tetanus. • Encephalopathy (e.g., coma, decreased level of consciousness, prolonged seizures) not attributable to another identifiable cause within 7 days after receiving a dose of a pertussis-containing vaccine.
VACCINE COMPONENTS	Diphtheria toxoid, tetanus toxoid, acellular pertussis [pertussis toxoid (PT), filamentous haemagglutinin (FHA), pertactin (PRN), fimbriae types 2 and 3 (FIM)], inactivated poliomyelitis vaccine [type 1 (Mahoney), type 2 (MEF1), type 3 (Saukett)] and purified polyribosylribitol phosphate capsular polysaccharide (PRP) of *Haemophilus influenzae* type b covalently bound to tetanus protein. **Excipients**: aluminum phosphate (adjuvant), 2-phenoxyethanol, polysorbate 80. **Manufacturing process residuals**: bovine serum albumin, neomycin, polymyxin B and trace amounts of streptomycin, formaldehyde and glutaraldehyde. Latex and thimerosal free.
EXPECTED REACTIONS	**Local**: Redness, tenderness, and swelling. **Systemic**: Irritability, crying, fevers greater than 38.3°C, drowsiness, decreased activity and decreased appetite, vomiting and diarrhea.

Diphtheria-Tetanus-acellular Pertussis-Polio-*Haemophilus influenzae* type b Adsorbed Vaccine (DTaP-IPV-Hib)

PEDIACEL®

(Sanofi Pasteur 2023 monograph available at: https://products.sanofi.ca/en/pediacel.pdf).

EFFECTIVENESS	One month after the third and fourth doses, no clinically significant differences were observed between the antibody responses to each of the vaccine antigens in children receiving PEDIACEL®. After the third and fourth doses, at least 97.9% of the PEDIACEL® vaccinees achieved seroprotective levels against Hib disease (anti-PRP antibody ≥ 0.15 mcg/mL), diphtheria (diphtheria antitoxin ≥ 0.01 IU/mL), tetanus (tetanus antitoxin ≥ 0.01 EU/mL) and poliomyelitis types 1, 2, and 3 (poliovirus neutralizing antibody titre ≥ 1:8). Seroconversion rates (≥ 4-fold rise) were high for each of the pertussis antibodies after the primary series. A robust booster response was observed after the fourth dose.

[1] Minimum age is 6 weeks.

[2] If a child's immunization schedule is delayed, the child may require fewer doses of Hib vaccine. Refer to SIM, Chapter 5, *Immunization Schedules* Section 1.2, *Hib Schedule for Children Delayed by 1 Month or More* .

[3] If required, this dose can be given as early as 24 weeks following dose number 3. For protection against Hib, do not give the 4th dose before 12 months of age.

[4] The 5th dose is not necessary if the 4th dose was given after the 4th birthday.

[5] May be administered off label to HSCT and solid organ transplant recipients (whose age is beyond the vaccine's licensed age range) to reduce the number of injections they require to meet the antigen requirements as noted in Appendix 7.6 or 7. 10 immunization schedules.

Diphtheria-Tetanus-acellular Pertussis-Hepatitis B-Polio-Haemophilus influenzae type b Adsorbed Vaccine (DTaP-HB-IPV-Hib)

[Non-publicly funded]

INFANRIX-hexa®
(GlaxoSmithKline 2023 monograph) https://ca.gsk.com/media/6247/infanrix-hexa.pdf

Refer to Appendix 5.1: DTaP-IPV-Hib and HB Vaccine Schedule for Children who have previously Received DTaP-HB-IPV-Hib (INFANRIX hexa®) Vaccine Doses for immunization directives.

Haemophilus influenzae type b Conjugate Vaccine (Hib)

Act-HIB®
(Sanofi Pasteur 2023 monograph available at: http://products.sanofi.ca/en/act-hib.pdf

INDICATIONS and DOSE / SERIES [1]	
1. As a component of DTaP-IPV-Hib 0.5 mL IM for children at 2, 4, 6, and 18 months of age [2]**.** **2. Children 2-59 months of age who are delayed by 1 month or more** [3] **3. People 5 years and older with the following medical conditions regardless of Hib immunization or Hib disease history:** [4] Anatomic or functional asplenia Including (sickle cell disease) [5, 7]; HIV [7]; immunosuppression related to disease [7] (e.g., congenital immunodeficiency states such as complement, properidin or factor D deficiency; malignant neoplasm including leukemia and lymphoma;) or therapy [7, 7]; candidates or recipients of solid organ or islet cell transplants [7], or cochlear implants [7]. **4. Haematopoietic stem cell transplant (HSCT) recipient** [6]	
CONTRAINDICATIONS	History of anaphylactic reaction to a previous dose of a Hib-containing vaccine or to any component of Act-HIB®.
VACCINE COMPONENTS	Purified Polyribosylribitol Phosphate Capsular Polysaccharide (PRP) of *Haemophilus influenzae* type b covalently bound to 18-30 mcg of Tetanus Protein 10 mcg. **Excipients**: Tris (hydroxymethyl) aminomethane, sucrose, sodium chloride. Thimerosal free. The stoppers of the vials containing Act-HIB® and the diluent (0.4% saline) do not contain latex (natural rubber).
EXPECTED REACTIONS	**Local**: redness, tenderness, swelling, pain. **Systemic:** fever more than 38.3°C, fussiness, irritability, lethargy, loss of appetite.
EFFECTIVENESS	After 4 doses, 99% of children maintained high antibody levels at age 4- 5 years.

[1] Minimum age is 6 weeks old.
[2] The 18 month reinforcement dose may be given at 12 months if there is an 8 week interval following the previous dose.
[3] Refer to SIM, Chapter 5 *Immunization Schedules,* section 1.2 *Hib Schedule for Children Delayed by 1 Month or More.*
[4] Refer to SIM, Chapter 7, *Immunization of Special Populations* for more information on specific conditions.
[5] Give vaccine at least 14 days prior to elective splenectomy, or if impossible, 14 days or more days post-splenectomy. If there is concern that the client may not present later for immunization, give vaccine before discharge.
[6] Refer to SIM, Chapter 7, *Immunization of Special Populations,* Section 3.6 *Transplant Recipient - Haematopoietic Stem Cell Transplant.*
[7] At least 1 year after any previous dose.

Publicly Funded [3] *
Hepatitis A (HA) Vaccine Indications

- People born since Jan. 1/82 who live in the Athabasca Health Authority; off reserves in Northern SK (former Mamawetan Churchill River and Keewatin Yatthé health regions excluding Creighton, Air Ronge and La Ronge); or on reserves anywhere is SK, regardless of where they access immunization services.
- Men who have sex with men.
- Individuals that use or share illicit drug snorting, smoking or injection equipment.
- Sexual partners and household contacts 6 months and older of individuals who use illicit drugs.
- Post-exposure prophylaxis of case contacts 6 months and older with one dose as outlined in the Saskatchewan Communicable Disease Control Manual.[1]
- Non-immune individuals 6 months and older with bleeding disorders and others who receive repeated infusions of blood or blood products or plasma-derived replacement clotting factors.
- Individuals 6 months and older who have liver disease (e.g., alcoholism, hepatitis C, hepatitis B, cirrhosis) who are non-immune to HA.
- Liver transplant candidates or recipients 6 months and older.
- Haematopoietic stem cell transplant (HSCT) recipients 6 months and older.

HA vaccine recommended for but not provided free: [2]

- Travellers to countries with endemic hepatitis A.
- Food handlers.
- Residents in certain institutions, such as correctional facilities and those for developmentally challenged individuals.
- Residents in communities in rural or remote areas lacking adequate sanitation or a secure supply of potable water.

[1] If a client received 1 dose of a HA-containing vaccine more than 6 months previously, provide a second dose of HA vaccine.

[2] These individuals should be referred to a travel clinic, family physician, nurse practitioner or pharmacist to receive non-publicly funded vaccine.

[3] CIG Hepatitis A chapter https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-4-active-vaccines/page-6-hepatitis-a-vaccine.html).

* Previously, HIV positive individuals were deemed eligible to receive HA vaccine based on this diagnosis. If such an individual had started a HA series, the series is to be completed.

Hepatitis A Vaccine (HA) (inactivated viral)

AVAXIM®
(Sanofi Pasteur 2021 monograph available at: http://products.sanofi.ca/en/avaxim.pdf

AVAXIM® - Pediatric
(Sanofi Pasteur 2021 monograph available at: http://products.sanofi.ca/en/avaxim-pediatric.pdf)

INDICATIONS	**Refer to publicly funded HA vaccine indications**
DOSE [1] / SERIES NOTE: Either vaccine may be used for persons between 12 to 15 years of age.	**Children 6 months up to and including 15 years of age:** (In SK, AVAXIM Pediatric may be provided off-label to those 6-11 months). **Dose 1**: AVAXIM® - Pediatric 0.5 mL IM **Dose 2**: AVAXIM® - Pediatric 0.5 mL IM 6-36 months after dose
	Persons 12 years and older: **Dose 1**: AVAXIM® 0.5 mL IM **Dose 2**: AVAXIM® 0.5 mL IM 6-36 months after dose
REINFORCEMENT	Currently no recommendations.
CONTRAINDICATIONS	History of an anaphylactic reaction to a previous dose of any HA vaccine or to any AVAXIM® vaccine components.
VACCINE COMPONENTS	Inactivated hepatitis A virus, (GBM strain, Phenoxyethanol-Ethanol (50% v/v solution) with 2 phenoxyethanol (2.5 µL) and ethanol anhydrous (2.5 µL); Formaldehyde (12.5 mcg); Aluminum hydroxide, hydrated (expressed as aluminum 0.3 mg); 1 x C Medium 199 Hanks (up to 0.5 mL). 1 x C Medium 199 Hanks (without phenol red) is a complex mixture of amino acids (including phenylalanine), mineral salts, vitamins and other components supplemented with polysorbate 80 and is reconstituted in water for injection. Hydrochloric acid and or sodium hydroxide can be used for pH adjustment; these components are only present in trace amounts. Neomycin is also present in trace amounts Latex and thimerosal free.
EXPECTED REACTIONS	Tend to be mild and transient. **Local:** Pain, swelling, redness at injection site. **Systemic:** Weakness, myalgia/arthralgia, headache, gastrointestinal symptoms and mild fever.
EFFECTIVENESS	In clinical studies involving over 1,000 volunteers, specific humoral antibodies against hepatitis A were elicited after the first injection and more than 90% of immunocompetent subjects were protected (titres above 20 mIU/mL) 14 days after vaccination. One month after the first injection, 100% of the subjects were protected. Immunity persisted for at least 36 months and was reinforced after a first booster dose.

[1] HA vaccines are interchangeable for any scheduled dose for children and adults, using the age-specific dosage for the particular product.

Hepatitis A Vaccine (HA) (inactivated viral)

HAVRIX® (for Havrix® 1440 and Havrix® 720 Junior)

(GlaxoSmithKline 2023 monograph available at: https://ca.gsk.com/media/6243/havrix.pdf)

INDICATIONS	**Refer to publicly funded HA vaccine indications**
DOSE / SERIES [1] **NOTE: The product monograph recommends 1 dose as the primary immunization requirement for all ages; and 1 booster dose 6-12 months later to ensure long-term protections.** **SK recommended that 2 doses always be given to all clients as indicated.**	**Children 6 months up to and including 18 years of age:** (In SK, HAVRIX 720 may be provided off-label to those 6-11 months). **USE HAVRIX® pediatric presentation of 720 ELU per 0.5 mL** **Dose 1**: 0.5 mL IM **Dose 2**: 0.5 mL IM 6-12 months after dose 1
	Adults 19 years and older: (In SK, HAVRIX 1440 may be provided off-label to those 18 years old if another adult HA vaccine brand is unavailable). • **USE HAVRIX® adult presentation of 1440 ELU per 1 mL** **Dose 1**: 1 mL IM **Dose 2**: 1 mL IM 6-12 months after dose 1 [2]
REINFORCEMENT	Currently no recommendations.
CONTRAINDICATIONS	History of an anaphylactic reaction to a previous dose of any HA vaccine, or to any HAVRIX® vaccine components.
VACCINE COMPONENTS	HAVRIX 1440 contains: 1440 ELISA units per 1 mL of formaldehyde-inactivated hepatitis A virus (HM175 hepatitis A virus strain); HAVRIX 720 Junior contains: 720 ELISA units per 0.5 mL of formaldehyde-inactivated hepatitis A virus (HM175 hepatitis A virus strain). The virus is adsorbed on aluminium (0.5 mg/1 mL adult dose, 0.25 mg/0.5 mL pediatric dose) in the form of aluminium hydroxide. Excipients: aluminium (as aluminium hydroxide), amino acids for injection, disodium phosphate, monopotassium phosphate, polysorbate 20, potassium chloride, sodium chloride, water for injection. Residue from the manufacturing process: neomycin sulphate (less than 10 ng for HAVRIX 720 Junior; less than 20 ng for HAVRIX 1440). Thimerosal and latex free.
EXPECTED REACTIONS	Tend to be mild and transient. **Local:** Soreness, swelling and redness at injection site. **Systemic:** Headache, fatigue, fever, malaise, and gastrointestinal symptoms.
EFFECTIVENESS	Protective serum antibody levels in 95-100% of people within 4 weeks of immunization.

[1] HA vaccines are interchangeable for any scheduled dose for children and adults, using the age-specific dosage for the particular product.

[2] In SK, all eligible adult recipients must receive 1440 ELU for each publicly funded dose, even though studies show that 720 ELISA units may provide an effective 2nd HA dose in adults.

Hepatitis A Vaccine (HA) (purified inactivated viral)

VAQTA®
(Merck Canada Inc. monograph available at:https://www.merck.ca/en/wp-content/uploads/sites/20/2021/04/VAQTA-PM_E.pdf)

INDICATIONS	**Refer to publicly funded HA vaccine indications**
DOSE / SERIES [1]	**Eligible children 6 months up to and including 17 years**: (In SK, VAQTA Pediatric may be provided off-label to those 6-11 months). • **USE VAQTA® pediatric presentation of 25U per 0.5 mL** **Dose 1**: 0.5 mL IM **Dose 2**: 0.5 mL IM 6-12 months after dose 1
	Eligible adults 18 years and older: • **USE VAQTA® adult presentation of 50U per 1 mL** **Dose 1**: 1 mL IM **Dose 2**: 1 mL IM 6-12 months after dose 1
REINFORCEMENT	Currently no recommendations.
CONTRAINDICATIONS	History of an anaphylactic reaction to a previous dose of any HA vaccine, to any VAQTA® vaccine components, or to latex (vials).
VACCINE COMPONENTS	Hepatitis A virus protein, aluminum (as amorphous aluminum hydroxyphosphate sulfate), sodium borate, sodium chloride, water for injection. **Manufacturing process residuals:** Within the limits of current assay variability, the 50 unit (1 mL) dose of VAQTA® contains less than 0.1 mcg (less than 100 ng) of non-viral protein, less than 4 x 10-6 mcg (less than 0.004 ng) of DNA, less than 10-4 mcg (less than 0.1 ng) of bovine albumin, less than 0.8 mcg (less than 800 ng) of formaldehyde and a trace of neomycin [≤ 0.002 mcg (≤ 2 ng)]. Other process chemical residuals are less than 10 parts per billion (ppb). VAQTA® meets the World Health Organization requirement for biological substances including those for final vaccine residual bovine serum albumin. The vial stopper contains latex.
EXPECTED REACTIONS	**Local:** Soreness, swelling and redness at injection site. **Systemic:** Headache, fatigue, fever, malaise, and gastrointestinal symptoms.
EFFECTIVENESS	Protective serum antibody levels in 95-100% of people within 4 weeks of immunization.

[1] HA vaccines are interchangeable for any scheduled dose for children and adults, using the age-specific dosage for the particular product.

Hepatitis A and B Vaccine (combined) (HAHB)

[Not publicly funded]

TWINRIX® and TWINRIX® Junior

(GlaxoSmithKline 2023 product monograph available at: https://ca.gsk.com/media/6262/twinrix.pdf)

Adult presents with history of:	**HA completion** [1]	**HB completion** [2]
1 dose HAHB 1.0 ml	2 doses of HA adult	2 doses of HB 1.0 ml
2 doses HAHB 1.0 ml	1 dose of HA adult	1 dose of HB 1.0 ml
Child or adolescent presents with history of:	**HA completion** [1]	**HB completion** [2]
1 dose of HAHB 0.5 ml	2 doses of HA pediatric	2 doses of 0.5 ml HB
1 dose of HAHB 1.0 ml	1 dose of HA pediatric	**6 mo. – 10 years:** 2 doses of HB 0.5 ml **11 – 15 years**: 1 dose of HB 1.0 ml **16 – 19 years**: 2 doses of HB 0.5 ml
2 doses of HAHB 0.5 ml	1 dose of HA pediatric	1 dose of HB 0.5 ml
2 doses of HAHB 1.0 ml [3]	Complete	Complete

[1] See SIM chapter 10 biologics page Hepatitis A for appropriate dosing and scheduling for age.
[2] See SIM chapter 10 biologics page Hepatitis B for appropriate dosing and scheduling for age.
[3] Two doses of HAHB adult 1.0 mL given 24 weeks apart for age 6 months up to including age 15 years is considered a complete series.

Publicly Funded [1, 4]
Hepatitis B (HB) Vaccine Indications

- Those born since January 1, 1984.
- Grade 6 students.
- Children of immigrants to Canada from regions of intermediate or high HB prevalence.
  - This includes all children born before the family's arrival in Canada **and** all children born after the family's arrival in Canada.
  - Go to map at: https://wwwnc.cdc.gov/travel/yellowbook/2024/infections-diseases/hepatitis-b#4621
- AHA/SHA/SCA/FNJ Healthcare workers (refer to SIM Chapter 7 section 6.2).
- Select students of health care professions
- Those who started a publicly funded series in another jurisdiction.
- Non-immune individuals with bleeding disorders and others who receive repeated infusions of blood or blood products or plasma-derived replacement clotting factors.
- Individuals with congenital immunodeficiencies. [3]
- Individuals who are HIV positive who are non-immune to HB[3].
- Individuals who have liver disease (e.g., alcoholism, hepatitis C, cirrhosis) who are non-immune to HB.
- Individuals with renal disease (predialysis, hemodialysis & peritoneal dialysis) who are non-immune to HB [3].
- Liver or kidney transplant candidates or recipients who are non-immune to HB [2].
- Haematopoietic stem cell transplant (HSCT) recipients [2].
- Household/sexual/close contacts of individuals who have an acute or chronic HB infection [6].
  - Includes children in a childcare setting in which there is an HB infected individual.
- Males and females with multiple sexual partners.
- Men who have sex with men
- Individuals that use or share illicit drug snorting, smoking or injection equipment.
- Sexual partners and household contacts of individuals who use illicit drugs.
- Group home residents
- Provincial correctional facility residents.
- Infant born to a HBsAg+ mother or high-risk mother whose HB status at delivery is unknown and STAT test results cannot be obtained within 12 hours after delivery [5, 7].
- Percutaneous (e.g., needle stick, bite) or mucosal exposure (e.g., sexual assault) [4, 6, 7].

HB vaccine recommended for but not provided free: [8]

- Travellers to countries with endemic hepatitis B.
- Non-healthcare workers who have an occupational risk of exposure.

[1] Most SK residents born since 1984 would have received routine HB vaccine in Grade 6. If records are unavailable and the client does not recall receiving HB series, proceed with HB vaccine as per indication.

[2] Refer SIM, Chapter 7, *Immunization of Special Populations* for specific medical conditions.

[3]. Refer SIM, Chapter 7, *Immunization of Special Populations,* Appendix 7.4: *High Dose Hepatitis B Immunization Algorithm.*

[4] Refer to *Guidelines for the Management of Exposures to Blood and Body Fluids* recommendations available at: http://www.ehealthsask.ca/services/manuals/Pages/hiv-guidelines.aspx

[5] Refer to SIM, *Chapter 7, Immunization of Special Populations, Section 4.2.1, Hepatitis B Infant Immunoprophylaxis Protocol.*

[6] Must present within 14 days of sexual assault.

[7] Post-vaccination testing should be performed no sooner than 1 month after completion of HB vaccine series.

[8] These individuals should be referred to a travel clinic, family physician, nurse practitioner or pharmacist to receive non-publicly funded vaccine.

Publicly Funded Hepatitis B Vaccine Eligibility for Students of Health Care Professions

Publicly funded HB vaccine is free **only** for the listed unimmunized, under-immunized or non-immune students of health care professions who:

- Were born before 1984; and
- Are studying in and/or out-of-province; and
- Have a reasonable anticipated risk of HB exposure via blood and body fluids, and/or sharps injuries during training.

1. Undergraduate students in Medicine, Nursing, Dentistry, Pharmacy, Midwifery, Naturopathy, and Health Science Students (e.g., University Departments of Anatomy who may work with cadavers).
2. Students training to be:
   - Biomedical Engineers
   - Blood Perfusion Technologists
   - Cytogeneticists
   - Dental Assistants
   - Dental Hygienists
   - Dental Technicians
   - Dental Therapists
   - Electrophysiologists (human)
   - Embalmers and Funeral Directors
   - EMT/paramedics
   - Licensed Practical Nurses
   - Long Term Care Attendants
   - Medical Laboratory Technicians
   - Medical Office Assistants
   - Nurses' Aides
   - Personal Care Attendants
   - Psychiatric Nurses
   - Radiology Technicians
   - Rehabilitation Medicine Specialists
   - Respiratory Therapists
   - Residential Care Aides
   - Sterile Supply Workers

Notes:

A. Students without documentation of a HB series must be immunized with a complete HB vaccines series **and** be tested for serological antibodies at least 4 weeks post immunization.

B. Individuals who have documentation of a complete HB immunization series prior to enrolment as a student in a health care profession **and** whose response to their initial HB vaccination is unknown, **should be** tested for HBsAg, anti-HBs and anti-HBc Total.
   Consider those who have documentation of a complete HB vaccine series and antiHBs ≥ 10 IU/L as immune.
   However, if anti-HBs < 10 IU/L **and:**
   A. anti-HBs is *detectable*: provide 1 dose of vaccine and retest 4 weeks later:
      - If level is ≥ 10 IU/L, consider as immune and no further doses are required.
      - If level is < 10 IU/L, complete the second vaccine series and retest 4 weeks later.

   B. anti-HBs is *undetectable*: provide a second series and retest 4 weeks later.

   If anti-HBs remains < 10 IU/L after 2 HB vaccine series, consider as a non-responder and susceptible to HB.

Hepatitis B Vaccine - Immigrant Populations Ineligibility List

- Children of immigrants/refugees from countries not listed in this table are eligible for publicly funded HB vaccine prior to Grade 6.

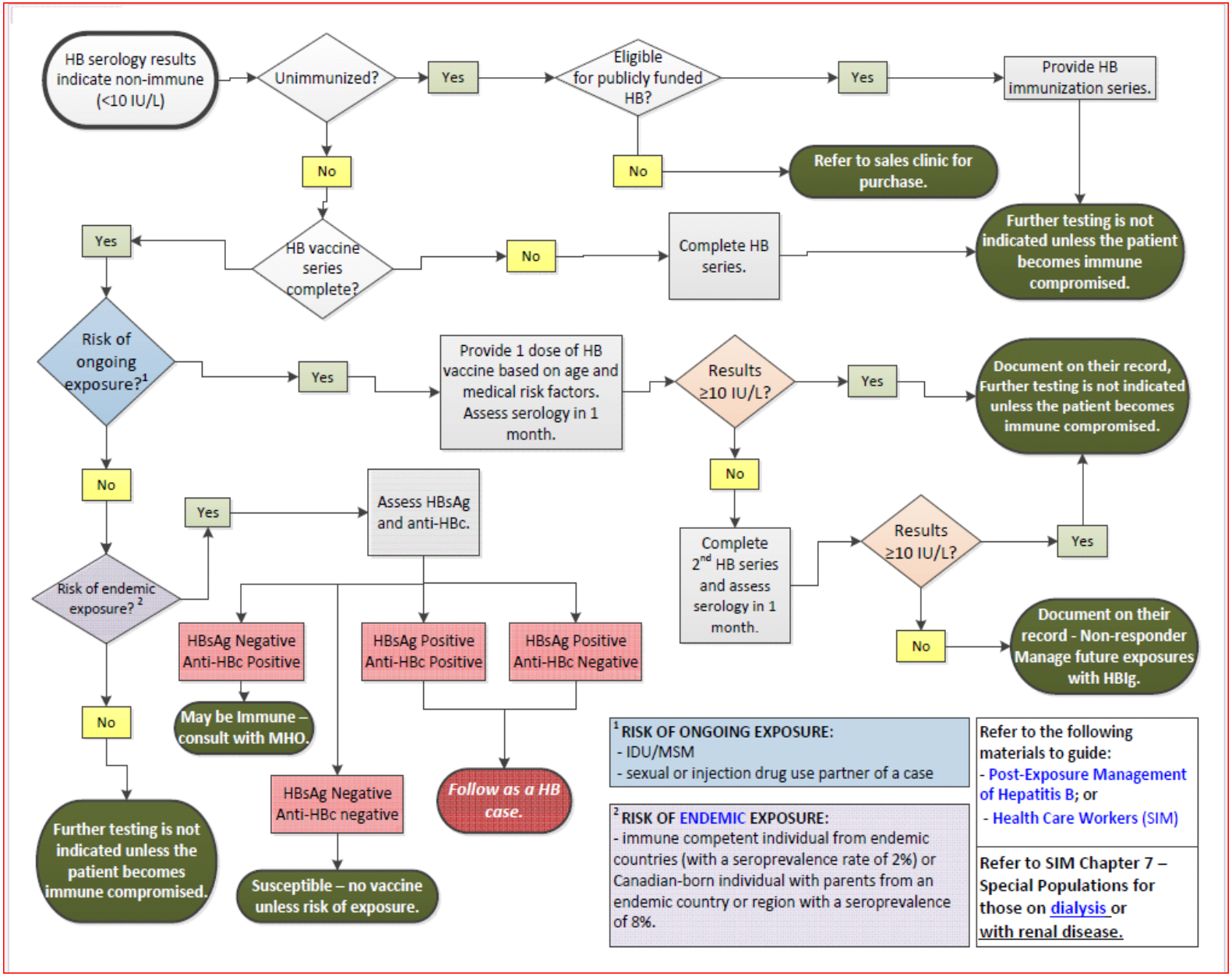
Afghanistan	Dominica	Japan	Poland
Belgium	Egypt	Jordan	Portugal
Andorra	Estonia	Latvia	Puerto Rico
Argentina	Finland	Lithuania	Slovakia
Australia	France	Luxembourg	Slovenia
Austria	French Guiana	Macedonia	Spain
Bahamas	Germany	Malaysia	St. Kitts
Barbados	Greece	Malta	St. Vincent
Belize	Grenada	Mexico	Sweden
Bolivia	Grenadines	Monaco	Switzerland
Bosnia	Guatemala	Montenegro	Trinidad
Brazil	Herzegovina	Morocco	Tobago
British Isles	Hungary	Nepal	Ukraine
Chile	Iceland	Netherlands	United Kingdom
Costa Rica	India	Nevis	Uruguay
Croatia	Indonesia	Nicaragua	USA
Cuba	Iran	Norway	Venezuela
Czech Republic	Iraq	Panama	Poland
Denmark	Ireland	Paraguay	Portugal

Hepatitis B Re-Vaccination Assessment Algorithm

This algorithm provides guidance in determining if vaccination is required in individuals that were tested for Hepatitis B immunity for no specific reason and have been assessed as non-immune for Hepatitis B. This algorithm should be used in conjunction with the eligibility criteria in Chapter 10.

This algorithm does not supersede Chapter 7 – dialysis patients; Chapter 10 – health care workers; or Post-exposure management of Exposures to Hepatitis B as outlined in the CDC Manual or the Guidelines for Exposures to Blood and Body Fluids or testing for Hepatitis B due to clinical suspicion

Ref: http://www.phac-aspc.gc.ca/publicat/hep/hbv-vhb/index-eng.php.



Hepatitis B Series Completion Recommendations for Children 11-15 Years Old

If a student has an incomplete HAHB or HB series:

1. The PHN should recommend completion of the original HAHB series [1].
2. If parent wishes to complete HB only, follow these Saskatchewan Committee on Immunization's (SCOI) recommendations for the appropriate scenario [2].
3. Applies to students in Grade 6 who are younger than 11 years old.

#	Historical (Valid) Dose(s) & Vaccine(s)	Dosing Recommendations / Comments
1	1) HAHB 0.5 ml at ≥ 6 months old	2) HB 0.5 ml min. 4 weeks later; then 3) HB 0.5 ml min. 8 weeks later from 2nd HB. There must be min. 16 weeks between 1st HB **&** 3rd HB.
2	1) HAHB 0.5 ml at ≥ 6 months old 2) HAHB 0.5 ml min. 4 weeks later	3) HB 0.5 ml min. 8 weeks later from 2nd HAHB. There must be min. 16 weeks between 1st HAHB **&** 3rd HB.
3	1) HAHB 0.5 ml at ≥ 6 months old 2) HAHB 1 ml min. 4 weeks later	3) HB 0.5 ml min. 8 weeks later from 2nd HAHB. There must be min. 16 weeks between 1st HAHB & 3rd HB.
4	1) HAHB 0.5 ml at ≥ 6 months old 2) HB 0.5 ml min. 4 weeks later	3) HB 0.5 ml min. 8 weeks later from 2nd HB. There must be min. 16 weeks between 1st HAHB **&** 3rd HB.
5	1) HAHB 0.5 ml at ≥ 6 months old 2) HB 1 ml min. 4 weeks later	3) HB 0.5 ml min. 8 weeks later from 2nd HB. There must be min. 16 weeks between 1st HAHB **&** 3rd HB.
6	1) HAHB 1 ml at ≥ 6 months old	2) HB 1.0 ml ≥ 24 weeks (min. 16 weeks) later.
7	1) HAHB 1 ml at ≥ 6 months old 2) HB 0.5 ml min. 4 weeks later	3) HB 0.5 ml min. 8 weeks later from 2nd HB. There must be min. 16 weeks between 1st HAHB **&** 3rd HB.
8	1) HAHB 1 ml at ≥ 6 months old 2) HB 1 ml min. 4 weeks later but less than 16 weeks	3) HB 0.5 ml min. 8 weeks later from 2nd HB. There must be min. 16 weeks between 1st HAHB **&** 3rd HB.
9	1) HB 0.5 ml at any age 2) HAHB 0.5 ml at ≥ 6 months old, min. 4 weeks later	3) HB 0.5 ml min. 8 weeks later from 2nd HAHB. There must be min. 16 weeks between 1st HB **&** 3rd HB.
10	1) HB 0.5 ml at any age 2) HAHB 1 ml at ≥ 6 months old, min. 4 weeks later	3) HB 0.5 ml min. 8 weeks later from 2nd HAHB. There must be min. 16 weeks between 1st HB **&** 3rd HB.
11	1) HB 1 ml at any age 2) HAHB 0.5 ml at ≥ 6 months old, min. 4 weeks later but less than 16 weeks	3) HB 0.5 ml min. 8 weeks later from 2nd HB. There must be min. 16 weeks between 1st HB **&** 3rd HB.
12	1) HB 1 ml at any age 2) HAHB 1 ml at ≥ 6 months old, min. 16 weeks later	Considered complete (CIG HB Table 3).
13	1) HAHB 1 ml at ≥ 6 months old 2) HB 1 ml min. 16 weeks later	Considered complete (CIG HB Table 3).
14	1) HAHB 1 ml at ≥6 months old 2) HAHB 1 ml min. 24 weeks later	Considered complete (CIG HB Table 3).

[1] If completing with HAHB, document HB refusal. Document in the Comments section of the consent directives: "Parent intends to complete HAHB to complete series."

[2] Document consent grant.

Hepatitis B Completion Scenarios (excluding children 11-15 years old)

- If a client was immunized by **Public Health in Saskatchewan**, SIM chapter 1, *Appendix 5.1 School Immunization Programs* **may be** consulted to determine the HB series the client was eligible for.
- If a client's documented immunization record does not show the HB-containing vaccine volumes **and** the client **was not immunized by Public Health in Saskatchewan** for previous doses in which a minimum 3-dose series has not been completed, it is recommended that:
  - 0.5 mL HB doses are administered to clients younger than 20 years of age at appropriate intervals to complete a 3-dose series.
  - 1 mL HB doses are administered to clients 20 years of age and older at appropriate intervals to complete a 3-dose series.
- **PHNs are to consult their regional MHO for case-by-case determination** before contacting the Ministry.

Scenario A: Client originally started on a 2-dose series when 11-15 years (or at 10 years old and in Grade 6):

#1 Q – A client between 16-19 years of age needs to complete the HB series. They received their first dose (1 mL) of a two dose series in Grade 6, when they were between 11-15 years of age. How should their series be completed?
#1 A – If the minimum interval of 4 weeks has passed since the first dose, and based on their age at this presentation, their schedule is complete when the get:

- A 2nd dose of 0.5 mL IM HB vaccine then;
- A 3rd dose of 0.5 mL IM HB vaccine 8 weeks after the second dose and at least 16 weeks after dose 1.

#2 Q – A client aged ≥ 20 years needs to complete the HB series. They received their first dose (1 mL) of a two dose series in Grade 6, when they were between 11-15 years of age. How should their series be completed?
#2 A – If the minimum interval of 4 weeks has passed since the first dose, and based on their age at this presentation, their schedule is complete when the get:

- A 2nd dose of 1 mL IM HB vaccine then;
- A 3rd dose of 1 mL IM HB vaccine 8 weeks after the second dose and at least 16 weeks after dose 1.

Scenario B: Client originally started on a 3-dose series of 0.5 mL

#3 Q – A client received their first and/or second dose(s) of 0.5 mL between 0-19 years, and presents between ages 0-19. How should the series be completed?
#3 A – Complete the series with 0.5 mL IM for each outstanding dose.

- A 2nd dose of 0.5 mL IM HB vaccine 4 weeks later (if required) then;
- A 3rd dose of 0.5 mL IM HB vaccine 8 weeks after the second dose and at least 16 weeks after dose 1.

#4 Q – If client received first and/or second dose of 0.5 mL dose between 0-19 years and presents ≥ age 20 years or older. How should their series be completed?
#4 A – Complete the series with 1 mL IM for each outstanding dose.

- A 2nd dose of 1 mL IM HB vaccine 4 weeks later (if required) then;
- A 3rd dose of 1 mL IM HB vaccine 8 weeks after the second dose and at least 16 weeks after dose 1.

Hepatitis B Vaccine (HB) (recombinant viral)

ENGERIX®-B

(GlaxoSmithKline 2023 monograph available at: https://ca.gsk.com/media/6239/engerix-b.pdf)

INDICATIONS	Refer to publicly funded HB vaccine indications
DOSE / SERIES [1, 2, 3, 4] **NOTE: Accelerated and Rapid vaccination Schedules noted in the product monograph should not be administered for publicly funded indications.**	**Children from birth up to and including 19 years old:** • **USE ENGERIX-B pediatric formulation 10 mcg per 0.5 mL** 0.5 ml IM (10 mcg) at 0, 1 and 6 months[5] or refer to minimum intervals in Ch. 5.
	2-dose regimen for adolescents 11 to 15 years of age (including Grade 6 students younger than 11 years old): • **USE ENGERIX-B adult formulation 20 mcg per 1 mL** **Dose 1**: 1 mL (20 mcg) IM **Dose 2**: 1 mL (20 mcg) IM 6 months after dose 1
	Eligible adults 20 years and older: • **USE ENGERIX-B adult formulation 20 mcg per 1 mL** 1 ml (20 mcg) IM at 0, 1 and 6 months
	Those with renal disease, HIV and Congenital Immunodeficiency Disorder [3] Refer to SIM, Chapter 7, *Appendix 7.4 High Dose Hepatitis B Immunization Algorithm*
REINFORCEMENT	Currently no recommendations.
CONTRAINDICATIONS	History of anaphylactic reaction to a previous dose of any hepatitis B vaccine or to any component of Engerix-B.
VACCINE COMPONENTS	Each 1.0 mL adolescent/adult dose of vaccine contains 20 mcg of hepatitis B surface antigen adsorbed onto 0.5 mg of Al3+ as aluminum hydroxide. Each 0.5 mL pediatric dose contains 10 mcg of hepatitis B surface antigen adsorbed onto 0.25 mg of Al3+ as aluminum hydroxide. Aluminium (as aluminium hydroxide), disodium phosphate dihydrate, sodium chloride, sodium dihydrogen phosphate dihydrate, and water for injection. Preservative, thimerosal and latex free. Rubber stoppers.
EXPECTED REACTIONS	**Local:** Soreness, swelling and redness at injection site. **Systemic:** Headache, fatigue, fever, nausea and malaise.
EFFECTIVENESS	50-99% response-varies with age and immunocompetence.

[1] Engerix®-B & RecombivaxHB® are interchangeable at any dose, using age-specific dosage and recommended schedule for the particular product.

[2] Refer to SIM, Chapter 5, *Immunization Schedules,* Section 2.1, *Minimum Intervals for Specific Vaccine Series* for minimum interval scheduling.

[3] Those with renal disease, HIV and Congenital Immunodeficiency Disorder require a specific HB vaccine dosage and series; refer to SIM, Chapter 7, *Appendix 7.4 High Dose Hepatitis B Immunization Algorithm*.

[4] High risk infants less than 2000 g require 4 dose series. Refer to SIM, Chapter 7, *Immunization of Special Populations,* Section 4.2.1, *Hepatitis B Infant Immunoprophylaxis Protocol.*

[5] Infant must be at least 24 weeks of age to receive 3rd dose.

- If a client was immunized by Public Health in Saskatchewan, SIM Chapter 1, Appendix 5.1 School Immunization Programs may be consulted to determine the HB series the client was eligible for.
- If a client's documented immunization record does not show the HB-containing vaccine volumes and the client was not immunized by Public Health in Saskatchewan for previous doses in which a minimum 3-dose series has not been completed, it is recommended that:
  - 0.5 mL HB doses are administered to clients younger than 20 years of age at appropriate intervals to complete a 3-dose series.
  - 1 mL HB doses are administered to clients 20 years of age and older at appropriate intervals to complete a 3-dose series.
  - PHNs are to consult their regional MHO for case-by-case determination before contacting the Ministry.

Hepatitis B Vaccine (recombinant)

RECOMBIVAX HB®

(Merck Canada product monograph available at: https://www.merck.ca/en/wp-content/uploads/sites/20/2021/04/RECOMBIVAX_HB-PM_E.pdf)

INDICATIONS	Refer to publicly funded HB vaccine indications
DOSE / SERIES [1, 2, 3, 4]	**Eligible children from birth up to and including 19 years:** • **USE RECOMBIVAX® HB pediatric formulation 5 mcg per 0.5 mL** 0.5 ml IM (5 mcg) at 0, 1 and 6 months[5] or refer to minimum intervals in Ch. 5.
	2-dose regimen for adolescents 11 to 15 years of age (including Grade 6 students younger than 11 years old): • **USE RECOMBIVAX ® HB adult formulation 10 mcg per 1 mL** **Dose 1**: 1 mL (10 mcg) IM **Dose 2**: 1 mL (10 mcg) IM 6 months after dose 1
	Eligible adults 20 years and older: • **USE RECOMBIVAX ® HB adult formulation 10 mcg per 1 mL** 1 mL (10 mcg) IM at 0, 1 and 6 months
	Those with renal disease, HIV and Congenital Immunodeficiency Disorder [3] Refer to SIM, Chapter 7, *Appendix 7.4 High Dose Hepatitis B Immunization Algorithm*
REINFORCEMENT	Currently no recommendations.
CONTRAINDICATIONS	History of anaphylactic reaction to a previous dose of any hepatitis B vaccine or to any component of RECOMBIVAX® HB.
PRECAUTION	Use caution when vaccinating latex-sensitive individuals since the vial stopper contains dry natural latex rubber that may cause allergic reactions.
VACCINE COMPONENTS	Hepatitis B surface antigen. **Excipients:** Aluminum (as amorphous aluminum hydroxyphosphate), sodium chloride, sodium borate, water for injection. **Manufacturing Process Residuals**: Each dose contains less than 1% yeast protein. The vaccine also contains < 15 mcg/mL formaldehyde as all preparations have been treated with formaldehyde prior to adsorption onto amorphous aluminum hydroxyphosphate. Thimerosal free.
EXPECTED REACTIONS	**Local:** Soreness, swelling and redness at injection site. **Systemic**: Headache, fatigue, fever, nausea and malaise.
EFFECTIVENESS	50-99% response-varies with age and immunocompetence.

[1] Engerix®-B & RECOMBIVAX HB® are interchangeable at any dose, using age-specific dosage and recommended schedule for the particular product.

[2] Refer to SIM, Chapter 5, *Immunization Schedules,* Section 2.1, *Minimum Intervals for Specific Vaccine Series* for minimum interval scheduling.

[3] Those with renal disease, HIV and Congenital Immunodeficiency Disorder require a specific HB vaccine dosage and series; refer to SIM, Chapter 7, *Appendix 7.4 High Dose Hepatitis B Immunization Algorithm*.

[4] High risk infants less than 2000 g require 4 dose series. Refer to SIM, Chapter 7, *Immunization of Special Populations,* Section 4.2.1, *Hepatitis B Infant Immunoprophylaxis Protocol.*

[5] Infant must be at least 24 weeks of age to receive 3rd dose.

- If a client was immunized by **Public Health in Saskatchewan**, SIM Chapter 1, *Appendix 5.1 School Immunization Programs* **may be** consulted to determine the HB series the client was eligible for.
- If a client's documented immunization record does not show the HB-containing vaccine volumes **and** the client **was not immunized by Public Health in Saskatchewan** for previous doses in which a minimum 3-dose series has not been completed, it is recommended that:
  - 0.5 mL HB doses are administered to clients younger than 20 years of age at appropriate intervals to complete a 3-dose series.
  - 1 mL HB doses are administered to clients 20 years of age and older at appropriate intervals to complete a 3-dose series.
  - **PHNs are to consult their regional MHO for case-by-case determination** before contacting the Ministry.

Hepatitis B Vaccine
(3-antigen Hepatitis B Vaccine (recombinant)) [Non-publicly funded]

PREHEVBRIO™
(VBI Vaccines 2023 product monograph available at (https://pdf.hres.ca/dpd_pm/00069966.PDF)

Herpes Zoster Vaccine (RZV)
(non-live recombinant, $AS01_B$ adjuvanted) [Non-publicly funded]

Shingrix™
(GSK 2022 monograph available at: https://ca.gsk.com/media/6259/shingrix-pm-en.pdf)

Human Papillomavirus Vaccine

[Non-publicly funded]

CERVARIX® (HPV-2)

(GlaxoSmithKline 2023 monograph link https://ca.gsk.com/media/6236/cervarix.pdf)

Human Papillomavirus 9-valent Vaccine (recombinant)

GARDASIL®9 (HPV-9)

(Merck Canada Inc. 2023 monograph available at https://www.merck.ca/en/wp-content/uploads/sites/20/2021/04/GARDASIL_9-PM_E.pdf

PUBLICLY FUNDED INDICATIONS	• Grade 6 students
	• Females (at birth) born since January 1, 1996, and males (at birth) born since January 1, 2006, up to and including 26 years old.
	• Immunocompromised females and males aged 9 up to and including 26 years old.
	NOTE: Individuals who are eligible to receive publicly funded HPV-9 vaccine must start their series prior to age 27.
	  • If their first dose is given prior to age of 27, then subsequent publicly funded doses can be given to complete series after this age.
	  • If series is not started before 27th birthday, they are ineligible to start a publicly funded series.

SERIES
 	
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Note: immune compromised individuals must always receive a 3-dose HPV series.
	• **2-dose schedule**: 0.5 mL IM at 0 and 6 months for those 9 to 14 years of age
	  ➢ Persons who received their first HPV dose before their 15th birthday **must** complete the 3-dose schedule if they present for their second dose after their 15th birthday.
	• **3-dose schedule**: 0.5 mL IM at 0, 2, and 6 months for eligible immune competent persons ≥15 years of age up to and including 26 years of age (ineligible at 27th birthday).
	--- 	
	• **3-dose schedule**: 0.5 mL IM at 0, 2, and 6 months for females (at birth) and males (at birth) aged 9 up to and including 26 years of age with the following risk factors (ineligible at 27th birthday). **NOTE: Birth cohort eligibility (as described above under Publicly Funded Indications) does not apply to these risk factors; age at presentation applies.**
	  ➢ Immunocompromised – Acquired complement deficiency
	  ➢ Immunocompromised – Congenital immunodeficiency
	  ➢ Immunocompromised – HIV
	  ➢ Immunocompromised – Related to Disease
	  ➢ Immunocompromised – Treatment – Additional Information

REINFORCEMENT	Currently no recommendations.
NOTE	GARDASIL®9 should be used to complete an HPV series that was initiated with HPV-u, HPV-2 or HPV-4. Clients should be informed that a complete series of GARDASIL®9 is recommended to ensure protection against the five additional HPV types in the vaccine; however, additional doses of GARDASIL®9 beyond a complete HPV series for healthy or immune compromised individuals **are not part of the publicly-funded program**.
CONTRA-INDICATIONS	History of anaphylactic reaction to a previous dose of a HPV vaccine, or to any component of GARDASIL®9.

Human Papillomavirus 9-valent Vaccine (recombinant)

GARDASIL®9 (HPV-9)

Merck Canada Inc. 2023 monograph available at https://www.merck.ca/en/wp-content/uploads/sites/20/2021/04/GARDASIL_9-PM_E.pdf:

VACCINE COMPONENTS	Each 0.5-mL dose contains approximately 30 mcg of HPV Type 6 L1 protein, 40 mcg of HPV Type 11 L1 protein, 60 mcg of HPV Type 16 L1 protein, 40 mcg of HPV Type 18 L1 protein, 20 mcg of HPV Type 31 L1 protein, 20 mcg of HPV Type 33 L1 protein, 20 mcg of HPV Type 45 L1 protein, 20 mcg of HPV Type 52 L1 protein, and 20 mcg of HPV Type 58 L1 protein, approximately 500 mcg of aluminum (as Amorphous Aluminum Hydroxyphosphate Sulfate adjuvant), 0.78 mg of L-histidine, 50 mcg of polysorbate 80, 35 mcg of sodium borate, 9.56 mg of sodium chloride, and water for injection. Latex, antibiotic and preservative free.
EXPECTED REACTIONS	**Local:** Mild to moderate pain, swelling, erythema and pruritus at injection site. **Systemic:** Headache, tiredness, fever, nausea, dizzyness. **Reported post-market**: vomiting, swollen glands (neck, armpit, or groin), Guillain-Barré syndrome, joint pain, aching muscles, unusual tiredness, weakness, or confusion, chills, stomach ache, muscle weakness, leg pain, shortness of breath, generally feeling unwell, bleeding or bruising more easily than normal, and skin infection.
EFFECTIVENESS	Please refer to the product monograph for data for females and males in specific age categories.
OTHER CONSIDERATIONS	• Immunization with HPV vaccine does not remove the need for screening for cervical, vulvar, vaginal, anal, and certain head and neck cancers, such as throat and back of mouth cancers as recommended by a health care professional; women should still get routine cervical cancer screening. • It is not known whether GARDASIL®9 is excreted in human milk. • There are no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, pregnancy should be avoided during the vaccination regimen for GARDASIL®9. Women who become pregnant before completion of the vaccine series should complete their vaccination schedule after childbirth. Pregnant women exposed to GARDASIL® are encouraged to report their exposure or suspected adverse reactions by contacting Merck Canada Inc., at 1-800-567-2594.

Influenza Vaccines 2023-24 [Non-Publicly Funded]

FLUAD® Pediatric and FLUAD®, and FLUCELVAX® QUAD
Seqirus product monographs available at https://www.cslseqirus.ca/products

FLUMIST® QUADRAVALENT
AstraZeneca product monograph available at https://www.astrazeneca.ca/en/our-medicines.html

Supemtek™
Sanofi Pasteur product monograph available at https://www.sanofi.ca/en/products-and-resources/vaccines

Influenza Vaccine (Inf) 2023-24
(inactivated split virion)

AFLURIA® TETRA
Seqirus Afluria Tetra 2023 product monograph

INDICATION	**DOSE / SERIES (Min. 5 years old)**		
Prevention of seasonal influenza **in those 5 years and older**	**Age group**	**Dosage**	**No. of Doses**
	5-8 years	**0.5 mL**	**1 or 2** [1]
	9 years and older	**0.5 mL**	**1**
CONTRA-INDICATIONS	1. History of anaphylactic reaction to a previous dose of any type of influenza vaccine. 2. History of anaphylactic reaction to any component of this influenza vaccine (e.g., certain antibiotics). 3. History of Guillain-Barré syndrome (GBS) within 6 weeks of receipt of a previous dose of influenza vaccine without another cause being identified. 4. Children younger than 5 years old.		
PRECAUTIONS	Severe oculo-respiratory syndrome (ORS) after a previous dose of influenza vaccine.		
VACCINE COMPONENTS	Each 0.5 mL dose of vaccine contains 15 micrograms haemagglutinin of each of the following four influenza virus strains: A/Victoria/4897/2022 (H1N1)pdm09-like virus (A/Victoria/4897/2022 IVR-238); A/Darwin/9/2021 (H3N2)-like virus (A/Darwin/6/2021 IVR-227); B/Austria/1359417/2021-like virus (B/Austria/1359417/2021 BVR-26); and B/Phuket/3073/2013-like virus (B/Phuket/3073/2013 BVR-1B)Non-medicinal ingredient: calcium chloride, dibasic sodium phosphate (anhydrous), monobasic potassium phosphate, monobasic sodium phosphate, potassium chloride, sodium chloride, thimerosal and water for injection. Each dose may also contain sodium taurodeoxycholate, ovalbumin (egg proteins) and trace amounts of beta-propiolactone, neomycin sulfate, polymyxin B sulfate, hydrocortisone and sucrose. Contains thimerosal. Latex-free.		
EXPECTED REACTIONS	In adults 18 to < 65 years, the most commonly reported injection-site adverse reaction observed in clinical studies with AFLURIA® TETRA was pain (≥ 40%). The most common systemic adverse events observed were myalgia (≥ 25%). and headache (≥ 20%). In adults ≥ 65 years of age, the most commonly reported injection-site adverse reaction observed in clinical studies with AFLURIA® TETRA was pain (≥ 20%). The most common systemic adverse event observed was myalgia (≥ 10%).		
ADVERSE EVENTS	Immediate, allergic-type responses, such as hives, allergic asthma, or systemic anaphylaxis occur extremely rarely.		
SPECIAL CONSIDERATIONS	Discard multi-dose vials 28 days after first entry. Protect from light. Do not freeze.		
EFFECTIVENESS	Refer to product monograph as data depends on age and studies design.		

[1] Children under 9 years of age who have not previously received seasonal influenza vaccine require 2 doses given 4 weeks apart. If the child has received 1 or more doses in any previous season, only a single dose is required.

Influenza Vaccine (Inf) (inactivated split virion)

FLULAVAL TETRA®

GlaxoSmithKline product monograph:

INDICATION	**DOSE / SERIES (Min. 6 months old)**		
Prevention of seasonal influenza	**Age group**	**Dosage**	**No. of Doses**
	6 months-8 years	**0.5 mL**	**1 or 2** [1]
	9 years and older	**0.5 mL**	**1**
CONTRA-INDICATIONS	1. History of anaphylactic reaction to a previous dose of any type of influenza vaccine. 2. History of anaphylactic reaction to any component of any influenza vaccine. 3. History of Guillain-Barré syndrome (GBS) within 6 weeks of receipt of a previous dose of influenza vaccine without another cause being identified. 4. Infants less than 6 months of age.		
PRECAUTIONS	Severe oculo-respiratory syndrome (ORS) after a previous dose of influenza vaccine.		
VACCINE COMPONENTS	Each 0.5 mL dose of vaccine contains 15 micrograms haemagglutinin of each of the four influenza virus strains recommended annually by the WHO. The vaccine is formulated with phosphate buffered saline composed of sodium chloride, potassium chloride, disodium hydrogen phosphate heptahydrate, potassium dihydrogen phosphate and water for injection. Each 0.5 mL dose contains, α-tocopheryl hydrogen succinate (267 μg), and polysorbate 80 (683 μg). Each 0.5 mL dose may also contain residual amounts of egg proteins (ovalbumin ≤0.3μg), sodium deoxycholate, ethanol, formaldehyde and sucrose from the manufacturing process. The multidose vial presentation contains thimerosal, a mercury derivative, added as a preservative. Each 0.5 mL dose contains 50 mcg thimerosal. The single-dose prefilled syringe presentation does not contain thimerosal or any other preservative. Antibiotics are not used in the manufacture of this vaccine.		
EXPECTED REACTIONS	In adults, the most common (≥10%) solicited local reaction was pain (60%); the most common solicited systemic adverse events were myalgia (26%), headache (22%), fatigue (22%), and arthralgia (15%). In children 3 to 17 years of age, the most common (≥10%) solicited local reaction was pain (65%). In children 3 to 4 years of age, the most common (≥10%) solicited systemic adverse events were irritability (26%), drowsiness (21%), and loss of appetite (17%). In children 5 to 17 years of age, the most common (≥10%) systemic adverse events were muscle aches (29%), fatigue (22%), headache (22%), arthralgia (13%), and gastrointestinal symptoms (10%). In children 6 to 35 months of age, injection site pain was the most common (≥10%) solicited local reaction (40%). The most common solicited systemic adverse events were irritability (49%), drowsiness (37%), and loss of appetite (29%).		
ADVERSE EVENTS	Immediate, allergic-type responses, such as hives, allergic asthma, or systemic anaphylaxis occur extremely rarely.		
SPECIAL CONSIDERATIONS	Discard multi-dose vials 28 days after first entry. Protect from light. Do not freeze.		
EFFECTIVENESS	Refer to product monograph as data depends on age and studies design.		

[1] Children under 9 years of age who have not previously received seasonal influenza vaccine require 2 doses given 4 weeks apart. If the child has received 1 or more doses in any previous season, only a single dose is required.

Influenza Vaccine (Inf)
(inactivated quadrivalent split virion)

FLUZONE® Quadrivalent
Sanofi Pasteur product monograph

INDICATION	**DOSE / SERIES (Min. 6 months old)**		
Prevention of seasonal influenza	Age group	Dosage	No. of Doses
	6 months-8 years	0.5 mL	1 or 2 [1]
	9 years and older	0.5 mL	1
CONTRA-INDICATIONS	1. History of anaphylactic reaction to a previous dose of any type of influenza vaccine. 2. History of anaphylactic reaction to any component of any influenza vaccine. 3. History of Guillain-Barré syndrome (GBS) within 6 weeks of receipt of a previous dose of influenza vaccine without another cause being identified. 4. Infants less than 6 months of age.		
PRECAUTIONS	Severe oculo-respiratory syndrome (ORS) after previous receipt of an influenza vaccine.		
VACCINE COMPONENTS	FLUZONE® Quadrivalent 0.5 mL dose contains 15 mcg HA of each of the four influenza strains recommended annually by the WHO. Each 0.5 mL dose: ≤100 mcg formaldehyde, up to 0.5 mL sodium phosphate buffered, isotonic sodium chloride solution and ≤250 mcg Triton® X-100. 0.01% w/v thimerosal in multidose presentation only (25 mcg mercury/0.5 mL dose). Latex, antibiotic and gelatin free.		
EXPECTED REACTIONS	**Very common (≥10%)**: pain at the injection site, myalgia, headache, myalgia and malaise. **Common (≥1% to <10%)**: shivering; redness, swelling, induration and ecchymosis at the injection site, fever. **Children 6 months-35 month** of age also experienced irritability, abnormal crying, drowsiness, loss of appetite and vomiting.		
ADVERSE EVENTS	Immediate, allergic-type responses, such as hives, allergic asthma, or systemic anaphylaxis occur extremely rarely.		
SPECIAL CONSIDERATIONS	Protect vials from light. A multidose vial of FLUZONE® Quadrivalent which has been entered and stored at 2° to 8° C may be used up to the expiry date indicated on the vial label. Do not freeze.		
EFFECTIVENESS	Refer to product monograph as data depends on age and studies design.		

[1] Children under 9 years of age who have not previously received seasonal influenza vaccine require 2 doses given 4 weeks apart. If the child has received 1 or more doses in any previous season, only a single dose is required.

Influenza High Dose Vaccine (InfHD QIV) (inactivated trivalent split virion)

FLUZONE® High Dose Quadrivalent
Sanofi Pasteur product monograph

INDICATION	Prevention of seasonal influenza in those ≥ 65 years old
DOSE / SERIES	0.7 mL IM annually.
CONTRA-INDICATIONS	1. History of anaphylactic reaction to a previous dose of any type of influenza vaccine 2. History of anaphylactic reaction to any component of any influenza vaccine. 3. History of Guillain-Barré syndrome (GBS) within 6 weeks of receipt of a previous dose of influenza vaccine without another cause being identified.
PRECAUTIONS	Severe oculo-respiratory syndrome (ORS) after previous receipt of an influenza vaccine.
VACCINE COMPONENTS	FLUZONE® High Dose contains: 60 mcg HA of each influenza strain recommended annually by the WHO. Each dose: ≤ 350 mcg octylphenol ethoxylate (Triton® X-100), ≤ 200 mcg/mL formaldehyde and up to 0.7 mL sodium phosphate buffered, isotonic sodium chloride solution. Each dose may contain traces of ovalbumin. Latex, antibiotic and thimerosal free.
EXPECTED REACTIONS	The most common reactions occurring after FLUZONE® High-Dose Quadrivalent administration were injection site pain (41%), myalgia (23%), headache (14%) and malaise (13%). Onset usually occurred within the first 3 days after vaccination. The majority of solicited reactions resolved within three days of vaccination.
ADVERSE EVENTS	Immediate, allergic-type responses, such as hives, allergic asthma, or systemic anaphylaxis occur extremely rarely.
SPECIAL CONSIDERATIONS	Protect vials from light. Do not freeze. Shake the prefilled syringe well to uniformly distribute the suspension before administering the dose.
EFFECTIVENESS	Immunogenicity of FLUZONE® High-Dose Quadrivalent was found to be non-inferior to FLUZONE® High-Dose. The pre-defined non-inferiority immunogenicity criteria for FLUZONE® High-Dose Quadrivalent were met for both GMTs and seroconversion rates for all four of the influenza strains common between the two vaccines. Additionally, FLUZONE® High-Dose Quadrivalent induced a higher immune response, as measured by GMTs and seroconversion rates, with respect to the additional B strain than the immune response induced by FLUZONE® High Dose that does not contain the corresponding B virus.

Japanese Encephalitis Vaccine

[Non-publicly funded]

IXIARO®

(Valneva 2018 product monograph available at: https://www.valneva.ca/en/

Measles-Mumps-Rubella Vaccine (MMR) (live, attenuated)

M-M-R® II (Merck Canada Inc. product monograph available at:https://www.merck.ca/en/wp-content/uploads/sites/20/2021/04/MMR_II-PM_E.pdf)

INDICATIONS [1] ▪ Series for those born **since** January 1, 1970 who are 12 months and older. According to CIG, 1 dose of rubella is considered sufficient for immunity in all ages. Refer to *Appendix 5.2: Publicly Funded MMR Vaccine Eligibility.* ▪ Recommended for post-exposure prophylaxis of measles contacts as outlined in the Saskatchewan Communicable Disease Control Manual. ▪ **Additional indications** as noted in SIM Chapter 5, *Appendix 5.2: Publicly Funded MMR Vaccine Eligibility.* • 1 dose for some adult travellers born before January 1, 1970. • Infants 6-11 months old who are travelling abroad may be offered 1 early publicly funded dose of MMR.	**DOSE / SERIES** **Dose 1**: 0.5 mL SC **Dose 2**: 0.5 mL SC minimum 4 weeks later

REINFORCEMENT	Not indicated after 2 MMR doses.
PRECAUTIONS	• MMR should be given at the same time as other live vaccines. Otherwise there must be 4 or more weeks between administering live vaccines. • For immune compromised clients only: separate the administration of MMR and Var by 4 weeks. • Anti-Rho (D) immune globulin may interfere with response to the rubella component of the vaccine. Rubella-susceptible women who receive anti-Rho (D) immune globulin post-partum should either be given MMR vaccine at the same time and tested 3 months later for rubella immunity, or should be immunized with MMR vaccine 3 months post-partum, with follow-up ensured (CIG). • Do TB skin testing on the same day as MMR immunization, or delay TB skin testing for 4 weeks. • Family history of congenital immunodeficiency. Refer to SIM, Chapter 6, *Contraindication and Precautions.* • Physician or NP diagnosed thrombocytopenia within 6 weeks after first dose of a MMR-containing vaccine.
CONTRA-INDICATIONS	• History of anaphylactic reaction to a previous dose of a measles/mumps/rubella-containing vaccine, to any component of MMRII. • **Immunocompromised individuals unless determined by their specialist.** Refer to SIM, Chapter 7, *Immunization of Special Populations,* under specific condition for information. • Pregnancy. Counsel female recipients to avoid pregnancy for 1 month following immunization. Inadvertent immunization during pregnancy is not considered a medical indication for therapeutic abortion. • People with active untreated tuberculosis. • Recent administration of an immune globulin preparation or blood product [3]
VACCINE COMPONENTS	Measles virus, Enders' Edmonston strain (live, attenuated); Mumps virus, Jeryl Lynn® (B level) strain (live, attenuated); and Rubella virus, Wistar RA 27/3 strain (live, attenuated). **Excipients**: sorbitol, hydrolyzed gelatin, medium 199 with Hank's salts, sodium phosphate monobasic, sodium phosphate dibasic (anhydrous), sucrose, sodium bicarbonate, minimum essential medium (Eagle), potassium phosphate dibasic (anhydrous), neomycin, monosodium L-glutamate monohydrate, potassium phosphate monobasic, phenol red, water for injection. **Manufacturing process residuals:** Recombinant human albumin, fetal bovine serum, may contain minute quantities of egg protein. Preservative, latex and thimerosal free.

Measles-Mumps-Rubella Vaccine (MMR) (live, attenuated) **M-M-R® II** (Merck Canada Inc. product monograph available at: https://www.merck.ca/en/wp-content/uploads/sites/20/2021/04/MMR_II-PM_E.pdf)	
EXPECTED REACTIONS	**Local:** Tenderness, redness, swelling, induration, wheal and flare reaction, urticaria. **Systemic:** • A fever lasting up to 3 days may occur 6 to 23 days after immunization. Monitor your child and treat their fever **if** they are uncomfortable, refusing fluids and not sleeping. • Swelling of the jawline (salivary glands), cheeks and neck 7 to 12 days later. • A blotchy red rash 4 to 12 days later. • Joint or muscle aches and pain. • Nausea, vomiting, diarrhea or decreased appetite. • Headache, dizziness, fussiness, tiredness. • Lymph nodes swelling near the immunized limb. **Extremely rare** reactions may include: • A temporary drop in the number of blood cells (platelets) that prevent bleeding (thrombocytopenia) within 6 weeks of being immunized. In most people, this resolves within 3 months without serious complications. • Encephalitis (less than 1 in a million). The risk of encephalitis from measles disease is about 1 in 1,000, which is much higher than from this vaccine.
SPECIAL CONSIDERATION	Re: Immunization of immunocompromised clients - consult the appropriate physician (i.e., either the primary care physician most familiar with the client's current medical status or a medical specialist) and obtain a completed *MMR Immunization Referral Form* (Chapter 7, *Immunization of Special Populations,* Appendix 7.3) before immunization.
EFFECTIVENESS	After 1st dose, 85-95% protection to measles; 95.5% to mumps; 99.3% to rubella. After 2nd dose 100% protection to all antigens.

[1] Refer to SIM, Chapter 5, *Immunization Schedules*, Section 3.5, *Spacing of Live Vaccines, Blood Products and Immune Globulin Preparations* and Section 3.51, *Immune Globulin Preparations or Blood: Timing Intervals for Vaccines Containing Live Measles, Mumps, Rubella, or Varicella Virus.*

Measles-Mumps-Rubella Vaccine (MMR) (live, attenuated)

PRIORIX® (GlaxoSmithKline Inc. 2023 monograph available at: https://ca.gsk.com/media/6254/priorix.pdf)

INDICATIONS [1]	**DOSE / SERIES**
▪ Series for those born **since** January 1, 1970 who are 12 months and older. According to CIG, 1 dose of rubella is considered sufficient for immunity in all ages. Refer to *Appendix 5.2: Publicly Funded MMR Vaccine Eligibility.* ▪ Recommended for post-exposure prophylaxis of measles contacts as outlined in the Saskatchewan Communicable Disease Control Manual. ▪ **Additional indications** as noted in SIM Chapter 5, *Appendix 5.2: Publicly Funded MMR Vaccine Eligibility.* • 1 dose for some adult travellers born before January 1, 1970. • Infants 6-11 months old who are travelling abroad may be offered 1 early publicly funded dose of MMR.	**Dose 1**: 0.5 mL SC **Dose 2**: 0.5 mL SC minimum 4 weeks later

REINFORCEMENT	Not indicated after 2 MMR doses.
PRECAUTIONS	• MMR should be given at the same time as other live vaccines. Otherwise there must be 4 weeks between administering live vaccines. • For immune compromised clients only: separate the administration of MMR and Var by 4 weeks. • Anti-Rho (D) immune globulin may interfere with response to the rubella component of the vaccine. Rubella-susceptible women who receive anti-Rho (D) immune globulin post-partum should either be given MMR vaccine at the same time and tested 3 months later for rubella immunity, or should be immunized with MMR vaccine 3 months post-partum, with follow-up ensured (CIG . • Do TB skin testing on the same day as MMR immunization, or delay TB skin testing for 4 weeks. • Family history of congenital immunodeficiency. Refer to SIM, Chapter 6, *Contraindication and Precautions.* • Physician-diagnosed thrombocytopenia within 6 weeks after first dose of a MMR-containing vaccine.
CONTRA-INDICATIONS	• History of anaphylactic reaction to a previous dose of a measles/mumps/rubella-containing vaccine, to any component of Priorix, or to latex when administering Priorix with the pre-filled syringe (latex is present in the pre-filled syringe of diluent for Priorix). • **Immunocompromised individuals unless determined by their specialist**. Refer to SIM, Chapter 7, *Immunization of Special Populations,* under specific condition for information. • Pregnancy. Counsel female recipients to avoid pregnancy for 1 month following immunization. Inadvertent immunization during pregnancy is not considered a medical indication for therapeutic abortion. • People with active untreated tuberculosis. • Recent administration of an immune globulin preparation or blood product [3]
VACCINE COMPONENTS	Not less than: $10^{3.0}$ $CCID_{50}$ of the Schwarz measles; $10^{3.7}$ $CCID_{50}$ of the RIT 4385 mumps; and $10^{3.0}$ $CCID_{50}$ of the Wistar RA 27/3 rubella virus strains/ per 0.5 mL dose, and amino acids, lactose, mannitol and sorbitol. Residual: neomycin sulphate. Vaccine and diluent vial stoppers made of natural rubber. Thimerosal free. The vaccine may contain minute quantities of egg protein

Measles-Mumps-Rubella Vaccine (MMR) (live, attenuated)

PRIORIX® (GlaxoSmithKline Inc. 2023 monograph available at: https://ca.gsk.com/media/6254/priorix.pdf)

EXPECTED REACTIONS	**Local:** Pain, redness, swelling, induration, wheal and flare reaction, urticaria. **Systemic:** • A fever lasting up to 3 days may occur 6 to 23 days after immunization. Monitor your child and treat their fever **if** they are uncomfortable, refusing fluids and not sleeping. • Pain, swelling and redness where the needle was given. • Swelling of the jawline (salivary glands), cheeks and neck 7 to 12 days later. • A blotchy red rash 4 to 12 days later. • Joint or muscle aches and pain. • Nausea, vomiting, diarrhea or decreased appetite. • Headache, dizziness, fussiness, tiredness. • Lymph nodes swelling near the immunized limb. **Extremely rare** reactions may include: • A temporary drop in the number of blood cells (platelets) that prevent bleeding (thrombocytopenia) within 6 weeks of being immunized. In most people, this resolves within 3 months without serious complications. • Encephalitis (less than 1 in a million). The risk of encephalitis from measles disease is about 1 in 1,000, which is much higher than from this vaccine.
SPECIAL CONSIDERATIONS	Re: Immunization of immunocompromised clients - consult the appropriate physician (i.e., either the primary care physician most familiar with the client's current medical status or a medical specialist) and obtain a completed *MMR Immunization Referral Form* (Chapter 7, *Immunization of Special Populations,* Appendix 7.3) before immunization.
EFFECTIVENESS	After 1st dose, 85-95% protection to measles; 95.5% to mumps; 99.3% to rubella. After 2nd dose 100% protection to all antigens.

[1] Refer to SIM, Chapter 5, *Immunization Schedules,* Section 3.5, *Spacing of Live Vaccines, Blood Products and Immune Globulin Preparations* and Section 3.5.1, *Immune Globulin Preparations or Blood: Timing Intervals for Vaccines Containing Live Measles, Mumps, Rubella, or Varicella Virus.*

Measles-Mumps-Rubella-Varicella Vaccine (MMRV)
(live, attenuated)

PRIORIX-TETRA™
(GlaxoSmithKline 2023 product monograph available at: https://ca.gsk.com/media/6253/priorix-tetra.pdf)

INDICATION [1]	**DOSE / SERIES**[2, 3, 4]
Healthy children 1 year up to and including 12 years of age who require protection against MMR and varicella diseases.	**Dose 1**: 0.5 mL SC (at 12 months) **Dose 2**: 0.5 mL SC (at 18 months) **NOTE:** According to CIG, 1 dose of rubella is considered sufficient for immunity in all ages. Refer to *Appendix 5.2: Publicly Funded MMR Vaccine Eligibility.*
PRECAUTIONS	• Those 18 years and younger should avoid taking salicylates for 6 weeks after receiving a varicella-containing vaccine. Specialist consultation is required prior to immunization of these children with a varicella-containing vaccine. • Physician-diagnosed thrombocytopenia within 6 weeks after first dose of a MMR-containing vaccine. • Family history of congenital immunodeficiency. Refer to SIM Chapter 7, *Immunization of Special Populations* Section 3.1, *Congenital Immunodeficiency* • Do TB skin testing on the same day as MMR immunization, or delay TB skin testing for 4 or more weeks. • Systemic antiviral therapy (e.g., acyclovir, valacyclovir, famciclovir) should be avoided for 24 hours, as it may affect the reproduction of the vaccine virus and may reduce the efficacy of varicella-containing vaccine (CIG). • It is recommended that people taking long-term antiviral therapy should discontinue these drugs, if possible, from at least 24 hours before administration of varicella-containing vaccine and should not restart antiviral therapy until 14 days after vaccine administration (CIG).
CONTRA-INDICATIONS	• History of anaphylactic reaction to a previous dose of a measles/mumps/rubella or varicella-containing vaccine, to any component of PRIORIX-TETRA™. • Recent administration of an immune globulin preparation or blood product [2]. • Pregnancy. • People with active untreated tuberculosis. • Immunocompromised individuals.
VACCINE COMPONENTS	Live, attenuated measles virus (Schwarz strain) not less than $10^{3.0}$ $CCID_{50}$; Live, attenuated mumps virus (RIT 4385 strain, derived from Jeryl Lynn strain) not less than $10^{4.4}$ $CCID_{50}$; Live, attenuated rubella virus (Wistar RA 27/3 strain) not less than $10^{3.0}$ $CCID_{50}$; Live, attenuated varicella virus (Oka strain) not less than $10^{3.3}$ PFU; amino acids for injection, lactose, mannitol, neomycin sulphate, sorbitol, water for injection. Vaccine and diluent vial stoppers contain rubber. The measles and mumps components of the vaccine are produced in chick embryo cell culture and may therefore contain traces of egg protein. Thimerosal free. Latex-free

Measles-Mumps-Rubella-Varicella Vaccine (MMRV)

(live, attenuated)

PRIORIX-TETRA™

(GlaxoSmithKline 2023 product monograph available at: https://ca.gsk.com/media/6253/priorix-tetra.pdf)

EXPECTED REACTIONS	**Local:** Pain, redness and swelling. **Systemic**: • A fever lasting up to 3 days may occur 7 to 10 days after getting this vaccine. Monitor your child and treat their fever (at least 6 to 8 hours after immunization) **if** they are uncomfortable, refusing fluids and not sleeping. • Less than 1 in 3,000 children with high fevers after getting their first dose of MMRV **may** have a febrile seizure. **Febrile seizures are temporary and not harmful to the child. If you are concerned, please talk to a public health nurse.** • Swelling of the jawline (salivary glands), cheeks and neck 7 to 12 days later. • Joint or muscle aches and pain. • Nausea, vomiting, diarrhea or decreased appetite. • Headache, dizziness, fussiness, tiredness. • Lymph nodes swelling near the immunized limb. • A blotchy red rash 4 to 12 days later. • A varicella-like (blister) rash 5 to 26 days after getting immunized. People who have this rash rarely spread the vaccine virus to others. To prevent possible viral spreading, the rash should be covered until the blisters have dried and crusted over**.** **Extremely rare** reactions may include: • A temporary drop of the number of blood cells (platelets) that prevent bleeding (thrombocytopenia) within 6 weeks of being immunized. In most people, this resolves within 3 months without serious complications. • Encephalitis (less than one in one million). The risk of encephalitis from measles disease is about one in 1,000, which is much higher than from this vaccine.
ADVERSE EVENTS	Following the administration of the first dose of PRIORIX-TETRA®, higher incidences of fever (approximately 1.5 fold) were observed when compared to the concomitant administration of PRIORIX® [*MMR*] and VARILRIX® vaccines at separate injection sites (p.6). Review fever management with client.
EFFECTIVENESS	One year after 2nd MMRV dose, 98.8% of all children were protected measles, rubella and varicella and 90.6% were protected against mumps.

[1] Minimum age for vaccine is 9 months and applies to exceptional circumstances only

[2] There must be 4 weeks minimum spacing between MMRV doses

[3] Refer to SIM, Chapter 5, *Immunization Schedules*, Section 3.5, *Spacing of Live Vaccines, Blood Products and Immune Globulin Preparations* and Section 3.5.1, *Immune Globulin Preparations or Blood: Timing Intervals for Vaccines Containing Live Measles, Mumps, Rubella, or Varicella Virus.*

[4] Individuals who are eligible for a 2-dose varicella series who have **documentation of lab confirmed** varicella after their first varicella-containing vaccine dose do not require a second varicella-containing vaccine dose as they will have developed immunity. Provide a second dose of varicella-containing vaccine to those without this documentation.

[5] MMRV vaccines are considered interchangeable.

Measles-Mumps-Rubella-Varicella Vaccine (MMRV) (live, attenuated)

ProQuad™

(Merck Frosst 2022 product monograph available at https://www.merck.ca/en/wp-content/uploads/sites/20/2021/04/PROQUAD-PM_E.pdf)

INDICATION [1]	**DOSE / SERIES** [2, 3, 4]
Healthy children 1 year up to and including 12 years of age who require protection against MMR and varicella diseases.	**Dose 1**: 0.5 mL SC (at 12 months) **Dose 2**: 0.5 mL SC (at 18 months) **NOTE:** According to CIG, 1 dose of rubella is considered sufficient for immunity in all ages. Refer to Appendix 5.2: *Publicly Funded MMR Vaccine Eligibility.*
PRECAUTIONS	• Those 18 years and younger should avoid taking salicylates for 6 weeks after receiving a varicella-containing vaccine. Specialist consultation is required prior to immunization of these children with a varicella-containing vaccine. • Physician-diagnosed thrombocytopenia within 6 weeks after first dose of a MMR-containing vaccine. • Family history of congenital immunodeficiency. Refer to SIM Chapter 7, *Immunization of Special Populations* Section 3.1, Congenital Immunodeficiency • Do TB skin testing on the same day as MMR immunization, or delay TB skin testing for 4 or more weeks. • Systemic antiviral therapy (e.g., acyclovir, valacyclovir, famciclovir) should be avoided in the peri-immunization period, as it may affect the reproduction of the vaccine virus and may reduce the efficacy of varicella-containing vaccine (CIG). • It is recommended that people taking long-term antiviral therapy should discontinue these drugs, if possible, from at least 24 hours before administration of varicella-containing vaccine and should not restart antiviral therapy until 14 days after vaccine administration (CIG).
CONTRA-INDICATIONS	• History of anaphylactic reaction to a previous dose of a measles/mumps/rubella or varicella-containing vaccine, or to any component of ProQuad™. • Recent administration of an immune globulin preparation or blood product [2]. • Pregnancy. • People with active untreated tuberculosis. • Immunocompromised individuals.
VACCINE COMPONENTS	Live, attenuated measles virus derived from Enders' attenuated Edmonston strain; live, attenuated mumps virus (JERYL LYNN® (B level) strain; live, attenuated rubella virus (Wistar RA 27/3 strain); live, attenuated Oka/Merck strain of varicella-zoster virus; sucrose, hydrolyzed gelatin, urea, sodium chloride, sorbitol, monosodium L-glutamate, sodium phosphate, recombinant human albumin, sodium bicarbonate, potassium phosphate, potassium chloride, residual components of MRC-5 cells including DNA and protein, neomycin, bovine serum albumin and other buffer and media ingredients. The vaccine may contain minute quantities of egg protein. Preservative, latex and thimerosal free.

Measles-Mumps-Rubella-Varicella Vaccine (MMRV) (live, attenuated)

ProQuad™

(Merck Frosst 2022 product monograph available at https://www.merck.ca/en/wp-content/uploads/sites/20/2021/04/PROQUAD-PM_E.pdf)

EXPECTED REACTIONS	**Local:** Pain, redness and swelling. **Systemic**: • A fever lasting up to 3 days may occur 7 to 10 days after getting this vaccine. Monitor your child and treat their fever (at least 6 to 8 hours after immunization) **if** they are uncomfortable, refusing fluids and not sleeping. • Less than 1 in 3,000 children with high fevers after getting their first dose of MMRV **may** have a febrile seizure. **Febrile seizures are temporary and not harmful to the child. If you are concerned, please talk to a public health nurse.** • Swelling of the jawline (salivary glands), cheeks and neck 7 to 12 days later. • Joint or muscle aches and pain. • Nausea, vomiting, diarrhea or decreased appetite. • Headache, dizziness, fussiness, tiredness. • Lymph nodes swelling near the immunized limb. • A blotchy red rash 4 to 12 days later. • A varicella-like (blister) rash 5 to 26 days after getting immunized. People who have this rash rarely spread the vaccine virus to others. To prevent possible viral spreading, the rash should be covered until the blisters have dried and crusted over**.** **Extremely rare** reactions may include: • A temporary drop of the number of blood cells (platelets) that prevent bleeding (thrombocytopenia) within 6 weeks of being immunized. In most people, this resolves within 3 months without serious complications. • Encephalitis (less than one in one million). The risk of encephalitis from measles disease is about one in 1,000, which is much higher than from this vaccine.
ADVERSE EVENTS	Administration of ProQuad™ (dose 1) to children 12 to 23 months old was associated with higher rates of fever and febrile seizures at 5 to 12 days after vaccination when compared to children vaccinated with M-M-R® II and VARIVAX® administered separately. Review fever management with client.
EFFECTIVENESS	The antibody persistence rates 1 year post-vaccination in recipients **of a single dose** of ProQuad™ were 98.9% (1722/1741) for measles, 96.7% (1676/1733) for mumps, 99.6 (1796/1804) for rubella, and 97.5% (1512/1550) for varicella (≥ 5 gp ELISA units/mL)

[1] Minimum age for this vaccine is 12 months. Consult MHO for recommendations regarding exceptional circumstances.

[2] There must be 4 weeks minimum spacing between MMRV doses

[3] Refer to SIM, Chapter 5, *Immunization Schedules*, Section 3.5, *Spacing of Live Vaccines, Blood Products and Immune Globulin Preparations* and Section 3.5.1, *Immune Globulin Preparations or Blood: Timing Intervals for Vaccines Containing Live Measles, Mumps, Rubella, or Varicella Virus.*

[4] Individuals who are eligible for a 2-dose varicella series who have **documentation of lab confirmed** varicella after their first varicella-containing vaccine dose do not require a second varicella-containing vaccine dose as they will have developed immunity. Provide a second dose of varicella-containing vaccine to those without this documentation.

[5] MMRV vaccines are considered interchangeable.

Meningococcal Conjugate C Vaccine (Men-C-C)

MENJUGATE® Liquid

(GlaxoSmithKline Inc. 2020 monograph available at: https://ca.gsk.com/media/6250/menjugate-liquid.pdf)

INDICATIONS [1,5]	DOSE / SERIES
1. Routine for children at 12 months of age. 2. Meningococcal serotype C post-exposure immunoprophylaxis.	**1.** One dose: 0.5 mL IM at 12 months or older **2.** Children 2 - 11 months old: [2, 3] • **Dose 1**: 0.5 mL IM • **Dose 2**: 0.5 mL IM 2 months later Those 12 months and older: [4] • One dose 0.5 mL IM
CONTRAINDICATIONS	History of anaphylactic reaction to a previous dose of any meningococcal vaccine or to any component of a MENJUGATE brand of Men-C-C vaccine.
VACCINE COMPONENTS	*Neisseria meningitidis* group C (strain C11) oligosaccharide conjugated to *Corynebacterium diphtheriae* protein CRM-$_{197}$, aluminum hydroxide, histidine, sodium chloride, water for injection with bromobutyl rubber stopper and tip cap (styrene butadiene Type II rubber). Although no natural rubber latex is detected in the syringe tip cap, the safe use of Menjugate in latex-sensitive individuals has not been established. Thimerosal free.
EXPECTED REACTIONS	**Local**: redness, swelling and pain at injection site. **Systemic**: fever, decreased appetite, drowsiness, crying, irritability, headache, vomiting, diarrhea or skin rash.
EFFECTIVENESS	Effectiveness: more than 90% in all age groups in the short-term.

[1] Minimum age for vaccine is 6 weeks.
[2] Men-C-C vaccines are interchangeable for infants younger than 12 months of age.
[3] If an infant has a history of receiving their last dose before 12 months of age, give an additional dose at 12 months or older.
[4] The recommended interval between Men-C-C doses is 8 weeks.
[5] Patients being treated with SOLIRIS (eculizumab) are at high risk for Invasive Meningococcal Disease despite being immunized with meningococcal vaccines (CDC, 2017, https://www.cdc.gov/mmwr/volumes/66/wr/mm6627e1.htm?s_cid=mm6627e1_e).

Meningococcal Conjugate C Vaccine (Men-C-C)

NeisVac-C®
(Pfizer Canada 2021 monograph https://webfiles.pfizer.com/file/68b9a4f6-23ee-46af-b2d7-efdb3d9b1e82?referrer=ccb731e5-4f2d-4f4a-b2dc-e5e912145fc6)

INDICATIONS [1,5]	**DOSE / SERIES**
1. Routine for children at 12 months of age.	**1.** One dose: 0.5 mL IM at 12 months or older
2. Meningococcal serotype C post-exposure immunoprophylaxis.	**2.** Children 2 - 11 months old: [2, 3] • **Dose 1**: 0.5 mL IM • **Dose 2**: 0.5 mL IM 2 months later Those 12 months and older: [4] • One dose 0.5 mL IM
CONTRAINDICATIONS	History of anaphylactic reaction to a previous dose of any meningococcal vaccine or to any component of NeisVac-C®.
VACCINE COMPONENTS	One dose 0.5 mL contains: *Neisseria meningitidis* group C polysaccharide 10 mcg, tetanus toxoid, aluminum hydroxide, sodium chloride. Latex and thimerosal free.
EXPECTED REACTIONS	**Local**: redness, swelling and pain at injection site. **Systemic**: fever, decreased appetite, drowsiness, crying, irritability, headache, vomiting, diarrhea or skin rash.
EFFECTIVENESS	Effectiveness: more than 90% in all age groups in the short-term.

[1] Minimum age for vaccine is 6 weeks.
[2] Men-C-C vaccines are interchangeable for infants younger than 12 months of age.
[3] If an infant has a history of receiving their last dose before 12 months of age, give an additional dose at 12 months or older.
[4] The recommended interval between Men-C-C doses is 8 weeks.
[5] Patients being treated with SOLIRIS (eculizumab) are at high risk for Invasive Meningococcal Disease despite being immunized with meningococcal vaccines (CDC, 2017, https://www.cdc.gov/mmwr/volumes/66/wr/mm6627e1.htm?s_cid=mm6627e1_e).

Meningococcal Conjugate ACYW-135 Vaccine (Men-C-ACYW-135)

Menactra®
(Sanofi Pasteur 2017 monograph available at: https://products.sanofi.ca/en/menactra.pdf)

DOSE : 0.5 mL IM

INDICATIONS [1, 5]

1. Grade 6 students – 1 dose [2, 3]
2. Those ≥ 9 months of age and older with the following medical conditions as noted in Chapter 7 Special Populations:
   - asplenia – congenital, acquired or functional [4]
   - HIV – ONLY for children up to and including 17 years of age
   - CSF disorders
   - Sickle cell disease
   - cochlear implant recipient or candidate
   - congenital immunodeficiency or acquired complement deficiency [6]
   - solid organ or islet transplant recipient or candidate
   - hematopoietic stem cell transplant (HSCT) recipient
3. Individuals who have previously been vaccinated with Men-P-ACYW-135 and for whom there is a need for re-vaccination due to high risk medical status: → administer Men-C-ACYW-135 as follows:

Age at first dose of Men-P-ACYW-135	**Immunize with Men-C-ACYW-135 when 2 years and older, and it has been:**
3-12 months of age	6 months since last dose of Men-P-ACYW-135
13-23 months of age	1 year since last dose of Men-P-ACYW-135
2-5 years of age	2 years since last dose of Men-P-ACYW-135
≥ 6 years of age	5 years since last dose of Men-P-ACYW-135

SERIES BASED ON AGE AT PRESENTATION FOR HIGH RISK CLIENTS (excludes routine Grade 6 program)	**9 months through 11 months -** 3-dose series a. 1st dose followed by 2nd dose at least 2 months later. b. Give 3rd at/after 12 months of age, with at least 2 months between doses 2 and 3. [5]
	12 to 23 months [5] **-** 2-dose series with at least 2 months between doses
	2 years and older [5] **-** 2-dose series with at least 2 months between doses
REINFORCE-MENT DOSES	Only for asplenia (congenital, acquired or functional), congenital immunodeficiency or acquired complement deficiency. • **1 dose every 5 years for all ages**.
CONTRA-INDICATIONS	History of anaphylactic reaction to a previous dose of any meningococcal-containing vaccine, or to any component of Menactra.
VACCINE COMPONENTS	Each dose contains 4 mcg each of meningococcal A, C, Y and W-135 polysaccharides conjugated to a total of approximately 48 mcg of a diphtheria toxoid protein carrier, sodium chloride 4.25 mg, sodium phosphate (dibasic, anhydrous), sodium phosphate (monobasic), water for injection. Vial presentations do not contain latex. Preservative free.
EXPECTED REACTIONS	**Local**: Pain, redness, swelling. **Systemic**: headache, tiredness, diarrhea, irritability, loss of appetite or fever.
EFFECTIVENESS	93-100% of children, adolescents & adults show a ≥4-fold rise in titres at day 28. Duration of protection remains unknown.

Meningococcal Conjugate ACYW-135 Vaccine (Men-C-ACYW-135)

Menactra®
(Sanofi Pasteur 2017 monograph available at: https://products.sanofi.ca/en/menactra.pdf)

[1] The recommended interval between the administration of Men-C-C vaccine and Men-C-ACYW-135 vaccine is 4 weeks (regardless of which vaccine was given first).
[2] Those born since January 1, 2000 up to and including 21 years of age (ineligible upon 22nd birthday).
[3] If a Grade 6 student has received a previous Men-C-ACYW-135 vaccine in the preceding 3 years, it is acceptable to withhold the Grade 6 dose and give the vaccine when the student is in Grade 8.
[4] Give vaccine at least 14 days prior to elective splenectomy, or if not possible, 14 or more days post-splenectomy. When there is concern that the patient may not present later for immunization, give vaccine before discharge.
[5] A high-risk child 12 months of age and older, or an adult who is cohort eligible for a Men-C-C, does not required Men-C-C vaccine when they are eligible to receive Men-C-ACYW-135 vaccine.
[6] Patients being treated with SOLIRIS (eculizumab) are at high risk for Invasive Meningococcal Disease despite being immunized with meningococcal vaccines (CDC, 2017, https://www.cdc.gov/mmwr/volumes/66/wr/mm6627e1.htm?s_cid=mm6627e1_e).

Meningococcal Conjugate ACYW-135 Vaccine (Men-C-ACYW-135)

[Non-publicly funded]

MenQuadfi™

(Sanofi Pasteur 2020 Product monograph https://pdf.hres.ca/dpd_pm/00058534.PDF)

Meningococcal Conjugate ACYW-135 Vaccine (Men-C-ACYW-135)

Menveo™
(GSK 2020 monograph available at: https://ca.gsk.com/media/6251/menveo.pdf)

DOSE: 0.5 mL IM

INDICATIONS [1, 5]

1. Grade 6 students – 1 dose [2, 3]
2. Those ≥ 6 weeks of age and older with the following medical conditions as noted in Chapter 7 Special Populations:
   - asplenia – congenital, acquired or functional [4]
   - HIV – ONLY for children up to and including 17 years of age
   - CSF disorders
   - Sickle cell disease
   - cochlear implant recipient or candidate
   - congenital immunodeficiency or acquired complement deficiency [6]
   - solid organ or islet transplant recipient or candidate
   - hematopoietic stem cell transplant (HSCT) recipient
3. Individuals who have previously been vaccinated with Men-P-ACYW-135 and for whom there is a need for re-vaccination due to high risk medical status: → administer Men-C-ACYW-135 as follows:

Age at first dose of Men-P-ACYW-135	**Immunize with Men-C-ACYW-135 when 2 years and older, and it has been:**
3-12 months of age	6 months since last dose of Men-P-ACYW-135
13-23 months of age	1 year since last dose of Men-P-ACYW-135
2-5 years of age	2 years since last dose of Men-P-ACYW-135
≥ 6 years of age	5 years since last dose of Men-P-ACYW-135

4. In meningococcal A, C, Y or W-135 outbreak exposure situations, **Menveo** may be used in children as early as 6 weeks of age. Refer to the Saskatchewan Communicable Disease Control Manual at http://www.ehealthsask.ca/services/manuals/Pages/CDCManual.aspx

SERIES BASED ON AGE AT PRESENTATION FOR HIGH RISK CLIENTS (excludes routine Grade 6 program)	**6 weeks through 6 months**: 4 dose series - 2 months, 4 months and 6 months of age followed by a 4th dose at/after 12 months of age[5].
	7 months through 11 months: 3 dose series - 1st dose, 2nd dose and 3rd dose with 2 month intervals between these 3 doses. • Give 3rd at/after 12 months of age, with at least 2 months between doses 2 and 3
	12 months and older: 2-dose series with at least 2 months between doses.
REINFORCE-MENT DOSES	Only for asplenia (congenital, acquired or functional), congenital immunodeficiency or acquired complement deficiency. ▪ **1 dose every 5 years for all ages**.
CONTRA-INDICATIONS	History of anaphylactic reaction to a previous dose of a meningococcal containing vaccine, or to any component of Menveo™.

Meningococcal Conjugate ACYW-135 Vaccine (Men-C-ACYW-135)

Menveo™
(GSK 2020 monograph available at: https://ca.gsk.com/media/6251/menveo.pdf)

VACCINE COMPONENTS	5 mcg each of meningococcal C, W-135 and Y oligosaccharides conjugated and 10 mcg of meningococcal A oligosaccharide conjugated to a total of approximately 47 mcg of Cross Reactive Material (CRM197) from *Corynebacterium diphtheriae*, potassium dihydrogen phosphate, sodium chloride, sodium dihydrogen phosphate monohydrate, di-sodium hydrogen phosphate bihydrate, sucrose, water for injection. Thimerosal and latex free.
EXPECTED REACTIONS	**Local**: Pain, redness, swelling at injection site. **Systemic**: headache, tiredness, diarrhea, irritability, loss of appetite or fever.
EFFECTIVENESS	93-100% of children, adolescents & adults show a ≥4-fold rise in titres at day 28.

[1] The recommended interval between the administration of Men-C-C vaccine and Men-C-ACYW-135 vaccine is 4 weeks (regardless of which vaccine was given first).

[2] Those born since January 1, 2000 up to and including 21 years of age (ineligible upon 22nd birthday).

[3] If a Grade 6 student has received a previous Men-C-ACYW-135 vaccine in the preceding 3 years, it is acceptable to withhold the Grade 6 dose and give the vaccine when the student is in Grade 8.

[4] Give vaccine at least 14 days prior to elective splenectomy, or if not possible, 14 or more days post-splenectomy. When there is concern that the patient may not present later for immunization, give vaccine before discharge.

[5] A high-risk child 12 months of age and older, or an adult who is cohort eligible for a Men-C-C, does not required Men-C-C vaccine when they are eligible to receive Men-C-ACYW-135 vaccine.

[6] Patients being treated with SOLIRIS (eculizumab) are at high risk for Invasive Meningococcal Disease despite being immunized with meningococcal vaccines (CDC, 2017, https://www.cdc.gov/mmwr/volumes/66/wr/mm6627e1.htm?s_cid=mm6627e1_e).

Meningococcal Conjugate ACYW-135 Vaccine (Men-C-ACYW-135)

NIMENRIX®

Pfizer Canada 2023 monograph https://webfiles.pfizer.com/file/c54383b5-9200-4af1-b18f-d8931c7ec367?referrer=ccb731e5-4f2d-4f4a-b2dc-e5e912145fc6)

DOSE: 0.5 mL IM

INDICATIONS

1. Grade 6 students -1 dose [2, 3]
2. Those ≥ 6 weeks of age and older (no age limit) with the following medical conditions as noted in Chapter 7 Special Populations:
   - asplenia – congenital, acquired or functional [4]
   - HIV – ONLY for children up to and including 17 years of age
   - CSF disorders
   - Sickle cell disease
   - cochlear implant recipient or candidate
   - congenital immunodeficiency or acquired complement deficiency [6]
   - solid organ or islet transplant recipient or candidate
   - hematopoietic stem cell transplant (HSCT) recipient
3. Individuals who have previously been vaccinated with Men-P-ACYW-135 and for whom there is a need for re-vaccination due to high risk medical status: → administer Men-C-ACYW-135 as follows:

Age at first dose of Men-P-ACYW-135	**Immunize with Men-C-ACYW-135 when 2 years and older, and it has been:**
3-12 months of age	6 months since last dose of Men-P-ACYW-135
13-23 months of age	1 year since last dose of Men-P-ACYW-135
2-5 years of age	2 years since last dose of Men-P-ACYW-135
≥ 6 years of age	5 years since last dose of Men-P-ACYW-135

SERIES BASED ON AGE AT PRESENTATION FOR HIGH RISK CLIENTS (excludes routine Grade 6 program	**6 weeks to <6 months** 3-dose series • 1st dose followed by 2nd dose at least 2 months later. • Give 3rd dose at/after 12 months of age, with at least 2 months between doses 2 and 3. [5]
	6 months to <12 months 2-dose series • 1st dose followed by 2nd dose at/after 12 months of age, with at least 2 months between doses 1 and 2. [5]
	12 months and older [5] **-** 2-dose series with at least 2 months between doses
REINFORCE-MENT DOSES	Only for asplenia (congenital, acquired or functional), congenital immunodeficiency or acquired complement deficiency. • **1 dose every 5 years for all ages**.
CONTRA-INDICATIONS	History of anaphylactic reaction to a previous dose of a meningococcal containing vaccine, or to any component of NIMENRIX™.
VACCINE COMPONENTS	*Neisseria meningitidis* serogroup A polysaccharide, *Neisseria meningitidis* serogroup C polysaccharide, *Neisseria meningitidis* serogroup W-135 polysaccharide, *Neisseria meningitidis* serogroup Y polysaccharide, sucrose, trometamol, sodium chloride, water for injection. Latex-free.
EXPECTED REACTIONS	**Local**: Pain, redness, swelling, bruising at injection site. **Systemic**: headache, tiredness, diarrhea, irritability, loss of appetite, fever.

Meningococcal Conjugate ACYW-135 Vaccine (Men-C-ACYW-135)

NIMENRIX®
Pfizer Canada 2023 monograph https://webfiles.pfizer.com/file/c54383b5-9200-4af1-b18f-d8931c7ec367?referrer=ccb731e5-4f2d-4f4a-b2dc-e5e912145fc6)

EFFECTIVENESS	For all serogroups (A, C, W-135, Y), the persistence of the antibodies elicited by NIMENRIX™ was similar or higher than those induced by the licensed Men-C-ACYW-135 vaccines.

[1] The recommended interval between the administration of Men-C-C vaccine and Men-C-ACYW-135 vaccine is 4 weeks (regardless of which vaccine was given first).
[2] Those born since January 1, 2000 up to and including 21 years of age (ineligible upon 22nd birthday).
[3] If a Grade 6 student has received a previous Men-C-ACYW-135 vaccine in the preceding 3 years, it is acceptable to withhold the Grade 6 dose and give the vaccine when the student is in Grade 8.
[4] Give vaccine at least 14 days prior to elective splenectomy, or if not possible, 14 or more days post-splenectomy. When there is concern that the patient may not present later for immunization, give vaccine before discharge.
[5] A high-risk child 12 months of age and older, or an adult who is cohort eligible for a Men-C-C, does not required Men-C-C vaccine when they are eligible to receive Men-C-ACYW-135 vaccine.
[6] Patients being treated with SOLIRIS (eculizumab) are at high risk for Invasive Meningococcal Disease despite being immunized with meningococcal vaccines (CDC, 2017, https://www.cdc.gov/mmwr/volumes/66/wr/mm6627e1.htm?s_cid=mm6627e1_e).

Meningococcal B vaccine (Multicomponent, recombinant, adsorbed)

BEXSERO® (Men-B4C)

(GSK 2023 product monograph available at: https://ca.gsk.com/media/6309/bexsero.pdf)

INDICATIONS	• Those ≥ 6 weeks of age with the following medical conditions as noted in Chapter 7: ○ asplenia – congenital, acquired or functional ○ sickle cell disease ○ congenital immunodeficiency ○ acquired complement deficiency [1] ○ solid organ or islet cell transplant candidates or recipients as per transplant agency recommendations ○ hematopoietic stem cell transplant (HSCT) recipients as per transplant agency recommendations • Children up to and including 17 years of age who are infected with HIV • Those ≥ 8 weeks of age who have been identified as 'close contacts' of persons infected with meningococcal B. Refer to Saskatchewan Communicable Disease Control Manual at http://www.ehealthsask.ca/services/manuals/Pages/CDCManual.aspx
DOSE	0.5 mL IM. Protect from light.
CONTRA-INDICATIONS	BEXSERO should not be administered to individuals who are hypersensitive to this vaccine or to any ingredient in the formulation or components of the container closure.
DOSE/SERIES AND REINFORCE-MENT RECOMMEN-DATIONS BASED ON AGE AT PRESENTATION for those with medical risk factors.	**Infants aged 6 weeks through 5 months** • **4-dose series**: 0.5 mL IM at 2 months, 4 months and 6 months of age followed by a 4th dose after 12 months of age. ○ Minimum 1 month interval between doses 1 & 2 and 2 & 3. ○ Dose 4 **is required** after 1 year old with an interval of at least 6 months between doses 3 & 4. • **3-dose series**: Dose 1 at 2 months, Dose 2 at 4 months, ensuring minimum of 2 months interval between doses 1 & 2). ○ Dose 3 **is required** after 1 year old with an interval of at least 6 months between dose 2 & 3.
	Infants aged 6 months through 11 months • **3-dose series**: 0.5 mL IM for 1st dose, 2nd dose and 3rd dose with 2 month intervals between the 1st and 2nd doses and the 2nd and 3rd doses. ○ The 3rd dose **is required** after 1 year old with an interval of at least 2 months between the second and third dose.
	Children aged 12 months to 23 months old: • **2-dose series** - 0.5 mL IM, with a 2-month interval between the 1st and 2nd doses.
	Individuals aged 2 years and older (including adults) • **2-dose series** - 0.5 mL IM, with at least a one-month interval between the 1st and 2nd doses.
VACCINE COMPONENTS	Recombinant *Neisseria meningitidis* serogroup B NHBA fusion protein; recombinant *Neisseria meningitidis* serogroup B NadA protein; recombinant *Neisseria meningitidis* serogroup B fHbp fusion protein; outer membrane vesicles (OMV) from *Neisseria meningitidis* serogroup B strain NZ98/254 measured as amount of total protein containing the PorA P1.4. **Excipients**: sodium chloride, histidine, sucrose, water for injection. Thimerosal free. The tip cap of the syringe may contain natural rubber latex. Although the risk for developing allergic reactions is very small, health professional should consider the benefit-risk prior to administering this vaccine to subjects with known history of hypersensitivity to latex.

Meningococcal B vaccine (Multicomponent, recombinant, adsorbed)

BEXSERO® (Men-B4C)

(GSK 2023 product monograph available at: https://ca.gsk.com/media/6309/bexsero.pdf)

EXPECTED REACTIONS	Common reactions to the vaccine may include: • Soreness, pain, redness and swelling at the injection site. Extensive swelling of the vaccinated limb, blisters at or around the injection site, and/or a hard lump at the injection site (which may last for more than one month) have also been reported. • Fever, loss of appetite, sleepiness, irritability, headache, vomiting, diarrhea, headache or rash. • Unusual crying in young children. • These reactions are mild and generally last 1 to 2 days. • High fever and seizures are uncommon. • Hypotonic-hyporesponsive episode, syncope or vasovagal responses to injection have been reported as post-market events. • Lymphadenopathy. • Allergic reactions (including anaphylactic reactions) have been reported as post-market events.
EFFECTIVENESS	Immunogenicity information in the product monograph indicates that administration of age-appropriate series provides 75% to 100% immunogenicity among the 4 meningococcal components. Duration of protection is unknown.

[1] Patients being treated with SOLIRIS (eculizumab) are at high risk for Invasive Meningococcal Disease despite being immunized with meningococcal vaccines (CDC, 2017, https://www.cdc.gov/mmwr/volumes/66/wr/mm6627e1.htm?s_cid=mm6627e1_e).

NOTES

1. BEXSERO® is a recombinant adsorbed vaccine that contains 4 serotype B components. According to the manufacturer (verbal communication, May 2014), there are no recommended interval requirements between BEXSERO® and other meningococcal serotype-containing vaccine that are conjugates or polysaccharides. However, case-by case review of an individual's immunization history in consultation with a MHO consultation may result in specific recommendations for administration of BEXSERO® doses.
2. An increased risk of hemolysis or low hemoglobin has been observed when patients already being treated with SOLIRIS (eculizumab) get vaccinated against serogroup B meningococcal infection with Bexsero® (Alexion Pharma Canada, 2017). Patients being treated with SOLIRIS (eculizumab) are at high risk for Invasive Meningococcal Disease despite being immunized with meningococcal vaccines (CDC, 2017, https://www.cdc.gov/mmwr/volumes/66/wr/mm6627e1.htm?s_cid=mm6627e1_e).

Meningococcal group B
Bivalent recombinant lipoprotein [Non-publicly funded]

Trumenba™ (MenB bivalent)
(Pfizer 2022 Product monograph available at https://www.pfizer.ca/files/Trumenba_PM_EN.pdf)

Pneumococcal Conjugate 10-Valent Vaccine

[Non-publicly funded]

SYNFLORIX™ (Pneu-C-10)

(GlaxoSmithKline 2023 monograph available at: https://ca.gsk.com/media/6260/synflorix.pdf)

Pneumococcal Conjugate 13-Valent Vaccine

Prevnar® 13 (Pneu-C-13)

(Pfizer 2019 monograph https://webfiles.pfizer.com/file/4c36f618-cb1a-412f-9d76-f8a7df560120?referrer=ccb731e5-4f2d-4f4a-b2dc-e5e912145fc6)

INDICATIONS & AGE-APPROPRIATE DOSE / SERIES [1, 2, 3, 4, 5]

Minimum age is 6 weeks old.

- This vaccine is not publicly funded for **healthy** individuals aged 5 years and older.

A. CHILDREN 2 – 59 MONTHS OF AGE:

(A1) Routine schedule for healthy infants:

Dose 1: 2 months of age: 0.5 mL IM
Dose 2: 4 months of age: 0.5 mL IM
Dose 3: 12 months of age: 0.5 mL IM

(A2) Routine schedule for medically high risk infants:

Dose 1: 2 months of age: 0.5 mL IM
Dose 2: 4 months of age: 0.5 mL IM
Dose 3: 6 months of age: 0.5 mL IM
Dose 4: 12 months of age: 0.5 mL IM (min. 8 weeks after 3rd dose).

(A3) Pneumococcal Conjugate Schedule for Healthy Children Delayed by 1 Month or More

Age at Presentation [1]	Pneumococcal conjugate vaccine history	Completion of primary series requirement	Reinforcement
3 to 11 months	0 doses	2 doses (min. 4 weeks apart)	One dose at 12 months of age or older [2]
	1 dose	1 dose (min. 4 weeks since first dose)	
	2 doses	0 doses	
12 to 23 months	0 doses	2 doses [2]	Not required
	1 dose at less than 12 months	2 doses [2]	Not required
	1 dose at 12 months or older	1 dose [2]	Not required
	2 or 3 doses at less than 12 months	1 dose [2]	Not required
	1 dose at less than 12 months and 1 dose at 12 months or older	1 dose [2]	Not required
	2 or 3 doses at less than 12 months and 1 dose at 12 months or older	Considered up to date	Not required
24 to 59 months	0 valid dose or incomplete vaccination schedule with any product	1 dose	Not required
	Completed, age-appropriate vaccination with Pneu-C-u, Pneu-C-7, Pneu-C-10 or Pneu-C-13	Considered up to date	Not required

(A4) Pneumococcal Conjugate Schedule for Medically High Risk Children Delayed by 1 Month or More [4]

Age at Presentation [1]	Pneumococcal conjugate vaccine history	Completion of primary series requirement	Reinforcement [3]
3 to 11 months	0 doses	3 doses (min. 4 weeks apart)	One dose at 12 months of age or older [2]
	1 dose	2 doses (min. 4 weeks apart)	
	2 doses	1 dose (min. 4 weeks since first dose)	
12 to 23 months	0 doses	2 doses [3]	Not required
	1 dose at less than 12 months	2 doses [3]	Not required
	1 dose at 12 months or older	1 dose [2]	Not required
	2 or 3 doses at less than 12 months	1 dose [2]	Not required
	1 dose at less than 12 months and 1 dose at 12 months or older	1 dose [2]	Not required
	2 or 3 doses at less than 12 months and 1 dose at 12 months or older	Considered up to date	Not required
24 to 59 months	0 valid dose or incomplete vaccination schedule with any product	1 dose	Not required
	Completed, age-appropriate vaccination with Pneu-C-u, Pneu-C-7 or Pneu-C-10 (0 doses of Pneu-C-13)	1 dose [2]	Not required

Pneumococcal Conjugate 13-Valent Vaccine

Prevnar® 13 (Pneu-C-13)

(Pfizer December 2019 monograph https://webfiles.pfizer.com/file/4c36f618-cb1a-412f-9d76-f8a7df560120?referrer=ccb731e5-4f2d-4f4a-b2dc-e5e912145fc6)

B. Medically High-Risk Children Aged 60 Months - 17 Years and Adults 18+ Who Are at Risk of Invasive Pneumococcal Disease [3] Medically high-risk children aged 60 months - 17 years who are Pneu-C-13 naïve (e.g., have not completed an age or risk appropriate Pneu-C-13 series prior to 59 months of age) and medically high risk adults who are Pneu-C-13 naive are eligible to receive **one dose of Pneu-C-13 vaccine** given no sooner than 8 weeks after a pneumococcal conjugate 7- or 10-valent vaccine dose. (CIG, 2012).	
CONTRA-INDICATIONS	History of an anaphylactic reaction to a previous dose of any pneumococcal vaccine, or to any component of Prevnar® 13.
VACCINE COMPONENTS	Each 0.5 mL dose of the vaccine is formulated to contain approximately 2.2 mcg of each saccharide for *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 7F, 9V, 14, 18C, 19A, 19F and 23F, 4.4 mcg of saccharide for serotype 6B, 34 mcg CRM_{197} carrier protein, 4.25 mg sodium chloride, 100 mcg polysorbate 80, 295 mcg succinic acid and 125 mcg aluminum as aluminum phosphate adjuvant. Latex free.
EXPECTED REACTIONS	**Local**: redness, swelling, pain, tenderness at injection site **Systemic**: fever, irritability, tiredness, headache, loss of appetite, diarrhea, vomiting, and rash.
EFFECTIVENESS	Completed series induces 97.8-100% protection against all strains in vaccine.

[1] If series is interrupted, complete series according to age at which child re-presents using minimum intervals as noted in SIM Chapter 5 Section 2.*1 Minimum intervals for Specific Vaccines.* Refer to SIM, Chapter 5, *Immunization Schedules*, Section 1.3A, *Pneumococcal Conjugate Schedule for Children Delayed by 1 Month or More* and Section 1.3B, *Pneumococcal Conjugate Schedule for Medically High Risk Children Delayed by 1 Month or More.*

[2] Minimum 8 weeks between doses and after the previous dose received.

[3] High risk children should receive one dose of Pneu-P-23 vaccine at 2 years of age, and at least 8 weeks after the final dose of Pneu-C-13 vaccine.

NOTE: 1-year minimum interval is required if Pneu-P-23 is given before Pneu-C-13 (all ages), and an 8 week interval is required if Pneu-C-13 is given before Pneu-P-23 for all ages. HSCT recipients may be an exception to this recommendation.

[4] Children up to and including 17 years old who have previously received Pneu-P-23 should received the recommended Pneu-C-13 doses.

[5] Refer to SIM, Chapter 7, Immunization of *Special Populations* for specific medical condition recommendations **and age restrictions.** Medical high-risk conditions may include:

- asplenia – congenital, acquired or functional (includes 1 dose for adults)
- renal disease
- liver disease including cirrhosis, hepatitis B, hepatitis C
- CSF disorders
- cardiac or lung disease (except asthma, unless management involves high dose oral corticosteroid therapy)
- cochlear implant recipient or candidate
- congenital immunodeficiency or acquired complement deficiency (includes 1 dose for adults)
- cystic fibrosis
- diabetes mellitus
- immunosuppressive medical treatment (e.g., high dose steroids, chemotherapy radiation therapy, post-solid organ transplant therapy) (includes 1 dose for adults)
- HIV (including Pneu-C-13 naïve adults)
- malignancies/cancer (includes 1 dose for adults)
- neurological conditions that impeded the clearance of oral/respiratory secretions
- sickle cell disease and other hemoglobinopathies (includes 1 dose for adults)
- solid organ or islet transplant recipient or candidate (includes 1 dose for adults)
- hematopoietic stem cell transplant (HSCT) recipient (includes adults)

Pneumococcal Conjugate 15-Valent Vaccine

[Non-publicly funded]

VAXNEUVANCE® (Pneu-C-15)

(Merck Canada Inc. 2023 monograph available at: https://www.merck.ca/en/wp-content/uploads/sites/20/2022/06/VAXNEUVANCE-PM_E.pdf)

Refer to Pneu-P-23 recommendations for adults 18+ immunized with only Pneu-C-15 or Pneu-C-20.

Pneumococcal Conjugate 20-Valent Vaccine

[Non-publicly funded]

PREVNAR 20™ (Pneu-C-20)

(Pfizer Canada 2023 monograph https://webfiles.pfizer.com/file/eaacb9cc-8b8c-4ddf-af69-93e374730387?referrer=ccb731e5-4f2d-4f4a-b2dc-e5e912145fc6)

Refer to Pneu-P-23 recommendations for adults 18+ immunized with only Pneu-C-15 or Pneu-C-20.

Pneumococcal Polysaccharide 23-Valent Vaccine (Pneu-P-23)

PNEUMOVAX® 23
(Merck Canada 2016 monograph available at: https://www.merck.ca/en/wp-content/uploads/sites/20/2021/04/PNEUMOVAX_23-PM_E.pdf)

INDICATIONS	• **All persons ≥ 65 years of age.** • **All residents of Extended or Intermediate Care Facilities.** • **All persons ≥ 2 years of age with:** ○ alcoholism ○ asplenia – congenital, acquired or functional [1] ○ renal disease ○ liver disease including cirrhosis, hepatitis B, hepatitis C ○ CSF disorders ○ cardiac or lung disease (except asthma, unless management involves high dose oral corticosteroid therapy) ○ cochlear implant recipient or candidate ○ congenital immunodeficiency or acquired complement deficiency ○ cystic fibrosis ○ diabetes mellitus ○ immunosuppressive medical treatment [2] (e.g., lymphoma, Hodgkin's, multiple myeloma, high dose steroids, chemotherapy radiation therapy, post-solid organ transplant therapy) ○ HIV [2] ○ malignancies/cancer **(individual must currently have)** [2] ○ neurological conditions that impeded the clearance of oral/respiratory secretions ○ sickle cell disease and other hemoglobinopathies ○ solid organ or islet transplant recipient or candidate ○ hematopoietic stem cell transplant (HSCT) recipient ○ residents of LTC facilities ○ homelessness and/or illicit drug use
DOSE / SERIES [3, 4]	• **Adults and children 2 years and older:** 0.5 mL SC or IM.
REINFORCEMENT **Reinforcement doses are not provided to healthy individuals**.	A **one-time** reinforcement dose should be offered 5 years later to those who have: • asplenia – congenital, acquired or functional • sickle cell disease and other hemoglobinopathies • immunosuppressive medical treatment • congenital immunodeficiency • acquired complement deficiency • renal disease • liver disease including cirrhosis, hepatitis B, hepatitis C • HIV • malignancies/cancer[4] • hematopoietic stem cell transplant (HSCT) recipient (as per agency guidelines)
CONTRA-INDICATIONS	History of an anaphylactic reaction to a previous dose of any pneumococcal vaccine or to any component of PNEUMOVAX® 23 vaccine.
PRECAUTIONS	Adverse reactions may intensify if revaccination occurs within 2 years.
VACCINE COMPONENTS	Purified capsular polysaccharides from the following 23 serotypes of *Streptococcus pneumoniae*: 1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19A, 19F, 20, 22F, 23F, 33F. **Excipients:** Sodium chloride**,** phenol**,** water for injection. Latex and thimerosal free.

Pneumococcal Polysaccharide 23-Valent Vaccine (Pneu-P-23) **PNEUMOVAX® 23** (Merck Canada 2016 monograph available at:https://www.merck.ca/en/wp-content/uploads/sites/20/2021/04/PNEUMOVAX_23-PM_E.pdf)	
EXPECTED REACTIONS	**Local:** Temporary pain, redness and swelling where the needle was given. In a few people, this reaction may last up to 10 days. **Systemic:** Headache, sore muscles, mild fever, nausea and vomiting.
EFFECTIVENESS	Efficacy ranges from 50-80% in immunocompetent persons. Antibody levels decline after 5-10 years.

[1] Give vaccine at least 14 days before splenectomy, or, if not possible 14 days post-splenectomy. If there is concern that the patient may not present later for immunization, give at hospital discharge.

[2] Give vaccine before initiation of immunosuppression therapy, and early in the course of HIV infection.

[3] **NOTE**: 1-year minimum interval is required if Pneu-P-23 is given before Pneu-C-13 (all ages), and an 8 week interval is required if Pneu-C-13 is given before Pneu-P-23 for all ages. HSCT recipients may be an exception to this recommendation.

[4] Individuals who are 'cancer-free' do not qualify for additional vaccine doses (i.e., a second dose of Pneu-P-23) as their risk is the same as everyone else.

Pneu-P-23 recommendations for adults 18+ immunized with only Pneu-C-15 or Pneu-C-20

Immunization History	Recommendations
Pneu-C-15 only	Eligible individuals to receive 1 publicly funded Pneu-P-23 vaccine dose 1 year (min. 8 weeks) later [1]
Pneu-C-20 only	Eligible individuals to receive 1 publicly funded Pneu-P-23 vaccine doses 1 year (min. 8 weeks) later [1, 2]

[1] Refer to SIM Ch. 10 Biological Products for publicly funded Pneu-P-23 vaccine eligibility.

[2] Pneu-P-23 is not necessary after receiving Pneu-C-20, but may be given as noted in footnote #1.

Poliomyelitis Vaccine (IPV)
(trivalent, inactivated, whole virus, Vero cell origin)

IMOVAX® Polio

(Sanofi Pasteur monograph available at: https://products.sanofi.ca/en/imovax-polio.pdf)

INDICATIONS NOTE: IPV is to replace OPV doses (for age requirements) documented as of April 1, 2016	DOSE / SERIES (0.5 mL)
1. Infants and children up to and including 3 years of age who do not require diphtheria, pertussis, tetanus, or Hib. **2**. Children 4 years to 17 years of age who do not require diphtheria or tetanus vaccine. **3.** Adults ≥18 years**.** **4**. Previously unimmunized children and adult solid organ transplant (SOT) candidates and recipients. **5**. HSCT recipients: [1]	**1. Infants and children up to and including 3 years of age:** **Dose 1**: 0.5 mL SC **Dose 2**: 0.5 mL SC given 1 month after dose 1 **Dose 3**: 0.5 mL SC given 6 months after dose 2 [2] **Dose 4**: 0.5 mL SC at school entry (min. interval is 6 months after dose 3). (This dose is not necessary if dose 3 was given on or after the 4th birthday). **2. & 3. Individuals 4 years and older that require a primary series** **Dose 1**: 0.5 mL SC **Dose 2**: 0.5 mL SC given 1 month after dose 1 **Dose 3**: 0.5 mL SC given 6 months after dose 2. **NOTE: At minimum, one dose must be given at or after 4 years of age.** **4.** Use schedule (1) or (2) above as appropriate for age **5. Dose 1**: 0.5 mL SC (1 year after HSCT) **Dose 2**: 0.5 mL SC (2 months after dose 1) **Dose 3**: 0.5 mL SC (1 year after dose 1)
REINFORCEMENT	**Reinforcement doses are not publicly funded**.
CONTRAINDICATIONS	History of anaphylactic reaction to any oral or injectable polio-containing vaccine, or to any IPV vaccine component.
VACCINE COMPONENTS	Each 0.5 mL dose contains: Type 1 (Mahoney) 40 D-antigen units; Type 2 (MEF1) 8 D-antigen units; Type 3 (Saukett) 32 D-antigen units. **Excipients**: 2-phenoxyethanol **Manufacturing Process Residuals**: Formaldehyde, residual calf serum protein. **Trace amounts of:** neomycin, streptomycin and polymyxin B, Medium 199 Hanks (without phenol red). Latex and thimerosal free.
EXPECTED REACTIONS	**Local**: Temporary pain, redness and swelling. **Systemic**: Mild fever, fatigue and headache.
EFFECTIVENESS	Immunity following injectable poliovirus vaccine series has been shown to persist for 4 or more years after a primary series.

[1] Refer to SIM, Chapter 7, *Immunization of Special Populations,* Section 3.6 *Transplant Recipient - Haematopoietic Stem Cell Transplant. Documentation of a 3-dose primary series given by any route with at least one dose received at 4 years of age or older.*

[2] Dose 3 must be given six months after dose 2 and at least after 1 year of age.

Rabies Vaccine (Rab) Post-Exposure Indication
[Human Diploid Cell Vaccine (HDCV)] (Inactivated whole virus)

IMOVAX® Rabies (Sanofi Pasteur 2021 monograph available at: https://products.sanofi.ca/en/imovax-rabies.pdf)

INDICATIONS	**ONLY Post-Exposure Prophylaxis is publicly funded:** • As determined by Regional Medical Health Officers. • Refer to the Saskatchewan Communicable Disease Control Manual Rabies chapter.
SERIES	**1. Previously Unimmunized Individuals:** **(1A) Unimmunized immunocompetent individuals to receive a 4 dose series:** • **1 mL IM on days 0 – 3 – 7 – 14** • **Day 0**: 1 mL IM as soon as possible after exposure **PLUS Rabies Immune globulin (RabIg).** • **Days 3, 7**, and **14**: 1 mL IM. **(1B) Unimmunized immunocompromised individuals* to receive a 5 dose series**: • **1 ml IM on days 0 – 3 – 7 – 14 – 28** • **Day 0:** 1 mL IM as soon as possible after exposure **PLUS RabIg.** • **Days 3, 7, 14** and **28:** 1 mL IM. *includes those taking antimalarials and/or any immunosuppressants (e.g., corticosteroids) that can result in immunosuppression. --- **2. Previously Immunized Individuals**: • Refer to the CDC Manual Rabies chapter for information.

Rabies Vaccine (Rab) Post-Exposure Indication [Human Diploid Cell Vaccine (HDCV)] (Inactivated whole virus)

IMOVAX® Rabies

(Sanofi Pasteur 2021 monograph available at: https://products.sanofi.ca/en/imovax-rabies.pdf)

RECONSTITUTION	**Package with Two Needles** 1. Attach the plunger and reconstitution needle to the syringe and reconstitute the freeze-dried vaccine by introducing the diluent provided into the vial of powder. 2. Gently swirl the contents until completely dissolved. 3. Withdraw the suspension from the vial into the syringe. 4. Remove the reconstitution needle and replace it with an appropriate needle for intramuscular injection. **Package with Attached Needle** 1. Reconstitute the freeze-dried vaccine in its vial with the diluent supplied in the syringe. 2. Gently swirl the contents until completely dissolved.
CONTRAINDICATIONS	1. There are **NO** contraindications to rabies vaccine given for post-exposure purposes**.** 2. **DO NOT GIVE RABIES VACCINE IN THE GLUTEAL REGION.** 3. Rabies vaccine and RabIg must not be administered in the same anatomical site. 4. Use separate needles and syringes for each product.
PRECAUTIONS	• Administer vaccine in an emergency room setting if history of anaphylactic reaction to a previous dose of rabies vaccine, IMOVAX® Rabies or to any of the components of IMOVAX® Rabies. • There are insufficient data regarding concurrent use of mefloquine with rabies immunization.
VACCINE COMPONENTS	Rabies virus (WISTAR Rabies PM/WI 38 1503-3M Strain), human albumin, neomycin, phenol red and may contain traces of beta propiolactone. Latex-free.
EXPECTED REACTIONS	**Local**: Pain, redness, swelling and itching at injection site. **Systemic:** Fever, nausea, headache, joint or muscle aches, fatigue, swollen lymph glands and dizziness.
SPECIAL CONSIDERATION	IMOVAX® Rabies is pink to red in color following reconstitution. Also, it does not contain any preservative and should be used immediately after reconstitution or discarded**.**
EFFECTIVENESS	After 3 pre-exposure doses, all vaccinees reached antibody levels to confer protection. 96% showed seroconversion at 5 years.

Rabies Vaccine (Rab) Post-Exposure Indication [Purified Chick Embryo Cell Vaccine (PCECV)] (Inactivated)

RabAvert® (2021 product monograph available at: https://www.valneva.ca/en/)

INDICATIONS	**ONLY Post-Exposure Prophylaxis is publicly funded:** • As determined by Regional Medical Health Officers. • Refer to the Saskatchewan Communicable Disease Control Manual Rabies chapter.
SERIES	**1. Previously Unimmunized Individuals:** **(1A) Unimmunized immunocompetent individuals to receive a 4-dose series:** • **1 mL IM on days 0 – 3 – 7 – 14** • **Day 0**: 1 mL IM as soon as possible after exposure **PLUS Rabies Immune globulin (RabIg).** • **Days 3, 7**, and **14**: 1 mL IM. **(1B) Unimmunized immunocompromised individuals* to receive a 5 dose series**: • **1 ml IM on days 0 – 3 – 7 – 14 – 28** • **Day 0:** 1 mL IM as soon as possible after exposure **PLUS RabIg.** • **Days 3, 7, 14** and **28:** 1 mL IM. *includes those taking antimalarials and/or any immunosuppressants (e.g., corticosteroids) that can result in immunosuppression. --- **2. Previously Immunized Individuals**: • Refer to the CDC Manual Rabies chapter for information.

Rabies Vaccine (Rab) Post-Exposure Indication [Purified Chick Embryo Cell Vaccine (PCECV)] (Inactivated)

RabAvert® (2021 monograph available at: https://www.valneva.ca/en/)

RECONSTITUTION	1. Use the **longer of the 2 needles supplied** (21g x 1.5") to withdraw the entire contents of the sterile diluent into the syringe. 2. Insert the needle at a 45° angle and slowly inject the entire contents of the diluent into the vaccine vial. 3. Mix gently to avoid foaming. Unscrew the syringe from the needle to eliminate negative pressure. 4. Reinsert the syringe into the needle. Withdraw the total amount of reconstituted vaccine into the syringe. 5. **Replace the long needle with the smaller needle (25g x 1") for IM injection.**
CONTRAINDICATIONS	1. There are **NO contraindications** to rabies vaccine given for post-exposure purposes**.** 2. **DO NOT GIVE RABIES VACCINE IN THE GLUTEAL REGION.** 3. Rabies vaccine and RabIg must not be administered in the same anatomical site. 4. Use separate needles and syringes for each product
PRECAUTIONS	• Administer vaccine in an emergency room setting if history of anaphylactic reaction to a previous dose of rabies vaccine, RabAvert®, eggs or egg products, or to any of the components of RabAvert®. • There are insufficient data regarding concurrent use of mefloquine with rabies immunization.
VACCINE COMPONENTS	Freeze-dried rabies antigen, polygeline, human serum albumin, neomycin, chlortetracycline, amphotericin B, ovalbumin, potassium glutamate, sodium EDTA and may contain traces of beta propiolactone.
EXPECTED REACTIONS	**Local**: Pain, redness, swelling and itching at injection site. **Systemic:** Fever, nausea, headache, joint or muscle aches, fatigue, swollen lymph glands and dizziness.
SPECIAL CONSIDERATION	RabAvert® does not contain a preservative and should be used immediately after reconstitution or discarded.
EFFECTIVENESS	Antibodies develop 7 days after 2nd dose and persist for at least 5 years after the third dose.

Respiratory Syncytial Virus Vaccine (RSV) (stabilized prefusion F protein subunit, bivalent) [Non-publicly funded]

ABRYSVO™
(Pfizer 2023) product monograph https://pdf.hres.ca/dpd_pm/00073900.PDF

Indications:

- Active immunization of pregnant individuals from 32 through 36 weeks gestational age for the prevention of lower respiratory tract disease (LRTD) and severe LRTD caused by respiratory syncytial virus (RSV) in infants from birth through 6 months of age.
- The prevention of lower respiratory tract disease caused by RSV in individuals 60 years of age and older by active immunization.

Respiratory Syncytial Virus Vaccine (recombinant, AS01E adjuvanted) (RSV) [Non-publicly funded]

AREXVY
(GSK 2023) product monograph https://ca.gsk.com/media/6988/arexvy.pdf

Indication:

- The prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus in adults 60 years of age and older.

Rotavirus vaccine
(human rotavirus, live, attenuated, oral vaccine) [Non-publicly funded]

ROTARIX™ (Rot-1)
(GlaxoSmithKline 2023 monograph available at: https://ca.gsk.com/media/6256/rotarix_pm_en.pdf

Rotavirus Vaccine
(oral live viral pentavalent human-bovine reassortant)

RotaTeq® (Rot-5)

Merck Canada Inc. 2023 monograph available at: https://www.merck.ca/en/wp-content/uploads/sites/20/2021/04/ROTATEQ-PM_E.pdf)

- **Under no circumstances should RotaTeq® be injected.**
- **RotaTeq® is to be administered orally without mixing with any other vaccines or solutions.**
- **Do not reconstitute or dilute.**

INDICATIONS [1]	**DOSE / PRIMARY SERIES** [2, 3, 4, 5, 6, 8]
SCHEDULE **Minimum age is 6 weeks old.**	**Dose 1:** 2 mL PO (entire contents of applicator) at 2 months of age. • **Dose 1 must be received between 6 weeks and 14 weeks 6 days of age.** **Dose 2**: 2 mL PO (entire contents of applicator) at 4 months of age. **Dose 3**: 2 mL PO (entire contents of applicator) at 6 months of age. • **Dose 3 must be received by 8 month minus 1 d old.**
REINFORCEMENT	Not indicated at this time.
CONTRA-INDICATIONS	• History of anaphylactic reaction to a previous dose of a rotavirus-containing vaccine or to any RotaTeq® vaccine component. • Infants who have a history of intussusception. • **HIV is not a contraindication to receiving a rotavirus vaccine series**. Infants with a known or suspected immunocompromising condition **excluding HIV should** not receive RotaTeq® without consultation with a specialist or expert in the condition. • Infants diagnosed with Severe Combined Immunodeficiency (SCID) disorder or who have a family history of SCID or recurrent, unexplained early deaths in the family. • Infants with a history of a chronic gastrointestinal tract condition or disease, or any uncorrected congenital malformations (e.g., Meckel's diverticulum). • Infants whose mothers took monoclonal antibody medications during pregnancy. Refer to Chapter 8 Administration of Biological Products *Appendix 8.2 Potentially Immunosuppressive Biologic Agents*
PRECAUTIONS	1. Preterm infants can receive rotavirus vaccine if: a) they are chronologically aged 6 weeks and; b) are clinically stable. If the infant is in hospital, the vaccine can only administered at the time of discharge or after discharge from the neonatal intensive care unit, nursery, etc. 2. Acute gastroenteritis: in infants with moderate to severe gastroenteritis, rotavirus vaccine should be deferred until the condition improves unless deferral will result in scheduling of the first dose at more than 14 weeks 6 days of age. 3. Excretion of the vaccine virus in the stools is known to occur after vaccination and lasts for 10 days on average with peak excretion around the 7th day. Contacts of recent vaccinees should be advised to observe careful hygiene (including washing their hands) when changing children's diapers.
VACCINE COMPONENTS [7]	Human-bovine rotavirus reassortants G1, G2, G3, G4, and P1A, sucrose, sodium citrate dihydrate, sodium phosphate monobasic monohydrate, sodium hydroxide, polysorbate 80, diluent and Vero cell culture media. Trace amounts of fetal bovine serum may be present. DNA fragments from porcine circoviruses (PCV) 1 and 2 have been detected in RotaTeq®. The source is porcine-derived material used in the manufacture of the vaccine. PCV-1 and PCV-2 are not known to cause disease in humans. Preservative-free, thimerosal-free and latex-free.

Rotavirus Vaccine
(oral live viral pentavalent human-bovine reassortant)

RotaTeq® (Rot-5)
(Merck Canada Inc. 2023 monograph available at: https://www.merck.ca/en/wp-content/uploads/sites/20/2021/04/ROTATEQ-PM_E.pdf)

EXPECTED REACTIONS	• Common temporary reactions such as fever, diarrhea, and vomiting may occur within 1 week after immunization. • Less common temporary reactions include irritability, loss of appetite, flatulence (gas), and abdominal pain. • Intussusception occurs in about 34 out of 100,000 babies in their first year. The current rotavirus vaccines have demonstrated a small increased risk of intussusception (1 to 7 cases per 100,000 doses). Intussusception related to rotavirus vaccines is extremely rare.
EFFECTIVENESS	In phase III clinical studies, 92.9% to 100% of recipients of RotaTeq® achieved a significant rise in serum anti-rotavirus IgA after a three-dose regimen.

- **Under no circumstances should RotaTeq® be injected.**
- **RotaTeq® is to be administered orally without mixing with any other vaccines or solutions.**
- **Do not reconstitute or dilute.**
- **NOTE:** The manufacturer has not addressed RotaTeq® be given via g-tube but the CDC considers administration of rotavirus vaccine via g-tube to be an acceptable practice. Ensure the g-tube is flushed before and after RotaTeq® has been administered (http://www.immunize.org/askexperts/experts_rota.asp).
- Refer to SIM chapter 8 *Appendix 8.4 Oral Vaccine Administration via Enteral Tube*.

[1] Age-appropriate infants who have had rotavirus gastroenteritis before starting or completing the full RotaTeq® series should still initiate or complete the RotaTeq® series because the initial infection frequently provides only partial immunity.
[2] The minimum interval is 4 weeks between all Rot-5 doses.
[3] If an infant spits out or regurgitates any of the Rot-5 dose no replacement dose should be administered.
[4] There are no restrictions on the infant's consumption of food or liquid, including breast milk, either before or after immunization with RotaTeq® vaccine.
[5] RotaTeq® vaccine may be administered at any time before, concurrently with, or after administration of any blood product, including antibody-containing products.
[6] There are no data on the interchangeability of RotaTeq® and ROTARIX™ vaccines. Whenever possible, the series should be completed with the same product. However, if the product used for a previous dose(s) is not known, complete the series with the available product. If any dose in the series was RotaTeq®, a total of 3 doses of rotavirus vaccine should be administered provided the age limit of 8 months minus 1 day is not exceeded.
[7] DNA fragments from porcine circoviruses (PCV) 1 and 2 have been detected in RotaTeq®. The source is porcine-derived material used in the manufacture of the vaccine. PCV-1 and PCV-2 are not known to cause disease in humans.
[8] For infants in whom the first dose of RV vaccine is inadvertently administered at age 15 weeks or older, the rest of the series should be completed with a minimum of 4 weeks between each dose, and all doses should be administered before 8 months minus 1 day of age (CIG).

Smallpox and Mpox Vaccine (SMV)
Modified Vaccinia Ankara-Bavarian Nordic® (live-attenuated, non-replicating)

IMVAMUNE®

Bavarian Nordic 2023 Product monograph: https://pdf.hres.ca/dpd_pm/00070186.PDF

Composition/Platform Vaccine Type, Vaccine Efficacy	• Each single-dose vial of liquid-frozen IMVAMUNE is formulated to have a titer of at least 0.5 x 10^8 infectious units (Inf.U) per 0.5 mL (1 dose) of Modified Vaccinia Ankara-Bavarian Nordic (MVA-BN). • Tris buffer (Tris-hydroxymethyl-amino methane, sodium chloride, water for injection and hydrochloric acid), Trometamol (Tris-hydroxymethyl-amino methane), sodium chloride, water for injection. The vaccine contains trace amounts of host cell DNA and protein, benzonase, gentamicin and ciprofloxacin. • No adjuvants or preservatives
Dosage by Route	**0.5 ml Subcutaneous (SC) injection** ❖ 0.1 ml Intradermal (ID) injection for **only as dose sparing strategy** when there is limited vaccine supply and a second dose is required NOTE: Off-label ID administration is **only for immunocompetent adults** when given as a second dose following a first dose given subcutaneously.
ID Route Administration	• Those <18 years of age, at risk of keloid scars, or moderately to severely immunocompromised should be immunized using the subcutaneous route of administration only.

Series and eligibility	• **Those with a documented history of prior monkeypox infection need not be vaccinated.**
	Post-exposure Prophylaxis (PEP) (1 dose; see second bullet re second dose)
	• For individuals with high risk exposures to a probable or confirmed case of mpox, or within a setting where transmission is happening, PEP should be offered as soon as possible and within 4 days of last exposure and can be considered up to 14 days since last exposure. PEP should not be offered to individuals who are symptomatic and who meet the definition of suspect, probable or confirmed case.
	• After 28 days, if an individual is assessed as having a predictable ongoing risk of exposure, a second dose may be offered in consultation with a Medical Health Officer. A second dose should not be offered to individuals who are symptomatic and therefore after medical evaluation meet suspect, probable or confirmed mpox case definitions.
	• For individuals who had received a live replicating 1st or 2nd generation smallpox vaccine in the past and who sustain a high-risk exposure to a probable or confirmed case of mpox, a single dose may be offered (i.e. as a booster dose) at least 28 days after the latest live replicating smallpox vaccine dose.
	Pre-exposure Prophylaxis (PrEP) (2 doses four weeks apart)
	• Those working in research laboratory settings with replicating orthopoxviruses
	• In the context of an active mpox outbreak, NACI recommends that immunization using the Imvamune vaccine should be offered to individuals with highest risk of mpox. During the outbreak in 2022, eligibility was as follows:
	  • Individuals who self-identify as sex workers, regardless of their self-identified gender.
	  • Men who have sex with men (MSM), and individuals who have sex with MSM, and who meet at least one of the following criteria:
	  • Having had a confirmed sexually transmitted infection acquired in the last year.
	  • Engage in sexual contact in sex-on-premises venues

	• Have had or plan to have sexual contact with an anonymous partner (at an event or via a hook-up app); • Are planning to travel in the next three months to an area in Canada or internationally currently reporting mpox cases (https://www.who.int/emergencies/disease-outbreak-news/item/2022-DON396); • Individuals who work or volunteer at in sex-on-premises venues (sauna, bath house, club) where workers may have contact with fomites potentially contaminated with mpox, without the use of personal protective equipment. **Imvamune® may be offered to the following individuals:** • Those who are pregnant or breastfeeding and who are at risk. • Those who are immunocompromised due to disease or treatment and are at risk. • Those younger than 18 years of age where infection could have significant negative outcomes. **For immunocompetent individuals** who have received a live replicating 1st or 2nd generation smallpox vaccine in the past and who are at high risk for occupational exposure, a single dose may be offered (i.e. as a booster dose), rather than the two dose primary vaccine series. This single dose should be given at least two years after the latest live replicating smallpox vaccine dose.
Contraindications	• Known severe hypersensitivity to a previous vaccine dose or any component of the vaccine. • Egg-allergic individuals may be immunized except if there is a known previous anaphylactic reaction to egg. Egg-allergic vaccine recipients should be kept under observation for 30 minutes following the administration of this vaccine. • Anaphylaxis to previous vaccine dose. If re-vaccinated, vaccine administration should be done in a controlled setting with expertise and equipment to manage anaphylaxis. Individuals should be observed for at least 30 minutes after re-vaccination.
Precautions	NACI (2022-06-10): • Myocarditis: First generation *orthopoxvirus* vaccines and mRNA COVID-19 vaccines both have a potential risk of cardiac adverse events (myocarditis). Risk for myo- or pericarditis with the newer generation non-replicating attenuated virus vaccine Imvamune® is still unknown. It would be prudent to wait for a period of at least 4 weeks **before** or **after** the administration of mRNA COVID-19 vaccine in order to prevent erroneous attribution of an AEFI to one particular vaccine or the other. This suggested minimum waiting period between vaccines is **precautionary** at this time. Protection from mpox exposure should be prioritized and recent mRNA vaccine receipt should not delay Imvamune® PEP or PrEP if protection is urgent. • In consultation with a physician, the benefit of protection against infection should be weighed against the risk of recurrent myocarditis for individuals with a history of myocarditis/pericarditis linked to a previous dose of live replicating 1st and 2nd generation smallpox vaccine and/or Imvamune®; a precautionary approach is warranted at this time until more information is available. • Imvamune® given as PEP or PrEP should not be delayed due to recent receipt of an mRNA COVID-19 vaccine. If vaccine timing can be planned (i.e. prior to employment within a research laboratory), NACI recommends that Imvamune® be given at least 4 weeks after or before an mRNA vaccine for COVID-19 . • Individuals with the following conditions should discuss vaccination with their physician, who will be able to advise on safe vaccination or on alternative preventative measures to avoid infection with smallpox, mpox or other orthopoxviruses: Pregnant or breast feeding women.

Possible reactions	• The adverse reactions listed below have been observed during clinical studies. The most common side effects reported were at the injection site. Most of the reported adverse reactions are mild to moderate in intensity and resolving without intervention within seven days following vaccination. • Local reactions may last longer/be more common if the vaccine was administered by the ID route. **Very common side effects** reported in at least 1 in 10 persons were: • Pain, redness, swelling, hardness, or itching at the injection site. • Tiredness, headache, aching muscles, nausea. **Common side effects** reported in at least 1 in 100 but less than 1 in 10 persons were: • Nodule, discolouration, bruising, warmth at the injection site, chills, fever, pain in extremity, joint pain, or loss of appetite. **Uncommon side effects** reported in at least 1 in 1000 but less than 1 in 100 persons were: • Irritation, bleeding, scaling, inflammation, sensitivity disorder, or reaction at the injection site. • Underarm swelling, malaise, flushing, axillary pain, chest pain, dizziness, sensibility disorder, musculoskeletal stiffness, back pain, neck pain, rash, pruritus, dermatitis, skin discolouration, diarrhea, vomiting, dry mouth, throat pain, flu-like symptoms, cough, sleep disorder, clinically not relevant increase of cardiac enzymes, hepatic enzyme increased, white blood cell count decreased, mean platelet volume decreased, contusion, nose and throat infection, upper respiratory tract infection or temporarily enlarged lymph nodes. **Rare side effects** reported in less than 1 in 1000 persons were: • Rash, anesthesia, dryness, movement impairment or vesicles at the injection site. • Weakness, influenza like illness, oedema peripheral, migraine, peripheral nerve sensations, muscle spasms, musculoskeletal pain, muscular weakness, urticarial, ecchymosis, increased sweating, night sweats, subcutaneous nodule, angioedema, abdominal pain, increased heartbeat, sinusitis, pink eye, mouth and throat pain, influenza, white blood cell count increased, vertigo.
Other Considerations	• IMVAMUNE is a non-replicating live vaccine and it can be co-administered with or given any time before or after another live vaccine, an immune globulin product or tuberculin skin testing. • Cardiac AESIs were reported to occur in 1.4% (91/6,640) of IMVAMUNE recipients and 0.2% (3/1,206) of placebo recipients who were smallpox vaccine-naïve. Cardiac AESIs were reported to occur in 2.1% (16/762) of IMVAMUNE recipients who were smallpox vaccine-experienced. Replicating smallpox vaccines have been associated with myopericarditis. If a vaccinated subject exhibits signs and symptoms potentially associated with a cardiac disorder (e.g. chest pain or discomfort, dyspnea, or palpitations), ECG and troponin I tests should be performed. In case of ECG changes or troponin I elevations, further cardiologic examination should be performed. • Persons who have atopic dermatitis may have more intense reactions or have a flare up after getting this vaccine. • The safety profile of IMVAMUNE® in immune compromised subjects has been shown to be comparable to that recorded for healthy individuals. IMVAMUNE has been studied in more than 690 subjects infected with HIV to evaluate its immunogenicity and safety in an immunocompromised population. Since HIV directly infects T helper cells, and also indirectly impairs other immune system responses, HIV infection can be considered as being exemplary also for other forms of immunodeficiency.
Storage, Stability and Disposal	• Vaccine is supplied in 2-mL injection vials each containing one single standard 0.5 ml

dose of liquid-frozen vaccine

Table 1: Overview of approved Imvamune shelf life in Canada for storage at -20°C, -50°C and -80°C from date of manufacture

Storage temperature	Approved shelf life from date of manufacture
-80°C ± 10°C	9 years

Table 2: Overview of approved Imvamune shelf life in Canada for storage at 2°C to 8°C

Storage temperature	Approved shelf life
After prior storage at -20°C, -50°C, or -80°C (if within approved respective shelf-life)	
2°C to 8°C	2 months (8 weeks)*

Analysis of stability data supports that the vaccine remains stable for up to 3 months (91 days) at -20°C following long-term storage at -80°C (within the approved -80°C shelf-life). Therefore, as per **Table 3**, to maintain the approved shelf-life of 9 years at -80°C, the cumulative time of shipment or storage at -20°C must not exceed 3 months (91 days) before return to long-term storage at -80°C . This assessment is applicable for batches already delivered to Canada and subsequent batches.

Table 3: Overview of allowable shipment and storage time at -20°C following long-term storage at -80°C to maintain a 9-year shelf-life

Storage Temperature	Cumulative Storage Time
After prior storage at -80°C (and within the approved shelf-life)	
-20°C ± 5°C	3 months (91 days)

- **If a vial is used for multiple doses, it should be discarded after 6 hours following first puncture.**
- **Do not refreeze a vial once it has been thawed.**
- Store in the original package in order to protect from light.
- Do not use after the expiry date shown on the label, unless batch certification documentation allows for use based on an updated expiry date.
- Refer to the Storage and Handling of IMVAMUNE Vaccine work standard, and Imvamune: Storage temperatures, shelf life, shipment and supportive temperature excursion information.

Prior to Administration

- Thaw at room temperature.
- To ensure homogeneity upon thawing, the vial should be swirled gently (not shaken) for at least 30 seconds.
- After thawing, the drug product should appear as a pale milky colored homogeneous suspension.
- The liquid vaccine should be visually inspected for any foreign particulate matter prior to administration. In case of foreign particulate matter being visible, the vaccine must not be used.

Reference:

- NACI (September 2022). NACI Rapid Response – Update interim guidance on the use of Imvamune® in the context of mpox outbreaks. https://www.canada.ca/content/dam/phac-aspc/documents/services/immunization/national-advisory-committee-on-immunization-naci/rapid-response-updated-interim-guidance-imvamune-mpox-outbreaks.pdf
- Imvamune: Storage temperatures, shelf life, shipment and supportive temperature excursion information https://www.canada.ca/en/public-health/services/diseases/mpox/technical-documents/imvamune-storage-temperatures-shelf-life-shipment-temperature-excursion.html

Tetanus-Diphtheria Vaccine (Td) (Adsorbed)

Td Adsorbed

(Sanofi Pasteur 2022 monograph available at: https://products.sanofi.ca/en/td-adsorbed.pdf

INDICATIONS (≥7 years old) [1, 2] For those who have a contraindication to a pertussis-containing vaccine.	**DOSE** 0.5 mL IM
CONTRAINDICATIONS 1. History of anaphylactic reaction to a previous dose of any tetanus or diphtheria-containing vaccine, or to any Td vaccine component. 2. When a contraindication exists to tetanus toxoid and a client sustains a major or unclean wound, TIg should be given • Refer to *Tetanus Immune Globulin* (TIg) in this chapter. • Refer to Chapter 5, Section 3.7, *Tetanus Prophylaxis in Wound Management.* 3. History of Guillain-Barré syndrome (GBS) occurring within 6 weeks of receipt of a tetanus-containing vaccine.	
VACCINE COMPONENTS Tetanus toxoid, diphtheria toxoid. Excipients: Aluminum phosphate (adjuvant), 2-phenoxyethanol, isotonic solution of sodium chloride in water for injection. Manufacturing process residuals: formaldehyde is present in trace amounts. Latex and thimerosal free.	
EXPECTED REACTIONS **Local:** Pain, swelling, redness at injection site. **Systemic**: Fatigue, headache, fever, dizziness, or sore or swollen joints.	
SPECIAL CONSIDERATION For wound prophylaxis, Td and TIg should be administered using separate syringes and different sites.	
EFFECTIVENESS May not protect 100% of susceptible individuals.	

[1] Refer to Chapter 5, Section 3.7, Tetanus Prophylaxis in Wound Management.

[2] Tetanus toxoid should not be given routinely to clients who have received a tetanus-containing vaccine in the previous 5 years. Refer to Chapter 5, Section 2.1, *Minimum Intervals for Specific Vaccine Series.*

Tetanus-Diphtheria-acellular Pertussis Vaccine (Tdap)

ADACEL®

(Sanofi Pasteur 2023 monograph available at: https://products.sanofi.ca/en/adacel.pdf

INDICATIONS, DOSES and SERIES [*, 1, 2] (0.5 mL IM) (Min. age 4 years old)	
1. Wound Management [1] **2.** Booster (5th) dose at age 4-6 years (school entry) who have met polio vaccine requirements. **3.** Reinforcement dose for Grade 8 students. [2] **4.** Reinforcement dose for adults every 10 years **5.** Adult caregivers of infants <6 months old who have not received Tdap as an adult. [3] **6.** Pregnant women: Tdap in every pregnancy, ideally between 27-32 weeks gestation. [4] **7.** Special Populations - Refer to Chapter 7, *Immunization of Special Populations* for specific medical condition. **8.** Unimmunized individuals 7+ years who do not require IPV: 1. Dose 1 2. Dose 2: 1 months after 1st dose 3. Dose 3: 6 months after 2nd dose **9.** Children 7+ and Adolescents who do not require IPV: **A.** Booster dose for those who missed receiving the school entry booster dose. **B.** Incompletely immunized children and adolescents [3]: a. **If the first dose of DTaP-containing vaccine was administered before the 1st birthday**, administer remaining dose(s) in order to complete a 4-dose primary series given as: 1. Dose 1 was administered before the 1st birthday 2. Dose 2: 1 month after 1st dose 3. Dose 3: 1 month after 2nd dose 4. Dose 4: 6 months after 3rd dose (must be given ≥ 4 years old) b. **If the first dose of DTaP-containing vaccine was administered after the 1st birthday**, administer remaining dose(s) in order to complete a 3-dose primary series given as: 1. Dose 1 was administered after the 1st birthday 2. Dose 2: 1 month after 1st dose 3. Dose 3: 6 months after 2nd dose (must be given ≥ 4 years old)	
REINFORCEMENT	Adults every 10 years
PRECAUTION	Acellular pertussis-containing vaccines may be administered to clients with the following conditions once a treatment regimen has been established and their condition has stabilized: • Progressive or unstable neurologic disorder (including infantile spasms for DTaP) • Uncontrolled seizures • Progressive encephalopathy
CONTRA-INDICATIONS	1. Children younger than 4 years old. 2. History of anaphylactic reaction to a previous dose of any tetanus, diphtheria or pertussis-containing vaccine, or to any Tdap vaccine component. 3. When a contraindication exists to tetanus toxoid and a client sustains a major or unclean wound, TIg should be given. Refer to *Tetanus Immune Globulin* (TIg) in this chapter. [1] 4. History of Guillain-Barré syndrome (GBS) occurring within 6 weeks of receipt of a tetanus-containing vaccine. 5. Encephalopathy (e.g., coma, decreased level of consciousness, prolonged seizures) not attributable to another identifiable cause within 7 days after receiving a dose of a pertussis-containing vaccine. 6. Individuals who have experienced transient thrombocytopenia or other neurological complications following an earlier immunization against diphtheria and/or tetanus.

Tetanus-Diphtheria-acellular Pertussis Vaccine (Tdap)

ADACEL®

(Sanofi Pasteur 2023 monograph available at: https://products.sanofi.ca/en/adacel.pdf

VACCINE COMPONENTS	Tetanus toxoid, diphtheria toxoid, acellular pertussis [pertussis toxoid (PT), filamentous haemagglutinin (FHA), pertactin (PRN), fimbriae types 2 and 3 (FIM)]. **Excipients**: Aluminum phosphate (adjuvant), 2-phenoxyethanol. **Manufacturing residuals**: Formaldehyde and glutaraldehyde are present in trace amounts. Latex and thimerosal free.
EXPECTED REACTIONS	**Local**: pain, redness and swelling at the injection site. **Systemic:** fatigue, headache, mild fever, dizziness, body aches or nausea.
EFFECTIVENESS	93-100% show protective levels for at least 5 years

***** According to the National Advisory Committee on Immunization (NACI), there is no upper age limit for the administration of Tdap. This differs from the information in the Tdap product monographs.

[1] Refer to Chapter 5, Section 3.7, *Tetanus Prophylaxis in Wound Management*.

[2] Children who complete their primary series or receive a booster dose of Tdap after their 11th birthday, do not require an additional dose of Tdap in Grade 8. See Chapter 5, Appendix 5.3 *Grade 8 Tdap Algorithm*.

[3] There is no minimum interval between a dose of Td and Tdap when Tdap is being given for pertussis protection years.

[4] Refer to Chapter 7 *Appendix 7.7: Tdap Immunization Decision Chart for Pregnant Women.*

Tetanus-Diphtheria-acellular Pertussis Vaccine (Tdap)

BOOSTRIX®

(GlaxoSmithKline 2023 monograph available at: https://ca.gsk.com/media/6234/boostrix.pdf)

INDICATIONS, DOSES and SERIES [*, 1, 2] (0.5 mL IM) (Min. age 4 years old)	
1. Wound Management [1] **2.** Booster (5th) dose at age 4-6 years (school entry) who have met polio vaccine requirements. **3.** Reinforcement dose for Grade 8 students. [2] **4.** Reinforcement dose for adults every 10 years **5.** Adult caregivers of infants <6 months old who have not received Tdap as an adult. [3] **6.** Pregnant women: Tdap in every pregnancy, ideally between 27-32 weeks gestation. [4] **7.** Special Populations - Refer to Chapter 7, *Immunization of Special Populations* for specific medical condition. **8.** Unimmunized individuals 7+ years who do not require IPV: 1. Dose 1 2. Dose 2: 1 months after 1st dose 3. Dose 3: 6 months after 2nd dose **9.** Children 7+ and Adolescents years of age who do not require IPV: **A.** Booster dose for those who missed receiving the school entry booster dose. **B.** Incompletely immunized children and adolescents [3]: a. **If the first dose of DTaP-containing vaccine was administered before the 1st birthday**, administer remaining dose(s) in order to complete a 4-dose primary series given as: 1. Dose 1 was administered before the 1st birthday 2. Dose 2: 1 month after 1st dose 3. Dose 3: 1 month after 2nd dose 4. Dose 4: 6 months after 3rd dose (must be given ≥ 4 years old) b. **If the first dose of DTaP-containing vaccine was administered after the 1st birthday**, administer remaining dose(s) in order to complete a 3-dose primary series given as: 1. Dose 1 was administered after the 1st birthday 2. Dose 2: 1 month after 1st dose 3. Dose 3: 6 months after 2nd dose (must be given ≥ 4 years old)	
REINFORCEMENT	Adults every 10 years
PRECAUTION	Acellular pertussis-containing vaccines may be administered to clients with the following conditions once a treatment regimen has been established and their condition has stabilized: • Progressive or unstable neurologic disorder (including infantile spasms for DTaP) • Uncontrolled seizures • Progressive encephalopathy
CONTRA-INDICATIONS	1. Children younger than 4 years old. 2. History of anaphylactic reaction to a previous dose of any tetanus, diphtheria or pertussis-containing vaccine, or to any Tdap vaccine component. 3. When a contraindication exists to tetanus toxoid and a client sustains a major or unclean wound, TIg should be given. Refer to *Tetanus Immune Globulin* (TIg) in this chapter. [1] 4. History of Guillain-Barré syndrome (GBS) occurring within 6 weeks of receipt of a tetanus-containing vaccine. 5. Encephalopathy (e.g., coma, decreased level of consciousness, prolonged seizures) not attributable to another identifiable cause within 7 days after receiving a dose of a pertussis-containing vaccine. 6. Individuals who have experienced transient thrombocytopenia or other neurological complications following an earlier immunization against diphtheria and/or tetanus.

Tetanus-Diphtheria-acellular Pertussis Vaccine (Tdap)

BOOSTRIX®

(GlaxoSmithKline 2023 monograph available at: https://ca.gsk.com/media/6234/boostrix.pdf)

VACCINE COMPONENTS	Diphtheria toxoid, three purified pertussis antigens [pertussis toxoid (PT), filamentous haemagglutinin (FHA) and pertactin (69 kDalton outer membrane protein)], and tetanus toxoid. It also contains aluminum (as 0.5 mg aluminum salts), sodium chloride, water for injection. **Residues from the manufacturing process**: disodium phosphate, formaldehyde, glutaraldehyde, glycine, monopotassium phosphate, polysorbate 80, and potassium chloride.Thimerosal free. Latex-free.
EXPECTED REACTIONS	**Local**: pain, redness and swelling at the injection site. **Systemic:** fatigue, headache, mild fever, dizziness, body aches or nausea.
EFFECTIVENESS	93-100% show protective levels for at least 5 years

***** According to the National Advisory Committee on Immunization (NACI), there is no upper age limit for the administration of Tdap. This differs from the information in the Tdap product monographs.

[1] Refer to Chapter 5, Section 3.7, *Tetanus Prophylaxis in Wound Management*.

[2] Children who complete their primary series or receive a booster dose of Tdap after their 11th birthday, do not require an additional dose of Tdap in Grade 8. See Chapter 5, Appendix 5.3 *Grade 8 Tdap Algorithm*.

[3] There is no minimum interval between a dose of Td and Tdap when Tdap is being given for pertussis protection years.

[4] Refer to Chapter 7 *Appendix 7.7: Tdap Immunization Decision Chart for Pregnant Women.*

Tetanus-Diphtheria-Acellular Pertussis-Inactivated Poliomyelitis Adsorbed Vaccine (Tdap-IPV)

ADACEL®-POLIO

(Sanofi Pasteur 2023 monograph available at: https://products.sanofi.ca/en/adacel-polio.pdf)

INDICATIONS, DOSES and SERIES (0.5 mL IM) (Min. age 4 years old)	
1. Wound Management [5] **2.** Booster (5th) dose at age 4-6 years (school entry) [1, 2] **3.** Unimmunized individuals 7+ years: 1. Dose 1 2. Dose 2: 1 months after 1st dose 3. Dose 3: 6 months after 2nd dose **4.** Children 7+ and Adolescents years of age: **A.** Booster dose for those who missed receiving the school entry booster dose. **B.** Incompletely immunized children 7+ and adolescents [3]: a. **If the first dose of DTaP-containing vaccine was administered before the 1st birthday**, administer remaining dose(s) in order to complete a 4-dose primary series given as: 1. Dose 1 was administered before the 1st birthday 2. Dose 2: 1 month after 1st dose 3. Dose 3: 1 month after 2nd dose 4. Dose 4: 6 months after 3rd dose (must be given ≥ 4 years old) b. **If the first dose of DTaP-containing vaccine was administered after the 1st birthday**, administer remaining dose(s) in order to complete a 3-dose primary series given as: 1. Dose 1 was administered after the 1st birthday 2. Dose 2: 1 month after 1st dose 3. Dose 3: 6 months after 2nd dose (must be given ≥ 4 years old)	
REINFORCEMENT	None
PRECAUTION	Acellular pertussis-containing vaccines may be administered to clients with the following conditions once a treatment regimen has been established and their condition has stabilized: • Progressive or unstable neurologic disorder (including infantile spasms for DTaP) • Uncontrolled seizures • Progressive encephalopathy
CONTRA-INDICATIONS	1. Children younger than 4 years old. 2. History of anaphylactic reaction to a previous dose of any tetanus, diphtheria or pertussis-containing vaccine, or to any Tdap vaccine component. 3. When a contraindication exists to tetanus toxoid and a client sustains a major or unclean wound, TIg should be given. Refer to *Tetanus Immune Globulin* (TIg) in this chapter. [1] 4. History of Guillain-Barré syndrome (GBS) occurring within 6 weeks of receipt of a tetanus-containing vaccine. 5. Encephalopathy (e.g., coma, decreased level of consciousness, prolonged seizures) not attributable to another identifiable cause within 7 days after receiving a dose of a pertussis-containing vaccine. 6. Individuals who have experienced transient thrombocytopenia or other neurological complications following an earlier immunization against diphtheria and/or tetanus.

Tetanus-Diphtheria-Acellular Pertussis-Inactivated Poliomyelitis Adsorbed Vaccine (Tdap-IPV) **ADACEL®-POLIO** (Sanofi Pasteur 2023 monograph available at: https://products.sanofi.ca/en/adacel-polio.pdf)	
VACCINE COMPONENTS	Tetanus toxoid, reduced diphtheria toxoid, acellular pertussis antigens [pertussis toxoid (PT), filamentous haemagglutinin (FHA), pertactin (PRN), fimbriae types 2 and 3 (FIM)], and inactivated poliomyelitis vaccine [type 1 (Mahoney), type 2 (MEF-1) and type 3 (Saukett)]. **Excipients**: Aluminum phosphate (adjuvant), 2-phenoxyethanol, ethanol, polysorbate 80. **Manufacturing residuals**: Bovine serum albumin, formaldehyde, glutaraldehyde, streptomycin, neomycin and polymyxin B are present in trace amounts. Latex and thimerosal free.
EXPECTED REACTIONS	**Local**: Temporary pain, swelling and redness where the vaccine was given. Up to 20% of children who get this vaccine may have redness, swelling and pain at the injection site/arm for up to 5 days afterward. The symptoms usually resolve without any treatment (e.g., antihistamines) given. **Systemic**: Tiredness, headache, mild fever, nausea, body aches and chills.
EFFECTIVENESS	Tetanus, diphtheria and polio antibodies are robust and pertussis antibodies in fully immunized children persist after 3 years of receiving Tdap-IPV as a replacement for DTaP-IPV.

[1] Not required if the 4th dose of DTaP-IPV-Hib, DTaP-IPV or Tdap was given after the 4th birthday.
[2] Refer to SIM, Chapter 5 *Appendix 5.6: Immunization Recommendations for Children 4-6 years of Age.*
[3] Children who complete their primary series, or receive a booster dose of Tdap after their 11th birthday, do not require an additional dose of Tdap in Grade 8. See Chapter 5, Appendix 5.3 *Grade 8 Tdap Algorithm*.
[4] As only 3 doses of polio are required, Tdap may be used as one of the doses in this series, ensuring the recommended intervals for polio are maintained.
[5] Refer to Chapter 5, Section 3.7, Tetanus Prophylaxis in Wound Management

Tetanus-Diphtheria-Acellular Pertussis-Inactivated Poliomyelitis Adsorbed Vaccine (Tdap-IPV)

BOOSTRIX®-POLIO

(GlaxoSmithKline 2023 monograph available at: https://ca.gsk.com/media/6235/boostrix-polio.pdf)

INDICATIONS, DOSES and SERIES (0.5 mL IM) (Min. age 4 years old)

1. Wound Management [5]
2. Booster (5th) dose at age 4-6 years (school entry) [1, 2]
3. Unimmunized individuals 7+ years:
   1. Dose 1
   2. Dose 2: 1 months after 1st dose
   3. Dose 3: 6 months after 2nd dose
4. Children 7+ and Adolescents years of age:
   - **A.** Booster dose for those who missed receiving the school entry booster dose.
   - **B.** Incompletely immunized children 7+ and adolescents [3]:
     - a. **If the first dose of DTaP-containing vaccine was administered before the 1st birthday**, administer remaining dose(s) in order to complete a 4-dose primary series given as:
       1. Dose 1 was administered before the 1st birthday
       2. Dose 2: 1 month after 1st dose
       3. Dose 3: 1 month after 2nd dose
       4. Dose 4: 6 months after 3rd dose (must be given ≥ 4 years old)
     - b. **If the first dose of DTaP-containing vaccine was administered after the 1st birthday**, administer remaining dose(s) in order to complete a 3-dose primary series given as:
       1. Dose 1 was administered after the 1st birthday
       2. Dose 2: 1 month after 1st dose
       3. Dose 3: 6 months after 2nd dose (must be given ≥ 4 years old)

REINFORCEMENT	None
PRECAUTION	Acellular pertussis-containing vaccines may be administered to clients with the following conditions once a treatment regimen has been established and their condition has stabilized: • Progressive or unstable neurologic disorder (including infantile spasms for DTaP) • Uncontrolled seizures • Progressive encephalopathy
CONTRA-INDICATIONS	1. Children younger than 4 years old. 2. History of anaphylactic reaction to a previous dose of any tetanus, diphtheria or pertussis-containing vaccine, or to any Tdap vaccine component. 3. When a contraindication exists to tetanus toxoid and a client sustains a major or unclean wound, TIg should be given. Refer to *Tetanus Immune Globulin* (TIg) in this chapter. [1] 4. History of Guillain-Barré syndrome (GBS) occurring within 6 weeks of receipt of a tetanus-containing vaccine. 5. Encephalopathy (e.g., coma, decreased level of consciousness, prolonged seizures) not attributable to another identifiable cause within 7 days after receiving a dose of a pertussis-containing vaccine. 6. Individuals who have experienced transient thrombocytopenia or other neurological complications following an earlier immunization against diphtheria and/or tetanus.

Tetanus-Diphtheria-Acellular Pertussis-Inactivated Poliomyelitis Adsorbed Vaccine (Tdap-IPV) **BOOSTRIX®-POLIO** (GlaxoSmithKline 2023 monograph available at: https://ca.gsk.com/media/6235/boostrix-polio.pdf)	
VACCINE COMPONENTS	Not less than 2.5 limit of flocculation ('Lf'), or 2 IU ('International Units') of diphtheria toxoid; not less than 5 Lf (20 IU) of tetanus toxoid; 8 mcg of pertussis toxoid, 8 mcg of filamentous haemagglutinin, 2.5 mcg of pertactin (69 kDa outer membrane protein), 40 D-antigen units (DU) of Type 1 poliovirus, 8 DU Type 2 polio virus and 32 DU Type 3 polio virus. Aluminum (as aluminum salts), sodium chloride, water for injection and medium 199. Residues*: disodium phosphate, formaldehyde, glutaraldehyde, glycine, monopotassium phosphate, neomycin sulphate, polymyxin B sulphate, polysorbate 80 and potassium chloride. Thimerosal free. Latex –free.
EXPECTED REACTIONS	**Local**: Temporary pain, swelling and redness where the vaccine was given. Up to 20% of children who get this vaccine may have redness, swelling and pain at the injection site/arm for up to 5 days afterward. The symptoms usually resolve without any treatment (e.g., antihistamines) given. S**ystemic**: Tiredness, headache, mild fever, nausea, body aches and chills.
EFFECTIVENESS	Tetanus, diphtheria and polio antibodies are robust and pertussis antibodies in fully immunized children persist after 3 years of receiving Tdap-IPV as a replacement for DTaP-IPV.

[1] Not required if the 4th dose of DTaP-IPV-Hib, DTaP-IPV or Tdap was given after the 4th birthday.
[2] Refer to SIM, Chapter 5 *Appendix 5.6: Immunization Recommendations for Children 4-6 years of Age*
[3] Children who complete their primary series or receive a booster dose of Tdap after their 11th birthday, do not require an additional dose of Tdap in Grade 8. See Chapter 5, Appendix 5.3 *Grade 8 Tdap Algorithm*.
[4] As only 3 doses of polio are required, Tdap may be used as one of the doses in this series, ensuring the recommended intervals for polio are maintained.
[5] Refer to Chapter 5, Section 3.7, Tetanus Prophylaxis in Wound Management.

Typhoid Vaccine (Typh-I)
(Salmonella typhi Vi Capsular Polysaccharide) (Inactivated) [Non-publicly funded]

TYPHIM Vi®
(Sanofi Pasteur 2021 monograph available at: https://products.sanofi.ca/en/typhim.pdf)

Typhoid Vaccine (Typh-O)
(Live Oral Attenuated Ty 21a) [Non-publicly funded]

Vivotif®
(Emergent Travel Health Inc. 2020 product information available at:
https://pdf.hres.ca/dpd_pm/00058906.PDF

Varicella Vaccine (Var)
(live, attenuated)

VARILRIX®
(GlaxoSmithKline 2023 monograph available at: https://ca.gsk.com/media/6263/varilrix.pdf)

INDICATIONS [1]	**DOSE / Series**
1. Those born since 1993-01-01 are eligible to receive an age or cohort appropriate series. 2. Non-immune HCW/post-secondary healthcare students as specified in Chapter 7. 3. Non-immune non-pregnant women of child-bearing age as specified in Chapter 5 Appendix 5.4, *Publicly Funded Varicella Immunization Eligibility and Panorama Directives.* [2] 4. Susceptible immunocompromised individuals as referred by their specialist via submission of Chapter 7, *Immunization of Special Populations.* Appendix 7.2: *Varicella Immunization Referral Form*.[4]	Two doses of 0.5 mL SC [3] given a minimum of 28 days apart.

CONTRAINDICATIONS

- History of an anaphylactic reaction to a previous dose of any varicella –containing vaccine, or to any component of VARILRIX®.
- Pregnancy. Women of childbearing age should avoid pregnancy for at least 28 days (1 month) post-vaccination.
- People with active untreated tuberculosis.
- Recent administration of an immune globulin preparation or blood product. [2] Refer to SIM, Chapter 5, *Immunization Schedules,* Section 3.5, *Spacing of Live Vaccines, Blood Products and Immune Globulin Preparations* and Section 3.5.1, *Immune Globulin Preparations or Blood: Timing Intervals for Vaccines Containing Live Measles, Mumps, Rubella, or Varicella Virus.* .

PRECAUTIONS

- Those 18 years and younger should avoid taking salicylates for 6 weeks after receiving a varicella-containing vaccine. Specialist consultation is required prior to immunization of these children with a varicella-containing vaccine.
- Family history of congenital immunodeficiency. Refer to SIM, Chapter 7, *Immunization of Special Populations* Section 3.1, *Congenital Immunodeficiency*
- Do TB skin testing on the same day as varicella immunization or delay TB skin testing for ≥ 4 weeks.
- Varicella immunization should be given on the same day as other live vaccines or delayed until 4 weeks after administration of any other live vaccine.
- Systemic antiviral therapy (e.g., acyclovir, valacyclovir, famciclovir) should be avoided for 24 hours as it may affect the reproduction of the vaccine virus and may reduce the efficacy of varicella-containing vaccine (CIG).
- It is recommended that people taking long-term antiviral therapy should discontinue these drugs, if possible, from at least 24 hours before administration of varicella-containing vaccine and should not restart antiviral therapy until 14 days after vaccine administration (CIG).

VACCINE COMPONENTS: Live, attenuated varicella virus vaccine (Oka-strain), amino acids, lactose, mannitol, sorbitol and water for injection. Neomycin sulphate is present as traces. Thimerosal free.

EXPECTED REACTIONS: Local: soreness, swelling, redness and rash where the needle was given. **Systemic:** fever, nausea, vomiting, diarrhea or decreased appetite, headache, dizziness, fussiness, tiredness. A varicella-like rash 5 to 26 days after getting immunized.

SPECIAL CONSIDERATION: Administer vaccine immediately after reconstitution.

*****Varicella footnotes are continued on next page.

Varicella Vaccine (Var) (live, attenuated)

VARILRIX®
(GlaxoSmithKline 2023 monograph available at https://ca.gsk.com/media/6263/varilrix.pdf)

[1] Varicella susceptible is defined as:

- Lack of documented evidence of serological of VZV IgG antibodies; or
- Lack of documented evidence of immunization with 2 doses of a varicella-containing.
- **NOTE**: verbal history of disease is unacceptable evidence of immunity for those born since Jan. 1, 2003.

[2] According to the Canadian Immunization Guide, (2012 Evergreen Ed., accessible at http://www.phac-aspc.gc.ca/publicat/cig-gci/p01-10-eng.php#meas) the first varicella vaccine dose should be given in the immediate post-partum period, before discharge from hospital unless they have received Rh immune globulin [RhIg].
To optimize response to vaccine, varicella-susceptible women who receive RhIg in the post-partum period should generally wait 3 months before being vaccinated with varicella vaccine. The risk of lowered vaccine efficacy needs to be weighed against the need for protection. However, if there is a risk of exposure to varicella, a risk of recurrent pregnancy in the 3-month post-partum period, or a risk that vaccines may not be given later, monovalent varicella vaccines may be given prior to discharge. In that context, serologic testing for varicella should be done 3 months later and non-immune women should be revaccinated with two Var doses given at appropriate intervals from the initial post-partum dose (NOTE: they may receive 3 vaccine doses in total). In the event that a post-partum woman receives varicella vaccine prior to receiving RhIg within 72 hours post-delivery, serologic testing for varicella should be done 3 months later and the woman revaccinated if non-immune with two Var doses given at appropriate intervals from the initial post-partum dose (NOTE: they may receive 3 vaccine doses in total).

[3] Individuals who are eligible for a 2-dose varicella series who have documented evidence of **viral culture confirmed** (breakthrough) varicella disease 42 days or more after their first varicella-containing vaccine dose do not require a second varicella-containing vaccine dose. Provide a second dose of varicella-containing vaccine to those without this documentation as verbal history and/or healthcare practitioner diagnosis of breakthrough disease is unreliable.

[4] Refer to Chapter 7, *Immunization of Special Populations.* Appendix 7.2: *Varicella Immunization Referral Form*.

Varicella Vaccine (Var)
(live, attenuated)

VARIVAX® III
(Merck Canada Inc. 2023 monograph available at: https://www.merck.ca/en/wp-content/uploads/sites/20/2021/04/VARIVAX_III-PM_E.pdf)

INDICATIONS [1].	DOSE / Series
1. Those born since 1993-01-01 are eligible to receive an age or cohort appropriate series. 2. Non-immune HCW/post-secondary healthcare students as specified in Chapter 7. 3. Non-immune non-pregnant women of child-bearing age as specified in Chapter 5 Appendix 5.4, *Publicly Funded Varicella Immunization Eligibility and Panorama Directives.*[2] 4. Susceptible immunocompromised individuals *when Varilrix is unavailable*, as referred by their specialist via submission of Chapter 7, *Immunization of Special Populations.* Appendix 7.2: *Varicella Immunization Referral Form*.[4]	**Two doses of 0.5 mL SC [3] given a minimum of 28 days apart.**

CONTRAINDICATIONS
- History of an anaphylactic reaction to a previous dose of any varicella –containing vaccine, or to any component of VARIVAX®.
- Pregnancy. Women of childbearing age should avoid pregnancy for at least 28 days (1 month) post-vaccination.
- People with active untreated tuberculosis.
- Recent administration of an immune globulin preparation or blood product.[2] Refer to SIM, Chapter 5, *Immunization Schedules,* Section 3.5, *Spacing of Live Vaccines, Blood Products and Immune Globulin Preparations* and Section 3.5.1, *Immune Globulin Preparations or Blood: Timing Intervals for Vaccines Containing Live Measles, Mumps, Rubella, or Varicella Virus.*

PRECAUTIONS
- Those 18 years and younger should avoid taking salicylates for 6 weeks after receiving a varicella-containing vaccine. Specialist consultation is required prior to immunization of these children with a varicella-containing vaccine.
- Family history of congenital immunodeficiency. Refer to SIM, Chapter 7, *Immunization of Special Populations* Section 3.1, *Congenital Immunodeficiency*
- Do TB skin testing on the same day as varicella immunization or delay TB skin testing for ≥ 4 weeks.
- Varicella immunization for immunocompetent clients should be given on the same day as other live vaccines or delayed until 4 weeks after administration of any other live vaccine.
- Systemic antiviral therapy (e.g., acyclovir, valacyclovir, famciclovir) should be avoided for 24 hours after the last dose as it may affect the reproduction of the vaccine virus and may reduce the efficacy of varicella-containing vaccine (CIG).
- It is recommended that people taking long-term antiviral therapy should discontinue these drugs, if possible, from at least 24 hours before administration of varicella-containing vaccine and should not restart antiviral therapy until 14 days after vaccine administration (CIG).

VACCINE COMPONENTS: Oka/Merck varicella strain (live, attenuated) ≥1350 PFU. **Excipients**: Sucrose, hydrolyzed gelatin, urea, sodium chloride, monosodium L-glutamate, sodium phosphate dibasic, potassium phosphate monobasic, potassium chloride, water for injection. Manufacturing Process Residuals: The product also contains residual components of MRC-5 cells including DNA and protein, and trace quantities of neomycin and fetal bovine serum from MRC-5 culture media. Preservative (thimerosal) free. Latex-free.

EXPECTED REACTIONS: Local: soreness, swelling, redness and rash where the needle was given. **Systemic:** fever, nausea, vomiting, diarrhea or decreased appetite, headache, dizziness, fussiness, tiredness. A varicella-like rash 5 to 26 days after getting immunized.

SPECIAL CONSIDERATION: Minimum potency remaining at expiry 90 minutes after reconstitution and storage at room temperature. Administer vaccine immediately after reconstitution.

*****Varicella footnotes are continued on next page.

Varicella Vaccine (Var) (live, attenuated)

VARIVAX® III
(Merck Canada Inc. 2023 monograph available at: https://www.merck.ca/en/wp-content/uploads/sites/20/2021/04/VARIVAX_III-PM_E.pdf)

[1] Varicella susceptible is defined as:

- Lack of documented evidence of serological of VZV IgG antibodies; or
- Lack of documented evidence of immunization with 2 doses of a varicella-containing vaccine.
- **NOTE**: verbal history of disease is unacceptable evidence of immunity for those born since Jan. 1, 2003.

[2] According to the Canadian Immunization Guide, (2012 Evergreen Ed., accessible at http://www.phac-aspc.gc.ca/publicat/cig-gci/p01-10-eng.php#meas) the first varicella vaccine dose should be given in the immediate post-partum period, before discharge from hospital unless they have received Rh immune globulin [RhIg].
To optimize response to vaccine, varicella-susceptible women who receive RhIg in the post-partum period should generally wait 3 months before being vaccinated with varicella vaccine. The risk of lowered vaccine efficacy needs to be weighed against the need for protection. However, if there is a risk of exposure to varicella, a risk of recurrent pregnancy in the 3-month post-partum period, or a risk that vaccines may not be given later, monovalent varicella vaccines may be given prior to discharge. In that context, serologic testing for varicella should be done 3 months later and non-immune women should be revaccinated with two Var doses given at appropriate intervals from the initial post-partum dose (NOTE: they may receive 3 vaccine doses in total). In the event that a post-partum woman receives varicella vaccine prior to receiving RhIg within 72 hours post-delivery, serologic testing for varicella should be done 3 months later and the woman revaccinated if non-immune with two Var doses given at appropriate intervals from the initial post-partum dose (NOTE: they may receive 3 vaccine doses in total).

[3] Individuals who are eligible for a 2-dose varicella series who have documented evidence of **viral culture confirmed** (breakthrough) varicella disease 42 days or more after their first varicella-containing vaccine dose do not require a second varicella-containing vaccine dose. Provide a second dose of varicella-containing vaccine to those without this documentation as verbal history and/or healthcare practitioner diagnosis of breakthrough disease is unreliable.

Yellow Fever Vaccine (YF)

[Non-publicly funded]

YF-VAX®

(Sanofi Pasteur 2019 monograph available at: http://products.sanofi.ca/en/yf-vax.pdf

Tuberculin Purified Protein Derivative (PPD) (Mantoux)

TUBERSOL®

(Sanofi Pasteur 2022 monograph available at: https://products.sanofi.ca/en/tubersol.pdf)

INDICATIONS	Screening for latent tuberculosis infection (LTBI). 1) Refer to TB Prevention and Control Saskatchewan: Clinical Policies and Procedures 30-001: TUBERCULIN SKIN TESTING at: https://www.saskatoonhealthregion.ca/locations_services/Services/TB-Prevention/Documents/PolicyandProcedures/Tuberculin%20skin%20testing%20%28policy%20and%20procedure%29.pdf	
DOSE/SERIES	PPD 5 TU 0.1 mL ID in anterior forearm (flexor or dorsal surface) between the wrist and the elbow: • For contact tracing, if the initial skin test is negative, a second test should be given 6 – 12 weeks after the last date of contact. • A second test, done 7 - 21 days after the first test, may be required in certain situations and would be on the advice of TB Control. • A small percentage of persons will only react after a second test or will react to a greater degree (so called "boosting" effect).	
EXPECTED REACTIONS	• **Read result in 48 – 72 hours.** • Possible redness, induration and blistering. • Measure only induration (raised) diameter in millimetres and record this measurement.	
CONTRA-INDICATIONS	• Pregnancy is not a contraindication to tuberculin testing. • A previous Bacille Calmette-Guerin (BCG) vaccine is not a contraindication to tuberculin testing**.** • History of anaphylactic reaction to a previous dose of Tubersol or any of its components. • **Tubersol should not be administered to:** ○ known tuberculin positive reactors; ○ persons with severe blistering tuberculin reactions in the past; ○ persons with documented active tuberculosis or a clear history of treatment for TB infection or disease; or ○ persons with extensive burns or eczema.	
PRECAUTION	Do TB skin testing on the same day as live vaccines are administered, or delay TB skin testing for ≥4 weeks after a live vaccine if possible.	
EXPECTED REACTIONS	Pain, pruritis and bruising at the test site may occur.	
TB skin test result interpretations		Refer to *Canadian Tuberculosis Standards* (7th Ed.) Available at: https://www.canada.ca/en/public-health/services/infectious-diseases/canadian-tuberculosis-standards-7th-edition/edition-16.html
COMPONENTS	Purified protein derivative of *M. tuberculosis*, phenol, polysorbate 80.	

Immune Globulin Preparation Injection Site, Needle Length and Daily Total Site Volume per Age Group

CLIENT AGE	SITE▲ (90° IM)	NEEDLE LENGTH	SIZE (Gauge)	MAX. VOLUME
Children				
• Birth to less than 12 months old	Vastus lateralis	1”	23	1 mL
• 12 months up to and including 4 years	Deltoid * Vastus lateralis	1” 1”	22-23 22-23	1 mL 2 mL
• 5 years up to and including 17 years	Deltoid [1] Vastus lateralis Ventrogluteal Dorsogluteal [2]	1” – 1½” 1” – 1½” 1” – 1½” 1” – 1½”	20-23 22-23 20-23 20-23	1 mL 2 mL 3 mL 3 mL
Adults				
• 18 years and older	Deltoid [1] Vastus lateralis Ventrogluteal Dorsogluteal [2]	1” – 1½” 1” – 1½” 1” – 1½” 1” – 1½”	20-22 20-22 20-22 20-22	2 mL 5 mL 4 mL 5 mL

(Adapted from BCCDC Immunization Manual, 2009)

* When the deltoid muscle is considered for use in young children 12 months of age or over, assesses the adequacy of the muscle size prior to administration.

▲ Different immune globulin preparations **must be** separated by minimum 2.5 cm if given in the same limb (e.g., TIg and RabIg in adult deltoid). **It is recommended to administer in different sites if possible.**

[1] One deltoid should be reserved for the administration of rabies vaccine **on day 0** of rabies post-exposure immunoprophylaxis.

[2] Use of the dorsogluteal site is **only recommended in adolescents and adults** when the deltoid, vastus lateralis and ventrogluteal sites have had maximum volumes of an immune globulin preparation injected and an additional volume still needs to be administered. This is due to the possibility of sciatic nerve injuries when the injection is administered in the dorsogluteal site.

Botulism Immune Globulin (BIg-IV)

BabyBIG
(Cangene USA https://www.infantbotulism.org/general/babybig.php)

This product is not manufactured in Canada and is only available through the *Special Access Program* (SAP). An information binder is shipped with every request for professional reference.

INDICATIONS	To treat patients younger than 12 months of age diagnosed with infant botulism.
INITIAL SERIES	Refer to binder.
REINFORCEMENT	Refer to binder.
CONTRAINDICATIONS	Refer to binder.
COMPONENTS	Refer to binder.
EXPECTED REACTIONS	Refer to binder.
SPECIAL CONSIDERATION	Refer to binder.

Hepatitis B Immune Globulin (HBIg) (Human)

HepaGam B®
(KI BioPharma LLC 2022 product monograph available at:https://hepagamb.ca/_uploads/documents/hepagam/HepagamB-CA-ENG.PDF)

INDICATIONS	**DOSE / SERIES** [1]
1. Infant born to known HBsAg positive woman. 2. Infant born to woman at high risk for hepatitis B infection (i.e., intravenous drug use, sex trade work)) whose infectious status is unknown or negative (possible window period) and cannot be determined within 12 hours of birth. 3. Percutaneous or mucosal exposure to HBsAg positive source. 4. Sexual contact with a person who has acute or chronic hepatitis B infection. 5. An at-risk known non-responder to two series of HB vaccine.	1. & 2. Give HBIg 0.5 mL IM within 12 hours of birth, along with first dose of hepatitis B vaccine series [2, 3] 3. Give HBIg 0.06 mL/kg of body weight IM and hepatitis B vaccine IM as required, considering the client's immune status and history of hepatitis B immunization [4, 5] 4. Give HBIg 0.06 mL/kg of body weight IM as soon as possible following the last sexual exposure, along with hepatitis B vaccine series [4, 5] 5. **Dose 1**: HBIg 0.06 mL/kg of body weight IM. **Dose 2**: HBIg 0.06 mL/kg of body weight IM 4 weeks later.
REINFORCEMENT	Currently no recommendations
CONTRA-INDICATIONS	• In patients who have severe thrombocytopenia or any coagulation disorder that would contraindicate intramuscular injections, HepaGam B should be given only if the expected benefits outweigh the potential risks. • Patients with a history of anaphylactic or severe system reaction to any component of the product. • Patients who are deficient in IgA. While HepaGam B contains less than 40 mcg/mL IgA, individuals who are deficient in IgA may have the potential to develop IgA antibodies and have an anaphylactoid reaction.
PRECAUTIONS	• Human Ig products are among the safest blood-derived products available. The method of preparation includes one or more steps that exclude or inactivate hepatitis B, C and HIV; therefore the risk of transmission is extremely low. However, it is possible that unknown infectious agents may be present in such products. • Regarding HBIg and the administration of live vaccines refer to SIM, Chapter 5, *Immunization Schedules,* Section 3.5, *Spacing of Live Vaccines, Blood Products and Immune Globulin Preparations* and Section 3.5.1, *Immune Globulin Preparations or Blood: Timing Intervals for Vaccines Containing Live Measles, Mumps, Rubella, or Varicella Virus.* • Give HBIg with caution (i.e., in a setting capable of managing anaphylaxis) if the person has a history of anaphylactic reaction following receipt of any human Ig product, or a history of anaphylactic reaction to latex (assess risks versus benefits). • HBIg must be given at a separate anatomic site from hepatitis B vaccine. • The preferred sites for immune globulin administration are the vastus lateralis (all ages) or the deltoid (those 12 months and older).

Hepatitis B Immune Globulin (HBIg) (Human)

HepaGam B®
(KI BioPharma LLC 2022 product monograph available at:https://hepagamb.ca/_uploads/documents/hepagam/HepagamB-CA-ENG.PDF)

COMPONENTS	Human plasma protein (≥96% Human IgG), maltose, polysorbate 80. May contain trace amounts of tri-n-butyl phosphate and Triton X-100®
EXPECTED REACTIONS	•Temporary pain, swelling, tenderness and hives where the needles was given. •Headache. •Fever and diarrhea in infants. •Rarely, blot clots may occur after the administration of HB immune globulin.

[1] There is no upper limit to the volume of HBIg that can be administered.

[2] Refer to SIM, Chapter 7, *Immunization of Special Populations*, Section 4.2.1, *Hepatitis B Infant Immunoprophylaxis Protocol* for more information.

[3] There is no outer time limit for administering HBIg in infants less than 12 months of age, when the infant's exposure to the known risk factor(s) is ongoing. For infants less than 8.3 kg, give 0.5 ml HBIg.

[4] HBIg dose for all clients ≥ 8.3 kg is 0.06 ml/kg. Give HBIg as soon as possible, preferably within 48 hours of the exposure. For a percutaneous or permucosal exposure, HBIg may be given up to 7 days following the exposure. If the client presents more than 7 days following a percutaneous or permucosal exposure, give Hepatitis B vaccine only. For sexual exposures, HBIg may be given up to 14 days following the last exposure. If the client presents more than 14 days following a sexual exposure, give HB vaccine only. Refer to *Saskatchewan Post-Exposure Prophylaxis* recommendations available at: http://www.ehealthsask.ca/services/manuals/Pages/hiv-guidelines.aspx

[5] Refer to *Immune Globulin Preparation Maximum Site Volumes*

Hepatitis B Immune Globulin (HBIg) (Human)

HyperHEP B®
(Grifols Therapeutics 2021 monograph available at: https://www.grifols.com/en/product/-/product/canada/hyperhep_b_hepatitis_b_immune_globul)

INDICATIONS	DOSE / SERIES [1]
1. Infant born to known HBsAg positive woman. **2**. Infant born to woman at high risk for hepatitis B infection (i.e., intravenous drug use, sex trade work) whose infectious status is unknown or negative (possible window period) and cannot be determined within 12 hours of birth. **3.** Percutaneous or mucosal exposure to HBsAg positive source. **4**. Sexual contact with a person who has acute or chronic hepatitis B infection. **5**. An at-risk known non-responder to two series of HB vaccine**.**	**1. & 2**. Give HBIg 0.5 mL IM within 12 hours of birth, along with first dose of hepatitis B vaccine series. [2, 3] **3.** Give HBIg 0.06 mL/kg of body weight and hepatitis B vaccine IM as required, considering the client's immune status and history of hepatitis B immunization. [4, 5] **4.** Give HBIg 0.06 mL/kg of body weight IM as soon as possible following the last sexual exposure, along with hepatitis B vaccine series [4, 5] **5**. **Dose 1**: HBIg 0.06 mL/kg of body weight IM. **Dose 2**: HBIg 0.06 mL/kg of body weight IM 4 weeks later.

CONTRAINDICATIONS	1. Patients who are hypersensitive to the immunoglobulin or to any ingredient in the formulation or component of the container 2. HyperHEP B® should not be administered to patients who have severe thrombocytopenia or any coagulation disorder that would contraindicate intramuscular injections. 3. IgA deficient patients with antibodies against IgA and a history of hypersensitivity.
PRECAUTIONS	• Human Ig products are among the safest blood-derived products available. The method of preparation includes one or more steps that exclude or inactivate hepatitis B, C and HIV; therefore the risk of transmission is extremely low. However, it is possible that unknown infectious agents may be present in such products. • Regarding HBIg and the administration of live vaccines refer to SIM, Chapter 5, *Immunization Schedules,* Section 3.5, *Spacing of Live Vaccines, Blood Products and Immune Globulin Preparations* and Section 3.5.1, *Immune Globulin Preparations or Blood: Timing Intervals for Vaccines Containing Live Measles, Mumps, Rubella, or Varicella Virus*. • Give HBIg with caution (i.e., in a setting capable of managing anaphylaxis) if the person has a history of anaphylactic reaction following receipt of any human Ig product, or a history of anaphylactic reaction to latex (assess risks versus benefits). • Clients with severe thrombocytopenia or coagulation disorders that contraindicate IM injections should not be given HBIg unless the benefits outweigh the risks. • HBIg must be given at a separate anatomic site from hepatitis B vaccine. • The preferred sites for immune globulin administration are the vastus lateralis (all ages) or the deltoid (those 12 months and older).

Hepatitis B Immune Globulin (HBIg) (Human)

HyperHEP B®
(Grifols Therapeutics 2021 monograph available at: https://www.grifols.com/en/product/-/product/canada/hyperhep_b_hepatitis_b_immune_globul)

COMPONENTS	Contains 15-18% human hepatitis B hyperimmune immune globulin≥ 220 IU/mL, glycine. Preservative free. Prefilled syringes contain rubber needle shield and stopper.
EXPECTED REACTIONS	•Temporary pain, swelling, tenderness and hives where the needles was given. •Headache. •Fever and diarrhea in infants. •Rarely, blot clots may occur after the administration of HB immune globulin.

[1] There is no upper limit to the volume of HBIg that can be administered.
[2] Refer to Chapter 7, Section 4.2.1, *Hepatitis B Infants Immunoprophylaxis Protocol* for more information.
[3] There is no outer time limit for administering HBIg in infants less than 12 months of age, when the infant's exposure to the known risk factor(s) is ongoing. For infants less than 8.3 kg, give 0.5 ml HBIg.
[4] HBIg dose for all clients ≥ 8.3 kg is 0.06 ml/kg. Give HBIg as soon as possible, preferably within 48 hours of the exposure. For a percutaneous or permucosal exposure, HBIg may be given up to 7 days following the exposure. If the client presents more than 7 days following a percutaneous or permucosal exposure, give Hepatitis B vaccine only. For sexual exposures, HBIg may be given up to 14 days following the last exposure. If the client presents more than 14 days following a sexual exposure, give HB vaccine only. Refer to *Saskatchewan Post-Exposure Prophylaxis* recommendations available at: http://www.ehealthsask.ca/services/manuals/Pages/hiv-guidelines.aspx
[5] Refer to *Immune Globulin Preparation Maximum Site Volumes*

Immune Globulin (Ig) (Human)

GamaSTAN®

(Grifols Therapeutics 2019 monograph available at: https://www.grifols.com/documents/260038/394583/GamaSTAN+-+English+PM+-+2019-03-13.pdf/cf972b79-69f1-0640-81e8-da018cc33339?t=1648130044619)

INDICATIONS	
1. Recommended and provided free for post-exposure prophylaxis of hepatitis A contacts as outlined in the *Saskatchewan Communicable Disease Control Manual*. [1] **2**. Recommended and provided free for post-exposure prophylaxis of measles contacts as outlined in the *Saskatchewan Communicable Disease Control Manual*. [1]	
CONTRA-INDICATIONS	**Do not give GamaSTAN® S/D product intravenously.**
PRECAUTIONS	• Health Canada has advised that the GamaSTAN® S/D product monograph has been updated to strengthen warnings on the rare but serious risk of blood clots. Blood clots have been reported in patients with and without risk factors, and can occur regardless of immunoglobulin dose or route of administration (injection into a muscle, vein or under the skin). [2] • Human Ig products are amongst the safest blood-derived products available. As the method of preparation includes one or more steps that exclude or inactivate hepatitis B, C and HIV, the risk of transmission is considered to be extremely low. However, it is possible that unknown infectious agents may be present in such products. • Persons with severe thrombocytopenia or coagulation disorders that contraindicate IM injections should not be give IM Ig unless the benefits outweigh the risks. • Give Ig with caution (e.g., in a setting capable of managing anaphylaxis) if the client has a history of anaphylactic reaction following receipt of any human Ig product, or history of anaphylactic reaction to glycine or to latex (assess risks versus benefits). • Persons with IgA deficiency have the potential for developing antibodies to IgA and could have an anaphylactic reaction to subsequent administration of blood products that contain IgA. Therefore, Ig should only be given to such persons if the expected benefits outweigh the risks. • Divide large volumes of Ig into two or more sites. Refer to *Immune Globulin Preparation Maximum Site Volumes* chart in this chapter. • The preferred sites for immune globulin administration are the vastus lateralis (all ages) or the deltoid (those 12 months and older). • If administration of Ig is necessary less than 14 days after MMR or varicella vaccine, repeat vaccine as per recommended intervals. Refer to SIM, Chapter 5, *Immunization Schedules,* Section 3.5 *Spacing of Live Vaccines, Blood Products and Immune Globulin Preparations* and Section 3.5.1, *Immune Globulin Preparations or Blood: Timing Intervals for Vaccines Containing Live Measles, Mumps, Rubella, or Varicella Virus*.
COMPONENTS	GamaSTAN® S/D contains 15-18% immune globulin (human) as active ingredient. It also contains 0.16-0.26 M glycine, USP. Preservative free.
EXPECTED REACTIONS	Pain, swelling, tenderness and hives where the needle was given Tiredness, fever, headache, nausea. Rarely, blood clots may occur after the administration of an immune globulin product.

[1] Immune globulin should be given as soon as possible after a known exposure and no later than 2 weeks after the exposure.

[2] Health Canada (Oct. 9, 2014). *Safety information on the risk of blood clots with immunoglobulin products*. Available at: http://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2014/41783a-eng.php

Rabies Immune Globulin (RabIg) (Human)

HyperRAB®

(Grifols Therapeutics 2021 monograph available at: https://www.staticweb.grifols.com/documents/3836559/0/HyperRAB+-+English+PM+-+2012-01-30.pdf/64ec0e5e-4f3b-468c-a4ec-3ff664117cf1)

INDICATIONS [1, 2, 4]	**RABIES POST-EXPOSURE PROPHYLAXIS (RPEP):** • As determined by Regional Medical Health Officers. • Refer to the SK CDC Manual Rabies chapter for information. • Rabies vaccine is given in conjunction with RabIg. Rabies vaccine and RabIg must be administered with separate needles and syringes at separate anatomical sites.	
DOSE/ INITIAL SERIES [3]	**RABIES POST-EXPOSURE PROPHYLAXIS:** • The recommended dosage for children and adults is the same: 20 IU/kg of body weight. Because of interference with active antibody production, do not exceed recommended dose. ○ **HYPERRAB® is supplied as a 1 ml 300 IU vial or as a 2 ml vial of 300 IU (150 IU/mL) so read the label carefully to ensure correct dose calculation!** ○ The dose of **HYPERRAB® S/D** is calculated as: $\frac{[20\ IU/kg \times weight\ in\ kg]}{[vaccine\ IU\ concentration/mL]} = \_\_\_\_\_mL$ ○ If anatomically feasible, the full dose of HyperRAB® should be thoroughly infiltrated in the area around the wound. If the wound covers a large area and the HyperRAB® dose has insufficient volume to infiltrate the entire wound, the HyperRAB® dose may be diluted with an equal volume of dextrose, 5% (D5W) in water**. Do not dilute with normal saline.** Inject the remainder, if any, intramuscularly, preferably in the deltoid muscle of the upper arm or lateral thigh muscle using a separate syringe and needle, and anatomical site. ○ When there is no wound site, the preferred sites for immune globulin administration are the vastus lateralis (all ages) or the deltoid (those 12 months and older).	
REINFORCEMENT	Currently no recommendations.	
CONTRA-INDICATIONS	**There are no contraindications to RabIg given for post-exposure purposes.**	
PRECAUTIONS	• If client has a history of anaphylactic reaction following receipt of any human Ig product or to any of the components of a RabIg product, administer RabIg in an emergency room setting. • Human Ig products are among the safest blood-derived products available. The method of preparation includes one or more steps that exclude or inactivate hepatitis B, C and HIV; therefore the risk of transmission is extremely low. However, it is possible, that unknown infectious agents may be present in such products.	

Rabies Immune Globulin (RabIg) (Human) **HyperRAB®** (Grifols Therapeutics 2021 monograph available at: https://www.staticweb.grifols.com/documents/3836559/0/HyperRAB+-+English+PM+-+2012-01-30.pdf/64ec0e5e-4f3b-468c-a4ec-3ff664117cf1)		
	• Regarding RabIg and the administration of live vaccines, refer to SIM, Chapter 5, *Immunization Schedules,* Section 3.5, *Spacing of Live Vaccines, Blood Products and Immune Globulin Preparations* and Section 3.5.1, *Immune Globulin Preparations or Blood: Timing Intervals for Vaccines Containing Live Measles, Mumps, Rubella, or Varicella Virus.* • Persons with IgA deficiency have the potential for developing antibodies to IgA and could have an anaphylactic reaction to subsequent blood products that contain IgA. Administer RabIg in an emergency room setting.	
COMPONENTS	Human rabies hyperimmune globulin, glycine, sodium carbonate. Preservative free.	
EXPECTED REACTIONS	Temporary tenderness, soreness, pain or stiffness where the needle was given, fever, headache, malaise, rash, chills, nausea, joint or muscle aches.	

[1] If RabIg is not administered on day 0, it can be administered up to and including day 7 of the RPEP series. Since vaccine induced antibodies begin to appear within one week, there is no value in administering RabIg more than 8 days after initiation of vaccine.

[2] Provide a written record to a client who receives any immune globulin product.

[3] When notification of an exposure is delayed, RPEP may be started as late as 6 or more months after an exposure.

[4] **RabIg should never be administered in the same syringe or needle or in the same anatomical site as vaccine.**

Rabies Immune Globulin (RabIg) (Human)

KamRAB™
(Valneva 2018 monograph available at https://www.valneva.ca/en/

INDICATIONS [1, 2, 4]	**RABIES POST-EXPOSURE PROPHYLAXIS (RPEP):** • As determined by Regional Medical Health Officers. • Refer to the CDC Manual Rabies chapter for information. • Rabies vaccine is given in conjunction with RabIg. Rabies vaccine and RabIg must be administered with separate needles and syringes at separate anatomical sites

INITIAL SERIES [3]	**RABIES POST-EXPOSURE PROPHYLAXIS:**
	• The recommended dosage for children and adults is the same: 20 IU/kg of body weight. Because of interference with active antibody production, do not exceed recommended dose.
	  ○ The dose of RabIg is calculated as:
	  [20 IU/kg x weight in kg] = _____mL
	  [vaccine IU concentration/mL]
	  ○ Infiltrate as much RabIg as possible deep into and around the wound(s) in order to neutralize the virus. When more than one wound site exists, each site should be infiltrated with a portion of the RabIg. If there are extensive wounds, where the calculated dose of RabIg (by weight) is not adequate in volume to infiltrate all wounds, dilute the RabIg 2-3 fold in normal saline to create an adequate volume to infiltrate all wounds (CIG).
	  ○ When there is no wound site, the preferred sites for immune globulin administration are the vastus lateralis (all ages) or the deltoid (those 12 months and older).

REINFORCEMENT	Currently no recommendations.
CONTRAINDICATIONS	**There are no contraindications to RabIg given for post-exposure purposes.**
PRECAUTIONS	• If client has a history of anaphylactic reaction following receipt of any human Ig product, to any of the components of RabIg (glycine) or to latex, administer RabIg in an emergency room setting. • Human Ig products are among the safest blood-derived products available. The method of preparation includes one or more steps that exclude or inactivate hepatitis B, C and HIV; therefore the risk of transmission is extremely low. However, it is possible, that unknown infectious agents may be present in such products. • Regarding RabIg and the administration of live vaccines refer to SIM, Chapter 5, *Immunization Schedules,* Section 3.5, *Spacing of Live Vaccines, Blood Products and Immune Globulin Preparations* and Section 3.5.1, *Immune Globulin Preparations or Blood: Timing Intervals for Vaccines Containing Live Measles, Mumps, Rubella, or Varicella Virus*. • Persons with IgA deficiency have the potential for developing antibodies to IgA and could have an anaphylactic reaction to subsequent blood products that contain IgA. Administer RabIg in an emergency room setting.

Rabies Immune Globulin (RabIg) (Human)

KamRAB™
(Valneva 2018 monograph available at: https://www.valneva.ca/en/)

COMPONENTS	KamRAB is a sterile, non-pyrogenic aqueous solution of anti-rabies immunoglobulin (≥95% protein as IgG). The product is stabilized with 0.3 M glycine and has a pH of 5.5 ± 0.5. Medicinal ingredients: Anti-rabies immunoglobulin (human antibodies to rabies) Non-medicinal ingredients: glycine, water for injection and sodium hydroxide. No preservatives are added. Latex free.
EXPECTED REACTIONS	Temporary tenderness, soreness, pain or stiffness where the needle was given, fever, headache, malaise, rash, chills, nausea, joint or muscle aches.

[1] If RabIg is not administered on day 0, it can be administered up to and including day 7 of the RPEP series. Since vaccine induced antibodies begin to appear within one week, there is no value in administering RabIg more than 8 days after initiation of vaccine.
[2] Provide a written record to a client who receives any immune globulin product.
[3] When notification of an exposure is delayed, RPEP may be started as late as 6 or more months after an exposure.
[4] **RabIg should never be administered in the same syringe or needle or in the same anatomical site as vaccine.**

Tetanus Immune Globulin (TIg) (Human)

HYPERTET®
(Grifols Therapeutics 2021 monograph available at:
https://www.staticweb.grifols.com/documents/3836559/0/HyperTET+-+English+PM+-2012-02-03.pdf/12626081-1a27-43a5-9c05-7125dd4098b9)

INDICATIONS	DOSE / SERIES
NOTE: **TIg must be given at separate anatomic sites from a tetanus toxoid-containing vaccine.** 1. TIg is indicated for prophylaxis against tetanus following a major or unclean wound in individuals whose immunization history is incomplete or uncertain. Refer to Chapter 5, Section 3.7, *Tetanus Prophylaxis in Wound Management*. 2. TIg is indicated when a contraindication to a tetanus toxoid-containing vaccine exists and an individual sustains a major or unclean wound. 3. TIg is indicated in individuals known to have a significant immune deficiency state (e.g., HIV) regardless of their immunization history, following any major or unclean wound. 4. TIg is also indicated, although evidence of effectiveness is limited, in the regimen of treatment of active cases of tetanus.	• Give 250 units IM (entire single dose pre-filled disposable syringe) to adults and children who require TIg. • If a contraindication to tetanus toxoid-containing vaccine exists or a client refuses a tetanus toxoid-containing vaccine, and a client sustains a major or unclean wound, consider offering a 2nd dose of TIg approximately 28 days post the 1st dose of TIg (ImmunoFacts, 2013). **NOTE:** The syringe fill volume for each lot is adjusted to ensure a potency of not less than 250 IU/syringe. The actual fill volume for HYPERTET syringes typically ranges between 0.75 ml and 1.3 ml. The needle on the pre-filled syringe is fixed and cannot be changed.

REINFORCEMENT	None if Td/Tdap/Td-IPV/Tdap-IPV vaccine is given concurrently with TIg.
CONTRA-INDICATIONS	1.Anaphylactic or severe systemic hypersensitivity reactions to Immunoglobulin (Human), or to any ingredient in the formulation, including any non-medicinal ingredient, or component of the container. 2.HyperTET® should not be administered to patients who have severe thrombocytopenia or any coagulation disorder that would contraindicate intramuscular injections. 3.IgA deficient patients with antibodies against IgA and a history of hypersensitivity.
PRECAUTIONS	• Human Ig products are among the safest blood-derived products available. The method of preparation includes one or more steps that exclude or inactivate hepatitis B, C and HIV; therefore the risk of transmission is considered to be extremely low. However, it is possible that unknown infectious agents may be present in such products. • Regarding TIg and administration of live vaccines refer to SIM, Chapter 5, *Immunization Schedules,* Section 3.5, *Spacing of Live Vaccines, Blood Products and Immune Globulin Preparations* and Section 3.5.1, *Immune Globulin Preparations or Blood: Timing Intervals for Vaccines Containing Live Measles, Mumps, Rubella, or Varicella Virus*. • Give TIg with caution (i.e., in a setting capable of managing anaphylaxis) if the client has a history of anaphylactic reaction following receipt of any human Ig product, or a history of anaphylactic reaction to latex (assess risks versus benefits).

Tetanus Immune Globulin (TIg) (Human)

HYPERTET®
(Grifols Therapeutics 2021 monograph available at:
https://www.staticweb.grifols.com/documents/3836559/0/HyperTET+-+English+PM+-2012-02-03.pdf/12626081-1a27-43a5-9c05-7125dd4098b9)

	• Persons with IgA deficiency have the potential for developing antibodies to IgA and could have an anaphylactic reaction to subsequent administration of blood products that contain IgA. Therefore, TIg should only be given to such persons if the expected benefits outweigh the risks. • In clients who have severe thrombocytopenia or any coagulation disorder that would contraindicate IM injections, TIg should be given only if the expected benefits outweigh the risks. • The preferred sites for immune globulin administration are the vastus lateralis (all ages) or the deltoid (those 12 months and older).
COMPONENTS	15%-18% Human tetanus hyperimmune globulin, glycine. Preservative free. Prefilled syringe has rubber needle shield and stopper. Latex-free
EXPECTED REACTIONS	• Temporary pain, soreness and tenderness where the needle was given. • Fever, rash and itching skin. • Rarely, blood clots may occur after the administration of an immune globulin product.

Varicella Zoster Immune Globulin (VarIg) (Human)

VariZIG™
(2022 product monograph available at:
https://varizig.com/capage/_uploads/documents/Varizig.PDF)

INDICATIONS [1, 2]	For post-exposure prevention of varicella in the following high-risk clients who cannot receive varicella vaccine and who are at increased risk of severe varicella disease: **Infants and children:** • Immunocompromised clients (congenital or acquired) due to treatment or disease, including some clients receiving high doses of corticosteroids. Clients receiving monthly IGIV may not require VariZIG. • Newborn infants whose mothers develop varicella disease 5 days before to 48 hours after delivery. • Hematopoietic stem cell transplant (HSCT) recipients. • Infants and children in neonatal or pediatric intensive care settings, as determined by infectious disease/infection control specialist. **Adults:** • Susceptible pregnant women. • Immunocompromised adults (congenital or acquired) due to disease or treatment, including clients receiving corticosteroid treatment. Clients receiving regular monthly infusions of IGIV may not require VariZIG™. • Hematopoietic stem cell transplant recipients.
DOSE / SERIES	• Give VariZIG IM or IV as soon as possible, and within 96 hours of the first exposure to varicella or zoster. Clinicians may opt to provide VarIg up to 10 days following exposure to attenuated illness. • 125 IU is given for each 10 kg of body weight and is the minimum dose. • The maximum dose is 625 IU. • The preferred sites for immune globulin administration are the vastus lateralis (all ages) or the deltoid (those 12 months and older). • If VariZIG™ is administered by an intramuscular route, it should be given as an injection into the deltoid muscle or the anterolateral aspects of the upper thigh. Due to the risk of sciatic nerve injury, the gluteal region should not be used as a routine injection site. If the gluteal region is used, use only the upper, outer quadrant.
REINFORCEMENT	If a 2nd varicella exposure occurs more than 3 weeks after a dose of VariZIG™, another dose of VariZIG™ should be given.
SPECIAL HANDLING INSTRUCTIONS	The product should be brought to room or body temperature immediately prior to use. The product should be clear or slightly opalescent. Do not use product that appears cloudy or contains deposits.
CONTRA-INDICATIONS	1 .With known immunity to varicella zoster virus; i.e. with previous varicella infections or varicella vaccination. 2. Who are deficient in IgA. While VariZIG contains less than 40 µg/mL IgA, individuals who are deficient in IgA may have the potential to develop IgA antibodies and have an anaphylactoid reaction. 3 .With a history of anaphylactic or other severe systemic reaction to immune globulins. 4. Who are hypersensitive to this drug or to any ingredient in the formulation or components of the container.

Varicella Zoster Immune Globulin (VarIg) (Human)

VariZIG™
(2022 product monograph available at: https://varizig.com/capage/_uploads/documents/Varizig.PDF**)**

PRECAUTIONS	• Regarding VariZIG and administration of live vaccines (MMR & Varicella) refer to SIM, Chapter 5, *Immunization Schedules,* Section 3.5, *Spacing of Live Vaccines, Blood Products and Immune Globulin Preparations* and Section 3.5.1, *Immune Globulin Preparations or Blood: Timing Intervals for Vaccines Containing Live Measles, Mumps, Rubella, or Varicella Virus.* • Human Ig products are amongst the safest blood-derived products available. The method of preparation includes one or more steps that exclude or inactivate hepatitis B, C or HIV; therefore the risk of transmission of these viruses is considered to be extremely low. However, it is possible that unknown infectious agents may be present in such products.
COMPONENTS	VariZIG is a sterile solution for injection. It is a gamma globulin (IgG) fraction of human plasma containing antibodies to varicella zoster virus. Non-medicinal ingredients include 10% maltose and 0.03% (w/w) polysorbate 80. Each 125 IU vial contains less than 156 mg human IgG. It contains no preservative and is intended for single use only. VariZIG does not contain mercury and the stopper is latex free.
EXPECTED REACTIONS	• Temporary pain and tenderness at the injection site. • Headache, rash, joint or muscle aches, chills, tiredness, nausea, vomiting, or flushing may occur. • Rarely, blood clots may occur after the administration of an immune globulin product.

[1] A dose of ≥ 2 mg/kg/day of prednisone or equivalent, or more than 20 mg/per day, particularly when given for more than 2 weeks.

[2] Patients receiving monthly infusions of ≥ 400 mg/kg of IVIG and whose most recent infusion was within 3 weeks of exposure do not require VariZIG™.

Botulism Antitoxin (BAT®)

Botulism Antitoxin
Heptavalent (A, B, C, D, E, F, G) – (Equine)
Emergent BioSolutions Canada Inc. 2020 Product monograph:
https://www.emergentbiosolutions.com/wp-content/uploads/2022/01/BAT-Canada-Monograph-English.pdf

INDICATIONS	Treatment of botulism
INITIAL SERIES	Refer to product monograph
REINFORCEMENT	Refer to product monograph
CONTRAINDICATIONS	Refer to product monograph
COMPONENTS	Refer to product monograph
EXPECTED REACTIONS	Refer to product monograph
SPECIAL CONSIDERATION	Refer to product monograph

Diphtheria Antitoxin (DAT)

Diphtheria Antitoxin

This product is not manufactured in North America and is only available through the *Special Access Program* (SAP). A product monograph is included with every vial.

INDICATIONS	For passive transient protection against or treatment of diphtheria infections.
INITIAL SERIES	
REINFORCEMENT	
CONTRAINDICATIONS	
COMPONENTS	
EXPECTED REACTIONS	
SPECIAL CONSIDERATION	