Moderna Bivalent (SpikeVax) COVID-19 Vaccine for 6 months – 4 years and Immunocompromised 5 years +

July 28, 2023

Reminder:
This videoconference/webinar will be recorded.

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Acknowledgement

The FNIHB Alberta Region CDC Team has created this training by using Alberta Health and Alberta Health Services documents.

First of all,

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Objective Today:

- To provide an update to clinical information related to the Moderna Bivalent COVID-19 vaccine, including usage as primary series, indications and scheduling

Reducing the Number of COVID-19 Vaccines

- Starting August 2, 2023, only the following COVID-19 vaccines will be used for the immunization program in Alberta:

mRNA Vaccines

- **Moderna Spikevax Bivalent** (royal blue cap and grey label) **(new vaccine)**
  - Ages 6 months to 4 years of age
  - Immunocompromised individuals 5 years of age and older
- **Pfizer/BioNTech Comirnaty Bivalent** (orange label)
  - Ages 5 – 11 years
- **Pfizer/BioNTech Comirnaty Bivalent** (grey cap)
  - 12 years of age and older

Non-mRNA Vaccine

- **Novavax** (recombinant protein vaccine) will also be an option at AHS facilities. Stock currently not available, unsure of future shipment date.

Biological Pages

- New biological pages will be posted on the AHS website on August 2, 2023.
  - **Moderna Spikevax Bivalent** (royal blue cap and grey label)
  - **Pfizer/BioNTech Comirnaty Bivalent Vaccines**
    - One biological page will have two vaccines on it:
      - ages 5 – 11 years (orange cap)
      - and the 12 years of age and older (grey cap)

Reminder: For complete and current information, always use the biological pages posted on the AHS website.

mRNA COVID-19 Vaccine Review

- The COVID-19 vaccine protects against COVID-19, which is the disease caused by SARS-CoV-2 coronavirus.
- The Moderna bivalent (SpikeVax) COVID-19 vaccine uses the messenger RNA (mRNA) manufacturing platform.
- mRNA (messenger ribonucleic acid) vaccines contain the genetic instructions for making the COVID-19 spike protein. This protein is found on the surface of the virus that causes COVID-19.
- When a person is given the vaccine, their cells will read the genetic instructions like a recipe and produce the spike protein.
- After the protein piece is made, the cell breaks down the instructions and gets rid of them.
- The cell then displays the protein piece on its surface. Our immune system recognizes that the protein doesn't belong there and begins building an immune response and making antibodies.
- mRNA vaccines do not affect, interact with or alter your DNA in any way.

Vaccine Information

- Licensed for use in Canada
- **August 2, 2023** – Program implementation date in Alberta
- Biological classification: mRNA vaccine
- Contains the Original COVID-19 vaccine and Omicron BA.4/BA.5)
- The manufacturer is Moderna.
  - 2.5 mL vial (5 x 0.5 mL doses or 10 x 0.25 mL doses)
- **Vaccine code:** COVMODmRNABA45
- **Antigen code:** COVID-19-19

Royal Blue Cap & Grey Label

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Use of Vaccine

Licensed Use

- Booster dose for individuals 6 years of age and older
  - (not the age group the vaccine is being used for in Alberta)

Off-License Use in Alberta

- Primary series for individuals 6 months of age and older.
- Third dose in a primary series for individuals who are moderately to severely immunocompromised.
- Third dose in a mixed Pfizer-BioNTech original monovalent and Moderna bivalent BA.4/5 primary series for healthy children aged 6 months to 4 years.
- Fourth dose in a mixed Pfizer-BioNTech original monovalent and Moderna bivalent BA.4/5 primary series for moderate to severely immunocompromised children aged 6 months to 4 years.

Indications Provincially Funded Vaccine

- Primary series for individuals 6 months to 4 years of age.
- Primary series for moderately to severely immunocompromised individuals 6 months of age and older.

Vaccine Administration: Dose and Route

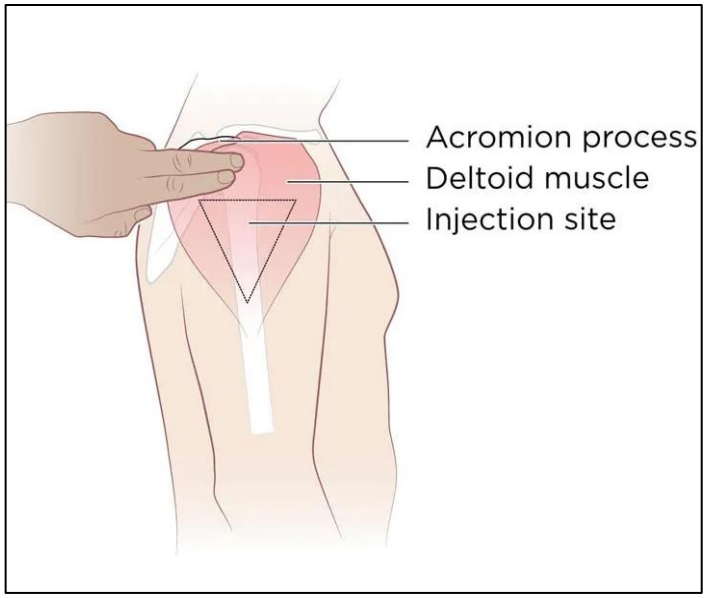
Dose and Route: Intramuscular (IM) injection in the deltoid or vastus lateralis muscle.

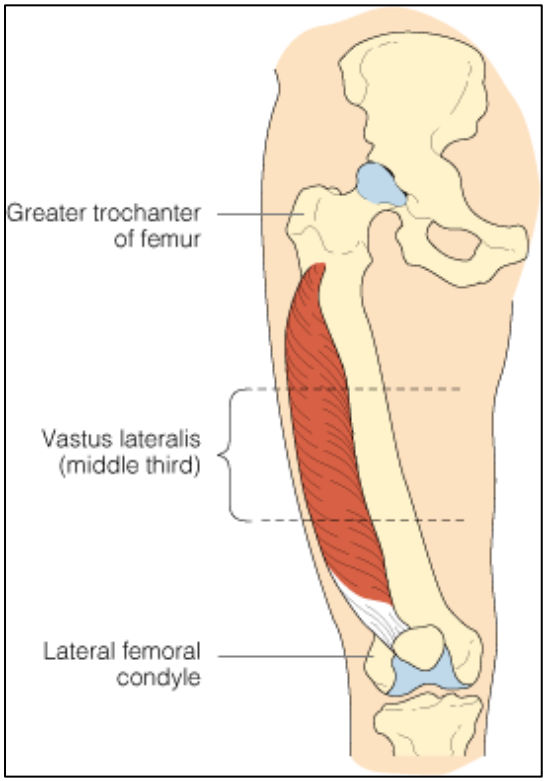
<u>6 months to 11 years of age</u>

- 0.25mL (25 mcg)

<u>12 years of age and older</u>

- 0.5mL (50mcg)





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Schedule: Healthy children 6 months – 4 years

Schedule: Healthy children 6 months to 4 years of age

- **Primary series: 2 doses**
  - Dose 1: Day 0
  - Dose 2: At least 8 weeks after dose 1
- **If a child has received one or two doses of Pfizer-BioNTech original monovalent vaccine as part of their primary series, they require 2 or 1 dose(s) of Moderna vaccine respectively to complete their primary series. (3 doses in total)**

Notes:

- Recommended spacing between doses is at least 8 weeks.
- If a primary series was started with an original monovalent vaccine, a bivalent Omicron-containing vaccine can be used to complete the series, noting the schedule requirements above.
- **For children who start their primary series at 4 years of age and are eligible for their next dose after turning 5 years of age, the Pfizer-BioNTech Comirnaty bivalent BA.4/5 should be used to complete the primary series.**

Primary Series – Currently considered complete

6 months to 4 years of age – healthy children	have had 2 doses of mRNA **Moderna Spikevax monovalent** vaccine for their primary series OR have had 3 doses of mRNA **Pfizer monovalent** for their primary series OR have had 3 doses of a mix of monovalent vaccines (mRNA **Moderna Spikevax monovalent** and **Pfizer monovalent**) for their primary series	Considered complete. No extra doses required at this time.

(Not eligible for a booster dose at this time)

Healthy Children 6 months – 4 years Primary Series		
If no previous COVID-19 vaccine	Child requires 2 doses of mRNA **Moderna Spikevax Bivalent** for their primary series	Dose 1: Day 0 Dose 2: At least 8 weeks after dose 1
Had one dose of mRNA **Moderna Spikevax monovalent** vaccine	Child requires 1 dose of mRNA **Moderna Spikevax Bivalent** to complete their primary series	Recommended spacing between doses is at least 8 weeks

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Healthy Children 6 months – 4 years (continued) **Primary Series**		
Had **one dose** of mRNA **Pfizer monovalent** vaccine	Child requires 2 doses of mRNA **Moderna Spikevax Bivalent** to complete their primary series	Recommended spacing between doses is at least 8 weeks
Had two doses of mRNA **Pfizer monovalent** vaccine	Child requires 1 dose of mRNA **Moderna Spikevax Bivalent** to complete their primary series	Recommended spacing between doses is at least 8 weeks
Had one dose of mRNA **Pfizer monovalent** vaccine AND one dose of **Moderna Spikevax monovalent** vaccine	Child requires 1 dose of mRNA **Moderna Spikevax Bivalent** to complete their primary series	Recommended spacing between doses is at least 8 weeks

Schedule: Immunocompromised 6 months – 4 years

Schedule: Immunocompromised 6 months to 4 years of age

- **Primary series 3 doses**
  - Dose 1: Day 0
  - Dose 2: 28 days after dose 1
  - Dose 3: 8 weeks after dose 2

- **If a child has received one, two or three doses of Pfizer-BioNTech original monovalent vaccine as part of their primary series, they require 3, 2 or 1 dose(s) of Moderna vaccine respectively to complete their primary series. (4 doses in total – see notes below for intervals)**

Primary Series – Currently considered complete

6 months to 4 years of age – immunocompromised children	Have had 3 doses of mRNA **Moderna Spikevax monovalent** vaccine for their primary series **OR** have had 4 doses of mRNA **Pfizer monovalent** for their primary series **OR** have had 4 doses of a mix of monovalent vaccines (mRNA **Moderna Spikevax monovalent** and **Pfizer monovalent**) for their primary series	Considered complete. No extra doses required at this time.

(Not eligible for a booster dose at this time)

Immunocompromised Children 6 months – 4 years Primary Series		
If no previous COVID-19 vaccine	Child requires 3 doses of mRNA **Moderna Spikevax Bivalent** for their primary series	Dose 1: Day 0 Dose 2: minimum 28 days after dose 1 Dose 3: 8 weeks after dose 2
Had one dose of mRNA **Moderna Spikevax monovalent** vaccine	Child requires 2 doses of mRNA **Moderna Spikevax Bivalent** to complete their primary series	Dose 1: 28 days after monovalent dose Dose 2: 8 weeks after bivalent dose
Had two doses of mRNA **Moderna Spikevax monovalent** vaccine	Child requires 1 dose of mRNA **Moderna Spikevax Bivalent** to complete their primary series	8 weeks after second monovalent dose

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Immunocompromised Children 6 months – 4 years (continued) Primary Series		
Had **one dose** of mRNA **Pfizer monovalent** vaccine	Child requires 3 doses of mRNA **Moderna Spikevax Bivalent** to complete their primary series	Dose 1: minimum 28 days after monovalent dose Dose 2: 8 weeks later Dose 3: 8 weeks later
Had two doses of mRNA **Pfizer monovalent** vaccine	Child requires 2 doses of mRNA **Moderna Spikevax Bivalent** to complete their primary series	Recommended spacing between doses is at least 8 weeks
Had three doses of mRNA **Pfizer monovalent** vaccine	Child requires 1 dose of mRNA **Moderna Spikevax Bivalent** to complete their primary series	At least 8 weeks after third monovalent dose

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Immunocompromised Children 6 months – 4 years (continued) Primary Series		
Had one dose of mRNA **Pfizer monovalent** vaccine AND one dose of **Moderna Spikevax monovalent** vaccine	Child requires 2 doses of mRNA **Moderna Spikevax Bivalent** to complete their primary series	Recommended spacing between doses is at least 8 weeks
Had a total of 3 doses with a mixed primary series of mRNA **Pfizer monovalent** vaccine and **Moderna Spikevax monovalent** vaccine	Child requires 1 dose of mRNA **Moderna Spikevax Bivalent** to complete their primary series	At least 8 weeks after third monovalent dose

Schedule: Immunocompromised 5 Years and Older

Schedule: Immunocompromised 5 years of age and older*

- **Primary series 3 doses**
  - Dose 1: Day 0
  - Dose 2: 28 days after dose 1
  - Dose 3: 8 weeks after dose 2

- ***Immunocompromised children 5 years of age and older, who initiated a primary series before turning 5 years of age, should complete their series as per the schedule above for immunocompromised individuals 6 months to 4 years of age.**

Primary Series – Currently considered complete		
5 years of age and older - immunocompromised	Have had 3 doses consisting of mRNA **Pfizer monovalent** vaccine AND/OR mRNA **Moderna Spikevax monovalent** vaccine for their primary series.	Considered complete. No extra doses required at this time.

Notes:

- Individuals were also eligible for, and may have received, one or two booster doses
- The mRNA **Moderna Spikevax Bivalent** vaccine is currently **not** approved for booster doses. See the mRNA **Pfizer bivalent** vaccine biological page for booster doses.

5 years of age and older - immunocompromised

Notes:

*Children who initiated a primary series before turning 5 years of age, should complete their series as per the schedule for immunocompromised individuals 6 months to 4 years of age.

*For individuals 12 to 29 years of age, Pfizer-BioNTech Comirnaty bivalent BA.4/5 is preferred over Moderna Spikevax bivalent BA.4/5 due to a lower risk of myocarditis and/or pericarditis. See Myocarditis/Pericarditis section on biological page for full information.

Immunocompromised Individuals 5 years of age and older Primary Series		
If no previous COVID-19 vaccine	requires 3 doses of mRNA **Moderna Spikevax Bivalent** for their primary series	Dose 1: Day 0 Dose 2: 28 days after dose 1 Dose 3: 8 weeks after dose 2
Had one dose of mRNA **monovalent** vaccine (**Moderna or Pfizer**)	requires 2 doses of mRNA **Moderna Spikevax Bivalent** to complete their primary series	Dose 1: 28 days after monovalent dose Dose 2: 8 weeks after bivalent dose
Had two doses of mRNA **monovalent** vaccine (**Moderna and/or Pfizer**)	requires 1 dose of mRNA **Moderna Spikevax Bivalent** to complete their primary series	8 weeks after second monovalent dose

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Note: See age-appropriate mRNA **Pfizer bivalent** vaccine biological page for booster eligibility.

Schedule: Immunocompromised Additional Notes

- If a primary series was started with an original monovalent vaccine (either mRNA or non-mRNA), a bivalent Omicron-containing vaccine can be used to complete the series. Regardless of which COVID-19 bivalent vaccine product is offered, the previous dose(s) should be counted, and the series should not be restarted, noting the schedule requirements above.
- It is recommended that individuals with certain immunocompromising conditions be immunized with a primary series of three doses of an mRNA COVID-19 vaccine. This is to provide stronger protection for those who may have a suboptimal immune response to vaccines. A bivalent mRNA vaccine should be administered except in the event of contraindication or refusal.

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Schedule: Immunocompromised Additional Notes

- The interval between dose 1 and dose 2 is 28 days. The interval between dose 2 and dose 3, and between dose 3 and 4, if required, is 8 weeks.
  - Emerging evidence from the general population indicates that a longer interval will likely result in a better immune response and duration of protection.
  - However, there is heterogeneity of risk from COVID-19 among those who are moderately to severely immunocompromised. In addition, the likelihood of a reduced response to vaccines will vary depending on the immunocompromising condition. Thus, a shortened interval no less than 28 days may be considered for those with increased risk of exposure and greater severity of immunodeficiency based on their clinician's recommendation.

Schedule: Immunocompromised Additional Notes

- Individuals who are moderately to severely immunocompromised may benefit from a primary series with Moderna Spikevax bivalent compared to Pfizer-BioNTech Comirnaty bivalent BA.4/5.
    - **However, for individuals 12 to 29 years of age, Pfizer-BioNTech Comirnaty bivalent BA.4/5 is preferred over Moderna Spikevax bivalent BA.4/5 due to a lower risk of myocarditis and/or pericarditis observed after dose 1 and dose 2 of the primary series with Pfizer-BioNTech Comirnaty original (30 mcg) compared to Moderna Spikevax original (100 mcg).**
        - Moderna can be provided if preferred by an individual or their specialist. See the Precautions section for further information on myocarditis/pericarditis.

Schedule: Immunocompromised Additional Notes

- **Specific immunocompromising conditions that make an individual eligible for a <u>three dose</u> primary series include:**
  - **Solid organ transplant** recipients – pre-transplant and post-transplant
  - Hematopoietic **stem cell transplants** recipients – pre-transplant and post-transplant while in immunosuppressed state (post-HSCT individuals are generally considered to be immunocompetent after 3 years as long as they are not on immunosuppressive drugs)
  - Individuals with **malignant hematologic disorders and non-hematologic malignant solid tumors** prior to receiving or while receiving active treatment which includes chemotherapy, targeted therapies, and immunotherapy or having received previous COVID-19 vaccines while on active treatment (does not include individuals receiving solely hormonal therapy, radiation therapy or a surgical intervention).
  - Individuals with **chronic kidney disease on peritoneal dialysis or hemodialysis**.
  - Individuals receiving chimeric antigen receptor **(CAR) T-cell therapy**.
  - **Individuals on:**
    - long term **high-dose systemic steroid treatment** (prednisone equivalent of ≥ 2 mg/kg/day or 20 mg/day if weight > 10 kg, for ≥ 14 days), **alkylating agents**, **anti-B-cell therapies** – including anti-CD19, anti-CD20, anti-CD22 and anti-CD52 monoclonal antibodies (such as rituximab, ocrelizumab, and ofatumumab), **antimetabolites** (e.g., methotrexate, azathioprine, mycophenolate), tumor-necrosis factor **(TNF) inhibitors** (e.g., adalimumab, certolizumab, etanercept, golimumab, infliximab), **other agents that are significantly immunosuppressive** at clinicians' discretion.
  - **HIV-infected individuals** without viral suppression or those with acquired immunodeficiency syndrome (**AIDS**).
  - Individuals with **moderate to severe primary immunodeficiency** (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome).

Schedule: Immunocompromised Additional Notes

- Documentation of immunocompromising conditions is not required. Individuals who identify themselves as meeting at least one of the criteria above should be offered the 3 dose primary series.
- Immunization of immunocompromised individuals should occur at a time when the individual is most likely to mount an immune response. Physician consultation is recommended regarding the timing of immunization (initiation and interval) based on the individual's treatment and unique circumstances.
- Hematopoietic stem cell transplant (HSCT) recipients who received COVID-19 vaccine pre-transplant are eligible to restart their COVID-19 vaccine series beginning at least 3 months post-transplant. Consultation with their HSCT physician is not necessary if the initial clearance letter has been received to proceed with inactivated vaccines.

Schedule: Immunocompromised Additional Notes

- CAR T-cell therapy recipients without a prior history of HSCT who received COVID-19 vaccine pre-CAR T-cell therapy are eligible to restart their COVID-19 vaccine series, beginning at least 3 months post-CAR T-cell therapy. Consultation with their physician is not necessary as long as a clearance letter has been received to proceed with inactivated vaccines.
- For HSCT recipients who had their post-HSCT vaccine series interrupted by CAR T-cell therapy, see the following HSCT recommendations:
  - Principles of Immunization in Hematopoietic Stem Cell Transplant Recipients and Solid Organ Transplant Recipients
  - Immunization for Adult HSCT Recipients
  - Immunization for Child HSCT Recipients

Interval between previous COVID-19 Infection and COVID-19 Immunization

For individuals with a history of COVID-19 infection the following guidance is provided on suggested intervals between infection and COVID-19 immunization:

Note:

- These suggested intervals are based on immunological principles and expert opinion, and may change as evidence on COVID-19, variants of concern (VOCs), and COVID-19 vaccines emerge. When considering whether or not to administer vaccine doses following the suggested intervals outlined in this table, biological and social risk factors for exposure (e.g., local epidemiology, circulation of VOCs, living settings) and risk of severe disease should also be considered. These intervals are a guide and clinical discretion is advised. Individuals can be immunized at less than the recommended intervals from infection upon request.
- **For individuals who have not had any previous doses, they may receive their first dose after acute symptoms of COVID-19 have resolved and they are no longer infectious, or they may follow these suggested intervals (except for those with MIS-C who should wait at least 90 days).**

Interval between previous COVID-19 Infection and COVID-19 Immunization

Infection prior to initiation or completion of a primary COVID-19 immunization series	**Individuals without certain immunocompromising conditions AND no history of multisystem inflammatory syndrome in children (MIS-C).**	**8 weeks after a positive test.**
	Individuals with certain immunocompromising conditions (as listed above) AND no history of MIS-C.	**4 to 8 weeks after a positive test.**
	History of MIS-C (regardless of immunocompromised status).	**Receive the vaccine when clinical recovery has been achieved or at least 90 days since the onset of MIS-C, whichever is longer.**

Pregnancy

- **A complete COVID-19 vaccine series should be offered to pregnant individuals regardless of trimester of pregnancy.** An mRNA vaccine is preferred due to reassuring published data on the safety of these vaccines in pregnancy.
- **The safety and efficacy of Moderna Spikevax Bivalent Original/Omicron BA.4/5 in pregnant women have not yet been established.**
- However, **data available on the original mRNA vaccines administered in pregnancy did not detect safety signals** from post-marketing surveillance. The bivalent COVID-19 mRNA vaccines can be offered to pregnant individuals as they are more at risk for severe illness from COVID-19 compared with non-pregnant individuals.
    - **Evidence to date shows that COVID-19 immunization during pregnancy is safe and does not increase risk for miscarriage, stillbirth, low birth weight, preterm birth, NICU admission, or other adverse pregnancy/birth outcomes.**
    - It is recommended that individuals consult their primary health care provider or obstetrician for any vaccine related questions or concerns.
    - However, consultation with a primary health care provider or obstetrician is not required to receive COVID-19 vaccine.

Lactation

- It is unknown whether this vaccine is excreted in human milk. A risk to the newborns/infants cannot be excluded.
- Recent reports have shown that breastfeeding people who have received mRNA COVID-19 vaccines have antibodies in their breastmilk, which could help protect their babies. More data are needed to determine the level of protection these antibodies might provide to the baby.
- A complete COVID-19 vaccine primary series is recommended for individuals who are breastfeeding.
    - It is recommended that individuals consult their primary health care provider or medical specialist for any vaccine related questions or concerns.
    - However, consultation with a primary health care provider or medical specialist is not required to receive COVID-19 vaccine.

Vaccine Contraindications

- **Known hypersensitivity to any component of the vaccine**.
- Two non-medicinal ingredients in the vaccine that have been associated with allergic reactions in other products:
  1. 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.
  2. Tromethamine (**trometamol** or **Tris**) – component found in contrast media, oral and parenteral medications.
- **Anaphylaxis to a previous dose of COVID-19 mRNA vaccine may not be an absolute contraindication.** See COVID-19 Immunization for Individuals with Allergies and Other Health Conditions for recommendations

Vaccine Precautions

- Individuals who have had a serious allergic reaction to another vaccine, drug or food should talk to their health care provider before receiving the vaccine.
- Individuals receiving anticoagulant therapy or those with a bleeding disorder that would contraindicate intramuscular injection should not be given the vaccine unless the potential benefit clearly outweighs the risk of administration.
- Administration should be postponed in individuals suffering from acute severe febrile illness.
- The safety and efficacy of Moderna Spikevax Bivalent Original/Omicron BA.4/5 in individuals under 6 years of age has not yet been established.

Vaccine Precautions: Continued

- However, the safety and immunogenicity of Moderna Spikevax bivalent BA.1 (25 mcg) as a primary series was evaluated in a Phase 3 open-label study in 179 unimmunized children 6 months to 5 years of age.
  - Local and systemic reactogenicity after dose 1 and dose 2 of Moderna Spikevax bivalent BA.1 (25 mcg) were similar compared to those after dose 1 and dose 2 of Moderna Spikevax original (25 mcg).
  - There were no reports of vaccine-related serious adverse events, myocarditis and/or pericarditis or deaths. Given the number of participants enrolled in the trial, it is unlikely that uncommon, rare or very rare adverse events would be detected.
- Available evidence from Canada and internationally show that overall, the safety profile of bivalent mRNA COVID-19 vaccine boosters is comparable to that of original mRNA vaccine boosters among individuals 5 years of age and older.
- Despite the limited evidence on the use of bivalent vaccines as a primary series, the precautionary principle indicates that scientific uncertainty should not prevent decision makers from taking action to reduce risks associated with COVID-19. Use of bivalent vaccines for the primary series primes naïve individuals with both Omicron and original SARS-CoV-2 variants, which will help to maximize the breadth of immunity at the earliest opportunity.

Myocarditis/Pericarditis

- Very rare cases of myocarditis and/or pericarditis following immunization with original mRNA COVID-19 vaccines have been reported during post-authorization use. However, the risk of myocarditis and/or pericarditis following a first and second booster dose of an original mRNA COVID-19 vaccine appears to be lower than the risk following the second dose of the primary series.
- **Anyone receiving a mRNA COVID-19 vaccine should be informed of the risk of myocarditis and pericarditis and advised to seek medical attention if they develop related symptoms including shortness of breath, chest pain, or the feeling of a rapid or abnormal heart rhythm.**
- Healthcare professionals are advised to consider the possibility of myocarditis and/or pericarditis in their differential diagnosis if individuals present with chest pain, shortness of breath, palpitations or other signs and symptoms of myocarditis and/or pericarditis following immunization with an mRNA COVID-19 vaccine.
- Generally, deferral of COVID-19 immunization is not required for those with a prior history of myocarditis or pericarditis that is unrelated to COVID-19 mRNA vaccines.
    - If these individuals have questions or concerns about their prior history of myocarditis or pericarditis and immunization, it is recommended that individuals consult with their clinician. However, consultation with a clinician is not required to receive COVID-19 vaccines.

(Continued)

Myocarditis/Pericarditis (continued)

- Individuals with a history compatible with pericarditis within 6 weeks of receiving a dose of a mRNA COVID-19 vaccine, who either had no cardiac workup or who had normal cardiac investigations, can be re-immunized when they are symptom free and at least 90 days have passed since previous immunization.

- In most circumstances, further doses of mRNA COVID-19 vaccines should be deferred among people who experienced myocarditis (with or without pericarditis) within 6 weeks of receiving a previous dose of an mRNA COVID-19 vaccine.
  - However, further doses may be offered if individuals with confirmed myocarditis or pericarditis with abnormal cardiac investigation choose to receive another dose of vaccine after discussing the risks and benefits with their clinician.
  - Informed consent should discuss the unknown risk of recurrence of myocarditis and/or pericarditis following additional doses of COVID-19 vaccine in individuals with a history of confirmed myocarditis and/or pericarditis after a previous dose of mRNA COVID-19 vaccine.

Possible Reactions

Common:

- Pain, redness, swelling, and induration at the injection site
- Axillary swelling/tenderness
- Fatigue
- Headache
- Myalgia
- Arthralgia
- Chills
- Nausea/vomiting
- Fever
- Hypoaethesia, paraesthesia
- Dizziness
- Lymphadenopathy
- As with any immunization, unexpected or unusual side effects can occur.
  - Refer to product monograph for more detailed information.

Rare:

- Anaphylaxis
- Allergic reaction
- Anaphylaxis
- Erythema multiforme
- Facial paralysis/Bell's palsy

Vaccine Composition

- Elasomeran (mRNA) encoding the pre-fusion stabilized Spike glycoprotein of 2019 novel Coronavirus (SARS-CoV-2), and davesomeran (mRNA) encoding the pre-fusion stabilized conformation variant (K981P and V982P) of the SARS-CoV-2 Spike glycoprotein (Omicronvariant B.1.1.529 [BA.4/5])
- **Non-medicinal ingredients:**
  - Acetic acid
  - Cholesterol
  - DSPC (1,2-distearoyl-sn-glycero-3-phosphocholine)
  - Lipid SM-102
  - **PEG2000**-DMG (1,2-dimyristoyl-rac-glycerol,methoxy-polyethyleneglycol)
  - Sodium acetate trihydrate
  - Sucrose
  - **Trometamol**
  - Trometamol hydrochloride
  - Water for injection
  - **Does not contain any preservatives, antibiotics, adjuvants, or human- or animal-derived materials, blood/blood products, bovine/porcine products, or latex.**

Administration with other products

- COVID-19 vaccines may be co-administered with, or at any time before or after other vaccines (including, live, inactivated, adjuvanted, or unadjuvanted vaccines) to individuals 6 months of age and older.
- Currently there is no data on the impact of the COVID-19 mRNA vaccines on tuberculin skin testing or IGRA (QFT) test results. There is a theoretical risk that COVID-19 vaccines may temporarily affect cell-mediated immunity, resulting in false-negative tuberculin skin testing or IGRA (QFT) test results.
    - In the absence of data and acknowledging the importance of both timely tuberculosis testing and immunization, immunization with COVID-19 vaccines can take place at any time before, after or at the same visit as the TST or IGRA test.
    - However, repeat tuberculin skin testing or IGRA (at least 4 weeks post-COVID-19 immunization) of individuals with negative TST or IGRA results for whom there is high suspicion of latent tuberculosis may be considered in order to avoid missing persons with TB infection.

Administration with other products: Continued

- **Deferral of COVID-19 immunization is not recommended for individuals who have received anti-SARS-CoV-2 monoclonal antibodies or convalescent plasma provided for treatment or prophylaxis of COVID-19 just because they received these pharmacological interventions.** This applies to people who received these before receiving any COVID-19 vaccine dose or between doses.
  - A study among nursing home residents and staff demonstrated that recipients of a SARS-CoV-2 monoclonal antibody (bamlanivimab), mounted a robust immune response to mRNA immunization, regardless of age, risk category or vaccine type.
  - Although antibody response was numerically lower in people who received monoclonal antibodies, they were still considered to be high and the clinical significance of the reduction is unknown.
  - There was no correlation between interval to COVID-19 immunization and neutralizing titres in recent monoclonal antibody recipients.
  - Intervals between previous COVID-19 infection and COVID-19 immunization outlined in this document would still apply to individuals who got the monoclonal antibodies or convalescent plasma for their infection.

Administration with other products: Continued

- Individuals who are to receive Evusheld (tixagevimab and cilgavimab) as pre-exposure prophylaxis should wait at least 2 weeks following COVID-19 immunization to minimize interference.

Note:

- Timing of administration and potential interference between COVID-19 vaccine and monoclonal products not used for treatment or prophylaxis of COVID-19 infection are currently unknown and the primary health care provider or medical specialist should be consulted on a case-by-case basis.
- mRNA COVID-19 vaccines may be given at any time before or after an immunoglobulin preparation (including RhIg) or blood product has been administered. There is no recommended minimum interval between these products and COVID-19 vaccine.

Appearance and Storage

Appearance

- White to off-white dispersion.
- It may contain white or translucent product-related particulates.

Storage

- Can be stored in a freezer between -25°C and -15 °C.
- Protect from light
- Do not refreeze after thawing
- Thawed, unpunctured:
  - Can be stored at +2°C to + 8°C up to 30 days,
  - Can be stored at +8°C to +25°C for up to 24 hours.
- Thawed, punctured vials:
  - (first dose is withdrawn) can be stored at +2°C to +25°C for 24 hours.
  - Discard after 24 hours.

Preparation/Reconstitution

- Thaw vaccine before use.
- Vaccine can be thawed in two ways:
    1. From the freezer to room temperature (between +15°C to +25°C), thaw for 45 minutes from frozen state.
    2. From the freezer to a vaccine fridge +2°C to +8°C; thaw for 2 hours from frozen state.
- Let the vial stand at room temperature for 15 minutes before administering.
- No dilution is required.
- Swirl the vial gently after thawing and between each withdrawal.
- Do not shake vial.

Ordering

- The COVID-19 mRNA bivalent vaccine is available for ordering through the AVI (Alberta Vaccine Inventory) system.

Informed Consent

- Clients must give informed consent before immunization
- Prior to immunizing, the immunizer must:
  - Determine that the client is eligible (based on current phase and/or eligibility requirements)
  - Review the disease being prevented
  - Review vaccine

  Discuss:

  - Risks and benefits of getting the vaccine and not getting the vaccine
  - Side effects and after care
  - How the vaccine is given
  - Provide the opportunity to ask questions
  - Affirm verbal consent

Reminder: Monovalent COVID-19 Vaccines

As of August 2, 2023, monovalent (original) mRNA COVID-19 vaccines will no longer be available or used in Alberta.

Manufacturer	Product	Formulation	Age Group	Policy as of August 2, 2023
Moderna	**SpikeVax 10 dose/vial** (Blue Cap)	monovalent	6 months – 5 years	Will no longer be available or used.
Pfizer	**Comirnaty Pediatric 10 dose/vial** (Maroon Cap)	monovalent	6 months – 4 years	Will no longer be available or used.
Pfizer	**Comirnaty Pediatric 10 dose/vial** (Orange Cap)	monovalent	5 – 11 years	Will no longer be available or used.
Pfizer	**Comirnaty 6 dose/vial** (Gray Cap)	monovalent	12 years+	Will no longer be available or used.

Reminder: Monovalent COVID-19 Vaccines

- **At the end of the day on August 1, 2023, please discard any <u>monovalent vaccines</u>** (listed on previous page) **remaining in your vaccine fridge.**

- You will need to document the number of doses discarded in AVI:
- Use the Category “Expired”.
- Use the reason “Expired multi-dose vial”.

Bivalent mRNA COVID-19 Vaccines

Starting August 2, 2023, bivalent mRNA COVID-19 vaccines will be used for both primary series and booster doses.

Manufacturer	Product	Formulation	Age Group	Policy as of August 2, 2023
Moderna	**SpikeVax Bivalent 5 dose/vial** (Royal Blue Cap & Grey Label)	Bivalent (Original and Omicron BA.4/BA.5)	• 6 months – 4 years • immunocompromised 5 years +	To be used as the primary series
Pfizer	**Comirnaty Bivalent Pediatric 10 dose/vial** (Orange cap and label)	Bivalent (Original and Omicron BA.4/BA.5)	5 – 11 years	To be used as the primary series and booster dose
Pfizer	**Comirnaty Bivalent 6 dose/vial** (Gray cap)	Bivalent (Original and Omicron BA.4/BA.5)	12 years+	To be used as the primary series and booster dose

INDIGENOUS SERVICES CANADA

Questions?

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