COVID-19 Vaccine – mRNA Moderna Spikevax XBB.1.5

October 4, 2023

Indigenous Services Canada
Services aux Autochtones Canada
Canada

Reminder:

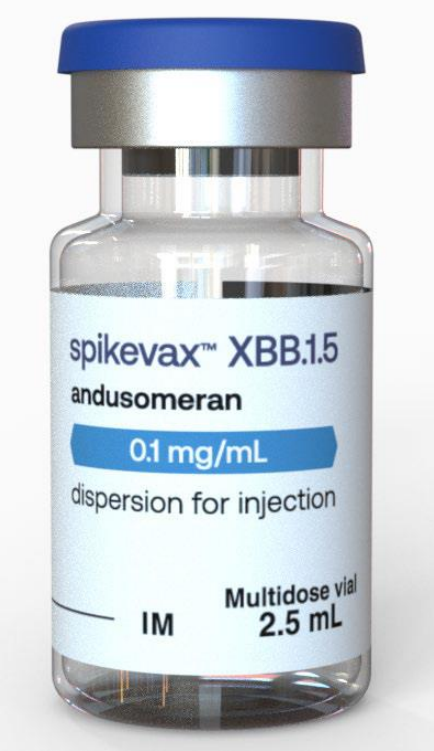
This videoconference/webinar will be recorded.

Acknowledgement

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

Today's Objective

To provide clinical information related to COVID-19 disease and immunization.



Reducing the Number of COVID-19 Vaccines

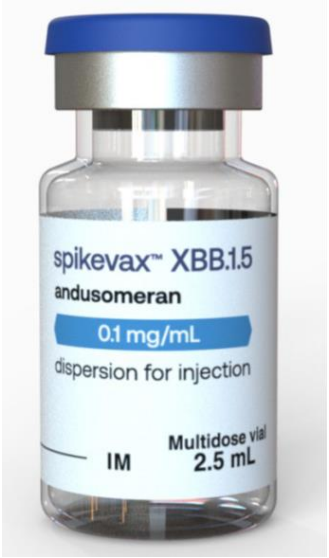
Starting October 2, 2023, only the following COVID-19 vaccine will be used for the immunization program in Alberta.

<u>mRNA Vaccine</u>

- **Moderna Spikevax XBB.1.5** (royal blue cap and coral label) **(new vaccine)**

  For immunocompetent and immunocompromised individuals 6 months of age and older

- **COVID Bivalent (BA 4/5) vaccines should no longer be available to Albertans as of October 2. Discard Now.**



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COVID-19 Vaccine Program Dates to Note

- Starting October 2, 2023, Moderna XBB.1.5 COVID-19 vaccine will be used for the immunization program in Alberta for congregate care facilities.

- Starting October 16, 2023, Moderna XBB.1.5 COVID-19 vaccine will be used for all individuals 6 months of age and older. This is the same date as the provincial influenza vaccine program rollout.

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AHS Vaccine Biological Page

- New biological page is posted on the AHS website as of October 2, 2023.

  – **Moderna Spikevax XBB 1.5** (royal blue cap and coral blue label)

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 (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 Efficacy & Effectiveness

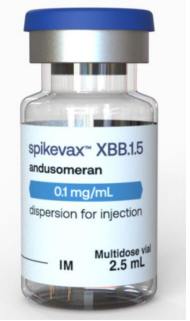
- **Vaccine efficacy**:
  - Percentage reduction of disease in an immunized group of people compared to an unimmunized group.
  - Calculated in clinical trials where the study conditions are controlled.
  - Does not describe whether an immunized person can still transmit the virus.

- **Vaccine effectiveness:**
  - Describes how the vaccine works in the real world where conditions cannot be controlled.
  - For example: previous exposure to the virus, immune status of the individual, receipt of recommended doses.

Vaccine effectiveness continues to be evaluated as the COVID-19 immunization program is rolled out.

Vaccine Information

- Licensed for use in Canada
- **October 2, 2023** – Program implementation date in Alberta
- Biological classification: mRNA vaccine
- Composition: Andusomeran (mRNA) of the SARS-CoV-2 Spike glycoprotein (Omicron subvariant XBB.1.5)
- The manufacturer is Moderna.
  - 2.5 mL vial (5 x 0.5 mL doses or 10 x 0.25 mL doses)
- Antigen code**:** COVID-19



Royal Blue Cap & Coral Blue Label

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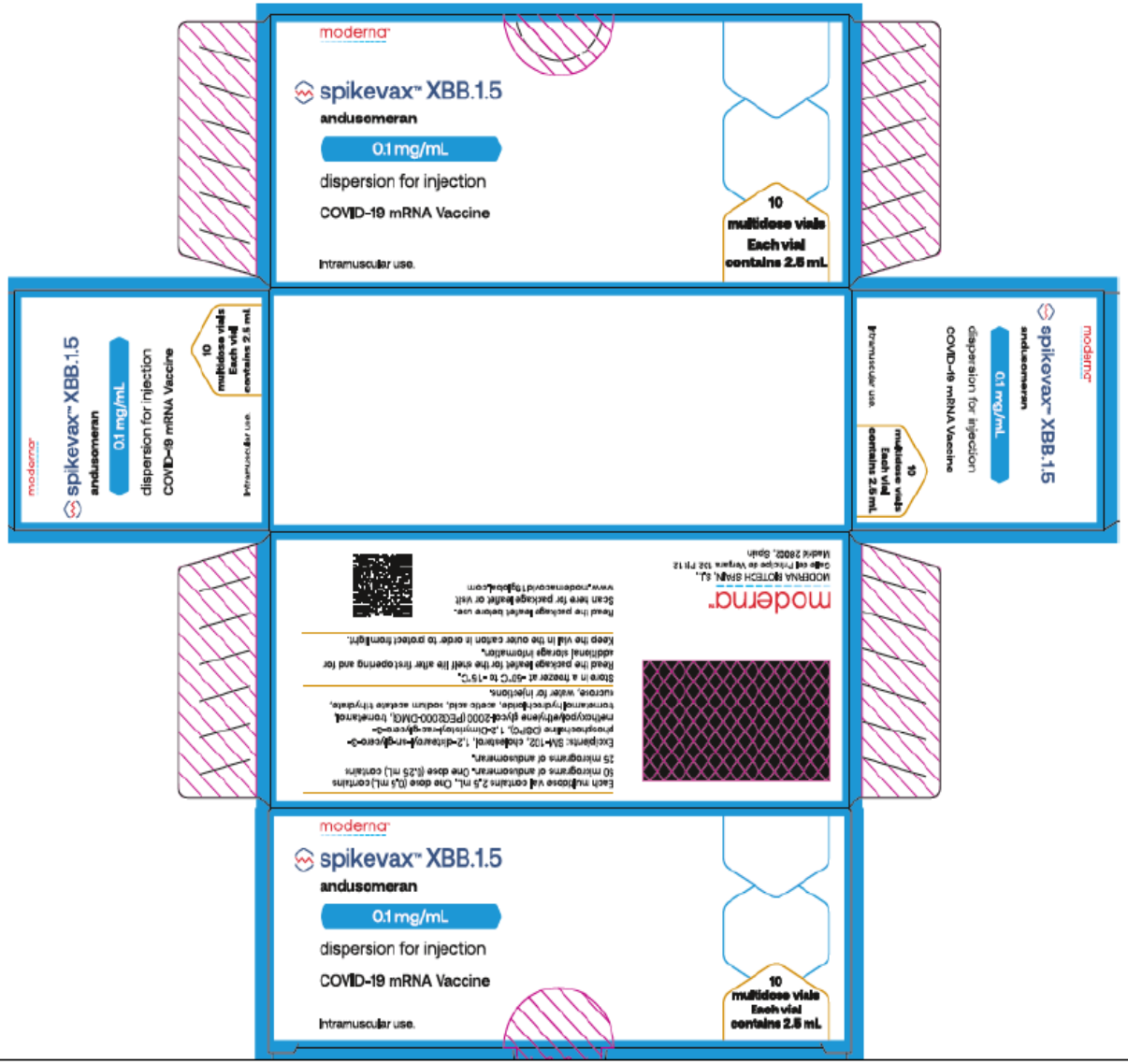
Use of Vaccine

SPIKEVAX XBB.1.5 – English-Only Carton Label

Licensed Use

- Individuals 6 months of age and older



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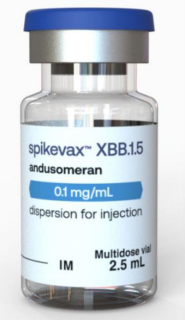
Indications Provincially Funded Vaccine

- One dose for immunocompetent individuals 6 months to 4 years of age who have previously completed a non-XBB series.
- Completion of a 2-dose series for immunocompetent individuals 6 months to 4 years of age who have not received 2 doses of a COVID-19 vaccine series.
- One dose for all immunocompetent individuals 5 years of age and older regardless of the product type and number of doses of COVID-19 vaccines received in the past.
- Completion of a 3-dose series for individuals 6 months of age and older who are moderately to severely immunocompromised.
- One dose for moderately to severely immunocompromised individuals who have completed a 3-dose non-XBB.1.5. series



Royal Blue Cap & Coral Blue Label

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Vaccine Administration: Dose and Route

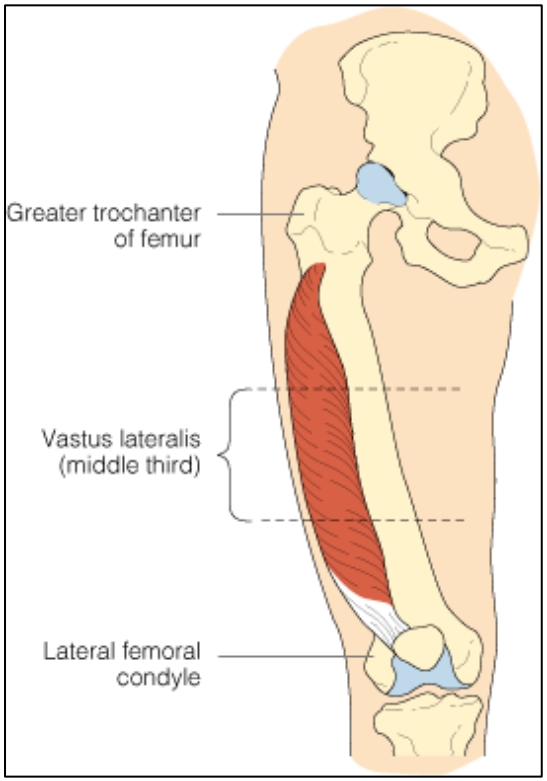
Dose and Route: Intramuscular (IM) injection in the deltoid or vastus lateralis muscle.

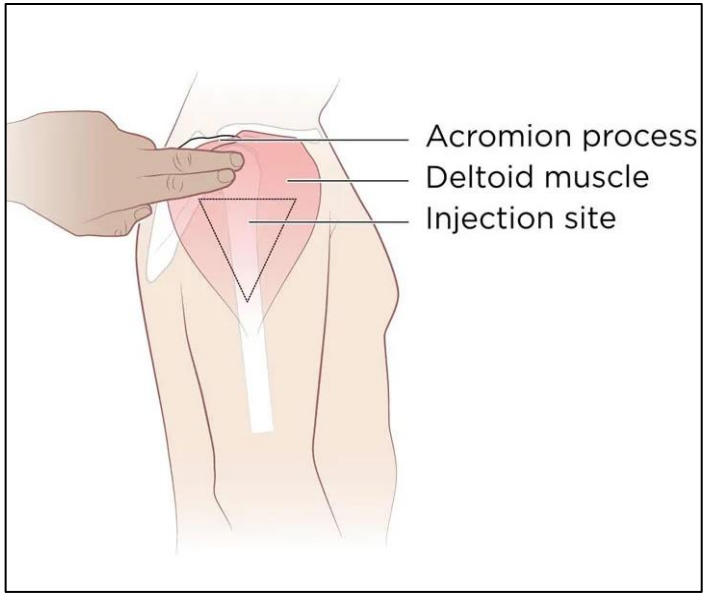
<u>6 months to 11 years of age</u>

- 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

- **Previously Unimmunized: 2 doses**
  - Dose 1: Day 0
  - Dose 2: At least 8 weeks after dose 1

- **Previously immunized with one dose of a non-XBB.1.5 COVID-19 vaccine series:**
  - 1 dose, at least 8 weeks from previous dose, regardless of product type

- **Previously completed non-XBB.1.5 COVID-19 vaccine series:**
  - 1 dose, at least 3 months from previous dose

NOTE:

- Individuals 6 months to 4 years of age should complete a two-dose series of COVID-19 vaccine. Regardless of which product was offered to start a series, the previous dose should be counted, and the series does not need to be restarted.

Schedule: Healthy children 5 years and older

Schedule: Healthy children 5 years of age and older

- 1 dose at least three months from previous COVID-19 vaccine dose, regardless of the number of doses received in the past.

CBC News March 2022

INDIGENOUS SERVICES CANADA

Schedule: Immunocompromised 6 months and older

Schedule: Immunocompromised 6 months of age and older

- **Previously received *fewer than 3 doses* of non-XBB.1.5 COVID-19 vaccine:**
  - Moderately to severely immunocompromised individuals should follow the schedule below and receive the appropriate number of Moderna Spikevax XBB.1.5 doses to complete a 3-dose series. Regardless of which COVID-19 vaccine product(s) were administered, the previous dose(s) should be counted, and the series does not need to be restarted.
  - Dose 1: Day 0
  - Dose 2: at least 28 days after dose 1
  - Dose 3: 8 weeks after dose 2

Schedule: Immunocompromised 6 months and older, cont.

NOTES:

- Based on data from studies of original mRNA COVID-19 vaccines, Moderna Spikevax original (100 mcg) induces somewhat higher antibody levels compared to Pfizer-BioNTech Comirnaty original (30 mcg) and protection (against infection and severe disease) may be more durable. It is reasonable to expect a similar result from Moderna Spikevax XBB.1.5.

- For individuals 12 to 29 years of age who are completing a three-dose series, Pfizer-BioNTech Comirnaty vaccine is preferred over Moderna Spikevax vaccine.
  - This aligns with NACI's previous recommendations based on the finding of a lower risk of myocarditis and/or pericarditis observed after dose 1 and dose 2 of a primary series with Pfizer-BioNTech Comirnaty original (30 mcg) compared to Moderna Spikevax original (100 mcg).
  - Post-market safety surveillance data on previous formulations of mRNA COVID-19 vaccine indicate that the risk of myocarditis following a booster dose is lower compared to that following the second dose in the primary series, and current data do not show a product-specific difference in the risks of myocarditis and/or pericarditis after a booster dose of an mRNA COVID-19 vaccine.
  - However, Moderna Spikevax XBB.1.5 can be provided if preferred by an individual or their specialist. See the precautions section for further information on myocarditis/pericarditis.

Schedule: Immunocompromised 6 months and older

Schedule: Immunocompromised 6 months of age and older

- **Previously received *3 or more* doses of non-XBB.1.5 COVID-19 vaccine:**
  - 1 dose, at least 3 months from previous dose

NOTES:

- It is recommended that individuals with certain immunocompromising conditions be immunized with a 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.

Schedule: Immunocompromised 6 months and older, cont.

- The interval between dose 2 and dose 3 is recommended to be 8 weeks because 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 across the board risk from COVID-19 disease 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 between dose 2 and 3 may be considered for those with increased risk of exposure and greater severity of immunodeficiency based on their clinician's recommendation.

Schedule: Immunocompromised 6 months and older

- **Specific immunocompromising conditions that make an individual eligible for a *three dose* COVID-19 vaccine series**:
  - 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

Schedule: Immunocompromised 6 months and older

Immunocompromised Individuals Continued:

- 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), or
  - alkylating agents, or
  - Individuals on anti-B-cell therapies – including anti-CD19, anti-CD20, anti-CD22 and anti-CD52 monoclonal antibodies (such as rituximab, ocrelizumab, and ofatumumab), or
  - antimetabolites (e.g., methotrexate, azathioprine, mycophenolate), or
  - tumor-necrosis factor (TNF) inhibitors (e.g., adalimumab, certolizumab, etanercept, golimumab, infliximab), or
  - 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 6 months and older

Notes:

- Documentation of immunocompromising conditions is not required. Individuals who identify themselves as meeting at least one of the criteria above should be offered a 3-dose 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 6 months and older

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 and Solid Organ Transplant Recipients
  - Child HSCT
  - Adult HSCT

AHS: Moderna mRNA COVID-19 Vaccine Summary

	Moderna COVID-19 Frozen
Dosage/Route	12 years of age and older - 0.5 mL / IM (deltoid or vastus lateralis) 6 months of age to 11 years of age – 0.25 mL/IM (deltoid or vastus lateralis)
Packaging	Multi-dose: Canadian packaging - 5 mL vial (10 doses)
Diluent	No
Eligibility	• Albertans 6 months of age or older
Indication	Albertans 6 months of age and older See biological page for specific information.
Ingredients	• mRNA (new technology) – nucleoside-modified mRNA (modRNA) platform • formulated in lipid nanoparticles (LNPs) • no adjuvants, preservatives and antibiotics
Schedule	**12 years of age and older** • Not previously vaccinated or previously vaccinated – one dose **5 to 11 years of age** • Not previously vaccinated or previously vaccinated – one dose **6 months to 4 years of age** • Not previously immunized – 2 doses • Previously immunized (1 or more previous doses) – one dose PLEASE SEE BIOLOGICAL PAGE FOR SPACING CONSIDERATIONS AND SCHEDULE FOR IMMUNOCOMPROMISED PERSONS.

Interval between infection and immunization

- 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 the tables found in the biological pages, 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 the intervals found in the tables in the biological pages (except for those with MIS-C who should wait at least 90 days).

Moderna mRNA COVID-19 Vaccine Reactions

Common:

- Pain, redness, swelling, and induration at the injection site
- Axillary swelling/tenderness
- Fatigue, Headache
- Myalgia, Arthralgia
- Chills, Fever
- Nausea/vomiting
- Dizziness
- Hypoaesthesia (decreased sense of touch or sensation)
- Paraesthesia (tingling, itching or pricking sensation)
- Irritability in children 5 years of age and younger
- Crying in children 5 years of age and younger
- Sleepiness in children 5 years of age and younger
- Loss of appetite in children 5 years of age and younger

Rare:

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

*There were no cases of facial swelling/Bell's Palsy, myocarditis/pericarditis and erythema multiforme following Moderna XBB immunization during the study period; however, these were reported post-market following Moderna (Original).

Refer to the product monograph for more detailed information.

Vaccine Composition

- Andusomeran (mRNA) encoding of the SARS-CoV-2 Spike glycoprotein (Omicron subvariant XBB.1.5)
- **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.**

Pregnancy

- **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 XBB.1.5 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. 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.

Breastfeeding

- 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

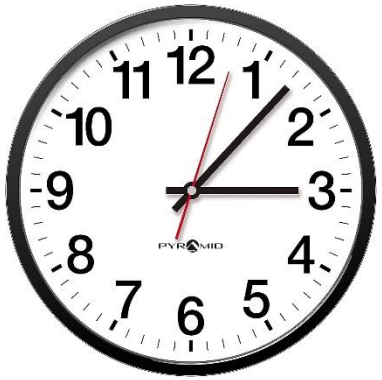
- **Known hypersensitivity to any component of the vaccine**.
- Two non-medicinal ingredients in the vaccine that have been associated with allergic reactions in other products:
  1. Polyethylene glycol **(PEG).** The potential allergen may be found in bowel preparation products for colonoscopy, laxatives, 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

- The safety and effectiveness of Spikevax XBB.1.5 for individuals 6 months of age and older is inferred from several studies of a primary series and booster dose of Spikevax Bivalent (Original/Omicron BA.1) in individuals 6 months to 5 years of age, a booster dose study of Spikevax Bivalent (Original/Omicron BA.1) in individuals 18 years of age and older, a booster dose study of Spikevax XBB.1.5 in individuals 18 years of age and older, as well as data from studies which evaluated the primary series and booster vaccination with Spikevax (Original).
- There are no known serious warnings or precautions associated with this product.
- Very rare cases of myocarditis and/or pericarditis following immunization with Moderna Spikevax vaccines have been reported during post-authorization use.
- 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.

Anaphylaxis

- **All clients are encouraged to wait for 15 minutes after immunization**
- For clients with any known anaphylactic allergies, extend this recommended wait period to **30 minutes**.
- Refer to the FNIHB Anaphylaxis Module on OneHealth.



Myocarditis/Pericarditis

- Very rare cases of myocarditis and/or pericarditis following immunization with Moderna Spikevax 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.

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.

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.
  - 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 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.

Vaccine Storage and Handling Principles

Every immunizer must:

- Understand cold chain excursions and the implications of them
- Identify the key staff members at the clinic responsible for vaccine management
- Understand the specific vaccine storage and handling recommendations for this product
- Understand how to monitor and interpret min/max thermometer readings
- Understand the actions required when a cold chain excursion.

If you have questions about vaccine storage and handling, cold chain breaks, see AB Onehealth (**FNIHB AB Region: Vaccine Management Standards** (February 2023) and/or reach out to a member of the **FNIHB CDC Team**.

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.

AHS: Vaccine Storage Summary

Moderna mRNA Vaccine	Storage temperatures and time limits
Primary storage: Freezer	-25°C to -15°C until expiration date
Storage: Thawed, Unpunctured	+2°C to +8°C for 30 days **OR** +8°C to +25°C for 24 hours
Usage Limit: Thawed, Punctured	+2°C to +25°C for 24 hours

DO NOT REFREEZE OR STORE ON DRY ICE OR BELOW -50°C
DO NOT SHAKE
PROTECT FROM LIGHT

mRNA Vaccine Management

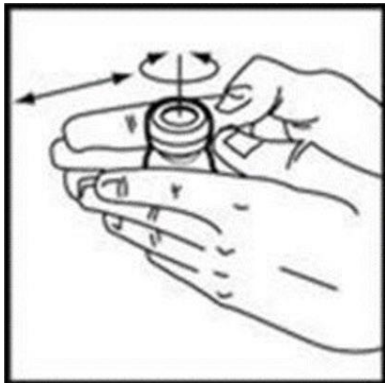
- All multi-dose vials to be thawed in the fridge must be marked with the **date and time** of removal from freezer.
  - Moderna COVID-19 vaccine must be used within 30 days of removal from freezer and stored in fridge at +2°C to +8°C
- All multi-dose vials must be marked with the **date and time** when thawed and stored at room temperature.
  - Moderna COVID-19 vaccine must be used within 24 hours if stored at room temperature
- All multi-dose vials must be marked with the **date and time** when **punctured**.
  - Moderna COVID-19 vaccine must be used within 24 hours if first dose is withdrawn
  - **A maximum of 20 doses can be withdrawn from a vial of any combination of doses; once 20 doses have been withdrawn the vial must be discarded**
- Communicate use of near expiry vials to other staff members, so the vaccine can be used before it expire; this becomes more important at the end of a clinic.
- Vaccine should be withdrawn from the vial by the immunizer administering the vaccine.

mRNA COVID-19 Vaccine Transport

- **Moderna vaccine:** time in transit in the thawed state should be considered part of the **30 days allowed for storage at +2°C to +8°C**
- Do not refreeze thawed product
- Do not transport vaccine at room temperature
- Do not transport vials that have been punctured
- Record transportation locations, dates and times, including the duration of time in transit

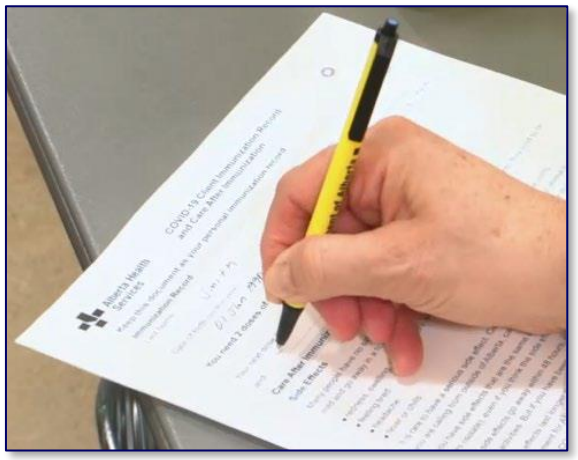
Preparation/Reconstitution

- 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.
- Must not be reconstituted, mixed with other medicinal products, or diluted.
- No dilution is required.
- Swirl the vial gently after thawing and between each withdrawal.
- Do not shake vial.



COVID-19 Vaccine Documentation

- Information required to be recorded on all clients includes:
  - Client demographic information
    - full name, personal health number, date of birth, gender, address including postal code
- Reason code for immunization
- Dose number
- Vaccine name & lot number
- Dosage administered
- Site of injection
- Route of administration
- Date of immunization
- Immunizer's first initial and last name, designation & signature



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Pharmacy/Facility Name _____

COVID-19 Client Immunization Record and Care After Immunization

Keep this document as your personal immunization record

Immunization Record		
Last Name	First Name	Middle Initial
Date of Birth *(dd-Mon-yyyy)*	Date of COVID-19 Immunization *(dd-Mon-yyyy)*	
☐ **Your next dose is due** _____ ☐ **You are not due for another dose at this time.** Visit alberta.ca/covid19-vaccine for up-to-date information about additional doses.	Dose ☐ 1 ☐ 2 (if needed) ☐ 3 (if needed) **Vaccine (Manufacturer)** ☐ SpikeVax XBB.1.5 (Moderna) **Lot Number** _____	

Care After Immunization

Common Side Effects

Many people have no side effects from COVID-19 vaccines. If you do have side effects, they tend to be mild and go away in a few days. Common side effects may include:

- redness, swelling, a hard spot, or feeling sore where you had the needle
- feeling tired, unwell, or have a headache
- a fever or chills
- body aches, sore joints
- feeling stiff
- feeling sick to your stomach (nausea), vomiting (throwing up)
- swollen lymph nodes
- swelling or feeling sore in your armpit or groin
- feeling dizzy
- a reduced sense of touch or a feeling of numbness
- a rash or hives

Children age 5 years and younger may also get upset easily, be sleepy, cry, or may not want to eat.

Call Health Link at 811 to report any serious or unusual side effects. It is rare to have a serious side effect.

Rare events after getting an mRNA vaccine

There have been very rare reports of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining around the heart) in the first 7 days after getting an mRNA COVID-19 vaccine. These rare events can cause shortness of breath, chest pain or pressure, or a very fast or abnormal heart rate. Get medical help **right away** if you have any of these symptoms.

For more information about the COVID-19 vaccines, read the COVID-19 vaccine information on **ahs.ca/immunize** or talk to your healthcare provider.

See reverse for more information,

Alberta Health Services

COVID-19 Immunization Record

Site/Clinic Location _____

Last Name	First Name	Initial	Gender

Provincial Health Care Number/ULI	Age	Date of Birth *(dd-Mon-yyyy)*

Alberta Address	Phone *(Home)*	Phone *(Cell)*

City	Province	Postal Code	Consent to receive appointment reminders or Public Health Notifications
	Alberta		☐ Yes ☐ No

Out of Province Address *(if applicable)*	Province	Status
		☐ New to Alberta ☐ Visitor

☐ Informed Consent | **Date** *(dd-Mon-yyyy)* | **Time** *(hh:mm)*

Vaccine Given ☐ No - go to **Not Administered** Section ▶
☐ Yes - go to **Administered** Section ▼

(✓)	**Vaccine Administered** *(provide reason code)*	
☐	22	Long-term Care/DSL Resident
☐	50	Routine Recommended Immunization
☐	66	Other Risk

(✓)	**Vaccine NOT Administered** *(provide reason code)*	
☐	NGADVREACT	Previous Adverse Reaction
☐	NGALLERGY	Allergic to Vaccine Ingredient/Component
☐	NGDEFERRED	Deferred
☐	NGIMMUNCOM	Immunocompromised
☐	NGNOCONSNT	No Consent or Unable to Contact
☐	NGNTELIGIB	Not Eligible/Recommended
☐	NGPREGNANT	Pregnancy
☐	NGREFUSE	Refused Vaccine Consent
☐	NGTEMPILL	Temporary Illness

Comment

Vaccine Administration Details

Manufacturer

☐ COVMODmRNAXBB *(Spikevax XBB.1.5)*
☐ 0.25 mL OR
☐ 0.50 mL IM
(Manufacturer: Moderna)
Lot # _____

Site **Arm** ☐ Left ☐ Right
Leg ☐ Left ☐ Right

Immunizer *(First Name, Last Name, Designation)*	Meditech ID	Signature

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Adverse Reaction Reporting

- Use Alberta Health form: “Report of Adverse Reaction following Immunization”
  - only available on FNIHB Onehealth Website
  - speak to FNIHB CDC Team before completing
  - send completed form to FNIHB CDC Team
  - expect written response from FNIHB CDC Team

- Severe reactions are reportable within **24 hours**. All other reactions within one week.

INFECTION PREVENTION AND CONTROL

Infection Prevention and Control

- Hand hygiene is critical
  - Must be done between each client
    - ✓*Waterless hand gel*
  - Hand creams to maintain skin integrity
- Gloves are ***not*** recommended during immunizations
- "Respiratory Etiquette" protocol.
  - coughing/sneezing into tissue or upper sleeve
  - providing masks PRN

Infection Prevention and Control

- Vaccine Administration
  - Ensure a clean workspace
    - Clean surface at start and end of day
    - Establish clean work area (blue pad, professional towel, etc.)
      - Avoid placing papers, pens in this area

- Sharps management
  - Use safety syringes and needles
  - Sharps disposal at point of contact

Ordering

- The COVID-19 mRNA Moderna Spikevax XBB.1.5 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

7 Rights of Immunization

- ✓ Right product (vaccine)
- ✓ Right client
- ✓ Right dose
- ✓ Right time (date/time, interval between doses, usage expiry of vial)
- ✓ Right route, needle length, site/land marking and technique
- ✓ Right reason (meets eligibility criteria)
- ✓ Right documentation (including reason code)

Reminder: Bivalent COVID-19 Vaccines

- On October 2, 2023 all COVID Bivalent product (including Comirnaty Bivalent, Comirnaty Pediatric Bivalent 5-11 years, Spikevax Bivalent BA 4/5) should be removed from cold chain and disposed onsite in a safe and secure manner using your routine procedures.

- Please remove the wasted bivalent vaccines from your AVI inventory using the category code “Recall” and reason code “Recall”. This reason code will help Alberta Health track what vaccine was removed due to the bivalent program ending vs. what vaccine was wasted due to vaccine expiry.

Alberta Health Services

Commitment to Comfort

Needle Fears

- Up to 25% of adults have needle fears
- Up to 10% of those are significant enough to avoid immunizations
  - This translates to **350,000** Albertans

Solution: The AHS Commitment to Comfort (CTC)

- There is strong evidence that these principles improve immunization experience, health outcomes, satisfaction, and repeat attendance to healthcare encounters

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Commitment to Comfort – 5 Core Principles

Make a Comfort Plan

- Establish client preference and offer choice

Use Positive Language

- *Always say:* "you did well", and leave them with a positive memory "by doing this today, you are saving lives"
- *Avoid:* pain descriptors; focus on what the client can do – to make the immunization feel better (see shift attention)

Use Comfort Positions

- When safe, sit client in an upright comfortable position
- Brief muscle tense and release or lie down if client feels faint

Shift Attention

- Shift client attention to a more pleasant activity or thought (e.g., smartphone game, music, small talk)

Use Numbing Cream

- Needs to be obtained and applied by the person being immunized prior to their appointment
- Numbing cream will not be offered at the immunization sites
- Client needs to talk with a pharmacist to select and obtain a product that is right for them

First of all,…

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Questions?

VCHELP@FNTN.CA