Pfizer Bivalent (Comirnaty)

COVID-19 Vaccine Orientation

October 24, 2022

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Reminder:
This videoconference/webinar will be recorded.

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Acknowledgement

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

COVID-19

- Consistent with other respiratory viruses, COVID-19 activity may increase in the fall and winter.
- Omicron is the most distinct variant of concern to date, with a number of key mutations distinguishing it from the original SARS-CoV-2 virus. The BA.4 and BA.5 Omicron subvariants are currently the dominant strains of the COVID-19 virus circulating in Canada.
- As Omicron and its sub-variants have become our dominant strains, the vaccine's main benefit over the longer term is to reduce the risk of severe outcomes. Boosters, and especially the bivalent boosters, can address waning protection over time and are also likely to improve protection against infection in the few months following the booster.

mRNA COVID-19 Vaccine Review

- The Pfizer bivalent (Comirnaty) COVID-19 vaccine protects against COVID-19, which is the disease caused by SARS-CoV-2 coronavirus.
- The Pfizer bivalent 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.

mRNA Bivalent COVID-19 Vaccines

- On October 7, 2022, Health Canada authorized the Pfizer-BioNTech Comirnaty BA.4/5 Bivalent (30 mcg) mRNA COVID-19 vaccine for use as a booster dose.
- There are now two authorized bivalent Omicron-containing mRNA COVID-19 vaccines:
  - the Moderna Spikevax BA.1 vaccine (18 years and over)
  - the Pfizer-BioNTech Comirnaty BA.4/5 vaccine (12 years and over).
- Evidence to date shows that both of the bivalent Omicron-containing mRNA vaccines induce a stronger and more robust immune response and are expected to provide improved protection against the Omicron variant and subvariants compared to original mRNA vaccines.
- **As a fall booster, individuals only require one of the bivalent Omicron-containing mRNA COVID-19 vaccines.**
- **Individuals who received the Moderna Spikevax bivalent vaccine, would not be eligible for the Pfizer Comirnaty bivalent vaccine at this time.**

Vaccine Information

- The Pfizer (Comirnaty) bivalent COVID-19 vaccine encodes for the viral spike protein of:
  - SARS-CoV-2 Original strain and,
  - SARS-CoV-2 Omicron BA.4/BA.5 strain.

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Vaccine Information (continued)

- October 7, 2022 – licensed for use in Canada
- October 24, 2022 – Program implementation date in Alberta
- Biological classification: mRNA vaccine
- The manufacturer is Pfizer-BioNTech.
- The vial has a gray coloured cap and a gray label border.
- There are 6 doses per vial.
- Dilution is NOT required.
- Vaccine code: COVPBmRNABA45
- Antigen code: COVID19-20

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Use of Vaccine

Licensed Use

- Booster: 12 years of age and older at least 3 calendar months after completion of the primary series

Indications for Provincially Funded Vaccine

- Booster dose for individuals 12 years of age and older after completion of a primary series and/or a previous booster dose of COVID-19 vaccine (regardless of vaccine type).

Note: The bivalent vaccine cannot be used as part of the primary series. The bivalent vaccine can only be given as one of the booster doses.

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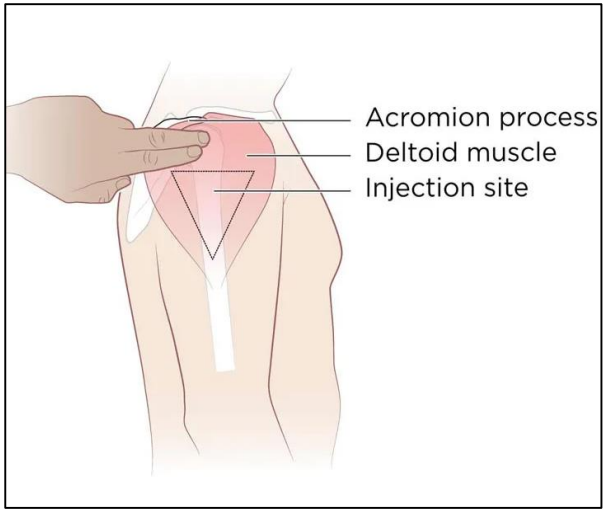
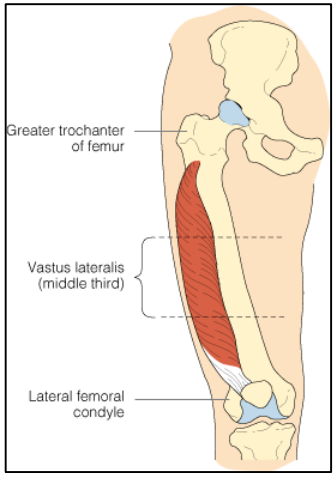
Vaccine Administration

Dose and Route:

Booster Dose:

- 0.3 ml (30 mcg)
- Intramuscular (IM) injection in the deltoid or vastus lateralis muscle.





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Schedule

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Schedule:

- Booster Dose
  - At least **5 calendar months after the last dose of COVID vaccine received, whether that was the final dose in the primary series or a booster dose** (regardless of vaccine type).

Notes:

- A shortened interval of at least 3 calendar months between the last dose and the bivalent booster may be considered (e.g. for individuals at higher risk for severe outcomes).
- A longer interval of at least 5 calendar months leads to a better immune response against COVID-19 that is also expected to last longer, because it allows time for the immune response to mature in breadth and strength. This needs to be considered in situations where individuals request an interval shorter than 5 months. However, individuals should not be turned away if they still choose a shortened interval.

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Schedule (con't)

- Eligible individuals can receive either Moderna BA 1 or Pfizer BA.4/BA.5 bivalent mRNA COVID-19 vaccine as a booster dose. At this time, it is not yet clear whether there will be a difference in protection between the BA.1 and BA.4/5 bivalent vaccines.
- The schedule for a booster dose in individuals with immunocompromising conditions is the same as the schedule for the general population.
- It is recommended that immunocompromised individuals consult with 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 with respect to COVID-19 immunization, including an individual's choice of vaccine for their fall booster.

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

- It is expected that individuals who have been infected with SARS-CoV-2 may optimize their benefit from future vaccine doses by timing them according to the interval since infection, using similar immunological principles to those informing intervals between vaccine doses.
- Emerging evidence indicates that a longer interval between SARS-CoV-2 infection and immunization is associated with improved immune responses to COVID-19 vaccines.
- Previously infected individuals are **recommended to receive a booster dose 5 months after symptom onset or positive test (if asymptomatic) AND 5 months after the last COVID-19 vaccine dose**.
- A *shortened interval of at least 3 calendar months after symptom onset or positive test (if asymptomatic) AND 3 calendar months after the last COVID-19 vaccine dose may be considered* (e.g., for individuals at higher risk for severe outcomes). Although a longer interval leads to a better immune response against COVID-19 that is also expected to last longer, *individuals should not be turned away if they choose a shortened interval*.

Vaccine Contraindications

- Less than 12 years of age.
- 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.
- There are no clinical data currently available for the use of Pfizer bivalent (Original & Omicron BA.4/5) vaccine. However, indirect data (clinical and post-market safety data from Pfizer-BioNTech Comirnaty BA.1 Bivalent and Comirnaty monovalent mRNA vaccine, respectively) suggest that Pfizer-BioNTech Comirnaty BA.4/5 Bivalent (30 mcg) will likely be well tolerated with a similar safety profile to Comirnaty monovalent (30 mcg) and Comirnaty BA.1 Bivalent (30 mcg), when used as a booster dose.

Myocarditis/Pericarditis

- There were no vaccine-related cases of myocarditis or pericarditis in the Pfizer bivalent BA.1 vaccine clinical trial. However, given the number of participants enrolled in the bivalent clinical trial it is unlikely that rare adverse events would be detected.
- Very rare cases of myocarditis and/or pericarditis following immunization with monovalent 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 a monovalent 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.**

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Myocarditis/Pericarditis (continued)

- 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.
- 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.

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Myocarditis/Pericarditis (continued)

- 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.

Pregnancy

- **A COVID-19 vaccine booster can be offered to eligible individuals at any stage of pregnancy.**
- The safety and efficacy of this bivalent COVID-19 mRNA vaccine in pregnant women have not yet been established in the clinical trials. However, data available so far on monovalent mRNA vaccines administered in pregnancy did not detect safety signals from post-marketing surveillance. The Bivalent COVID-19 mRNA vaccine can be offered to pregnant individuals as they are more at risk for severe illness from COVID-19 compared with non-pregnant individuals.
  - It is recommended that individuals consult with their primary health care provider or obstetrician for any vaccine related questions or concerns.
  - 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.
  - However, consultation with a primary health care provider or obstetrician is not required to receive COVID-19 vaccine.

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Additional resource: SOGC Statement on COVID-19 Vaccination in Pregnancy

Lactation

- It is unknown whether this vaccine is excreted in human milk as breastfeeding individuals were excluded from the initial trials. A risk to the newborns/infants cannot be excluded
- However, based on how this vaccine works, **the bivalent COVID-19 mRNA vaccine is not expected to be a risk to lactating individuals or their breastfed newborns/infants.**
- **COVID-19 vaccine can be offered to individuals in the eligible group who are breastfeeding.**
  - It is recommended that individuals consult with 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.

Additional resource:
SOGC Statement on COVID-19 Vaccination in Pregnancy

Other considerations

- Individuals presenting for immunization do not need to be tested for previous COVID-19 infection.
- It is not recommended that serology testing be completed to determine if an immune response to the COVID-19 vaccine has been mounted in individuals.
  - It is still unknown what antibody level correlates with protection against COVID-19, and serology testing in many labs may also not detect antibodies developed as a response to vaccine.
  - Serology testing should not be used as evidence to inform whether vaccine doses have been effective.

Possible Reactions

Refer to product monograph for more detailed information.

Common:

- Pain, redness, and swelling at the injection site
- Fever, chills
- Fatigue
- Headache, myalgia, arthralgia
- Pain in extremity*
- Nausea*, vomiting, diarrhea
- Lymphadenopathy*

Uncommon:

- Malaise*
- Asthenia*
- Decreased appetite*
- Hyperhidrosis*
- Lethargy*
- Night sweats*

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*No reported cases following Pfizer-BioNTech Bivalent during the study period, however these were reported following Pfizer-BioNTech (original).

Rare:

- Anaphylaxis
- Allergic reaction
- Facial swelling/Bell's Palsy*
- Myocarditis/pericarditis*
- Erythema multiforme*
- Hypoaesthesia* (decreased sense of touch or sensation, numbness) or paraesthesia* (tingling, itching or prickling sensation)
- Skin rash*
- As with any immunization, unexpected or unusual side effects can occur*

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Vaccine Composition

Each 0.3 ml dose contains:

- Tozinameran encodes for the viral spike protein of SARS-CoV-2 Original strain.
- Famtozinameran encodes for the viral spike(s) protein of SARS-CoV-2 Omicron BA.4/BA.5 strain.

Non-medicinal ingredients:

- ALC-0315 & ALC-0159 lipid nanoparticles to help the mRNA enter the cell
- Other lipids to provide structural integrity of the nanoparticles (1,2-distearoyl-sn-glycero-3-phosphocholine, cholesterol, tromethamine, tromethamine hydrochloride)
- Sodium chloride (salt) to help maintain the vaccine pH
- Sucrose to protect the nanoparticles when frozen
- Water for injection

- Does not contain adjuvants or preservatives
- Does not contain human blood/blood products
- Does not contain animal-derived materials
- Does not contain latex

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Administration with other products

- No participants in the bivalent clinical trial were concurrently administered other vaccines. Data with regard to the safety and immunogenicity of other authorized COVID-19 vaccines (including original monovalent mRNA vaccines) when given concurrently with other vaccines, are currently limited. However, no specific safety concerns have been identified to date.
- **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 12 years of age and older.**

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Administration with other products (continued)

- 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.2
- However, re-testing (at least 28 days after a dose of COVID-19 vaccine) of individuals with negative results for whom there is high suspicion of TB infection may be prudent in order to avoid missing cases due to potentially false-negative results.

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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

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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: Anti-SARS-CoV-2 monoclonal antibodies or convalescent plasma should not be administered concomitantly with COVID-19 vaccines (i.e., administer on different days).

- 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

Appearance

- Thawed, prior to mixing
  – may contain white to off-white opaque particles

- Thawed and mixed (by inverting vaccine vial gently 10 times)
  – white to off-white with no visible particles.

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Storage

- At the vaccine depot, it is stored in the frozen state.
- Vaccine can be thawed in two ways:
  - From the freezer to room temperature (between +15°C to +25°C); thawing takes approximately 30 minutes from frozen state.
  - From the freezer to a vaccine fridge +2°C to +8°C; thawing can take up to 6 hours.
- Do not refreeze.

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Storage (continued)

- Thawed vials that <u>have not been punctured</u> can be stored:
  - in the refrigerator at +2°C to +8°C for up to 10 weeks, or
  - at room temperature (up to +25°C) for no more than 12 hours.
- After first puncture, the vaccine can be stored at +2° C to +25°C for up to 12 hours.
- During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.
- Thawed vials can be handled in room light conditions.

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Transportation

- If transportation must occur in the thawing/thawed state:
  - Vials can be transported a maximum of three separate occasions in a thawing/thawed state; e.g. vaccine depot to public health office(1), public health office to outreach site(2), and outreach site to public health office(3).
  - The total transportation time for the maximum allowance of three separate shipments should be no longer than 10 hours.
  - The transported vaccine must be labelled “transported thawing/thawed” and the total time in transportation must be tracked.
  - This time can be extended to 12 hours in extenuating circumstances e.g. vehicle breakdown, poor road conditions. This would not be routine practice.
- The time in transit in the thawing/thawed state at +2°C to +8°C must be considered as part of the 10 weeks allowed for storage at refrigerator temperatures.
- The thawing/thawed product should be appropriately packed in a validated container to prevent contact with ice packs.

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Transportation (continued)

- In addition for ultra-frozen and thawing/thawed vaccine:
  - Label the container as “Fragile: Handle with Care, Do Not Drop” and “Temperature Sensitive”.
  - Keep the vaccine vials upright.
  - As much care as possible should be taken to minimize movement during onward transportation both within the container and the vehicle.
  - The temperature must be maintained and recorded during transport.
  - Record the transportation locations, dates and times, including the duration of time in transit.
  - Do not transport the vaccine at room temperature.
  - **Do not transport vials that have been punctured.**

Preparation

- The Pfizer bivalent COVID-19 vaccine multiple dose vial contains a frozen suspension that does not contain preservative and must be thawed prior to administration.
- **No reconstitution is required**
- The product should be thawed as indicated in the *Storage* section
- Swirl vial gently after thawing and between each withdrawal. **Do not shake.**

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Ordering

- The Pfizer (Comirnaty) COVID-19 mRNA bivalent vaccine should be available for ordering through the AVI (Alberta Vaccine Inventory) system.
  - Contact your vaccine depot if the vaccine has not been added to your COVID-19 order set.
  - Found in the order set that you order other COVID-19 vaccines
  - Vaccine: COVID-19 bivalent, BNT162b2 - mRNA
  - Vaccine Name: **Comirnaty® <u>Bivalent</u> 6 dose/vial**
- Reminders:
  - Vials can only be stored in a vaccine fridge under cold chain for 10 weeks. Please take this into consideration when ordering.
  - The bivalent vaccine can only be given to individuals who have already had a primary series, which will affect the number of eligible individuals.

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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

COVID-19 Vaccines

There are many different COVID-19 vaccines, different ages, different doses – need to be diligent to avoid errors.

Vaccine	Age	Colour Cap
Moderna (Spikevax)	6 months – 5 years	Blue
Moderna (Spikevax)	6 years – 11 years 12 years and older	Red
Moderna (Spikevax) Bivalent	18 years and older (following a primary series)	Royal blue cap and green label
Pfizer (Comirnaty)	5 – 11 years	Orange
Pfizer (Comirnaty)	12 years and older	Purple
Pfizer (Comirnaty) Bivalent	**12 years and older** (following a primary series)	**Gray cap and gray label border**

Additional Information – Novavax & Janssen

In planning for the roll-out of the COVID-19 mRNA bivalent vaccine booster doses, several questions came forward regarding plans for additional booster doses of Novavax and Janssen vaccine for individuals who do not want to receive a mRNA vaccine.

- **Novavax:** Albertans can continue to receive a second booster dose with Novavax, however a third booster dose of Novavax is not allowed at this time.
- **Janssen:** Only a single booster dose is licensed at this time (and there is no permissive off-label statement from NACI). An additional booster dose of Janssen vaccine will not be offered this fall.

- **Novavax and Janssen vaccines are not being administered in First Nations health centres. Individuals should contact Alberta Health Services or a pharmacy for Novavax or Janssen vaccine.**

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Questions?

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