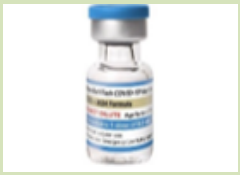
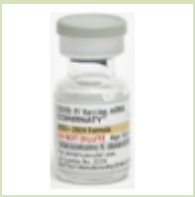
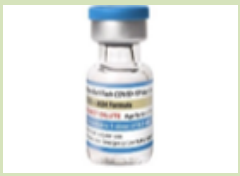
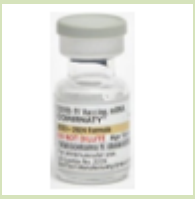
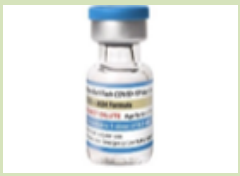
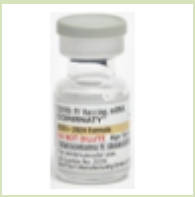
COVID-19 Vaccine – mRNA Pfizer-BioNTech Comirnaty XBB.1.5 – Ultra Frozen Vaccine Biological Page

Section 7:	**Biological Product Information**		**Standard #: 07.225**
Created by:	Provincial Immunization Program Standards and Quality		
Approved by:	Provincial Immunization Program Standards and Quality		
Approval Date:	October 12, 2023	**Revised:**	April 15, 2024

	 **5-11 years** **Blue Cap with Blue Label Border**	 **12 years and older** **Grey Cap with Grey Label Border**
Manufacturer	Pfizer-BioNTech	
Biological Classification	(mRNA) Omicron XBB.1.5 vaccine	
Indications for Provincially Funded Vaccine	• Individuals 5 years of age and older (see scheduling section for specifics)	
Preferred Use		
Dose	0.3 mL (10 mcg)	0.3 mL (30mcg)
Route	IM in the vastus lateralis or deltoid muscle	
Schedule for healthy immunocompetent individuals *(See below Schedule for individuals with certain immunocompromising conditions)*	**<u>Individuals 5 years of age and older:</u>** • 1 dose, at least three months from previous non-XBB.1.5 COVID-19 vaccine dose, regardless of the number of doses received in the past.	
Additional XBB.1.5 COVID-19 vaccine dose	• Starting April 15, 2024, the following individuals who are at increased risk of severe illness from COVID-19 may receive an additional dose of XBB.1.5 COVID-19 vaccine: ○ Individuals 65 years of age and older ○ Adults 18 years of age and older who reside in senior's congregate care living settings. ○ Individuals 5 years of age and older who have certain moderate to severe immunocompromising conditions. ○ First Nations, Métis, and Inuit individuals who are 5 years of age and older, including First Nations on and off reserve. • One dose, at least 6 months from previous XBB.1.5 COVID-19 dose. However, a shorter interval of 3 months may be used in seniors' congregate care settings.	

	 **5-11 years** **Blue Cap with Blue Label Border**	 **12 years and older** **Grey Cap with Grey Label Border**
Schedule for individuals with certain moderate to severe immunocompromising conditions	**<u>Individuals 5 years of age and older:</u>** <u>Previously unimmunized:</u> • Dose 1: day 0 • Dose 2: at least 8 weeks after dose 1; however, a minimum interval of 4 weeks may be considered. <u>Unimmunized post-HSCT and/or CAR T-cell therapy recipients</u> • Dose 1: day 0 • Dose 2: 28 days after dose 1 • Dose 3: 8 weeks after dose 2; however, a minimum interval of 4 weeks may be considered. <u>Previously received 1 or 2 doses of non-XBB.1.5 COVID-19 vaccine:</u> If an individual has received one or two non-XBB.1.5 COVID-19 vaccine doses, the previous dose(s) should be counted, and the series should not be restarted • Dose 1: day 0 • Dose 2: 28 days after dose 1 • Dose 3: 8 weeks after dose 2; however a minimum interval of 4 weeks may be considered. <u>Previously received 3 or more doses of non-XBB.1.5 COVID-19 vaccine:</u> • 1 dose, at least 3 months from previous dose. 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, there is no longer a product preference between Moderna Spikevax and Pfizer BioNTech Comirnaty with the use of XBB.1.5- containing COVID-19 vaccines. ○ Compared to the original monovalent primary series, the risk of myocarditis and/or pericarditis is now expected to be lower due to the use of a 1-dose schedule in most individuals and potentially due to a lower dosage of the available Moderna Spikevax vaccine (50 mcg in the XBB.1.5 formulation compared to 100 mcg in the original monovalent formulation). ○ 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. • It is recommended that individuals with certain immunocompromising conditions be immunized with a mRNA COVID-19 vaccine series. This is to provide stronger protection for those who may have a suboptimal immune response to vaccines.	

	 **5-11 years** **Blue Cap with Blue Label Border**	 **12 years and older** **Grey Cap with Grey Label Border**
	• Specific immunocompromising conditions that make an individual eligible for a 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 and individuals receiving Chimeric Antigen Receptor (CAR) T-Cell therapy. See: ▪ Standard for Immunization of Transplant Candidates and Recipients ▪ Child HSCT ▪ Adult HSCT ○ 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 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). Note: • Documentation of immunocompromising conditions is not required. Individuals who identify themselves as meeting at least one of the criteria above should be offered a COVID-19 vaccine 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.	

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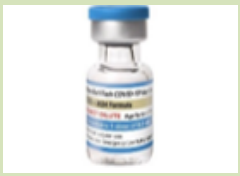
<tr><td></td><td> 
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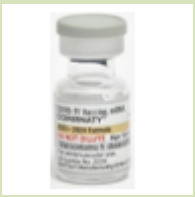
Blue Cap with Blue Label Border</td><td> 
12 years and older
Grey Cap with Grey Label Border</td></tr>
<tr><td>Additional XBB.1.5 COVID-19 vaccine dose</td><td colspan="2">• Starting April 15, 2024, moderately to severely immunocompromised individuals who are at an increased risk of severe illness from COVID-19 may receive an additional dose of XBB.1.5 COVID-19 vaccine:
○ One dose, at least 6 months from previous XBB.1.5 COVID-19 vaccine dose. However, a shorter interval of 3 months may be used in senior congregate care settings.</td></tr>
<tr><td>Interval between previous COVID-19 infection and COVID-19 immunization</td><td colspan="2">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 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 (with the exception of those with MIS-C who should wait at least 90 days).</td></tr>
<tr><td></td><td>Infection prior to initiation or completion of a COVID-19 immunization series.</td><td>Individuals without certain immunocompromising conditions AND no history of multisystem inflammatory syndrome in children (MIS-C).</td><td>8 weeks after a positive test.</td></tr>
<tr><td></td><td></td><td>Individuals with certain immunocompromising conditions (as listed above) AND no history of MIS-C.</td><td>4 to 8 weeks after a positive test.</td></tr>
<tr><td></td><td></td><td>History of MIS-C (regardless of immunocompromised status).</td><td>Receive the vaccine when clinical recovery has been achieved or at least 90 days since the onset of MIS-C, whichever is longer.</td></tr>
<tr><td></td><td>Infection after COVID-19 vaccine series.</td><td>All individuals.</td><td>3 months after a positive test.</td></tr>
<tr><td>Contraindications/ Precautions</td><td colspan="2">Contraindications:
• Known severe hypersensitivity to any component of the vaccine.</td></tr>
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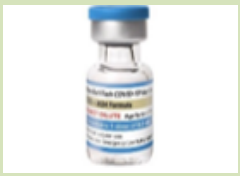
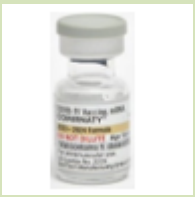
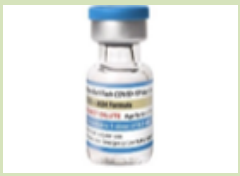
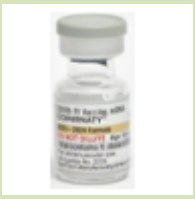
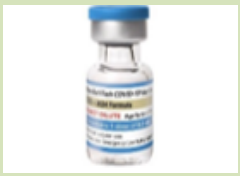
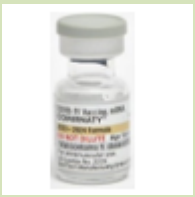
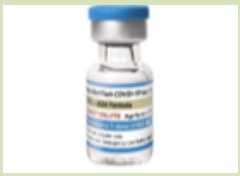
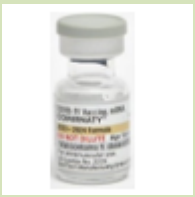
	 **5-11 years** **Blue Cap with Blue Label Border**	 **12 years and older** **Grey Cap with Grey Label Border**

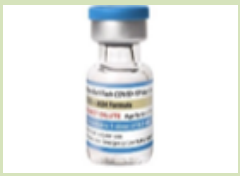
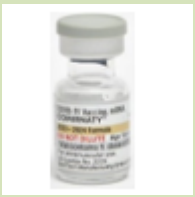
	• Two non-medicinal ingredients in the vaccine that have been associated with allergic reactions in other products:
	  ○ Polyethylene glycol (PEG). The potential allergen may be found in bowel preparation products for colonoscopy, laxatives, cough syrup, cosmetics, contact lens care solutions, skin products and some food and drinks.
	  ○ Tromethamine (trometamol or Tris) – component found in contrast media, oral and parenteral medications.
	• Anaphylaxis to 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.
	
	Precautions:
	• The safety and effectiveness of Pfizer-BioNTech Omicron XBB.1.5 for individuals 6 months of age and older are inferred from studies which evaluated the primary series and booster vaccination with Pfizer-BioNTech and supported by studies which evaluated a booster dose of Pfizer-BioNTech Original & Omicron BA.4/BA.5 in individuals 6 months of age and older (in Alberta, Pfizer XBB.1.5 vaccine is only being used for individuals 5 years of age and older).
	• There are no known serious warnings or precautions associated with this product.
	• 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.	

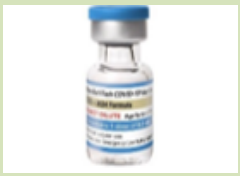
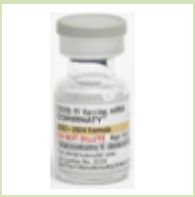
Myocarditis/Pericarditis	• Very rare cases of myocarditis and/or pericarditis following immunization with Pfizer-BioNTech vaccines have been reported during post-authorization use. • Anyone receiving an mRNA COVID-19 vaccine should be informed of the risk of myocarditis and pericarditis and advised to 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	

	 **5-11 years** **Blue Cap with Blue Label Border**	 **12 years and older** **Grey Cap with Grey Label Border**
	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 an 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 at the injection site • Fatigue • Headache • Myalgia • Arthralgia • Chills • Fever • Diarrhea • Swelling/Induration at injection site • Erythema at injection site • Nausea/vomiting **Uncommon:** • Lymphadenopathy • Malaise • Asthenia • Decreased appetite • Hyperhidrosis • Lethargy • Night sweats • Hypoaesthesia (decreased sense of touch or sensation) • Paraesthesia (tingling, itching or pricking sensation) • Dizziness **Rare:** • Allergic reaction • Anaphylaxis • Erythema multiforme	

	 **5-11 years** **Blue Cap with Blue Label Border**	 **12 years and older** **Grey Cap with Grey Label Border**
	• Myocarditis/Pericarditis • Facial paralysis/Bell's palsy Refer to the product monograph for more detailed information.	
Pregnancy	• COVID-19 vaccine 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 Pfizer-BioNTech XBB.1.5 in pregnant women has 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. Additional resources: Society of Obstetricians and Gynecologists of Canada Statement on COVID-19 Immunization in Pregnancy	
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. • COVID-19 vaccine 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, consultations with a primary health care provider or medical specialist is not required to received COVID-19 vaccine.	
Composition	• Raxtozinameran (mRNA) encodes for the viral spike (S) protein of SARS-CoV-2 Omicron XBB.1.5 strain Non-medicinal ingredients: • ALC-0315 = ((4-hydroxybutyl) azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) • ALC-0159 = 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide • cholesterol • DSPC = 1,2-distearoyl-sn-glycero-3-phosphocholine • sucrose	

	 **5-11 years** **Blue Cap with Blue Label Border**	 **12 years and older** **Grey Cap with Grey Label Border**
	• tromethamine • tromethamine hydrochloride • water for injection Does not contain any preservatives	
Blood/Blood Products	Does not contain blood/blood products.	
Bovine/Porcine Products	Does not contain bovine/porcine products.	
Latex	Does not contain 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), tuberculin skin tests or IGRA (QFT) tests to individuals 6 months of age and older. (In Alberta, Pfizer XBB.1.5 vaccine is only being used for individuals 5 years 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. • 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.	

	 **5-11 years** **Blue Cap with Blue Label Border**	 **12 years and older** **Grey Cap with Grey Label Border**
	• 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	• Thawed suspension may contain white to off-white amorphous particles.	
Storage	• Store in ultra low temperature freezer between -90˚C to -60˚C for up to 18 months from the date of manufacture. • Protect from light until thawed. • Do not refreeze after thawing. • Thawed, unpunctured: o Thawed, unpunctured vials can be stored at +2˚C to +8˚C for up to 10 weeks. o Thawed, unpunctured vials can be stored at +8˚C to +25˚C for up to 12 hours. • Thawed, punctured vials: o Thawed, punctured vials (first dose is withdrawn) can be stored at +2°C to +25°C for 12 hours. o Discard after 12 hours.	
Packaging	• 6 doses per vial (Low dead-volume syringes and/or needles can be used to extract 6 doses from a single vial. If standard syringes and needles are used, there may not be sufficient volume to extract a 6th dose from a single vial) • 10 vials per carton	
Preparation/ Reconstitution	Multidose vials are supplied as a frozen dispersion, does not contain preservative. **Thaw vaccine before use:** • Vaccine can be thawed in two ways: o From the freezer to room temperature (between +15˚C to +25˚C), thaw for 30 minutes from frozen state. o From the freezer to a vaccine fridge (+2˚C to +8˚C), thaw for 6 hours from the frozen state. • Must not be reconstituted, mixed with other medicinal product, or diluted. • No dilution is required. • Before use, mix the thawed vaccine by inverting the vial gently 10 times. • Do not shake vial.	
Vaccine Code	COVPBmRNAXBB	
Antigen Code	COVID-19	
Licensed for	Single dose for individuals 6 months of age and older. In Alberta, Pfizer XBB.1.5 vaccine is only being used for individuals 5 years of age and older.	

	 **5-11 years** **Blue Cap with Blue Label Border**	 **12 years and older** **Grey Cap with Grey Label Border**
	Off-license use: • An interval of less than 6 months from previous dose for individuals 5 to 11 years of age who previously completed a non-XBB.1.5 series. • 2nd and 3rd doses in a series for individuals who are moderately to severely immunocompromised.	
Off-license use	• An interval of less than 6 months from previous dose for individuals 5 to 11 years of age who previously completed a non-XBB.1.5 series. • Second or third doses in a series for individuals who are moderately to severely immunocompromised. • Three-dose series for unimmunized post-hematopoietic stem cell transplant (HSCT) and/or chimeric antigen receptor (CAR) T-cell therapy recipients. • Additional XBB.1.5 COVID-19 vaccine dose for eligible individuals.	

Program Notes:

- September 28, 2023 – Licensed for use in Canada.
- October 16, 2023 – Implemented in Alberta.
- December 4, 2023 – Updated schedule for unimmunized individuals 5 years of age and older who are moderately to severely immunocompromised as per NACI recommendations. Removal of preferential statement recommending Pfizer-BioNTech for individuals 12 to 29 years of age, as per NACI recommendations.
- January 29, 2024 – Updated to include CAR T-cell therapy.
- April 15, 2024 – Includes indications for an additional COVID-19 XBB.1.5 vaccine dose for eligible individuals. Three-dose series for unimmunized post-hematopoietic stem cell transplant (HSCT) and/or chimeric antigen receptor (CAR) T-cell therapy recipients.

Related Resources:

- Alberta Health Services Website (2024). COVID-19 mRNA Vaccine Information
- COVID-19 mRNA Vaccine Information Sheet (105240)

References:

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3. Centers for Disease Control and Prevention. (updated 2022 October 20) Information about COVID-19 Vaccines for People who are Pregnant or Breastfeeding. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/pregnancy.html
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5. Comirnaty® Omicron XBB.1.5 COVID-19 mRNA vaccine, Monovalent (Omicron XBB.1.5). Suspension for Intramuscular Injection: *Product Monograph*
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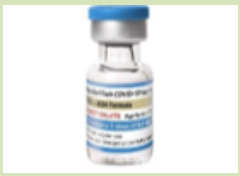
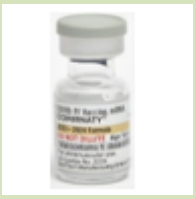
	 **5-11 years** **Blue Cap with Blue Label Border**	 **12 years and older** **Grey Cap with Grey Label Border**

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10. National Advisory Committee on Immunization. (2023 October 27). Updated guidance on the use of COVID-19 vaccines in individuals who have not previously been vaccinated against COVID-19. https://www.canada.ca/content/dam/phac-aspc/documents/services/publications/vaccines-immunization/national-advisory-committee-immunization-updated-guidance-covid-19-vaccines-individuals-not-previously-vaccinated/naci-statement-2023-10-27.pdf
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