COVID-19 Vaccine – Moderna Spikevax mRNA Vaccine and Pfizer-BioNTech Comirnaty mRNA Vaccine

Alberta Health Services
Communicable Disease Control

BIOLOGICAL PAGE

Section 7	Biological Product Information	**Standard # 07.228**	
Created and approved by	Provincial Immunization Program Standards and Quality		
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	Moderna Spikevax Vaccine	Pfizer-BioNTech Comirnaty Vaccine
Manufacturer	Moderna Biopharma Canada Corp.	BioNtech Manufacturing GmbH
Classification	mRNA vaccine	
COVID-19 vaccine strain	LP.8.1	
Indications for use	Individuals 6 months of age and older	Individuals 12 years of age and older

Fall/Winter 2025 Eligibility for Provincially Funded COVID-19 vaccine	• COVID-19 vaccines will be available to individuals through a phased approach to ensure that individuals who are at an increased risk of severe outcomes from COVID-19 infection can access this vaccine first.
	• The following individuals are at an increased risk of severe illness from COVID-19 infection or at an increased risk of exposure and transmission to others, and are eligible for COVID-19 vaccine, free of charge:
	  ○ **Phase 1 (October 1):**
	  ▪ Eligible healthcare workers
	  ▪ Albertans who reside in continuing care homes, senior supportive living accommodations
	  ▪ Home care clients who are homebound
	  ▪ Individuals 6 months of age and older who have certain moderate to severe immunocompromising conditions or underlying medical conditions, individuals experiencing houselessness, and individuals 65 years of age and older receiving the Alberta Seniors Benefit
	  ○ **Phase 2 (October 20):** All other individuals 6 months of age and older; an administrative fee will apply
	Eligible healthcare workers include the following:
	• Individuals actively registered with one of our colleges.
	• Union members (for example, UNA, HSAA, AUNP, AUPE, CUPE) as well as individuals who work in patient-facing settings such as:
	  ○ Hospital staff (including students in health disciplines, contract workers and volunteers)
	  ○ Staff in community health settings (for example, clinical labs, home care and shelters)
	  ○ Medical first responders
	  ○ Staff in continuing care and supportive living
	  ○ Disability support workers and staff working in recovery settings
	  ○ Health care aides on the provincial registry
	  ○ Students training in facilities such as hospitals, clinics, pharmacies, continuing care homes and supportive living accommodations	

	Moderna Spikevax Vaccine	Pfizer-BioNTech Comirnaty Vaccine
Dose	**Moderna Spikevax vaccine** **6 months to 11 years of age:** • 0.25mL (25 mcg) **12 years of age and older:** • 0.5mL (50 mcg)	**Pfizer-BioNTech Comirnaty Vaccine** **12 years of age and older:** • 0.3mL (30 mcg)
Recommendations for pediatric Moderna Spikevax COVID-19 vaccine doses	**To minimize vaccine wastage, immunization sites are encouraged to follow the appointment booking guidelines below:** • Rural Immunization Sites: Schedule a minimum of 4 pediatric appointments • Urban Immunization Sites: Schedule a minimum of 6 pediatric appointments **If there are remaining doses of the COVID-19 vaccine after pediatric appointments:** • These doses may be offered to individuals 12 years of age and older	**Not applicable**
Route	Intramuscular injection	
Schedule for healthy immunocompetent individuals (See below for the schedule for individuals with certain immunocompromising conditions)	**Moderna Spikevax vaccine** **Individuals 6 months to 4 years of age:** <u>Previously unimmunized</u> • Dose 1: day 0 • Dose 2: at least 8 weeks after dose 1 <u>Previously immunized with one dose of COVID-19 vaccine, regardless of product type</u> • One dose, at least 8 weeks from the previous dose <u>Previously received two or more COVID-19 vaccine doses, regardless of product type</u> • One dose, at least 3 months from the previous dose **Note:** • Individuals 6 months to 4 years of age should complete a two-dose series of COVID-19 vaccine regardless of the product that was administered for the first dose. The series should not be restarted. **<u>Individuals 5 years of age and older:</u>** • One dose, at least 3 months from previous COVID-19 vaccine dose, regardless of the number of doses received in the past.	**Pfizer-BioNtech Comirnaty vaccine** **Individuals 12 years of age and older:** • One dose, at least 3 months from previous COVID-19 vaccine dose, regardless of the number of doses received in the past**.**

	Moderna Spikevax Vaccine	Pfizer-BioNTech Comirnaty Vaccine

Schedule for individuals with certain moderate to severe immunocompromising conditions	**Individuals 6 months of age and older:**
	Unimmunized/previously received fewer than 3 doses of non-LP.8.1 COVID-19 vaccine:
	• Immunocompromised individuals should follow the schedule below and receive the appropriate number of COVID-19 vaccine doses to complete a three-dose COVID-19 vaccine series. Regardless of whether they have received one or two non-LP.8.1 COVID-19 vaccine doses, count the previous dose(s) and do not restart the series.
	  ○ Dose 1: day 0
	  ○ Dose 2: at least 28 days after dose 1
	  ○ Dose 3: 8 weeks after dose 2
	  ▪ A minimum interval of 4 weeks may be considered.
	Previously received 3 or more doses of COVID-19 vaccine:
	• 1 dose, at least 3 months from previous non-LP.8.1 COVID-19 vaccine dose, regardless of the number of doses received in the past.
	Note:
	• Specific immunocompromising conditions that make an individual eligible for provincially funded COVID-19 vaccine include:
	  ○ Solid organ transplant recipients:
	  ▪ Immunization for Children Expecting Solid Organ Transplant Before 18 Months of Age
	  ▪ Immunization for Children Expecting Solid Organ Transplant After 18 Months of Age
	  ▪ Immunization for Adult Solid Organ Transplant (SOT) Candidates and Recipients
	  ○ 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
	  ▪ Immunization for Child HSCT Transplant Recipients
	  ▪ Immunization for Adult HSCT Transplant Recipients
	  ○ Individuals with malignant hematologic disorders and non-hematologic malignant solid tumors while receiving active treatment which includes chemotherapy, targeted therapies, and immunotherapy (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 greater than or equal to 2 mg/kg/day or 20 mg/day if weight greater than 10 kg, for greater than or equal to 14 days)
	  ▪ Alkylating agents
	  ▪ Anti-B-cell therapies (including anti-CD19, anti-CD20, anti-CD22 and anti-CD52 monoclonal antibodies such as rituximab, ocrelizumab, and ofatumumab)
	  ▪ Antimetabolites such as methotrexate, azathioprine, mycophenolate
	  ▪ Tumor-necrosis factor (TNF) inhibitors such as adalimumab, certolizumab, etanercept, golimumab, infliximab.
	  ○ Individuals with HIV without viral suppression or those with acquired immunodeficiency syndrome (AIDS).
	  ○ Individuals with moderate to severe primary immunodeficiency (such as DiGeorge syndrome, Wiskott-Aldrich syndrome).	

	Moderna Spikevax Vaccine	Pfizer-BioNTech Comirnaty Vaccine

	• Documentation of immunocompromising conditions is not required.
	  ○ Offer a COVID-19 vaccine series to individuals who identify themselves as meeting at least one of the criteria above should be offered COVID-19 vaccine.
	• Consult physician on the timing of immunization (initiation and interval) based on the individual's treatment and unique circumstances.
	  ○ Immunize individuals who are immunocompromised at a time when the individual is most likely to mount an immune response.	

Underlying medical conditions that would allow individuals to access provincially funded LP.8.1 COVID-19 vaccine	Individuals with the following underlying medical conditions will be eligible for COVID-19 vaccine that is provincially funded: • Cancer (currently receiving treatment) • Cerebrovascular disease • Chronic kidney disease and not on peritoneal dialysis or hemodialysis • Chronic liver diseases • Chronic lung diseases • Cystic fibrosis • Diabetes mellitus • Disabilities (for example, down syndrome, learning, intellectual, or developmental disabilities; ADHD; cerebral palsy; congenital disabilities; spinal cord injuries) • Heart conditions (for example, cardiomyopathies, coronary artery disease, heart failure) • HIV infection • Mental health disorders (limited to: mood disorders, including depression, schizophrenia spectrum disorders) • Obesity • Pregnancy • Tuberculosis • Primary immunodeficiency diseases that are not mentioned above • Use of corticosteroids or other immunosuppressive medications that are not mentioned above.	
Interval between previous COVID-19 infection and COVID-19 immunization	• Individuals who have had a recent COVID-19 infection may receive COVID-19 vaccine after acute symptoms of COVID-19 have resolved and they are no longer infectious, unless there is a history of multisystem inflammatory syndrome in children or adults (MIS-C or MIS-A). • Individuals with a history of multisystem inflammatory syndrome in children or adults (MIS-C or MIS-A), regardless of immunocompromised status, should receive the vaccine when clinical recovery has been achieved or at least 90 days since the onset of MIS-C or MIS-A, whichever is longer.	

Contraindications/ Precautions	**Contraindications:**
	• Known severe hypersensitivity to any component of the vaccine.
	• Two non-medicinal ingredients in the vaccine that have been associated with allergic reactions in other product:
	  ○ 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.	

	Moderna Spikevax Vaccine	Pfizer-BioNTech Comirnaty Vaccine
	Precautions: • The safety and effectiveness of Moderna Spikevax and Pfizer-BioNTech is inferred from studies and based on safety data from clinical trials which evaluated primary and booster vaccination and post marketing safety data; safety data accrued are relevant to the subsequent variant updated vaccines because these vaccines are manufactured using the same process. • There are no known serious warnings or precautions associated with this product at the time of authorization. • 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 COVID-19 vaccines have been reported during post-authorization use.
	  ○ 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.
	  ○ 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.
	• Inform individuals receiving an mRNA COVID-19 vaccine 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.
	• 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 they consult with their clinician. However, consultation with a clinician is not required to receive COVID-19 vaccines.
	• In most circumstances, defer further doses of mRNA COVID-19 vaccines for individual who experienced myocarditis and/or 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.
	  ○ 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
	  ○ Informed consent should discuss the low 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, swelling/induration, erythema at the injection site • Axillary swelling/tenderness	

	Moderna Spikevax Vaccine	Pfizer-BioNTech Comirnaty Vaccine
	• Fatigue, • Headache, chills, fever • Myalgia, arthralgia • Diarrhea, nausea, vomiting, loss of appetite • Irritability, crying • Hypoaesthesia (decreased sense of touch or sensation) • Paraesthesia (tingling, itching or pricking sensation) **Uncommon:** • Lymphadenopathy • Asthenia • Hyperhidrosis, night sweats **Rare:** • Allergic reaction • Anaphylaxis • Erythema multiforme • Myocarditis/Pericarditis • Facial paralysis/Bell's palsy Unexpected or unusual side effects can occur. Refer to the product monograph for more detailed information.	
Pregnancy	May use during pregnancy. • Offer vaccine to pregnant individuals regardless of trimester of pregnancy due to the increased risk that infection poses in pregnancy. • The safety and efficacy of LP.8.1 COVID-19 vaccine in pregnant women has not yet been established. • An mRNA vaccine is preferred due to reassuring published data on the safety of these vaccines in pregnancy. • 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. • 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	May use for individuals who are lactating and feeding their milk to infants and children. • 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 individuals who have received mRNA COVID-19 vaccines have antibodies in their breastmilk, which could help protect their babies. More data is needed to determine the level of protection these antibodies might provide to the baby.	

	Moderna Spikevax Vaccine	Pfizer-BioNTech Comirnaty Vaccine
	• COVID-19 vaccine is indicated 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. • Consultations with a primary health care provider or medical specialist is not required to received COVID-19 vaccine.	
Composition	**Moderna Spikevax Vaccine** • Each 0.25 ml dose of Spikevax contains 25 micrograms of mRNA encoding SARS-CoV-2 spike protein. The mRNA encoding spike protein is derived from the omicron variant LP.8.1. • Each 0.5 ml dose of Spikevax contains 50 micrograms of mRNA encoding SARS-CoV-2 spike protein. The mRNA encoding spike protein is derived from the omicron variant LP.8.1. • Non-medicinal ingredients: ○ Acetic acid ○ Cholesterol ○ SM-102 (Heptadecan-9-yl 8-((2hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino) octanoate) ○ PEG2000-DMG (1,2-dimyristoyl-racglycero-3-methoxypolyethylene glycol2000) ○ Sodium acetate trihydrate ○ DSPC (1,2-distearoyl-sn-glycero-3-phosphocholine) ○ Sucrose ○ Trometamol ○ tromethamine hydrochloride ○ water for injection. ○ Does not contain any preservatives.	**Pfizer-BioNtech Comirnaty Vaccine** • Each 0.3 ml dose of Comirnaty contains 30 mcg of mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2. The mRNA encoding spike protein is derived from Omicron variant LP.8.1. • Non-medicinal ingredients: ○ ALC-0315 = ((4-hydroxybutyl) azanediyl)bis (hexane-6,1-diyl)bis(2hexyldecanoate) ○ ALC-0159 = 2-[(polyethylene glycol)2000]-N,N-ditetradecylacetamide ○ cholesterol ○ DSPC = 1,2-distearoyl-sn-glycero-3phosphocholine ○ sodium chloride ○ sucrose ○ 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. • TST and COVID-19 vaccines: ○ 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.	

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<tr><th></th><th>Moderna Spikevax Vaccine</th><th>Pfizer-BioNTech Comirnaty Vaccine</th></tr>
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However, re-testing (at least 28 days after a dose of COVID-19 vaccine) of individuals with negative TST or IGRA results for whom there is high suspicion of latent tuberculosis may be prudent in order to avoid missing cases due to potentially false-negative results. Consult with TB services.

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.

Note:

Consult the primary health care provider or medical specialist as 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 should be consulted on ca case-by-case basis.
Give mRNA COVID-19 vaccines 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.

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<tr><td>Preparation</td><td>
Moderna Spikevax Vaccine
<u>Multi-dose vials:</u>

Multi-dose vials are supplied as a frozen dispersion and do not contain preservatives.
Must not be reconstituted, mixed with other medicinal products or diluted.
Swirl the vial gently after thawing and between each withdrawal.
Do not shake vial.
Thaw vaccine before use:
From the freezer to room temperature (between +15˚C to +25˚C): Thaw for 45 minutes from frozen state.
From the freezer to a vaccine fridge (+2˚C to +8˚C): Thaw for 2 hours from the frozen state.

<u>Pre-filled syringe:</u>

Individual syringe
Thaw time between +2° to +8°C is 1 hour and 40 minutes.
Thaw time at room temperature between +15° to +25°C is 40 minutes.
Carton of 10 syringes
Thaw time between +2° to +8°C is 2 hours and 40 minutes.
Thaw time at room temperature between +15° to +25°C is 1 hours and 20 minutes.
Do not shake syringe.

</td><td>
Pfizer-BioNtech Comirnaty Vaccine
<u>Pre-filled syringe:</u>

Prior to use, the pre-filled syringes can be stored for up to 12 hours at temperatures between +8˚C to +25˚C and can be handled in room light conditions.
If the pre-filled syringe has been frozen, discard.
Do not shake
Remove the tip cap slowly turning the cap counterclockwise while holding the luer lock.
Attach a needle appropriate for intramuscular injection and administer the entire volume to deliver a 0.3 mL dose.

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<tr><td>Appearance</td><td>The liquid is white to off-white dispersion. It may contain white or translucent product-related particulates.</td><td>The liquid is a clear to slightly opalescent suspension and may contain white to off-white opaque amorphous particles.</td></tr>
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	Moderna Spikevax Vaccine	Pfizer-BioNTech Comirnaty Vaccine

Storage	**Moderna Spikevax Vaccine**
	Multi-dose vials
	• Store frozen in freezer between -50˚C to -15˚C.
	• Protect from light until thawed.
	• Do not refreeze after thawing.
	• Thawed, unpunctured vials:
	  ○ Can be stored between +2˚C to +8˚C for up to 50 days prior to first use.
	  ○ Can be stored between +8˚C to +25˚C for up to 12 hours. Discard after 12 hours.
	• Thawed, punctured vials:
	  ○ Can be stored at +2°C to +8°C for 24 hours. Discard after 24 hours.
	  ○ Can be stored at +8°C to +25°C for 12 hours. Discard after 12 hours.
	Pre-filled syringe
	• Store frozen between -50˚C to -15˚C. Store in the original carton to protect from light.
	• Syringes can be stored refrigerated between +2° to +8°C for up to 50 days prior to first use.
	• Pre-filled syringes may be stored between +8°C to +25°C for up to 12 hours after removal from refrigerated conditions. Discard thawed pre-filled syringe if not used within this time.
	• Syringes **should not** be returned to the refrigerator after being thawed at room temperature
	• Do not refreeze once thawed.
	
	General Considerations:
	• Do not use vaccine after the expiration date printed on the vials/syringes and cartons regardless of storage condition.
	• Do not refreeze once thawed.
	• Store in the original carton to protect from light.
	• Thawed vials and pre-filled syringes can be handled in room light conditions.
		Pfizer-BioNtech Comirnaty Vaccine
		Pre-filled syringe
		• Store in a refrigerated suspension and **do not freeze.**
		• Can be stored between +2˚C to +8˚C until the expiration date printed on the carton and syringe label.
		• Pre-filled syringes may be transported between +2˚C to +8˚C.
		• Minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.
		• Pre-filled syringes can be handled in room light conditions.
		• Do not use vaccine after the expiration date printed on the syringes and cartons regardless of storage condition.

Packaging	**Moderna Spikevax Vaccine** **6 months to 11 years** • Multi-dose vial: 10 pediatric doses per vial • Low dead-volume syringes and/or needles can be used to extract 10 doses from a single vial.	**Pfizer-BioNtech Comirnaty Vaccine** **12 years and older** • Pre-filled syringe: 10 doses per package.

	Moderna Spikevax Vaccine	Pfizer-BioNTech Comirnaty Vaccine
	○ If standard syringes and needles are used, there may not be sufficient volume to extract a 10th dose from a single vial. **12 years and older** • Pre-filled syringe: 10 doses per package.	
Vaccine Codes	COVMODmRNALP	COVPBmRNALP
Antigen Code	COVID-19	
Licensed for	Individuals 6 months of age and older, at least 6 months from previous COVID-19 vaccine dose.	Individuals 12 years of age and older, at least 3 to 6 months from previous COVID-19 vaccine dose.
Off-license use	• An interval of less than 6 months from previous COVID-19 vaccine dose. • An interval of less than 4 moths from previous COVID-19 vaccine dose for immunocompromised individuals who previously completed a COVID-19 vaccine series. • Three-dose series for individuals who are moderately to severely immunocompromised.	• Three-dose series for individuals who are moderately to severely immunocompromised.
Notes	• 2024 September 24: Licensed for use in Canada. • 2024 October: Implemented in Alberta. • 2025 March 14: Indications for an additional (biannual) COVID-19 KP.2 vaccine dose for eligible individuals as of April 28, 2025. • 2025 August 19: Pfizer BioNTech LP.8.1 COVID-19 vaccine licensed for use in Canada. • 2025 August 22: Moderna Spikevax LP.8.1 COVID-19 vaccine licensed for use in Canada. • 2025 October 1: Implemented in Alberta.	
Related Resources	• Alberta Health Services Website: COVID-19 mRNA Vaccine Information • COVID-19 mRNA Vaccine Information Sheet (105240)	

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