COVID-19 Vaccine – mRNA Moderna Spikevax KP.2 - Frozen Vaccine 6 months of age and older

Alberta Health Services
Communicable Disease Control

BIOLOGICAL PAGE

Section 7	Biological Product Information	**Standard # 07.226**	
Created and approved by	Provincial Immunization Program Standards and Quality		
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	COVID-19 Vaccine – mRNA Moderna Spikevax KP.2 – Frozen Vaccine		Royal blue cap & coral blue label
Manufacturer	Moderna		
Classification	mRNA vaccine.		
Indications for Provincially Funded Vaccine	Individuals 6 months of age and older (see scheduling section for specifics).		
Dose	**6 months to 11 years of age:** • 0.25 mL (25 mcg) **12 years of age and older:** • 0.5 mL (50mcg)		
Route	IM in the vastus lateralis or deltoid muscle		
Schedule for healthy immunocompetent individuals (See below for the schedule for individuals with certain immunocompromising conditions)	**Individuals 6 months to 4 years of age** **Previously unimmunized:** • Dose 1: day 0 • Dose 2: at least 8 weeks after dose 1. **Previously immunized with 1 dose of a non-KP.2 COVID-19 vaccine series, regardless of product type:** • 1 dose, at least 8 weeks from previous dose. **Previously received 2 or more non-KP.2 COVID-19 vaccine doses, regardless of product type:** • 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 the product that was administered for the first dose. Do not restart the series. **Individuals 5 years of age and older** One dose, at least 3 months from previous non-KP.2 COVID-19 vaccine dose, regardless of the number of doses received in the past.		
Additional KP.2 COVID-19 vaccine dose	**Biannual Dose Implementation Date: April 28, 2025** The following individuals who are at an increased risk of severe illness from COVID-19 may receive an additional (biannual) dose of KP.2 COVID-19 vaccine: • Individuals 65 years of age and older		

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	• Adults 18 years of age and older who reside in continuing care homes and senior supportive living accommodations • Individuals 6 months of age and older who have certain moderate to severe immunocompromising conditions • First Nations, Métis, and Inuit individuals who are 6 months of age and older, no matter where they live ○ One dose, at least 3 months from previous KP.2 COVID-19 dose		

Schedule for individuals with certain moderate to severe immunocompromising conditions	**Individuals 6 months and older**
	Unimmunized/previously received fewer than 3 doses of non-KP.2 COVID-19 vaccine:
	• Immunocompromised individuals should follow the schedule below and receive the appropriate number of doses of Moderna KP.2 COVID-19 vaccine to complete a three-dose COVID-19 vaccine series. Count the previous dose(s) and do not restart the series regardless of whether they have received one or two non-KP.2 COVID-19 vaccine doses.
	  ○ Dose 1: day 0
	  ○ Dose 2: 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 non-KP.2 COVID-19 vaccine:
	• 1 dose, at least 3 months from previous COVID-19 vaccine dose, regardless of the number of doses received in the past.
	Note:
	• Specific immunocompromising conditions that make an individual eligible for a three-dose COVID-19 vaccine series include:
	  ○ Solid organ transplant recipients:
	  ▪ Child SOT Before 18 Months
	  ▪ Child SOT After 18 Months
	  ▪ Adult SOT
	  ○ 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 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 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		

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<tr><th></th><th colspan="3">COVID-19 Vaccine – mRNA Moderna Spikevax KP.2 – Frozen Vaccine</th><th>  </th><th>Royal blue cap & coral blue label</th></tr>
<tr><td></td><td colspan="4">▪ 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 and Wiskott-Aldrich syndrome.
• 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.
• 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.</td></tr>
<tr><td>Additional KP.2 COVID-19 vaccine dose</td><td colspan="4">Biannual Dose Implementation Date: April 28, 2025
• Moderately to severely immunocompromised individuals 6 months of age and older who are at an increased risk of severe illness from COVID-19 may receive an additional dose of KP.2 COVID-19 vaccine:
○ One dose, at least 3 months from previous KP.2 COVID-19 vaccine dose.</td></tr>
<tr><td rowspan="4">Interval between previous COVID-19 infection and COVID-19 immunization</td><td colspan="4">The following guidance is provided on suggested intervals between COVID-19 infection and COVID-19 immunization.
Note:
• 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.
• Consider biological and social risk factors for exposure (such as local epidemiology, circulation of VOCs, living settings) and risk of severe disease when deciding whether to administer vaccine doses following the suggested interval in the table below.
• 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.
○ Exception: Wait at least 90 days before immunizing individuals with multisystem inflammatory syndrome in children (MIS-C) or adults (MIS-A).</td></tr>
<tr><td rowspan="3">Infection prior to initiation or completion of a COVID-19 immunization series.</td><td>Individuals without certain immunocompromising conditions AND no history of MIS-C or MIS-A.</td><td>8 weeks after a positive test.</td></tr>
<tr><td>Individuals with certain immunocompromising conditions (as listed above) AND no history of MIS-C or MIS-A.</td><td>4 to 8 weeks after a positive test.</td></tr>
<tr><td>History of MIS-C or MIS-A (regardless of immunocompromised status).</td><td>Receive the vaccine when clinical recovery has been achieved or at least 90 days</td></tr>
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<tr><td></td><td colspan="2"></td><td colspan="2">since the onset of MIS-C or MIS-A, whichever is longer.</td></tr>
<tr><td></td><td colspan="2">Infection after COVID-19 vaccine series.</td><td>All individuals.</td><td colspan="2">3 months after a positive test.</td></tr>
<tr><td>Contraindications/ Precautions</td><td colspan="5">Contraindications:
• Known severe hypersensitivity to any component of the vaccine.
• 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:
• 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.
• The safety and effectiveness of Spikevax KP.2 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).</td></tr>
<tr><td>Myocarditis/Pericarditis</td><td colspan="5">• Very rare cases of myocarditis and/or pericarditis following immunization with Moderna Spikevax 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.
• 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.
• 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 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, defer further doses of mRNA COVID-19 vaccines for people who experienced myocarditis and/or pericarditis within 6 weeks of receiving a previous dose of an mRNA COVID-19 vaccine.</td></tr>
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	○ 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. ○ If an individual is 12 years of age and older and another dose of vaccine is offered, use Pfizer-BioNTech KP.2 COVID-19 vaccine. This is due to the lower reported rate of myocarditis and/or pericarditis following the Pfizer-BioNTech original (30 mcg) vaccine compared to the Moderna Spikevax original (100 mcg) vaccine among individuals 12 years of age and older.		
Possible Reactions	**Common:** • Pain, erythema, swelling/ induration at the injection site • Fatigue • Myalgia • Headache • Arthralgia • Axillary swelling or tenderness • Chills • Nausea/vomiting • Fever • Hypoaesthesia (decreased sense of touch or sensation) • Paraesthesia (tingling, itching or pricking sensation) • Dizziness • 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 • Otitis media in children 5 years of age and younger. **Rare:** • Allergic reaction • Anaphylaxis • Erythema multiforme • Facial paralysis/Bell's palsy. Refer to the product monograph for more detailed information.		
Pregnancy	May use during pregnancy. • Offer vaccine to pregnant individuals regardless of trimester of pregnancy because of the increased risk that infection poses in pregnancy. • The safety and efficacy of Moderna Spikevax KP.2 in pregnant women have not yet been established. • 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.		

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	• 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 people 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 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 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. • Consultation with a primary health care provider or medical specialist is not required to receive COVID-19 vaccine.		
Composition	• 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 KP.2. (25 mcg for 0.25 mL dose). • **Non-medicinal ingredients:** ○ Acetic acid ○ Cholesterol ○ DSPC (1,2-distearoyl-sn-glycero-3- phosphocholine) ○ SM-102(Heptadecan-9-yl 8-((2-hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino) octanoate) ○ PEG2000-DMG (1,2-dimyristoyl-rac-glycero-3-methoxypolyethyleneglycol-2000) ○ 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	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. ○ **Exception:** Respiratory Syncytial Virus (RSV) vaccine ▪ Limited studies have been conducted on concurrent administration of the RSV vaccine with other vaccines and is not recommended until more evidence is available. ▪ Give RSV vaccine with **two-weeks spacing** before or after influenza and/or COVID-19 vaccines. • 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		

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	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, 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. • 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.		
Appearance	• White to off-white dispersion. • May contain white or translucent product-related particulates.		
Storage	• Store in freezer between -50˚C to -15˚C. • Protect from light. • Do not refreeze after thawing. • Thawed, unpunctured vials: o Can be stored at +2˚C to +8˚C for up to 50 days. o Can be stored at +8˚C to +25˚C for up to 12 hours. • Thawed, punctured vials: o 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. • Do not use vaccine after the expiration date printed on the vials and cartons regardless of storage conditions.		
Packaging	• 2.5 mL vial (5 x 0.5 mL doses or 10 x 0.25 mL doses) • 10 vials per carton		
Preparation	• Multidose vials are supplied as a frozen dispersion and do not contain preservative. • **Thaw vaccine before use**: o From the freezer to a vaccine fridge (+2˚C to +8˚C): Thaw for 6hours from the frozen state. After thawing, let vial stand at room temperature for 15 minutes before administering. o From the freezer to room temperature (between +15˚C to +25˚C): Thaw for 45 minutes from frozen state. • Must not be reconstituted, mixed with other medicinal product, or diluted. • Swirl gently after thawing and before each withdrawal. • Do **not** shake vial.		
Vaccine Code	COVMODmRNAKP		
Antigen Code	COVID-19		

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Licensed for	Individuals 6 months of age and older.		
Off-license use	• An interval of less than 6 months from previous dose for individuals who previously received a COVID-19 vaccine dose series. • Three-dose series for individuals who are moderately to severely immunocompromised.		
Notes	• 2024 September 17: 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.		
Related Resources	• Alberta Health Services Website (2024). COVID-19 mRNA Vaccine Information • COVID-19 mRNA Vaccine Information Sheet (105240)		

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