

Section 7:	Biological Product Information		Standard #: 07.208
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	COVID-19 Vaccine - mRNA Moderna (SpikeVax) Frozen Vaccine Children 6 Years to 11 Years of Age	
Manufacturer	Moderna	
Biological Classification	 mRNA (new technology) – nucleoside-modified messenger RNA (modRNA) encoding the viral spike glycoprotein Formulated in lipid nanoparticles (LNPs) 	
Indications for Provincially Funded Vaccine	Persons 6 years to 11 years of age	
Preferred Use	N/A	
Dose	0.25 mL (50 mcg)	
	 Notes: Vaccine dosage is based on age at presentation, regardless of vaccine/dosage received for first dose. Children who received a first dose of the adult formulation of Pfizer-BioNTech or adult dose (100 mcg) of Moderna COVID-19 vaccine at age 11 years will complete their second dose with the pediatric Pfizer-BioNTech formulation or Moderna dosing for children (50 mcg) if still 11 years of age when presenting for second dose. Children who received pediatric dosing (50 mcg) for their first dose of Moderna COVID-19 vaccine at 11 years of age and are now 12 years of age when presenting for second dose, will receive the adult dose (100 mcg) of Moderna COVID-19 vaccine for their second dose. 	
Route	IM in the deltoid or vastus lateralis muscle	
Schedule See below Schedule for Individuals with Certain Immunocompromising Conditions	 Primary series 2 doses Dose 1: day 0 Dose 2: at least 8 weeks after dose 1 Optimal spacing between dose 1 and dose 2 is at least 8 weeks. Currently, there is no direct evidence to establish an optimal interval between doses in pediatric populations. However, evidence on COVID-19 mRNA vaccines in adolescents and adults shows that extending the interval between the first and second dose by several weeks leads to even higher immune responses and better protection against COVID-19 infection that is also expected to last longer. Emerging Canadian safety surveillance data suggest an extended interval between the first and second dose may reduce the risk of myocarditis/pericarditis following the second dose of an mRNA COVID-19 vaccine. Due to the currently unknown risk of myocarditis and/or pericarditis for Moderna (50 mcg) in children 6 to 11 years of age, and the known lower risk of myocarditis/pericarditis with the Pfizer-BioNTech COVID-19 vaccine (30 mcg) compared to Moderna COVID-19 vaccine (100mcg) in individuals 12 to 29 years of age, Pfizer-BioNTech COVID-19 vaccine is preferentially recommended for children 6 to 11 years of age to start and/or complete their primary series. However, Moderna COVID-19 vaccine could be provided if preferred by the individual. 	

Notes:

- A shortened interval between dose 1 and dose 2 (no less than 21 days) may be considered in certain situations: required for travel, increased risk for infection based on local transmission and the degree of individual risk of exposure.
- Minimum spacing between doses 1 and 2 is 21 days and is required for a dose to be considered valid.
- Currently, no data on a maximum interval between doses is available. In general, regardless of the time between doses, interruption of a vaccine series does not require restarting the series.

Schedule for Individuals with Certain Immunocompromising Conditions

Primary series 3 doses

- Dose 1: day 0
- Dose 2: 28 days after dose 1
- Dose 3: 8 weeks after dose 2
- It is recommended that individuals with certain immunocompromising conditions be immunized with a primary series of three doses of an mRNA COVID-19 vaccine.
- It is recommended that the interval between dose 1 and dose 2 be 28 days and the interval between dose 2 and dose 3 be 8 weeks.
 - The interval between dose 2 and 3 is recommended to be 8 weeks because emerging evidence from the general population indicates that a longer interval will likely result in a better immune response and duration of protection.
 - However, there is heterogeneity among those who are moderately to severely immunocompromised, and risks from COVID-19, as well as the likelihood of a reduced response to vaccines, will vary depending on the immunocompromising condition. Thus, a shortened interval no less than 28 days may be considered for those with increased risk of exposure and greater severity of immunodeficiency, based on their clinician's recommendation.
- Due to the currently unknown risk of myocarditis and/or pericarditis for Moderna (50 mcg) in children 6 to 11 years of age, and the known lower risk of myocarditis/pericarditis with the Pfizer-BioNTech COVID-19 vaccine (30 mcg) compared to Moderna COVID-19 vaccine (100mcg) in individuals 12 to 29 years of age, Pfizer-BioNTech COVID-19 vaccine is preferentially recommended for children 6 to 11 years of age to start and/or complete their primary series.
 - O However, indirect data from adult populations (≥18 years of age) suggest Moderna SpikeVax (100 mcg) may result in higher vaccine effectiveness after a 2-dose primary series compared to Pfizer-BioNTech Comirnaty (30 mcg) and is associated with a higher seroconversion rate among adult immunocompromised patients. Given this potential benefit, administration of the Moderna SpikeVax (50 mcg) vaccine as a 3-dose primary series may be considered for some immunocompromised individuals. It is recommended that individuals consult with their clinician. However, consultation with a clinician is not required to receive Moderna SpikeVax (50 mcg) COVID-19 vaccine.
- There are currently no data on the safety, immunogenicity, or efficacy of an additional dose of a COVID-19 vaccine in children who are immunocompromised; studies have shown that a third dose of an mRNA vaccine leads to increased immune response in some adults who are immunocompromised. An additional dose provides another opportunity for those who are immunocompromised to develop a better immune response and in turn better protection against COVID-19.
- Specific immunocompromising conditions that make an individual eligible:
 - Solid organ transplant (SOT) recipients pre-transplant and post-transplant.
 - Hematopoietic stem cell transplant (HSCT) recipients pre-transplant and posttransplant while in an immunosuppressed state (post-HSCT individuals are generally considered to be immunocompetent after 3 years as long as they are not on immunosuppressive drugs).

- Individuals with malignant hematologic disorders and non-hematologic malignant solid tumors prior to receiving or 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 on anti-B cell therapies including anti-CD19, anti-CD20, anti-CD22 and anti-CD52 monoclonal antibodies (such as rituximab, ocrelizumab, and ofatumumab).
- o Individuals with chronic kidney disease on peritoneal dialysis or hemodialysis.
- o Individual receiving chimeric antigen receptor (CAR)-T-cell therapy.
- o Individuals on:
 - long term high-dose systemic steroid treatment (prednisone equivalent of equal to or greater than 2 mg/kg/day or 20 mg/day if weight greater than 10 kg, for 14 days or greater), or
 - alkylating agents, 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.
- Individuals with advanced untreated HIV infection or acquired immunodeficiency syndrome (AIDS).
- o Individuals with moderate to severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome).

Notes:

- Immunization for immunocompromised individuals should occur at a time when the
 individual is most likely to mount an immune response. Physician consultation is
 recommended regarding the timing of immunization (initiation and interval) based on the
 individual's treatment and unique circumstances.
- Hematopoietic stem cell transplant (HSCT) recipients who received COVID-19 vaccine
 pre-transplant are eligible for three doses of COVID-19 vaccine beginning 6 months posttransplant. Consultation with their HSCT physician is not necessary as long as the initial
 clearance letter has been received to proceed with inactivated vaccines.

Interval Between Previous COVID-19 Infection and COVID19 Immunization

For individuals with a history of confirmed COVID-19 infection the following guidance is provided on suggested intervals between infection and COVID-19 immunization.

Notes:

- Please see <u>CMOH Order 02-2022</u> and <u>Order 04-2022</u> for definition of confirmed COVID-19 infection.
- 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 or not 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 severe disease should also be taken into account. 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).

	COVID-19 Vaccine - mRNA Moderna (SpikeVax) Frozen Vaccine Children 6 Years to 11 Years of Age				
	Infection prior to initiation or completion of a primary COVID-19 immunization series	Individuals without certain immunocompromising conditions AND no history of multisystem inflammatory syndrome in children (MIS-C)	8 weeks after symptom onset or positive test (if asymptomatic)		
		Individuals with certain immunocompromising conditions (as listed above) AND no history of MIS-C	4 to 8 weeks after symptom onset or positive test (if asymptomatic)		
		History of MIS-C (regardless of immunocompromised status)	Receive the vaccine when clinical recovery has been achieved or at least 90 days since the onset of MIS-C, whichever is longer		
Contraindications/	Contraindications:				
Precautions	Persons under 6 years of	_			
	reactions in other pro Polyethylene gly	e been associated with allergic n may be found in bowel cough syrup, cosmetics, contact			
		•	found in contrast media, oral and		
	parenteral medic				
		us dose of COVID-19 mRNA vac			
		VID-19 Immunization for Individuals with Allergies and Other			
	Health Conditions for recommendations.				
	 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 illness.	e postponed in individuals suffer	ing from acute severe febrile		
	 Immunization of children with a previous history of multisystem inflammatory syndrome in children (MIS-C) should be postponed until clinical recovery has been achieved or until it has been 90 days or greater since diagnosis, whichever is longer. 				
	 Refer to Immunocompro information on these po 	omised and Auto-Immune Disord pulations.	lers sections for specific		
Myocarditis	The clinical trials for children 6 to 11 years of age did not identify any cases of myocarditis following immunization; however, rare, or very rare adverse events that occur at the frequency of less than 1 in 1,000 would not be detected with that trial size.				
	 More information will assist in further assessment of the risk of myocarditis/pericarditis among individuals aged 6 to 11 years of age after receiving Moderna vaccine. At this time, the risk of myocarditis/pericarditis after the second dose when using an extended interval of at least 8 weeks among children ages 6 to 11 years of age and the safety of a third dose of COVID-19 vaccine in individuals aged 6 to 11 years of age are unknown. Available information indicates that cases of myocarditis and pericarditis: 				
	 Available information inc 	dicates that cases of myocarditis	and pericarditis:		
		ly after the second dose,	•		

- more frequently following Moderna COVID-19 vaccine than Pfizer-BioNTech COVID-19 vaccine.
- Typically onset of symptoms begins within a week after the receipt of an mRNA COVID-19 vaccine. The majority of cases are mild and individuals tend to recover quickly and investigation into long-term outcomes is ongoing.
- It is unknown if individuals with a history of previous myocarditis and/or pericarditis are at higher risk of vaccine associated myocarditis and/or pericarditis
 - 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.
 - o 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.
- In general, individuals who experienced myocarditis after receiving a first dose of mRNA COVID-19 vaccine are advised to defer receiving a second dose until more data is available as per <u>NACI's recommendation</u>. If they prefer not to wait, they should discuss decisions around the second dose with their clinician.
- 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.

Immunocompromised and Auto-Immune Disorders

- At this time, there is very limited data on the use of Moderna COVID-19 mRNA vaccine 50 mcg formulation in immunocompromised 6-11 year olds and those with auto-immune disorders.
- Individuals who are immunocompromised and those with auto-immune disorders who are receiving immunosuppressive therapy may have a diminished immune response.
- COVID-19 vaccine may be offered to individuals in the eligible group who are immunosuppressed due to disease or treatment and those with an auto-immune disorder if an informed consent is given by the parents/guardians after a discussion on benefits and potential risks.
 - It is recommended that individuals consult with their primary health care provider or medical specialist for any vaccine related questions, especially regarding the timing of immunization based on the individual's treatment.
 - However, consultation with a primary health care provider or medical specialist is not required to receive COVID-19 vaccine.
 - Response for immunizers if individual has not consulted with their primary health care provider: "Vaccine studies are not complete on the use of this vaccine in immunocompromised individuals or those with auto-immune disorders. We recommend you speak to your physician regarding the timing of immunization based on your treatment or if you have questions about the immunization, but it is not required to receive the vaccine."

Exceptions:

- SOT client require consultation with their primary health care provider or medical specialist prior to receiving COVID-19 vaccine.
- HSCT clients do not require consultation as long as the initial clearance letter has been received to proceed with inactivated vaccine.

Other Considerations

- Individuals presenting for immunization do not need to be tested for previous COVID-19 infection.
- Immunization of individuals who may be currently infected with SARS-CoV-2 is not known to have a detrimental effect on the illness.
 - However, individuals with COVID-19-like symptoms should not go to an immunization/venue in order to minimize the risk of COVID-19 transmission. They should isolate, seek testing and get immunized as per guidance in the 'Interval between previous COVID-19 infection and COVID-19 immunization' section.

	COVID-19 Vaccine - mRNA Moderna (SpikeVax) Frozen Vaccine		
	Children 6 Years to 11 Years of Age		
	 Individuals within facilities who are isolated due to COVID-19-like symptoms can be provided COVID-19 vaccine as long as they are well enough to be immunized. It is not recommended that serology testing be completed to determine if an immune response to 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	Common: Pain, erythema/redness, and swelling at the injection site Axillary (or groin) swelling/tenderness Fever, chills Fatigue Headache, myalgia, arthralgia Nausea, vomiting Hypersensitivity (injection site rash or urticarial) Rare: Allergic reactions Anaphylaxis As with any immunization, unexpected or unusual side effects can occur.		
	Refer to product monograph for more detailed information.		
Composition	Each 0.5 mL dose contains:		
	Lipid nanoparticles (these help the mRNA enter the cell): PEG2000-DMG LSM-102, 1,2-dimyristoyl-rac-glycero-3-methoxy-polyethyleneglycol 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]) Cholesterol Lipid SM-102 PH stabilizers (help maintain the PH of the vaccine) acetic acid sodium acetate tromethamine tromethamine hydrochloride Other: sucrose (protects the nanoparticles when frozen) No adjuvants, preservatives, or antibiotics		
Blood/Blood Products	Contains no human blood/blood products		
Bovine/Porcine Products	Contains no animal-derived materials		
Latex	Does not contain latex		
Administration with Other Products	 COVID-19 vaccines should not routinely be administered on the same day with other live or inactivated vaccines to children 6 to 11 years of age due to the need to monitor for adverse events following COVID-19 immunization. In the absence of evidence, it is recommended but not required to wait for a period of at least 14 days before and after the administration of COVID-19 vaccine and the administration of another vaccine, if it does not create a barrier to receipt of vaccines. This is to allow for accurate attribution of adverse events following immunization and inform risk estimates of any adverse event that may be associated with the COVID-19 vaccine. Clients should not be turned away if presenting for administration of more than one vaccine on the same day or if they are within the 14 day period between the COVID-19 vaccine and another vaccine. 		

COVID-19 Vaccine - mRNA Moderna (SpikeVax) Frozen Vaccine Children 6 Years to 11 Years of Age Routine school immunizations can be administered regardless of spacing from COVID-19 vaccine. • Based on evidence including real world experience from the use of COVID-19 vaccine in adolescents and adults, administering the pediatric COVID-19 vaccine on the same day or within 14 days of any other live or inactivated vaccine is not expected to have an impact on the safety or effectiveness of the vaccine. If a COVID-19 vaccine is administered on the same day as another vaccine or within 14 days of another vaccine, neither dose should be repeated. 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. If tuberculin skin testing or an IGRA test is required for baseline screening, it should be administered and read before administration of any COVID-19 vaccine immunization or delayed for at least 28 days after a dose of COVID-19 vaccine. Immunization with COVID-19 vaccines may take place at any time after all steps of tuberculin skin testing (including read) have been completed. If tuberculin skin testing is required for other reasons (e.g., contact tracing, immigrants, query LTBI), testing should not be delayed, as these are theoretical considerations. 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 falsenegative results. COVID-19 vaccines should be delayed for at least 90 days after the receipt of SARS-CoV-2 monoclonal antibodies or convalescent plasma provided for treatment of COVID-19 infection. This applies to people who received these therapies before receiving any COVID-19 vaccine dose and between doses. o Timing of administration and potential interference between COVID-19 vaccine and monoclonal products or convalescent plasma as part of COVID-19 treatment are currently unknown and administering these products close together may result in less effectiveness of the COVID-19 vaccine. A deferral for at least 90 days is based on the estimated half-life of such therapies and evidence suggesting that reinfection is uncommon within the 90 days after initial infection. This is a precautionary measure until additional information becomes available, to avoid potential interference of the antibody therapy with vaccine-induced immune responses. o COVID-19 vaccine doses inadvertently received within 90 days after receipt of passive antibody therapy do not need to be repeated. Timing of administration and potential interference between COVID-19 vaccine and monoclonal products not used for the treatment of COVID-19 infection are currently unknown and the primary 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 Rhlg) or blood product has been administered. There is no recommended minimum interval between these products and COVID-19 vaccine. **Appearance** Frozen and thawed: white to off-white solution

Storage

Can be stored in a freezer between -25°C to -15°C storage.

o From the freezer to room temperature (between +15°C to +25°C), thaw for 1 hour

from frozen state. Let vial stand at room temperature for 15 minutes before

From the freezer to a vaccine fridge +2°C to +8°C; thaw for 2 hours and 30 minutes

Vaccine can be thawed in two ways:

from frozen state.

administering.

	COVID-19 Vaccine - mRNA Moderna (SpikeVax) Frozen Vaccine		
	Children 6 Years to 11 Years of Age		
	 Do not refreeze after thawing. Thawed, unpunctured vials Thawed unpunctured vials can be stored at +2°C to+ 8°C up to 30 days, Thawed unpunctured may be stored at +8°C to +25°C for up to 24 hours. Thawed, punctured vials Thawed punctured vials (first dose is withdrawn), the vial can be stored at +2°C to +25°C for 24 hours. Discard after 24 hours. Vials can be punctured to a maximum of 20 times and any remaining vaccine after 20 punctures is to be discarded. Protect from light. Do not store on DRY ice or below -40°C. 		
Packaging	Canadian Packaging: 10 doses per vial 100 doses per package 12 boxes/carton (1200 doses/carton)		
Preparation/ Reconstitution	The Moderna COVID-19 Vaccine multiple dose vial contains a frozen suspension that does not contain preservative and must be thawed prior to administration. • No reconstitution required • The product should be thawed as indicated in the Storage section • Swirl vial gently after thawing and between each withdrawal. Do not shake. Thawed pre-puncture • Stored at +2°C to +8°C for 30 days • Stored at +8°C to +25°C for 24 hours Thawed post-puncture • 24 hours at +2°C to +25°C • Discard after 24 hours		
Vaccine Code	COVMODmRNA		
Antigen Code	COVID-19-2		
Licensed Use	6 years to 11 years of age		
Off-License Use	Third dose as part of the primary series for individuals 6 to 11 years of age with certain immunocompromising conditions		

Program Notes

- 2022 March 17: Licensed for use in Canada.
- 2022 April 12: Implemented in Alberta.

Related Resources

Alberta Health Services Website (2022). COVID-19 mRNA Vaccine Information Sheet.

References

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