

COVID-19 Vaccine - mRNA Moderna (SpikeVax) - Frozen Vaccine Children 6 Months to 5 Years of Age Biological Page

Section 7:	Biological	Biological Product Information		Standard #: 07.216
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	COVID-19 Vaccine - mRNA Moderna (Moderna) Frozen Vaccine Children 6 Months to 5 Years of Age		
Manufacturer	Moderna Moderna		
Biological Classification	 Nucleoside-modified messenger RNA (modRNA) encoding the viral spike glycoprotein¹ Formulated in lipid nanoparticles (LNPs) 		
Indications for	Children 6 months to 4 years of age		
Provincially Funded Vaccine	Children who are 6 months to under 5 years of age are eligible.		
Vaccine	Use in children who are 5 years of age		
	Children who are starting their primary series at 5 years of age should be offered the Pfizer BioNTech pediatric formulation licensed for children 5 to 11 years of age. There is a limited supply of the Moderna (6m-5yr) vaccine and the National Advisory Committee on Immunization (NACI) recommends that for children beginning their COVID-19 vaccine primary series at 5 years of age, Pfizer-BioNTech pediatric vaccine is preferred to Moderna (6m-5yr) vaccine.		
	Moderna (6m-5yr) vaccine may be offered to 5 year olds who:		
	 Begin their primary series prior to 5 years of age with Moderna (6m-5yr) vaccine and need to complete their primary series after turning five, or 		
	 Are immunocompromised and their specialist recommends, or their parent/guardian requests Moderna (6m-5yr) vaccine instead of Pfizer BioNTech pediatric formulation, or 		
	 If a parent/guardian refuses the Pfizer BioNTech pediatric formulation for their 5 year old and requests Moderna (6m-5yr) vaccine. 		
	Note:		
	 Vaccine dosage is based on age at presentation, regardless of vaccine type/dosage received for first dose. 		
Preferred Use	N/A		
Dose	0.25 mL (25 mcg)		
Route	IM		
Schedule	Primary series 2 doses		
See below Schedule for Individuals with Certain Immunocompromising Conditions	• 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 the 6 months to 5 years of age population. 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.

Notes:

- A shortened interval between dose 1 and dose 2 (no less than 28 days) may be considered in certain situations: required for travel, increased risk of infection based on local transmission and the degree of individual risk of exposure.
- Minimum spacing between dose 1 and 2 is 28 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 dose 3 is recommended to be 8 weeks because emerging evidence from the older general population indicates that a longer interval will likely result in a better immune response and longer 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 for exposure and greater severity of immunodeficiency, based on their clinician's recommendation.
- There are currently no data on the safety, immunogenicity, or efficacy of an additional dose of a COVID-19 vaccine in children 6 months to 5 years of age 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. The 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:
 - o solid organ transplant recipients pre-transplant and post-transplant
 - hematopoietic stem cell transplants recipients pre-transplant and posttransplant while in 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 with chronic kidney disease on peritoneal dialysis or hemodialysis.
- o individuals receiving chimeric antigen receptor CAR T-cell therapy.
- 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
 - 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).

Notes:

- Documentation of immunocompromising conditions is not required. Individuals
 who identify themselves as meeting at least one of the criteria above should be
 offered the 3 dose primary series.
- 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 to restart their COVID-19 vaccine series beginning at least 3 months post-transplant. Consultation with their HSCT physician is not necessary as long as the initial clearance letter has been received to proceed with inactivated vaccines.
- CAR T-cell therapy recipients (who are not HSCT recipients) who received COVID-19 vaccine pre- CAR T-cell therapy are eligible to restart their COVID-19 vaccine series beginning at least 3 months post CAR T-cell therapy. Consultation with their physician is not necessary as long as a clearance letter has been received to proceed with inactivated vaccines.
- For individuals who receive both HSCT and CAR T-cell therapy, see the HSCT guidance:
 - <u>Principles of Immunization in Hematopoietic Stem Cell Transplant Recipients</u>
 <u>and Solid Organ Transplant Recipients</u>
 - o Child HSCT Recipients

Interval between previous COVID-19 infection and COVID-19 immunization

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

Notes:

 These suggested intervals are based on immunological principles and expert opinion, and may change as evidence on COVID-19, variants of concern

COVID-19 Vaccine - mRNA Moderna (Moderna) Frozen Vaccine Children 6 Months to 5 Years of Age (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 considered infectious, or they may follow these suggested intervals (with the exception of those with MIS-C who should wait at least 90 days). Individuals without Infection prior to initiation 8 weeks after symptom or completion of a certain onset or positive test (if primary COVID-19 immunocompromising asymptomatic). immunization series conditions AND no history of multisystem inflammatory syndrome in children (MIS-C), Individuals with certain 4 to 8 weeks after symptom immunocompromising onset or positive test (if conditions (as listed asymptomatic). above) AND no history of MIS-C, History of MIS-C Receive the vaccine when (regardless of clinical recovery has been immunocompromised achieved or at least 90 days since the onset of status), MIS-C, whichever is longer. Contraindications/ Contraindications: **Precautions** 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 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 Moderna (6m-5yr) vaccine. Precautions: Individuals who have had a serious allergic reaction to another vaccine, drug or food should talk to their health care provider before receiving the vaccine. Individuals receiving anticoagulant therapy or those with a bleeding disorder that would contraindicate intramuscular injection should not be given the vaccine unless the potential benefit clearly outweighs the risk of administration. Administration should be postponed in individuals suffering from acute severe febrile illness. Immunization of children with a previous history of 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. Myocarditis The clinical trials for children 6 months to 5 years of age did not identify any cases of myocarditis following immunization with Moderna vaccine; however,

rare, or very rare adverse events that occur at the frequency of less than 6 in 10,000 would not be detected with that trial size.

- At this time, the risk of myocarditis/pericarditis after receiving Moderna (6m-5yrs) vaccine including after the second dose when using an extended interval of at least 8 weeks and after a third dose in individuals aged 6 months to 5 years of age are unknown. More information is needed.
- Canadian and international post-market safety surveillance data for other mRNA COVID-19 vaccines in older populations have reported the rare risk of myocarditis and/or pericarditis with mRNA vaccines, which varies by sex, age, interval between doses, vaccine dose, and vaccine product. Current data suggests the risk of myocarditis and/or pericarditis in children 5 to 11 years of age is lower than that of adolescents or young adults.
- Available information on myocarditis and/or pericarditis following mRNA vaccines (from individuals twelve years of age and older) indicates that cases of myocarditis and pericarditis:
 - o occur more commonly after the second dose;
 - o more often in adolescents and young adults (12 to 29 years of age);
 - o more often in males;
 - more frequently following Moderna COVID-19 vaccines than Pfizer-BioNTech COVID-19 vaccine;
 - typically have onset of symptoms within a week after the receipt of an mRNA COVID-19 vaccine;
 - the majority of cases were mild, individuals recovered quickly and the 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 if they are no longer followed clinically for cardiac issues.
 - If there are questions or concerns about prior history of myocarditis or pericarditis and immunization, it is recommended that the child's clinician be consulted. However, consultation with a clinician is not required to receive COVID-19 vaccines.
- In general, individuals who experienced confirmed myocarditis (with or without pericarditis) within 6 weeks 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 NACI's recommendation. If there is a preference not to wait, decisions around the second dose should be discussed with the child's 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 receive the next dose of vaccine when they are symptom free and at least 90 days have passed since previous immunization.
- 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.

	COVID-19 Vaccine - mRNA Moderna (Moderna) Frozen Vaccine		
	Children 6 Months to 5 Years of Age		
Immunocompromised and Auto-Immune Disorders	At this time, there is no data on the use of Moderna (6m-5yr) vaccine in immunocompromised children aged 6 months to 5 years 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. 		
	Exceptions:		
	 SOT clients 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 vaccines. 		
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. 		
	 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 the COVID-19 vaccine has been mounted in immunocompromised 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 or very common:		
	 Pain, erythema, swelling at the injection site Injection site lymphadenopathy Axillary (or groin) swelling or tenderness Fever, chills Fatigue, sleepiness Headache Myalgia, arthralgia Irritability, crying Loss of appetite Nausea, vomiting Otitis media 		
	Rare:Allergic reactions		
	- Allergic reactions		

	COVID-19 Vaccine - mRNA Moderna (Moderna) Frozen Vaccine
	Children 6 Months to 5 Years of Age
	AnaphylaxisFebrile convulsion
Composition	Lipid nanoparticles (these help the mRNA enter the cell) ¹ :
	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 trihydrate
	trometamol
	trometamol hydrochloride
	Other:
	sucrose (protects the nanoparticles when frozen)
Blood/Blood Products	Contains no human blood/blood products
Bovine/Porcine Products	Contains no bovine/porcine products
Latex	Does not contain latex
Administration with Other Products	SpikeVax (6m-5yr) vaccine should not routinely be administered on the same day with other live or inactivated vaccines to children 6 months to 5 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. If the parents/guardians want to proceed after the importance of having a 14-day spacing has been emphasized, COVID-19 immunization can occur on the same day or within 14 days of administration of another 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.

COVID-19 Vaccine - mRNA Moderna (Moderna) Frozen Vaccine Children 6 Months to 5 Years of Age 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 false-negative results. 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. Timing of administration and potential interference between COVID-19 vaccine and monoclonal products not used for treatment 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 Rhlg) or blood product not specific to COVID-19 treatment has been administered. There is no recommended minimum interval between these products and COVID-19 vaccine. **Appearance** Frozen and thawed - white to off-white **Storage** Can be stored in a freezer between -25°C and -15 °C. Protect from light Vaccine can be thawed in two ways: 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 frozen state. Let the vial stand at room temperature for 15 minutes before administering. Do not refreeze after thawing. Thawed, unpunctured Thawed, unpunctured vials can be stored at +2°C to +8°C up to 30 days, Thawed, unpunctured vials may be stored at +8°C to +25°C for up to 24 hours. Thawed, punctured vials Thawed, punctured vials (first dose is withdrawn) can be stored at +2°C to +25°C for 24 hours Discard after 24 hours.

	COVID-19 Vaccine - mRNA Moderna (Moderna) Frozen Vaccine Children 6 Months to 5 Years of Age	
	 Vials can be punctured a maximum of 10 times and any remaining vaccine after 10 punctures is to be discarded. 	
	Thawed vials and filled syringes can be stored in room light conditions.	
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 is required.	
	The product should be thawed in ways indicated in the "Storage and Handling" 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	COVPBmRNA	
Antigen Code	COVID-19-1	
Licensed for	6 months to 5 years of age	
Off-License Use	Third dose as part of primary series for individuals 6 months to 5 years of age with certain immunocompromising conditions	

Program Notes:

- July 14, 2022 Licensed for use in Canada
- August 2, 2022 Implemented in Alberta

Related Resources:

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

References:

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- National Advisory Committee on Immunization. (2021 December 3). Rapid response: Updated recommendations on the use
 of authorized COVID-19 Vaccines in individuals aged 12 years and older in the context of myocarditis and pericarditis
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- 8. National Advisory Committee on Immunization. (2022 February 4) NACI rapid response: Updated guidance on COVID-19 vaccination timing for individuals previously infected with SARS-CoV-2. https://www.canada.ca/en/public-

- health/services/immunization/national-advisory-committee-on-immunization-naci/rapid-response-guidance-covid-19-vaccination-timing-individuals-previously-infected-sars-cov-2.html.
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