COVID-19 Vaccine - mRNA Moderna - Frozen Vaccine Biological Page

Section 7:	**Biological Product Information**		**Standard #: 07.204**
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	COVID-19 Vaccine - mRNA Moderna Frozen Vaccine
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 18 years of age and older** • This vaccine is being offered in a staged approach, please follow operational guidelines to assess eligibility. • Eligibility will be rolled out in cohorts by year of birth, therefore persons 17 years of age may receive this vaccine if born in an eligible year (those born in 2003 or earlier). **Note:** • mRNA COVID-19 vaccine is preferentially recommended for eligible individuals who are at highest risk of severe illness and death and highest risk of exposure to COVID-19.
Preferred Use	N/A
Dose	**0.5 mL**
Route	IM
Schedule	2 doses • Dose 1 – day 0 • Dose 2 – day 21 to 28* *The interval between dose 1 and dose 2 should be extended up to 4 months (16 weeks/112 days) for all populations with the following exceptions: • Solid organ transplants (SOT) recipients - pre-transplant and post-transplant. • Hematopoietic stem cell transplants (HSCT) recipients - pre-transplant and post-transplant 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 (does not include individuals receiving solely hormonal therapy, radiation therapy or a surgical intervention). • Individuals on anti-CD20 monoclonal antibodies (such as rituximab, ocrelizumab, and ofatumumab). Immunization of these groups should occur at a time when the patients are most likely to mount immune responses. These individuals are eligible to receive their second dose 21 to 28 days after dose 1. Physician consultation is recommended regarding the optimal spacing recommendations based on the client's treatment. *See section below for rationale/evidence*. **Notes:** • Minimum spacing between doses is 21 days • Currently, no data on a maximum interval between doses or on medium or long-term efficacy of COVID-19 vaccines are available. In general, interruption of a vaccine series resulting in a greater than recommended interval between doses does not require restarting the series.

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Rationale/Evidence for Extending the Interval Between Dose 1 and Dose 2	• Data from clinical trials show a high vaccine efficacy after the initial dose of the Moderna vaccine. Estimated efficacy 95.2% (95% CI: 91.2 to 97.4%) against symptomatic COVID-19 disease 14 days after the first dose and before dose two. • Evidence from England, Quebec and BC shows 70 to 80% protection from infection for up to two months with no significant waning. It is important to note that vaccine effectiveness in a general population setting is typically lower than efficacy seen in a controlled setting of a clinical trial. • Disease modelling has suggested that there is increased effectiveness in reducing the number of COVID-19 cases and achieving overall benefit by administering one dose to more people quickly when there is limited vaccine supply and widespread community transmission, compared to the strategy of saving early doses to ensure delivery of second dose according to manufacturers' recommendations. • In studies on vaccines for other infections, a longer time between the first and second dose can make the overall immune response to the vaccine better, while a shorter time between them can lower the overall response. • The rate of waning protection without the administration of the second dose is unknown, but short term sustained protection is consistent with immunological principles and vaccine science where it is not expected to see rapid waning of a highly effective vaccine in adults over a relatively short period of time. Extending the interval between doses was shown to be a good strategy through modelling, even in scenarios considering a six month interval and in theoretical scenarios where waning protection was considered. A second dose continues to be recommended.
Rationale/Evidence for Exceptions to Extended Interval	• Emerging evidence shows suboptimal/poor immune responses after one dose in individuals with cancer or solid organ transplant. Immune response was greatly and rapidly increased by administering the second dose at 21 days. • The exceptions are focused only on those with the most profound immune compromising conditions given the currently available evidence and the fact that increasing population level protection as quickly as possible also protects those with immune compromising conditions.

Contraindications/ Precautions	**Contraindications:**
	• Persons under 17 years of age.
	• 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). This 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.
	• Anaphylactic or other allergic reactions to a previous dose of COVID-19 mRNA 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.
	• Refer to Immunocompromised and Auto-Immune Disorders, Pregnancy and Lactation sections for specific information on these populations.

Immunocompromised and Auto-Immune Disorders	• At this time, there is an absence of evidence on the use of COVID-19 vaccine in immunocompromised individuals and those with auto-immune disorders. These groups were not included in large enough numbers in the initial trials to provide solid information. • 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

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	if a risk assessment with their primary health care provider or medical specialist determines that the benefits outweigh the potential risks. Risks would include that: ○ Immunocompromised persons may have a diminished immune response to the vaccine and ○ There is a theoretical concern that mRNA vaccine may elicit an inflammatory response and possibly exacerbate existing autoimmune diseases. However, current applications of mRNA technology for COVID-19 vaccines have been optimized to reduce this risk. • With the exception of SOT and HSCT clients, the individual may also be immunized without consulting their primary health care provider or medical specialist following their acknowledgment of the risks mentioned above and the absence of evidence on the use of COVID-19 vaccine in these populations. ○ Response for immunizers if individual has not consulted with their primary health care provider: "The vaccine studies have not tested whether this vaccine is safe or effective for you. We recommend that you do not receive the immunization until you have discussed the potential risks and benefits with your doctor. However, it is your choice whether to proceed without consulting your doctor." • SOT and HSCT clients require consultation with primary health care provider or medical specialist prior to immunization, including timing of when vaccine should be given. • Additional resources: ○ COVID-19 Scientific Advisory Group Rapid Evidence Report. ○ Advisory Committee on Immunization Practices (ACIP) interim recommendations for the use of Pfizer-BioNTech and Moderna COVID-19 vaccines
Pregnancy	• The safety and efficacy of Moderna COVID-19 Vaccine in pregnant women have not yet been established in the clinical trials, however preliminary data on mRNA vaccines administered in pregnancy is now available from post marketing surveillance with no safety signals detected. • COVID-19 vaccine can be offered to pregnant individuals in the eligible group as they are more at risk for severe illness from COVID-19 compared with non-pregnant individuals. ○ It is recommended that individuals consult with their primary health care provider or obstetrician for any vaccine related questions or concerns. ○ However, consultation with a primary health care provider or obstetrician is not required to receive COVID-19 vaccine. ○ 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 pregnant women. Early information has not identified any safety issues. If you have questions about the immunization, we recommend you speak to your physician but it is not required to receive the vaccine." • Additional resources: ○ Society of Obstetricians and Gynecologists of Canada Statement on COVID-19 Immunization in Pregnancy. • It would be prudent to delay pregnancy by 28 days or more after the administration of the complete two-dose vaccine series of an mRNA COVID-19 Vaccine.
Lactation	• It is unknown whether Moderna COVID-19 Vaccine is excreted in human milk as breastfeeding individuals were excluded from the initial trials. A risk to the newborns/infants cannot be excluded. • However, based on how these vaccines work, COVID-19 vaccines are not expected to be a risk to lactating individuals or their breastfed newborns/infants. • COVID-19 vaccine can be offered to individuals in the eligible group who are breastfeeding. ○ It is recommended that individuals consult with their primary care provider of medical specialist for any vaccine related questions or concerns. ○ 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

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	breastfeeding women. Early information has not identified any safety issues. If you have questions about the immunization, we recommend you speak to your physician but it is not required to receive the vaccine."
Other Considerations	• Individuals with a history of lab confirmed COVID-19 infection who have no contraindications can be provided COVID-19 vaccine. • 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 and their immunization should be deferred.
Possible Reactions	**Common:** • Pain, redness, and swelling at the injection site • Fever, chills • Fatigue • Headache, myalgia, arthralgia • Nausea, vomiting • Lymphadenopathy **Rare:** • Anaphylaxis • Facial swelling • 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: <u>Lipid nanoparticles (these help the mRNA enter the cell):</u> • PEG2000-DMG LSM-102, 1,2-dimyristoyl-rac-glycero-3-methoxy-polyethyleneglycol • 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]) • Cholesterol • Lipid SM-102 <u>pH stabilizers (help maintain the PH of the vaccine)</u> • acetic acid • sodium acetate • tromethamine • tromethamine hydrochloride <u>Other</u>: • 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
Interchangeability	• Currently, no data exists on the interchangeability of COVID-19 vaccines. • The vaccine series should be completed with the same COVID-19 vaccine product. ○ However, if a different mRNA vaccine is given as a second dose with appropriate spacing, both doses should be considered valid, and the series would be complete. • If the vaccine product used for a previously received dose is not known, or not available, attempts should be made to complete the vaccine series with a similar type of COVID-19 vaccine (e.g., mRNA vaccine). The previous dose may be counted, and the series need not be restarted.

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Administration with Other Products	• In the absence of evidence, COVID-19 vaccines should not be given simultaneously with other live or inactivated vaccines due to the potential for immune interference and the need to be able to monitor for potential symptoms of COVID-19 and COVID-19 vaccine adverse events without potential confounding from adverse events following other vaccines. • If a COVID-19 vaccine is inadvertently administered at the same time as another vaccine, neither dose should be repeated. • In the absence of evidence, it would be prudent to wait for a period of at least 28 days between the administration of a dose of COVID-19 vaccine and the administration of another vaccine (except in the case where another vaccine is required for post-exposure prophylaxis). • In the absence of evidence, it would be prudent to wait for a period of at least 14 days after the administration of another vaccine before administrating a COVID-19 vaccine. • 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. o 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. o Immunization with COVID-19 vaccines may take place at any time after all steps of tuberculin skin testing (including read) have been completed. o 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. • Timing of administration and potential interference between COVID-19 vaccine and monoclonal products are currently unknown and the primary care provider or medical specialist should be consulted on a case-by-case basis. • Timing of administration and potential interference between COVID-19 vaccine and convalescent plasma as part of COVID-19 treatment 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 RhIg) 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. • Vaccine can be thawed in two ways: o From the freezer to room temperature (between +15°C to +25°C), thaw for 1 hour from frozen state. o From the freezer to a vaccine fridge +2°C to +8°C; thaw for 2 hours and 30 minutes from frozen state. Let vial stand at room temperature for 15 minutes before administering. • Do not refreeze after thawing • Thawed, unpunctured vials o Thawed unpunctured vials can be stored at +2°C to+ 8°C up to 30 days, o Thawed unpunctured may be stored at +8°C to +25°C for up to 12 hours. • Thawed, punctured vials o Thawed punctured vials (first dose is withdrawn), the vial can be stored at +2°C to +25°C for 6 hours o Discard after 6 hours. • Protect from light • Do not store on DRY ice or below -40°C

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Packaging	**Vaccine:**
	• 10 doses per vial
	  ○ Box 51 mm long, 126 mm wide, 60 mm high
	  ○ 12 boxes/carton (1200 doses/carton)
	  ○ Carton 267 mm long, 169 mm wide, 135 mm high
	• 100 doses per package

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 12 hours Thawed post-puncture • 6 hours at +2°C to +25°C • Discard after 6 hours
Vaccine Code	COVMODmRNA
Antigen Code	COVID-19-2
Licensed for	Individuals 18 years of age and older

Program Notes:

- 2020 December 23: Licensed for use in Canada
- 2020 December 28: Implemented in Alberta
- 2021 January 13: Interval between dose 1 and dose 2 extended to 42 days except for LTC/DSL residents
- 2021 March 10: Interval between dose 1 and 2 extended up to 4 months for all populations
- 2021 April 21: Exceptions to extended interval to include SOT, HSCT, and individuals with malignant hematologic disorders and non-hematologic malignant solid tumors receiving specific types of active treatment, and individuals on anti-CD20 monoclonal antibodies.
- 2021 May 4: Updated considerations for pregnancy and lactation

Related Resources

- Alberta Health Services Website (2021). COVID-19 Vaccine Information.

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