COVID-19 mRNA Vaccine
SPIKEVAX™                Supplier: Moderna

INDICATIONS:
• Individuals 12 years of age and older.
• See COVID-19 Vaccine Eligibility

The vaccine is not approved for use in those less than 12 years of age.

DOSES AND SCHEDULE:
• Primary series for individuals 12 years of age and older A: 2 doses given as 0.5 mL IM, 8 weeks apart. B, C, D

For individuals who are moderately to severely immunosuppressed (see COVID-19 Vaccine Eligibility), a 3-dose primary series is recommended. E The 3rd dose should be provided at least 28 days after the 2nd dose. For those 12 years of age and older, Moderna COVID-19 vaccine is preferentially recommended for all doses in the primary series. If Moderna is unavailable, Pfizer-BioNTech can be given.

• Booster dose:
  o Residents of long term care (LTC), assisted living and independent living facilities, alternate level of care clients awaiting placement in LTC and individuals 70 years of age and older: 1 dose given as 0.5 mL IM, at least 6 months after completion of the primary series. F
  o All other individuals 12-69 years of age G: 1 dose given as 0.25 mL IM, at least 6 months after completion of the primary series. F

ADMINISTRATION:
• No reconstitution required.

A The minimum age for vaccine receipt is based on age at presentation (i.e., the vaccine may be offered to individuals on or after their 12th birthday). The Pfizer-BioNTech COVID-19 vaccine is preferred for those 12-29 years of age due to the lower risk of myocarditis/pericarditis with this vaccine (with the exception of those 18-29 years of age who are moderately to severely immunosuppressed due to a potentially greater immune response induced by the Moderna vaccine in these populations). However, if the Pfizer-BioNTech vaccine is unavailable, or upon client request, the Moderna COVID-19 vaccine can be used provided informed consent includes the elevated risk of myocarditis/pericarditis associated with this product.

B While the Health Canada authorized schedule for this product is 28 days between dose 1 and 2, the preferred interval in BC is 8 weeks. This interval may be shortened in outbreak communities at the direction of the Medical Health Officer and for individuals who meet approved criteria for an expedited dose 2. If administration of the second dose is delayed beyond 8 weeks, the series does not need to be restarted.

C The minimum interval between doses is 21 days. For optimal response, immunizers should observe recommended intervals as much as possible, however, doses given earlier than recommended may still be considered valid and need not be repeated if minimum intervals are observed.

D NACI recommends that mRNA vaccine (Pfizer-BioNTech or Moderna) can be offered as a second dose to individuals who received a first dose of the AstraZeneca/COVISHIELD vaccine, unless contraindicated.

E For individuals who received a single dose of Janssen vaccine, one additional dose of Moderna COVID-19 vaccine is recommended at least 28 days later.

F The minimum interval between completion of the primary series and the booster dose is 8 weeks. This interval may be applied for a minority of individuals for practical reasons, including pregnant persons, with consideration of the individual benefits and risks, but is not to be used as a routine interval.

G The Pfizer-BioNTech COVID-19 vaccine is preferred for those 12-29 years of age due to the lower risk of myocarditis/pericarditis with this vaccine (with the exception of the booster dose for those 18-29 years of age who are moderately to severely immunosuppressed, see BOOSTER DOSES).
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ADMINISTRATION (continued):
• If there is enough vaccine left in the vial for a complete 0.5 mL dose after 10 or 14 A doses have been removed from the vial, another dose can be drawn and administered. This depends, in part, on the type of syringes and needles used to withdraw doses from the vials; low dead-volume syringes and/or needles should be used if available, as standard syringes and needles may not facilitate the extraction of an additional dose from a single vial.
• Following withdrawal of all available 0.5 mL doses, the residual vaccine from up to three vials may be withdrawn into the same syringe to constitute a full dose provided the vials are from the same manufacturer and the same lot number. See addendum for more information.
• Do not puncture the vial more than 20 times.

Storage and Handling: B
• The vaccine can be stored at:
  o -20°C (-25°C to -15°C) up to the end of its expiry date c, kept in the original packaging and protected from light. Do not store on dry ice.
  o +2°C to +8°C for up to 30 days prior to first use, protected from light.
  o Room temperature (up to +25°C) for up to 24 hours (cumulative).
  o After first vial puncture, the vaccine must be used within 24 hours. o The vaccine can be pre-loaded into a syringe for up to 24 hours from first vial puncture.
  o Ensure that the vial/syringe is clearly labelled with the date and time of first vial entry.
• Product should be thawed/held prior to use, in one of the following ways:
  o From the freezer to room temperature:
    ▪ 10-dose vial requires 1 hour to thaw
    ▪ 14-dose vial requires 1 hour and 30 minutes to thaw
  o From the freezer to the refrigerator:
    ▪ 10-dose vial requires 2 hours and 30 minutes to thaw
    ▪ 14-dose vial requires 3 hours to thaw
    ▪ Allow at least 15 minutes at room temperature prior to administration. D
  o Swirl the vial gently after thawing and between each withdrawal. Do not shake.
• Do not refreeze thawed vials.

BOOSTER DOSES:
A booster dose of a COVID-19 mRNA vaccine is recommended for individuals 12 years of age and older at least 6 months after the primary series has been completed.

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A Moderna vaccine is available in 10-dose and 14-dose vials. The U.S. labelled product yields at least 14 doses and contains a different carton and vial label. Continue to reference the Canadian Product Monograph for all product information for use in Canada. Note: to consistently extract 14 doses, a minimum ratio of 7 low-dead-volume syringes and 7 non-low-dead volume syringes are recommended.
B For more information on storage and handling and temperature monitoring refer to Appendix E: Management of Biologicals and Guidance for Receiving and Handling the Moderna COVID-19 mRNA Vaccine.
C The expiry date is not printed on the US-labelled product. The expiry date for the corresponding lots can be found in the ‘Products affected’ section of the Health Canada alert. On Dec 23, 2021, Health Canada authorized a 2 month shelf life extension, from 7 months to 9 months, for 5 mL vials of Moderna’s COVID-19 mRNA vaccine with printed expiry dates of February 15, 2022 through August 31, 2022, as long as the approved storage conditions have been maintained. Refer to the Health Canada alert for the updated expiry dates.
D The recommendation to allow the vaccine to sit for at least 15 minutes at room temperature prior to administration is intended for patient comfort only, and is not a requirement.
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BOOSTER DOSES (continued):

<table>
<thead>
<tr>
<th>Preferred vaccine for booster dose</th>
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<tbody>
<tr>
<td>12-29 years of age – immunocompetent individuals</td>
<td>Pfizer-BioNTech A</td>
</tr>
<tr>
<td>Individuals 12-17 years of age who are moderately to severely immunosuppressed</td>
<td>Pfizer-BioNTech A</td>
</tr>
<tr>
<td>Individuals 18 years of age and older who are moderately to severely immunosuppressed</td>
<td>Moderna B</td>
</tr>
<tr>
<td>30 years of age and older – immunocompetent individuals</td>
<td>Pfizer-BioNTech or Moderna</td>
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SEROLOGICAL TESTING:
Serological testing is not recommended before or after immunization.

CONTRAINDICATIONS:
1. History of anaphylactic reaction to any component of the vaccine is generally considered a contraindication, however for more details on the administration of COVID-19 vaccines to individuals with allergies to components of the COVID-19 vaccines, please see the PRECAUTIONS section. C

PRODUCT COMPONENTS:
Other components: cholesterol; 1,2-distearoyl-sn-glycerophosphocholine (DSPC); acetic acid; lipid SM-102; sodium acetate; sucrose; tromethamine; tromethamine hydrochloride.

PRECAUTIONS:
- For individuals with a history of anaphylactic reaction to a previous dose of an mRNA COVID-19 vaccine, re-vaccination (i.e., administration of a subsequent dose in the series when indicated) may be offered with the same vaccine or the same mRNA platform if a risk assessment deems that the benefits outweigh the potential risks for the individual and if informed consent is provided. Prior to re-vaccination, consultation with an allergist or another appropriate physician (e.g., Medical Health Officer) is advised. If re-vaccinated, vaccine administration should be done in a controlled setting with expertise and equipment to manage anaphylaxis, with an extended period of observation of at least 30 minutes after re-vaccination. C
- For individuals with suspected hypersensitivity or non-anaphylactic allergy to COVID-19 vaccine components, the vaccine should be administered in a controlled setting with

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A Preferred due to the lower risk of myocarditis/pericarditis with this vaccine. However, if the Pfizer-BioNTech vaccine is unavailable, or upon client request, the Moderna COVID-19 vaccine can be used provided informed consent includes the elevated risk of myocarditis/pericarditis associated with this product.

B Age-based booster dosing recommendations apply to Moderna COVID-19 booster doses for moderately to severely immunosuppressed clients (See DOSES and SCHEDULE). However, a 0.5 mL (100 mcg) dose may be provided upon request for those 18-69 years of age.

C Although such individuals may be offered a viral vector vaccine, re-vaccination with an mRNA vaccine is preferred due to the better effectiveness and immunogenicity of mRNA vaccines and the possible adverse effects specifically associated with viral vector vaccines (e.g., Thrombosis with Thrombocytopenia Syndrome [TTS]).
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PRECAUTIONS (continued):
  - expertise and equipment to manage anaphylaxis, with an extended period of observation post-vaccination of at least 30 minutes.
  - Wait until symptoms of an acute illness are resolved before vaccinating with COVID-19 vaccine to differentiate symptoms of illness from vaccine side effects.
  - Individuals diagnosed with Multisystem Inflammatory Syndrome in Children (MIS-C) or Adults (MIS-A) should delay COVID-19 vaccination until they have recovered from illness and for 90 days after the date of diagnosis of MIS-C or MIS-A.
  - Additional doses of a COVID-19 vaccine should be deferred in individuals who experienced a physician-diagnosed myocarditis or pericarditis event following a previous dose of a COVID-19 mRNA vaccine. However those with a history compatible with pericarditis who had no cardiac workup or had normal investigations may proceed to further vaccination once symptoms have resolved and 90 days have passed since receipt of the dose associated with the event. For those with confirmed myocarditis (with or without pericarditis), an individual risk/benefit discussion between the patient and their healthcare provider should occur so that the patient (with their parent/guardian as applicable) can make an informed decision about proceeding with a subsequent dose. If another dose is offered, the Pfizer-BioNTech COVID-19 vaccine should be offered because of the lower rate of myocarditis/pericarditis compared to the Moderna vaccine. Informed consent should include the unknown rates of recurrence of myocarditis and/or pericarditis following receipt of additional doses of the Pfizer-BioNTech COVID-19 vaccine, as well as the need to seek immediate medical assessment and care should symptoms develop. Deferral is not required for those with a prior history of myocarditis or pericarditis that is unrelated to COVID-19 mRNA vaccines and are no longer being followed by a medical professional for heart issues. For more information refer to the NACI summary.

SPECIAL CONSIDERATIONS:
  - COVID-19 vaccines can be administered concomitantly or at any time before or after the administration of another inactivated or live vaccine.
  - Deferral of COVID-19 vaccination is no longer recommended for individuals who have received anti-SARS-CoV-2 monoclonal antibodies or convalescent plasma for treatment or prevention of COVID-19.
  - A complete series of COVID-19 vaccine may be offered to individuals without contraindications who have recovered from confirmed SARS-CoV-2 infection.
  - Recipients should practice public health measures for prevention of SARS-CoV-2 infection and transmission regardless of vaccination with COVID-19 vaccine, at this time.

ADVERSE EVENTS:
Local: pain, swelling, redness, axillary lymphadenopathy. Delayed injection site reactions, with onset on or after day 8 following vaccination, may occur in a small percentage of vaccine recipients, mostly after the first dose.
Systemic: fatigue, headache, myalgia, chills, arthralgia, fever, nausea and vomiting.

Rare cases of facial paralysis/Bell's palsy have been reported.
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ADVERSE EVENTS (continued):
Pericarditis and myocarditis in association with the mRNA vaccines have been observed internationally and in Canada (see Public Health Agency of Canada reports). These events have been reported in Canada at a rate of 3.0 per 100,000 doses administered following any dose of the Moderna 100 mcg vaccine, and 1.9 per 100,000 doses administered following any dose of the Pfizer-BioNTech 30 mcg vaccine. It is seen more often after the second dose, and in males 12-29 years of age. The reported rates among males 18-29 years of age after the second vaccine dose are 15.9 per 100,000 for the Moderna vaccine and 2.6 per 100,000 for the Pfizer-BioNTech vaccine. Most cases recover fully. In BC, information to support health care provider recognition and reporting of this event in association with the mRNA vaccines has been issued. The exact cause of these events is not known but is thought to be related to the immune response to the spike protein which is also important in immunity against COVID-19 virus.

REFERENCES:
1. Moderna vaccine product monograph
2. National Advisory Committee on Immunization: Recommendations on the use of COVID-19 Vaccine(s)

ADDENDUM: Pooling residual vaccine from up to three vials to constitute an extra dose

Following withdrawal of all available doses, a 0.25 mL or 0.5 mL dose may be constituted from the residual vaccine volume from up to three separate vials, provided the vials are from the same manufacturer and same lot number. In order to minimize the risk of microbial contaminants and maintain product quality, the following processes should be followed:

- Only vials containing residual vaccine volume are to be used to prepare a 0.25 mL or 0.5 mL dose when using multiple vials to constitute a single dose. Residual volume should not be combined with contents from a different vial that still contains at least one dose of the vaccine (to minimize the chance of contaminating the contents of a vial that still contains multiple doses of the vaccine).
- Given this vaccine does not contain preservative, and therefore has a short timeline for its use following first vial puncture, pooling of residual vaccine from two or three vials must occur as soon as possible - it is not recommended to save multiple vials with residual volume for use at one time (e.g., the end of the clinic).
- Perform hand hygiene before handling the vaccine. Strictly adhere to aseptic technique while handling the vaccine and minimize the number of vial punctures.
- Firmly and briskly wipe the surface of the rubber stopper with an alcohol swab for initial and subsequent uses, being sure to apply friction, and allow it to dry for at least 10 seconds.
- To assist with the withdrawal of residual vaccine from the vial, invert the vial and ensure the end of the needle is below fluid level and situated in the groove of the vial stopper.
- Once the residual vaccine is withdrawn, keep the needle in the vial when expelling air bubble(s) to minimize vaccine wastage.
- Check the syringe to ensure it contains the appropriate dose prior to administration.
- If not administered immediately, the syringe should be clearly labeled with the date and time of the vial with the shortest timeframe for use.