COVID-19 Vaccine - mRNA
Moderna Spikevax Omicron-Containing Bivalent (Original and Omicron BA.1) - Frozen Vaccine

Revision Date: March 20, 2023

Rationale for Update:

- Updated to include additional bivalent booster dose indications for eligible individuals and updated booster spacing considerations to 6 months between last dose or infection.

_This policy is evergreen and will be updated as new information becomes available._

Please consult the Product Monograph\(^1\) for further information about the vaccine.

<table>
<thead>
<tr>
<th>Product Monograph(^1)</th>
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COVID-19 mRNA Omicron-Containing Bivalent Vaccine (Frozen Vaccine)

Royal blue cap & green label

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Moderna</th>
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<table>
<thead>
<tr>
<th>Licensed use</th>
<th>Booster dose for individuals 18 years of age and older at least 4 calendar months after completion of a primary series and/or a previous COVID-19 booster.</th>
</tr>
</thead>
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<table>
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<tr>
<th>Off-license use</th>
<th>Second bivalent booster dose for eligible individuals.</th>
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<tr>
<th>Indications for use of vaccine</th>
<th>Booster dose for individuals 18 years of age and older after completion of a primary series and/or a previous original (non-bivalent) or non-mRNA booster dose of COVID-19 vaccine (regardless of vaccine type).</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Additional booster dose for individuals 18 years of age and older who have received one dose of a bivalent booster vaccine and who are at an increased risk of severe outcomes from COVID-19 (see below for eligibility).</td>
</tr>
</tbody>
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<table>
<thead>
<tr>
<th>Dose</th>
<th>Booster</th>
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<tbody>
<tr>
<td></td>
<td>0.5 mL (50 mcg)</td>
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<thead>
<tr>
<th>Route</th>
<th>Intramuscular injection(^1)</th>
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<thead>
<tr>
<th>Schedule</th>
<th>Booster dose</th>
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<tbody>
<tr>
<td></td>
<td>All individuals 18 years of age and older are eligible for a single bivalent booster dose:</td>
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<tr>
<td></td>
<td>- At least 6 calendar months after completion of a primary series (regardless of vaccine type) or an mRNA original (non-bivalent) or non-mRNA booster dose or infection.</td>
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<tr>
<td></td>
<td>- If an individual received an original (non-bivalent) or non-mRNA booster on or after September 21, 2022 and an Omicron-containing bivalent booster dose is refused, no additional booster doses are to be offered.</td>
</tr>
</tbody>
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Archived

Archived
Additional booster dose

The following individuals are eligible for an additional bivalent COVID-19 booster dose: 2

- Individuals 65 years of age and older
- Individuals 18 years of age and older who are residents of a long term care facility or other congregate care living setting.
- Individuals 18 years of age and older who are moderately to severely immunocompromised (due to underlying condition or treatment).

- At least 6 calendar months after previous bivalent booster dose or infection.

- A shortened interval of at least 3 calendar months between the previous COVID-19 vaccine dose (or infection) and the Omicron-containing bivalent booster may be considered for individuals who are living in a long-term care facility or in other congregate care living settings. However, a longer interval of at least 6 calendar months leads to a better immune response against COVID-19 that is also expected to last longer, because it allows time for the immune response to mature in breadth and strength. 2

Note:

- Applicable congregate settings include, but are not limited to, all private and public long-term care facilities, licensed supportive living facilities and seniors' lodges including First Nations elder care lodges.
- Documentation of immunocompromising conditions is not required. Individuals who identify themselves as meeting at least one of the criteria below could be offered the additional bivalent booster dose.
- Immunization for immunocompromised individuals should occur at a time when the individual is most likely to mount an immune response. Clients are recommended to consult with their physician regarding the timing of immunization based on their individual treatment and unique circumstances, respecting the NACI recommended minimum spacing of at least 6 months since last COVID-19 dose (or infection). See exception below for HSCT / CAR T-cell therapy recipients.
- 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 without a prior history of HSCT 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.
- If requested by their specialist, a shortened interval of at least 3 calendar months between the previous COVID-19 vaccine dose (or infection) and the Omicron-containing bivalent booster doses may be provided for HSCT and/or CAR T-cell therapy recipients. A written request from the specialist is not required if the client provides verbal confirmation.
For HSCT recipients whose post-HSCT vaccine series were interrupted by CAR T-cell therapy, see the following HSCT guidance:

- Principles of Immunization in Hematopoietic Stem Cell Transplant Recipients and Solid Organ Transplant Recipients
- Immunization for Adult HSCT Recipients
- Immunization for Child HSCT Recipients

Immunocompromising conditions that places individuals at high risk of severe outcomes due to COVID-19

- Specific immunocompromising conditions that make an individual eligible for an additional bivalent booster dose include:
  - Solid organ transplant recipients — pre-transplant and post-transplant
  - Hematopoietic stem cell transplants 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 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 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
    - Individuals on 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).

Contraindications

- Known severe hypersensitivity to any component of the vaccine.1
- 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.2,3
• Tromethamine (trometamol or Tris) – component found in contrast media, oral and parenteral medications.2

• 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

• 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.2,3

• 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.1

• Administration should be postponed in individuals suffering from acute severe febrile illness.1,2

• There were no vaccine-related cases of myocarditis or pericarditis in the Omicron-containing bivalent mRNA vaccine clinical trial. However, given the number of participants enrolled in the bivalent clinical trial it is unlikely that rare adverse events would be detected.

• Very rare cases of myocarditis and/or pericarditis following immunization with an original (non-bivalent) mRNA COVID-19 vaccines have been reported during post-authorization use.1 However, the risk of myocarditis and/or pericarditis following a first and second booster dose of an original (non-bivalent) mRNA COVID-19 vaccine appears to be lower than the risk following the second dose of the primary series.2

• 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.

• 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.

• 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.2

• In most circumstances, further doses of mRNA COVID-19 vaccines should be deferred among people who experienced myocarditis (with or without pericarditis) within 6 weeks of receiving a previous dose of an mRNA COVID-19 vaccine.2

• 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.

• Informed consent should discuss the unknown risk of recurrence of myocarditis and/or pericarditis following additional doses of COVID-19 vaccine in individuals with a history of confirmed myocarditis and/or pericarditis after a previous dose of mRNA COVID-19 vaccine.
**Pregnancy**

- A COVID-19 vaccine booster should be offered at any stage of pregnancy, regardless of the number of previous doses received.\(^2\)
- The safety and efficacy of this Omicron-containing bivalent COVID-19 mRNA vaccine in pregnant women have not yet been established in the clinical trials.\(^1\) However, data available so far on original (non-bivalent) mRNA vaccines administered in pregnancy did not detect safety signals from post-marketing surveillance. The Omicron-containing bivalent COVID-19 mRNA vaccine can be offered to pregnant individuals as they are more at risk for severe illness from COVID-19 compared with non-pregnant individuals.\(^2,4\)
  - 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.\(^2\)
  - 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.

**Additional resources:**

**Lactation**

- It is unknown whether this vaccine is excreted in human milk as breastfeeding individuals were excluded from the initial trials. A risk to the newborns/infants cannot be excluded.\(^1,2\)
- However, based on how this vaccine works, the bivalent COVID-19 mRNA vaccine is not expected to be a risk to lactating individuals or their breastfed newborns/infants.\(^6\)
- COVID-19 vaccine should be offered to individuals in the eligible group who are breastfeeding.
  - It is recommended that individuals consult with their primary health care provider or 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.

**Other Considerations**

- Individuals presenting for immunization do not need to be tested for previous COVID-19 infection.
- It is not recommended that serology testing be completed to determine if an immune response to the COVID-19 vaccine has been mounted in individuals and serology testing should not be used as evidence to inform whether vaccine doses have been effective.
- Immunization of individuals who may be currently infected with SARS-CoV-2 is not known to have a detrimental effect on the illness.
- 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.

**Administration with Other Products**

- No participants in the Omicron-containing bivalent clinical trial were concurrently administered other vaccines. Data with regard to the safety and immunogenicity of other authorized COVID-19 vaccines (including original non-bivalent mRNA vaccines) when given concurrently with other vaccines, are currently limited. However, no specific safety concerns have been identified to date.\(^2\)
COVID-19 vaccines may be co-administered with, or at any time before or after other vaccines (including, live, inactivated, adjuvanted, or unadjuvanted vaccines) to individuals 6 months of age and older.²

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 QFT test results.²

- 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.²
- However, repeat tuberculin skin testing or IGRA (at least 4 weeks post-COVID-19 immunization) of individuals with negative TST or IGRA results for whom there is high suspicion of latent tuberculosis may be considered in order to avoid missing persons with TB infection.²

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.⁵
- 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.⁵
- There was no correlation between interval to COVID-19 immunization and neutralizing titres in recent monoclonal antibody recipients.⁵
- 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.

Individuals who are to receive Evusheld (tixagevimab and cilgavimab) as pre-exposure prophylaxis should wait at least 2 weeks following COVID-19 immunization to minimize interference.

Note:

- 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 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 RhIg) or blood product has been administered. There is no recommended minimum interval between these products and COVID-19 vaccine.

Program Notes

- September 1, 2022 – Licensed for use in Canada
- September 21, 2022 – Implemented in Alberta
- October 24, 2022 – Updated booster dose recommendation, and updated pregnancy and breastfeeding recommendations.
- March 01, 2023 – Updated booster dose recommendations.
- March 20, 2023 - Updated to include additional bivalent booster dose indications for eligible individuals and updated spacing considerations to 6 months between last dose or infection.
References


