COVID-19 Vaccine – mRNA Moderna Spikevax Bivalent (Original and Omicron BA.4/BA.5) – Frozen Vaccine

Biological Page

<table>
<thead>
<tr>
<th>Section 7:</th>
<th>Biological Product Information</th>
<th>Standard #: 07.222</th>
</tr>
</thead>
<tbody>
<tr>
<td>Created by:</td>
<td>Provincial Immunization Program Standards and Quality</td>
<td></td>
</tr>
<tr>
<td>Approved by:</td>
<td>Provincial Immunization Program Standards and Quality</td>
<td></td>
</tr>
<tr>
<td>Approval Date:</td>
<td>August 2, 2023</td>
<td>Revised:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Moderna</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biological Classification</td>
<td>Bivalent Original/Omicron BA.4/BA.5(elasomeran/davesomeran mRNA vaccine)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Indications for Provincially Funded Vaccine</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Primary series for individuals 6 months to 4 years of age.</td>
</tr>
<tr>
<td>• Primary series for moderately to severely immunocompromised individuals 6 months of age and older.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Preferred Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dose</td>
</tr>
<tr>
<td>6 months to 11 years of age</td>
</tr>
<tr>
<td>• 0.25mL (25 mcg)</td>
</tr>
<tr>
<td>12 years of age and older</td>
</tr>
<tr>
<td>• 0.5mL (50mcg)</td>
</tr>
</tbody>
</table>

| Route |
| IM in the vastus lateralis or deltoid muscle |

| Schedule |
| See below Schedule for individuals with certain immunocompromising conditions |

<table>
<thead>
<tr>
<th>Healthy children 6 months to 4 years of age</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary series 2 doses</td>
</tr>
<tr>
<td>• Dose 1: Day 0</td>
</tr>
<tr>
<td>• Dose 2: At least 8 weeks after dose 1</td>
</tr>
</tbody>
</table>

If a child has received one or two doses of Pfizer-BioNTech original monovalent vaccine as part of their primary series, they require 2 or 1 dose(s) of Moderna vaccine respectively to complete their primary series. (3 doses in total)

<table>
<thead>
<tr>
<th>Note:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Recommended spacing between doses is at least 8 weeks.</td>
</tr>
<tr>
<td>• If a primary series was started with an original monovalent vaccine, a bivalent Omicron-containing vaccine can be used to complete the series, noting the schedule requirements above.</td>
</tr>
<tr>
<td>• For children who start their primary series at 4 years of age and are eligible for their next dose after turning 5 years of age, the Pfizer-BioNTech Comirnaty bivalent BA.4/5 should be used to complete the primary series.</td>
</tr>
<tr>
<td>Schedule for individuals with certain immunocompromising conditions</td>
</tr>
<tr>
<td>---------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>6 months to 4 years of age</strong></td>
</tr>
<tr>
<td><strong>Primary series 3 doses</strong></td>
</tr>
<tr>
<td>• Dose 1: Day 0</td>
</tr>
<tr>
<td>• Dose 2: 28 days after dose 1</td>
</tr>
<tr>
<td>• Dose 3: 8 weeks after dose 2</td>
</tr>
</tbody>
</table>

If a child has received one, two or three doses of Pfizer-BioNTech original monovalent vaccine as part of their primary series, they require 3, 2 or 1 dose(s) of Moderna vaccine respectively to complete their primary series. (4 doses in total – see notes below for intervals)

<table>
<thead>
<tr>
<th><strong>5 Years of age and older</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary series 3 doses</strong></td>
</tr>
<tr>
<td>• Dose 1: Day 0</td>
</tr>
<tr>
<td>• Dose 2: 28 days after dose 1</td>
</tr>
<tr>
<td>• Dose 3: 8 weeks after dose 2</td>
</tr>
</tbody>
</table>

*Children 5 years of age and older, who initiated a primary series before turning 5 years of age, should complete their series as per the Schedule above for immunocompromised individuals 6 months to 4 years of age.

**Note:**

- If a primary series was started with an original monovalent vaccine (either mRNA or non-mRNA), a bivalent Omicron-containing vaccine can be used to complete the series. Regardless of which COVID-19 bivalent vaccine product is offered, the previous dose(s) should be counted, and the series should not be restarted, noting the schedule requirements above.
- It is recommended that individuals with certain immunocompromising conditions be immunized with a primary series of three doses of an mRNA COVID-19 vaccine. This is to provide stronger protection for those who may have a suboptimal immune response to vaccines. A bivalent mRNA vaccine should be administered except in the event of contraindication or refusal.
- The interval between dose 1 and dose 2 is 28 days. The interval between dose 2 and dose 3, and between dose 3 and 4, if required, is 8 weeks.
  - 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 of risk from COVID-19 among those who are moderately to severely immunocompromised. In addition, 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.
- Individuals who are moderately to severely immunocompromised may benefit from a primary series with Moderna Spikevax bivalent compared to Pfizer-BioNTech Comirnaty bivalent BA.4/5.
COVID-19 Vaccine – mRNA Moderna Spikevax Bivalent (Original and Omicron BA.4/BA.5) – Frozen Vaccine 6 Months of Age and Older

However, for individuals 12 to 29 years of age, Pfizer-BioNTech Comirnaty bivalent BA.4/5 is preferred over Moderna Spikevax bivalent BA.4/5 due to a lower risk of myocarditis and/or pericarditis observed after dose 1 and dose 2 of the primary series with Pfizer-BioNTech Comirnaty original (30 mcg) compared to Moderna Spikevax original (100 mcg).

- Moderna can be provided if preferred by an individual or their specialist. See the Precautions section for further information on myocarditis/pericarditis.

- Specific immunocompromising conditions that make an individual eligible for a three dose primary series 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 while 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).

Note:
- 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 of 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 if 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.

- For HSCT recipients who had their post-HSCT vaccine series interrupted by CAR T-cell therapy, see the following HSCT recommendations:
  - Principles of Immunization in Hematopoietic Stem Cell Transplant Recipients and Solid Organ Transplant Recipients
  - Immunization for Adult HSCT Recipients
  - Immunization for 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.

**Note:**

- 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 risk of severe disease should also be considered. 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 (except for those with MIS-C who should wait at least 90 days).

<table>
<thead>
<tr>
<th>Infection prior to initiation or completion of a primary COVID-19 immunization series</th>
<th>Individuals <strong>without</strong> certain immunocompromising conditions AND no history of multisystem inflammatory syndrome in children (MIS-C).</th>
<th>8 weeks after a positive test.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Individuals <strong>with</strong> certain immunocompromising</td>
<td>4 to 8 weeks after a positive test.</td>
</tr>
</tbody>
</table>
## Contraindications/Precautions

### Contraindications:

- 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 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.
- 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.
- The safety and efficacy of Moderna Spikevax Bivalent Original/Omicron BA.4/5 in individuals under 6 years of age has not yet been established.
- However, the safety and immunogenicity of Moderna Spikevax bivalent BA.1 (25 mcg) as a primary series was evaluated in a Phase 3 open-label study in 179 unimmunized children 6 months to 5 years of age.
  - Local and systemic reactogenicity after dose 1 and dose 2 of Moderna Spikevax bivalent BA.1 (25 mcg) were similar compared to those after dose 1 and dose 2 of Moderna Spikevax original (25 mcg).
  - There were no reports of vaccine-related serious adverse events, myocarditis and/or pericarditis or deaths. Given the number of participants enrolled in the trial, it is unlikely that uncommon, rare or very rare adverse events would be detected.
- Available evidence from Canada and internationally show that overall, the safety profile of bivalent mRNA COVID-19 vaccine boosters is comparable to that of original mRNA vaccine boosters among individuals 5 years of age and older.
**COVID-19 Vaccine – mRNA Moderna Spikevax Bivalent (Original and Omicron BA.4/BA.5) – Frozen Vaccine 6 Months of Age and Older**

- Despite the limited evidence on the use of bivalent vaccines as a primary series, the precautionary principle indicates that scientific uncertainty should not prevent decision makers from taking action to reduce risks associated with COVID-19. Use of bivalent vaccines for the primary series primes naïve individuals with both Omicron and original SARS-CoV-2 variants, which will help to maximize the breadth of immunity at the earliest opportunity.

<table>
<thead>
<tr>
<th>Myocarditis/Pericarditis</th>
</tr>
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<tbody>
<tr>
<td>- Very rare cases of myocarditis and/or pericarditis following immunization with Moderna vaccines have been reported during post-authorization use. There is an increased risk for myocarditis following immunization with Moderna vaccine, particularly within the first week following receipt of the second primary series dose or first booster dose in male young adults.</td>
</tr>
<tr>
<td>- The risk of myocarditis and/or pericarditis after a primary series dose of an original mRNA COVID-19 vaccine in children 5 to 11 years of age is now known to be substantially lower compared to the risk following mRNA COVID-19 vaccines in individuals 12 to 29 years of age (in whom the risk of myocarditis and/or pericarditis is the highest) and individuals 30 to 49 years of age (in whom there is no preference between Pfizer-BioNTech Comirnaty original or Moderna Spikevax original for the primary series). However, it should be noted that the low rates of myocarditis and/or pericarditis with the primary series in children 5 to 11 years of age have been in the context of the predominant use of Pfizer-BioNTech Comirnaty original (10 mcg) in this age group.</td>
</tr>
<tr>
<td>- 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.</td>
</tr>
<tr>
<td>- 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.</td>
</tr>
<tr>
<td>- 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.</td>
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<tr>
<td></td>
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<tr>
<td>- 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.</td>
</tr>
<tr>
<td>- 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.</td>
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<tr>
<td>COVID-19 Vaccine – mRNA Moderna Spikevax Bivalent (Original and Omicron BA.4/BA.5) – Frozen Vaccine 6 Months of Age and Older</td>
</tr>
<tr>
<td>---</td>
</tr>
<tr>
<td>○ 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.</td>
</tr>
</tbody>
</table>

**Pregnancy**

- A complete COVID-19 vaccine series should be offered to pregnant individuals regardless of trimester of pregnancy. An mRNA vaccine is preferred due to reassuring published data on the safety of these vaccines in pregnancy.
- The safety and efficacy of Moderna Spikevax Bivalent Original/Omicron BA.4/5 in pregnant women have not yet been established.
- However, data available on the original mRNA vaccines administered in pregnancy did not detect safety signals from post-marketing surveillance. The bivalent COVID-19 mRNA vaccines can be offered to pregnant individuals as they are more at risk for severe illness from COVID-19 compared with non-pregnant individuals.
  - ○ 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.
  - ○ It is recommended that individuals consult 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:*

[Society of Obstetricians and Gynecologists of Canada Statement on COVID-19 Immunization in Pregnancy.](#)

**Lactation**

- It is unknown whether this vaccine is excreted in human milk. A risk to the newborns/infants cannot be excluded.
- Recent reports have shown that breastfeeding people who have received mRNA COVID-19 vaccines have antibodies in their breastmilk, which could help protect their babies. More data are needed to determine the level of protection these antibodies might provide to the baby.
- A complete COVID-19 vaccine primary series is recommended for individuals who are breastfeeding.
  - ○ It is recommended that individuals consult 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.
To minimize the risk of COVID-19 transmission, individuals with COVID-19-like symptoms should defer their immunization appointment.

### Possible Reactions

**Common:**
- Pain, erythema, swelling at the injection site
- Axillary swelling/tenderness
- Fatigue
- Headache
- Myalgia
- Arthralgia
- Chills
- Nausea/vomiting
- Fever
- Hypoaesthesias, paraesthesia
- Dizziness
- Lymphadenopathy

**Rare:**
- Allergic reaction
- Anaphylaxis
- Erythema multiforme
- Facial paralysis/Bell’s palsy

Refer to the product monograph for more detailed information.

### Composition

- Elasomeran (mRNA) encoding the pre-fusion stabilized Spike glycoprotein of 2019 novel Coronavirus (SARS-CoV-2), and davesomeran (mRNA) encoding the pre-fusion stabilized conformation variant (K981P and V982P) of the SARS-CoV-2 Spike glycoprotein (Omicronvariant B.1.1.529 [BA.4/5])

Non-medicinal ingredients:
- Acetic acid
- Cholesterol
- DSPC (1,2-distearoyl-sn-glycero-3-phosphocholine)
- Lipid SM-102
- PEG2000-DMG (1,2-dimyristoyl-rac-glycerol,methoxy-polyethyleneglycol)
- Sodium acetate trihydrate
- Sucrose
- Trometamol
- Trometamol hydrochloride
- Water for injection
- Does not contain any preservatives, antibiotics, adjuvants, or human- or animal-derived materials.

### Blood/Blood Products

- Does not contain blood/blood products

### Bovine/Porcine Products

- Does not contain bovine/porcine products

### Latex

- Does not contain latex
Administration with Other Products

- 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.

- 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.
  - 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.
  - 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.

- 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.

- 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.
| **Appearance** | White to off-white dispersion.  
It may contain white or translucent product-related particulates. |
| **Storage** | Can be stored in a freezer between -25°C and -15 °C.  
Protect from light  
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. |
| **Packaging** |  
- 2.5 mL vial (5 x 0.5 mL doses or 10 x 0.25 mL doses)  
- 10 vials per carton |
| **Preparation/Reconstitution** | **Thaw vaccine before use:**  
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.  
No dilution is required.  
Swirl the vial gently after thawing and between each withdrawal.  
Do not shake vial. |
| **Vaccine Code** | COVMODmRNABA45 |
| **Antigen Code** | COVID-19-19 |
| **Licensed for** | Booster dose for individuals 6 years of age and older  
Off-license use:  
- Primary series for individuals 6 months of age and older.  
- Third dose in a primary series for individuals who are moderately to severely immunocompromised.  
- Third dose in a mixed Pfizer-BioNTech original monovalent and Moderna bivalent BA.4/5 primary series for healthy children aged 6 months to 4 years.  
- Fourth dose in a mixed Pfizer-BioNTech original monovalent and Moderna bivalent BA.4/5 primary series for moderate to severely immunocompromised children aged 6 months to 4 years. |
| **Program Notes:** |  
- August 1, 2023 – Off license use for a primary series implemented in Alberta |
| **Related Resources:** |  
- Alberta Health Services Website (2022). COVID-19 mRNA Vaccine Information |
COVID-19 Vaccine – mRNA Moderna Spikevax Bivalent (Original and Omicron BA.4/BA.5) – Frozen Vaccine 6 Months of Age and Older

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References: