Yukon Immunization Program Manual

Section 8 - Biological Products

Moderna Spikevax® XBB.1.5

SECTION 8 – BIOLOGICAL PRODUCTS

Contents

September 2023

COVID-19 mRNA Vaccine (Spikevax ® XBB.1.5)

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Panorama Alternate ID:	COVID-19 mRNA SPIKEVAX XBB.1.5 (Moderna) 2.5mL multi-dose 10 vials per box	**Panorama Catalogue Number** (level 5)	490
Manufacturer	Moderna	**Biological Classification**	mRNA vaccine
Indications	• COVID-19 immunization for individuals ages 6 months and older.		

Schedule

Individuals ages 6 months – 4 years of age (inclusive):

- **Previously vaccinated with 2 or more doses of an authorized COVID-19 vaccine**: 1 dose given as 0.25mL (25mcg) IM at least 6 months after last dose of COVID-19 vaccine. (minimum interval 5 months).
- **Previously vaccinated with 1 dose of an authorized COVID**-19 vaccine: 1 dose given as 0.25mL (25mcg) IM at least 8 weeks after the last dose of COVID-19 vaccine.
- **Not previously vaccinated with any authorized COVID**-19 vaccine: 2 doses given as 0.25mL (25mcg) IM 8 weeks apart.

Individuals ages 5 – 11 years of age (inclusive): 1 dose given as 0.25mL (25mcg) IM at least 6 months after last dose of COVID-19 vaccine, regardless of previous COVID-19 vaccination history. (minimum interval 5 months).

Individuals 12 years of age and older (inclusive): 1 dose given as 0.5mL (50mcg) IM at least 6 months after last dose of COVID-19 vaccine, regardless of previous COVID-19 vaccination history. (minimum interval 5 months).

Individuals ages 6 months and older who are moderately to severely immunocompromised: Individuals who are moderately to severely immunosuppressed (see COVID-19 vaccine eligibility) should have a total of at least 3 doses of an authorized COVID-19 vaccine with at least one of three doses being the COVID-19 XBB 1.5 formulation per age-appropriate dosing recommendations above. Refer to intervals in table below.

Recommendations for Moderately to Severely Immunosuppressed Clients

Previous COVID-19 Vaccination History	Number of Dose(s) of COVID-19 XBB.1.5 Vaccine	Recommended Interval Between Doses	Minimum Interval *(For optimal response, the recommended interval should be observed whenever possible)*
3 or more doses	1 dose	6 months after last dose	8 weeks after last dose
2 doses	1 dose	8 weeks after last dose	28 days after last dose
1 dose	2 doses	8 weeks after last dose and between doses	
0 doses	3 doses	8 weeks between doses	

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Booster Doses	• No additional doses beyond the schedule above are recommended at this time.
Interval Between Previous COVID-19 Infection and COVID-19 Immunization	• Yukon Immunization Program permits individuals to make informed decisions to receive vaccine post-infection irrespective of the intervals below, however, **all individuals** must maintain minimum intervals between vaccine doses. • Residents of long term care that are recommended to to receive a dose of COVID-19 vaccine in the fall of 2023 and who experienced SARS CoV-2 infection may receive a dose at least 2 weeks after COVID-19 resolution of acute symptoms. • All other individuals who are recommended to receive a dose of COVID-19 vaccine in the fall of 2023 and who experienced SARS CoV-2 infection may receive a dose 6 months after COVID-19 infection symptom onset.
Contraindications	• Individuals 5 months of age and younger. • History of anaphylactic reaction to a previous dose of the vaccine or to any component of the vaccine.
Precautions and Special Considerations	• Do not inject the vaccine intravascularly, subcutaneously or intradermally. • For individuals with suspected hypersensitivity or non-anaphylactic allergy to COVID-19 vaccine components, consultation with an allergist is advised. If there is a specific concern about a possible allergy to a component of the COVID-19 vaccine being administered, an extended period of observation post-vaccination of 30 minutes may be warranted; alternately, the vaccine can be administered in an emergency room setting, also with a prolonged observation period. • There is insufficient evidence on the receipt of both a COVID-19 vaccine and any monoclonal antibodies or convalescent plasma for treatment or prevention of COVID-19. Therefore, timing of administration and potential interference between these two products are currently unknown and expert clinical opinion should be sought on a case-by-case basis. • Future doses of mRNA COVID-19 vaccine should be deferred in those who experienced a physician-diagnosed myocarditis or pericarditis event following the first dose with no other cause identified, until further information about the risk of recurrence is available. Deferral is not required for those with a prior history of myocarditis or pericarditis that is unrelated to COVID-19 mRNA vaccines. • **Additional dose(s) for travel:** Receiving an additional dose for travel purposes is not considered clinically necessary. It is up to the traveler to know the COVID-19 vaccine requirements for their destination and travelers should otherwise follow routine intervals for COVID-19 vaccination

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Precautions and Special Considerations (continued)	• 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.
Myocarditis and Pericarditis	• Research determines the risk myocarditis (inflammation of the heart muscle) and/or pericarditis (inflammation of the lining around the heart) after COVID-19 mRNA vaccines is very low in the general population. In adolescent or young adults (ages 12 to 29), especially males, although the risk remains low, it is higher than other age groups. Research estimates the risk of myocarditis or pericarditis approaches 1 episode in every 10,000 doses of vaccines for adolescent/young adult males. Cases following mRNA COVID-19 vaccination are consistently reported to have occurred more often after the second dose, usually within a week after vaccination. • Evidence from bivalent and original mRNA COVID-19 vaccines across different age groups show that the risk of myocarditis is lower following boosters compared to dose 2 of the primary series, and that no product-specific difference in the risk of myocarditis has been identified following a booster dose at this time. However, while these observations were also seen in adolescents 12 to 17 years of age, the use of Moderna Spikevax COVID-19 vaccines have been limited in those 5 to 17 years of age. • Yukon Immunization Program monitors research and recommendations from the National Advisory Committee on Immunizations. In doses and schedules currently recommended, there isn't clear evidence showing one COVID-19 mRNA vaccine product (i.e. Moderna Spikevax or Pfizer BioNTech Comirnaty) is more effective or has a different risk of adverse effects. For the fall 2023 COVID-19 Immunization update, Yukon Immunization Program does not provide preferential recommendations for Spikevax or Comirnaty mRNA vaccines in any specific age group or patient population. • Clients or their health care providers may prefer a specific COVID-19 mRNA vaccine product. Yukon Immunization Program and immunizers will make every effort to accommodate preferences, but there may be constraints in supply and distribution that limit availability of specific brands. • **All adults, including those 12-29 years of age, can receive a dose of COVID-19 vaccine with any available mRNA COVID-19 vaccine for which they are currently eligible during the fall 2023 vaccine campaign.**

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Myocarditis and Pericarditis	• Available post-market vaccine safety data from V-safe, Vaccine Safety Datalink (VSD) and Vaccine Adverse Event Reporting System (VAERS) in the US as of September 2022 show that the Moderna Spikevax (25 mcg) and Pfizer-BioNTech Comirnaty (3 mcg) mRNA COVID-19 vaccines are well tolerated among children aged 6 months to 5 years. No safety signals (including myocarditis) have been identified after administration of about 1.5 million vaccine doses. • When counselling about risks and benefits of mRNA COVID-19 vaccines, health care providers should review the risk of severe outcomes from natural COVID-19 infection including Multisystem Inflammatory Syndrome, and myocarditis and pericarditis. Research estimates the risk of these conditions is higher with more severe outcomes after natural infection.
Pregnancy and Lactation	• Vaccination against COVID-19 is recommended for individuals who are pregnant, breastfeeding, immunocompromised, or have an autoimmune condition. If clients have questions, have an informed discussion with them. Further information is available in the SOGC Statement on COVID-19 Vaccination in Pregnancy.
Interchangeability and Preferred Products	• Current evidence shows that interchanging mRNA COVID-19 vaccine products is safe and effective for subsequent doses. • A COVID-19 immunization series may be started with or completed with any available and authorized COVID-19 vaccine, including BA.4/BA.5 or XBB.1.5 formulations. Regardless of which product is offered to start a primary series, the previous dose should be counted, and the series does not need to be restarted. • XBB.1.5 formulations are the preferred products for fall 2023 COVID-19 boosters in all eligible age groups, however, BA.4/BA.5 formulations may be used permissively if XBB.1.5 formulations are not available while quantities last. • Refer to the appropriate product pages for the client's age.
Reconstitution and Dilution	• Do not reconstitute or dilute Spikevax XBB.1.5.

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Administration	• Use aseptic technique for preparation and administration. • The vial contains 2.5mL of vaccine (5 doses of 0.5mL or 10 doses of 0.25mL). • This vial can be used in anyone ages 6 months and older using the age-appropriate dose. • Swirl the vial gently after thawing and between each withdrawal. Do not shake. • Administer IM only. The preferred injection site for children under one year of age is the vastus lateralis. The preferred injection site for individuals one year of age and older with adequate muscle mass is the deltoid. • Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab. Withdraw each dose of vaccine from the vial using a new sterile needle and syringe (preferentially a low dead-volume syringe and/or needle) for each injection. Pierce the stopper preferably at a different site each time.
Concurrent Administration with Other Vaccines	• Spikevax XBB.1.5 may be administered at the same time, or anytime before or after another inactivated or live vaccine.
Serological Testing	• Serological testing is not recommended before or after immunization.
Vaccine Components	• **Potential allergens:** PEG2000-DMG (1,2-dimyristoyl-rac-glycerol,methoxy-polyethyleneglycol) • **Other components:** acetic acid, cholesterol, DSPC (1,2-distearoyl-sn-glycero-3-phosphocholine), lipid SM-102, sodium acetate trihydrate, sucrose, trometamol, trometamol hydrochloride, water for injection.
Appearance	• The 0.10 mg/mL multi-dose vial is supplied with a royal blue flip-off plastic cap and has a vial label with the strength printed in coral blue. • Spikevax XBB.1.5 is a white to off-white dispersion. It may contain white or translucent product-related particulates. • Visually inspect Spikevax XBB.1.5 vials for foreign particulate matter and/or discoloration prior to administration. If either of these conditions exists, the vaccine should not be administered.
Blood/ Blood Products	• Spikevax XBB.1.5 does not contain any blood or blood products.
Bovine/ Porcine Products	• Spikevax XBB.1.5 does not contain any bovine or porcine products.
Latex	• Spikevax XBB.1.5 does not contain latex.

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Expected Reactions	**Local:** pain, swelling, redness, axillary swelling/ tenderness **Systemic:** fatigue, myalgia, headache, arthralgia, chills, nausea/vomiting, fever, irritability/ crying (infants/ children), loss of appetite (infants/ children)
Storage and Handling	**Storage prior to use (unpunctured vials):** • -50°C to -15°C up to the end of its expiry date, kept in the original packaging and protected from light. Do not store on dry ice. • +2°C to +8°C for up to 30 days prior to first use, protected from light • Room temperature (up to +25°C) for up to 24 hours (punctured or unpunctured). • Do not re-freeze vials after thawing. **Thawing:** • Thaw for 2 hours at 2° to 8°C and let stand for an additional 15 minutes at room temperature (15° to 25°C) prior to administration, **OR** • Thaw for 45 minutes at room temperature (15° to 25°C) **During use (punctured vials):** • After first vial puncture, the vaccine must be used within 24 hours. • Swirl the vial gently between each withdrawal. Do not shake. • The vaccine can be pre-loaded into a syringe for up to 24 hours. Thawed vials and filled syringes can be handled in room light conditions. • Ensure that the vial/syringe is clearly labelled with the date and time of first vial entry. Do not re-freeze vials after thawing.

PROGRAM NOTES

- Spikevax XBB.1.5 introduced into Yukon Immunization Program September 2023.
- Interval between COVID-19 infection and vaccination updated for long term care residents October 2023.

RELATED RESOURCES

- Yukon Immunize Website

REFERENCES

1. Product Monograph
2. Canadian Immunization Guide
3. NACI