Yukon Immunization Program Manual

Section 8 - Biological Products

Pfizer Comirnaty XBB.1.5

SECTION 8 – BIOLOGICAL PRODUCTS

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○ Previously vaccinated with 3 or more doses of an authorized COVID-19 vaccine: 1 dose given as 0.2mL (3mcg) IM at least 6 months after last dose of COVID-19 vaccine. (minimum interval 5 months).
○ Previously vaccinated with 2 or doses of an authorized COVID-19 vaccine: 1 dose given as 0.2mL (3mcg) IM at least 8 weeks after the last dose of COVID-19 vaccine.
○ Previously vaccinated with 1 dose of an authorized Covid-19 vaccine: 2 doses given as 0.2ml (3mcg) IM 8 weeks from last dose and between doses.
○ Not previously vaccinated with any authorized COVID-19 vaccine: 3 doses given as 0.2mL (3mcg) IM 8 weeks apart.

Individuals ages 5 – 11 years of age (inclusive): 1 dose given as 0.3ml (10mcg) 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 0.3ml (30mcg) IM at least 6 months after last dose of COVID-19 vaccine, regardless of previous COVID-19 vaccination history. (minimum interval 5 months).</td></tr>
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Schedule:

Fall 2023 Recommendations *(continued)*

Individuals ages 6 months to 4 years 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 4 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 6 months to 4 years (inclusive)

Previous COVID-19 Vaccination History of non XBB1.5	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)*
4 or more doses	1 dose	6 months after last dose	5 months after last dose
3 doses	1 dose	8 weeks after last dose	28 days after last dose
2 doses	2 doses	8 weeks after last dose and between doses	
1 dose	3 doses	8 weeks after last dose and between doses	
0 doses	4 doses	8 weeks between doses	

Recommendations for Moderately to Severely Immunosuppressed Clients 5 years and older

Previous COVID-19 Vaccination History of non XBB1.5	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	5 months 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: **Spring 2024 Recommendations**	**Starting in the spring of 2024, the following individuals who are at increased risk of severe illness from COVID-19 may receive an additional dose of XBB.1.5 COVID-19 vaccine:** • Adults 65 years of age and older • Adult residents of long term care homes and other congregate living settings for seniors • Individuals 6 months of age and older who are moderately to severely immunocompromised (see COVID-19 vaccine eligibility) due to underlying medical conditions or treatments If a high risk individual identified above has not recieved the dose(s) that they were eligible for in the fall of 2023, they should do so as soon as possible according to the fall 2023 schedule and reevaluate their COVID-19 vaccine eligibility in the fall of 2024. All other non-high risk individuals that have not recieved the dose(s) that they were eligible for in fall of 2023 should so as soon as possible and reevaluate their COVID-19 vaccine eligibility in the fall of 2024. Non-high risk individuals that have recieved their fall 2023 dose(s) are not recommended to recieve another booster dose in the spring of 2024, but may proceed with a booster after an informed discussion on the risks and benefits of vaccination provided that it has been 6 months since their last dose (minimum interval 5 months).
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. • **All individuals** who are recommended to receive a dose of COVID-19 vaccine and who experienced SARS CoV-2 infection may receive a dose **6 months** after COVID-19 infection symptom onset. • Residents of long term care homes and other congregate living settings for seniors that are not eligible for the spring 2024 COVID-19 vaccine campaign due to COVID-19 infection within the past 6 months may defer their next COVID-19 immunization to the fall of 2024 to ensure immunological protection against severe outcomes during anticipated peak infection periods. However, individuals or their substitute decision makers may choose to be immunized sooner with informed consent provided that minimum intervals between vaccine doses are respected.
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.

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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 • 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.

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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 spring 2024 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 spring 2024 vaccine campaign.** • 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.

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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	• 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 spring 2024 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	• **For 6 months to 4-year-old formulation: DILUTE PRIOR TO USE** • Multiple dose vial with maroon cap and maroon label border • Dilute the multiple dose vaccine vial with 2.2mL of provided sterile 0.9% sodium chloride diluent solution. Do not use bacteriostatic sodium chloride.
	• **For 5 -11-year-old formulation: do not dilute.** • Multiple dose vial with blue cap and blue label border.
	• **For 12 years of age and older formulation: do not dilute.** • Multiple dose vial with gray cap and gray label border
Administration	**For 6 months to 4 year old formulation: maroon cap and maroon label border.** • Use aseptic technique for preparation and administration. • Vial contains 10 doses of 0.2mL (0.3mcg) after dilution. • After thawing, inspect the vial to ensure there is no particulate and no discoloration. If any is observed do not administer the vaccine. • Before use, mix by inverting vaccine vial gently 10 times. Do not shake. • Go slow: withdrawing the diluted vaccine too quickly may result in fizzing. • Adjustments to remove air bubbles and dose calibration should be done with the needle still in the vial to avoid loss of vaccine. • Administer IM. 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. • Record the date and time that the product was removed from the fridge and time of first puncture.

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Administration (continued)	**For 5 – 11 year old formulation: blue cap and blue label border** • Use aseptic technique for preparation and administration. • Vial contains 6 doses of 0.3mL (10mcg) each. • After thawing, inspect the vial to ensure there is no particulate and no discoloration. If any is observed do not administer the vaccine. • Before use, mix by inverting vaccine vial gently 10 times. Do not shake. • Go slow: withdrawing the diluted vaccine too quickly may result in fizzing. • Adjustments to remove air bubbles and dose calibration should be done with the needle still in the vial to avoid loss of vaccine. • Administer IM. The preferred injection site for individuals one year of age and older with adequate muscle mass is the deltoid. • Record the date and time that the product was removed from the fridge and time of first puncture.
	For 12 years of age and older formulation: gray cap and gray label border • Contains 6 doses of 0.3mL (30mcg) each. • After thawing, inspect the vial to ensure there is no particulate and no discoloration. If any is observed do not administer the vaccine. • Before use, mix by inverting vaccine vial gently 10 times. Do not shake. • Go slow: withdrawing the diluted vaccine too quickly may result in fizzing. • Adjustments to remove air bubbles and dose calibration should be done with the needle still in the vial to avoid loss of vaccine. • Administer IM. The preferred injection site for individuals one year of age and older with adequate muscle mass is the deltoid. • Record the date and time that the product was removed from the fridge and time of first puncture.
Concurrent Administration with Other Vaccines	• Comirnaty 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 administration.
Vaccine Components	**Potential allergens:** 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide **Other components:** ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), cholesterol, DSPC (1,2-distearoyl-sn-glycero-3-phosphocholine), sodium chloride, sucrose, tromethamine, tromethamine hydrochloride, water for injection
Appearance	• The liquid is a white to off white suspension and may contain white to off-white opaque amorphous particles. Do not use if liquid is discoloured or if other particles are observed.

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Blood/ Blood Products	• Pfizer-BioNTech Comirnaty® Omicron XBB.1.5 does not contain any blood or blood products.
Bovine/ Porcine Products	• Pfizer-BioNTech Comirnaty® Omicron XBB.1.5 does not contain any bovine or porcine products.
Latex	• Pfizer-BioNTech Comirnaty® Omicron XBB.1.5 does not contain latex.
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:** • The date printed on the vial and carton reflects the expiry date. • -90°C to -60°C up to the end of its expiry date, kept in the original packaging and protected from light. Do not store on dry ice. • **Do not store vials at -25°C to -15°C.** • +2°C to +8°C for up to 10 weeks (70 days) within the expiry date, prior to first use, protected from light. • Room temperature (up to +25°C) for up to 12 hours before the first vial puncture. **Thawing:** • From the ultra low freezer to room temperature; will require up to 30 minutes to thaw • From the ultra low freezer to the refrigerator; will require up to 6 hours to thaw, and then requires at least 15 minutes at room temperature prior to administration. • Invert the vial gently 10 times after thawing. Do not shake **During use:** • After first vial puncture, the vaccine must be used within the next 12 hours. • The vaccine can be pre-loaded into a syringe for up to 12 hours. • Thawed vials and filled syringes can be handled in room light conditions. Avoid exposure to direct sunlight and ultraviolet light. • Ensure that the vial/syringe is clearly labelled with the date and time of first vial entry. • Swirl gently between each withdrawal. Do not shake. **Do not refreeze thawed vials**

PROGRAM NOTES

- Pfizer-BioNTech Comirnaty® Omicron 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.
- Spring 2024 booster recommendations added March 2024.
- Interval between COVID-19 infection and vaccination updated for long term care residents March 2024.

RELATED RESOURCES

- Yukon immunization Manual

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REFERENCES

1. Canadian Immunization Guide
2. National Advisory Committee on Immunization (NACI): Statements and publications
3. Product Mongraph