COVID 19 Vaccine Implementation Task Force **Clinic Reference**	
Title:	**COVID-19 Vaccine Pfizer COMIRNATY™ Quick Reference for Immunizers**
Area:	**Reference for Immunizers**
Effective Date:	January 15, 2021 (Adult formulation), November 25, 2021 (Pediatric formulation), October 7, 2022 (Bivalent formulation) October 21, 2022 (Infant formulation)
Revised Date:	October, 2022
Approver:	FINAL

Pfizer COMIRNATY™ vaccine indicated for active immunization against coronavirus disease 2019 (COVID-19)

Disclaimer: this Quick Reference is not intended to replace other product specific vaccine references. The document is intended a quick reference for frequently referred to information. Please refer to the product monograph and other Pfizer COMIRNATY™ specific resources for all current and complete information.

Additional resources:

Product Monograph: https://www.gov.mb.ca/asset_library/en/covidvaccine/pfizer-biontech-pm.pdf

Bivalent Product Monograph: https://www.gov.mb.ca/asset_library/en/covidvaccine/pfizer-cominarty-bivalent-ba4-5-pm.pdf

Eligibility Criteria:

Please refer to Province of Manitoba | Eligibility Criteria (gov.mb.ca) for the most up to date information on primary series and booster dose eligibly criteria.

Canadian Immunization Guide:

For the guidance on special populations, please refer to and follow guidance in the Canadian Immunization Guide.

Fact Sheets:

For information on vaccine risk and intended benefits, please refer to the Provincial factsheets

Summary of document tables:

Table 1: Additional dose recommendations: immunocompromised
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<tr><td colspan="5">6 months to ≤ 5 years of age</td></tr>
<tr>
<td>Primary series:
<u>Individuals 6 months to ≤5 years of age</u>:
3 dose regimen of 0.2mL (3 mcg)

Note: An extended primary series is recommended for those who are moderately to severely immunocompromised. See table 1 for preferential recommendation.

Children living in First Nation communities:
Moderna 25mcg is the preferred vaccine due to being a 2-dose series instead of a 3-dose series. However, Pfizer 3mcg can also be used for this age group.

Booster dose: Not approved for this age group</td>
<td><u>Primary series intervals</u>
Recommended Interval: 8 weeks between all doses

Authorized Interval:
21 days

Minimum Interval:
Between dose 1 and dose 2: 19 days
Between dose 2 and dose 3: 52 days</td>
<td>Cap: Maroon

Vial volume: 0.4 ml (multidose vial)
Requires dilution

After dilution, one vial contains 10 doses of 0.2 ml.
Dose: 3 mcg (0.2ml)

Inspect vials: After dilution, the vaccine will be a white to off-white suspension. Inspect vials to confirm there are no particulates and no discolouration is observed.</td>
<td>Thaw time*:
<u>2◦ to 8◦C (Refrigerator):</u> up to 2 hours/carton.
<u>15◦ to 25◦ C (Room temperature):</u> 30 min

Let stand at room temperature 30 min prior to dilution.

Discard time:
Undiluted:
12 hours at room temperature.

Diluted:
refrigerate or store at room temperature for maximum 12 hours

Once drawn up, administer immediately and no later than 12 hours after dilution.

Thawed vials can be handled in room light conditions.</td>
<td>Administered: Intramuscular

Requires dilution (0.9% Sodium Chloride Injection, USP 2.2 mL required for dilution)

Pediatric Intramuscular needle length selection
Ages 6 months to under 5 years
<table>
<tr><th>AGE</th><th>SITE</th><th>NEEDLE LENGTH</th></tr>
<tr><td>Infants (6 to 12 months)</td><td>Anterolateral thigh</td><td>1”</td></tr>
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<tr><td>Children 3+</td><td>Deltoid</td><td>5/8” to 1”</td></tr>
</table>
Low dead-volume syringes and/or needles should be used to extract 10 doses from a single vial.</td>
</tr>
<tr><td></td><td>See Table 3 (Recommended mRNA schedule)</td><td></td><td>*Do not refreeze once thawed</td><td>Do not use infant formulation to prepare doses for individuals 5 years of age and older.</td></tr>
<tr><td colspan="5">Potential allergens: Polyethylene glycol (PEG), Tromethamine (trometamol or Tris)
Product is latex and preservative free</td></tr>
</table>

NACI recommends children 6 months to ≤ 5years should start and finish the primary series with the same product. If mixed products are used, the Pfizer interval schedule should be used (3 doses for immunocompetent, 4 doses for immunocompromised).

Product Information	Approved immunization intervals	Presentation	Clinic Setting Considerations	Administration
5 years to ≤ 11 years of age				
Primary series: Individuals 5 years to ≤11 years of age: 2 dose regimen of 0.2mL (10 mcg) *Note: 3rd dose may be recommended for some individuals. See table 2* **Boosters*:** Individuals **6** to 11 years of age: One dose: 0.2ml (10mcg)	**Primary series intervals** **Recommended Interval:** 8 weeks **Authorized Interval:** 21 days **Minimum Interval:** 19 days **Booster dose intervals:** **Recommended Interval**: 6 months **Minimum Interval**: *3 months	**Cap**: Orange **Vial volume:** 1.3 ml (multidose vial) ***Requires dilution*** After dilution, one vial contains 10 doses of 0.2 ml. **Dose**: 10 mcg (0.2ml) **Inspect vials:** After dilution, the vaccine will be a white to off-white suspension. Inspect vials to confirm there are no particulates and no discolouration is observed.	**Thaw time*:** 2◦ to 8◦C (Refrigerator): up to 4 hours/carton. 15◦ to 25◦ C (Room temperature): 30 min Let stand at room temperature 30 min prior to dilution. **Discard time:** Undiluted: 12 hours at room temperature. Once the vial has been diluted/punctured, refrigerate or store at room temperature for maximum 12 hrs, then discard. Thawed vials can be handled in room light conditions.	**Administered**: Intramuscular **Requires dilution** (0.9% Sodium Chloride Injection, USP **1.3 mL** required for dilution) **Site:** deltoid **Needle length:** 5/8" to 1 ½" Clinical judgement should be used when selecting needle length for IM injections. Consider clients weight, age, gender and muscle mass. Low dead-volume syringes and/or needles should be used to extract 10 doses from a single vial.
*Entire cohort eligible, but recommended for those at high risk of severe outcomes from COVID-19 infection.	*For those who identify as being at increased risk See Table 3 (Recommended mRNA schedule)		*Do not refreeze once thawed	Do not use pediatric formulation to prepare doses for individuals 12 years of age and older.
Potential allergens: Polyethylene glycol (PEG), Tromethamine (trometamol or Tris) Product is latex and preservative free				

NOTE: If more than the expected number of doses are drawn from a vaccine vial (greater than 6 or greater than 10 doses depending on formulation, vaccine may be administered, provided the full dose can be drawn from one vial (do not pool vaccine from multiple vials), all infection control practices have been maintained, and inventory is updated accordingly.

Product Information	Approved immunization intervals	Presentation	Clinic Setting Considerations	Administration
≥ 12 years of age and older				
Primary Series: Individuals ≥ 12 years of age: 2 dose regimen of 0.3ml (30 mcg) *Note: 3rd dose may be recommended for some individuals. See table 2* **Booster doses:** Individuals ≥ 12 years of age: Dose: 0.3ml (30 mcg)	**Primary series Intervals** **Recommended Interval**: 8 weeks **Authorized Interval**: 21 days **Minimum Interval**: 19 days **Booster dose intervals:** **Recommended Interval**: 6 months **Minimum Interval**: *3 months	**Cap**: **Purple** **Vial volume:** 0.45 ml (multidose vial) ***Requires dilution*** After dilution, one vial contains 6 doses of 0.3ml **Dose**: 30 mcg (0.3ml) **Inspect vials:** After dilution, the vaccine will be a white to off-white suspension. Inspect vials to confirm there are no particulates and no discolouration is observed.	**Thaw time*:** 2◦ to 8◦C (Refrigerator): up to 3 hours/carton. 15◦ to 25◦ C (Room temperature): 30 min Let stand at room temperature 30 min prior to dilution. Must be diluted within 2 hours of exposure to room temperature. **Discard time:** Undiluted: 12 hours at room temperature. Once the vial has been diluted/punctured, refrigerate or store at room temperature for maximum 6 hrs, then discard. Thawed vials can be handled in room light conditions.	**Administered**: Intramuscular **Requires dilution** (0.9% Sodium Chloride Injection, USP **1.8 mL** required for dilution) **Site:** deltoid **Needle length:** 5/8" to 1 ½" Clinical judgement should be used when selecting needle length for IM injections. Consider clients weight, age, gender and muscle mass. Low dead-volume syringes and/or needles should be used to extract 6 doses from a single vial.
	*For those who identify as being at increased risk See Table 3 (Recommended mRNA schedule)		*Do not refreeze once thawed	
Potential allergens: Polyethylene glycol (PEG). This product does NOT contain Tromethamine. Product is latex and preservative free				

Product Information	Approved immunization intervals	Presentation	Clinic Setting Considerations	Administration
Bivalent: ≥ 12 years of age and older				
Not for use as primary series **Booster dose:** Individuals 6 to 11 years of age: *Not approved for this age group.* Individuals ≥ 12 years of age: One dose 0.3ml (30mcg) Current eligibility criteria available online: https://www.gov.mb.ca/covid19/vaccine/eligibility-criteria.html	**Recommended Interval**: 6 months **Minimum Interval**: *3 months	**Cap**: Grey **Vial volume:** 2.25 ml (6 doses in a multidose vial) ***Does NOT require dilution*** **Dose**: 30 mcg (0.3ml) **Inspect vials:** • Prior to mixing, the thawed vaccine may contain white to off-white opaque amorphous particles. • After mixing, the vaccine should appear as a white to off-white suspension with no visible particles.	**Thaw time*:** 2◦ to 8◦C (Refrigerator): up to 6 hours/carton. 15◦ to 25◦ C (Room temperature): 30 min **Discard time:** 12 hours at room temperature after first puncture. Vaccine should be administered immediately after being drawn into the syringe. If this is not possible (i.e. using pre-drawn syringes) the vaccine must be administered within 12 hours of when the vial was punctured. *Example: if the vial is punctured at 8 am (expires at 8pm), and the syringe is drawn at 6pm, the syringe must be discarded at 8pm with the vial.*	**Administered**: Intramuscular ***Does NOT require dilution*** **Site:** deltoid **Needle length:** 5/8" to 1 ½" Clinical judgement should be used when selecting needle length for IM injections. Consider clients weight, age, gender and muscle mass. Low dead-volume syringes and/or needles should be used to extract 6 doses from a single vial.
	*For those who identify as being at increased risk See Table 3 (Recommended mRNA schedule)		*Do not refreeze once thawed	
Potential allergens: Polyethylene glycol (PEG), Tromethamine (trometamol or Tris). If individual is 12+ and has a known allergy to Tromethamine they should be offered a Pfizer monovalent (purple cap) vaccine for their booster dose. Product is latex and preservative free				

See **Table 5: Bivalent Considerations** for detailed information about bivalent recommendations and administration.

Recommendations on COVID-19 Immunization Doses for the Primary Series:

- Children who will turn from 4 to 5 years of age between their doses in the vaccination series should receive their age-appropriate dose at the time of the vaccination and the interval between doses is determined by the child's age at the start of the vaccination series.
- Children that are 5 years of age should initiate the pediatric Pfizer COMIRNATY™ primary series.
- For children 6 years to 11 years of age, the use of Pfizer COMIRNATY TM (10mcg) is preferred to Moderna Spikevax (50 mcg) to start or continue the primary vaccine series.
- Manitoba recommends that young people age 12 - 29 years receive Pfizer COMIRNATY™ for their primary series to minimize the rare potential increased risk of myocarditis/pericarditis
- A person who received a first dose of an mRNA vaccine (COMIRNATY™ or SPIKEVAX™) should be offered the same mRNA vaccine for their second dose.
    - If the same mRNA vaccine is not available or unknown, another mRNA vaccine can be considered interchangeable and should be offered to complete the vaccine series.
    - If a different mRNA vaccine is given as a second dose with appropriate spacing, both doses are considered valid and the series complete.
- While the **recommended** interval for the primary series, of 8 weeks is preferred, if a person presents for an immunization and would otherwise not return within that recommended interval, the immunizer may proceed with administering the subsequent dose if the **authorized minimum** interval has passed, provided the first dose product received was an mRNA vaccine (COMIRNATY™ or SPIKEVAX™).
    - The **minimum** interval of 19 days is not recommended; however, would be considered a valid dose in PHIMS.
- Individuals who are moderately to severely immunocompromised are recommended to receive a third dose in the primary series. This requires a prescription if given outside of a physician or pharmacists office and must be given at least 28 days after the second dose.

Recommendations on COVID-19 Immunization Booster doses:

- The recommended interval for booster doses is 6 months between the most recent dose (primary series, previous booster dose) and the eligible booster. However, a booster dose may be administered using a 3-month interval after discussing the risk and benefits of a shortened interval with the client.
- It is recommended for individuals to wait 6 months since their last COVID-19 infection. At minimum, they need to be fully recovered and completed their isolation period before receiving a booster dose.
- Individuals who have already received an mRNA COVID-19 vaccine as part of a fall COVID-19 vaccine booster program will not be eligible for an additional dose of a COVID-19 vaccine at this time. This includes individuals who were vaccinated using any authorized original or bivalent mRNA COVID-19 vaccine. Both original and bivalent mRNA COVID-19 vaccines will boost immune responses and are likely to provide significant protection against hospitalization and severe disease.
- See **Table 5: Bivalent Considerations** for detailed information about bivalent recommendations and administration.

NOTE: The date the first vaccine was administered is considered "day 0" when counting minimum intervals. Interruption of a vaccine series resulting in a greater than recommended interval between doses does not require restarting the series.

Allergies:

Refer to Manitoba COVID-19 Vaccine: Clinical Practice Guidelines for Immunizers and Health Care Providers – Appendix C for precautionary information on national guidance related to allergic responses to vaccines.

Table 1 (Pfizer Additional dose {primary series} recommendation, immunocompromised)

Additional dose recommendations for those moderately to severely immunocompromised			
Cohort	**Product**	**Dose**	**Recommended interval**
6 months to ≤ 5 years	***Moderna (25mcg) *preferred***	● ***3 dose series***	≥ 28 days between all doses in a 3 or 4 dose series. Considered part of the primary series.
	Pfizer (3mcg) **Maroon cap**	● 4 dose series	
5 to 11 years	Pfizer (10mcg) **Orange cap**	● 3 dose series	≥ 28 days after their second dose. Considered part of the primary series.
≥ 12 years	Pfizer (30mcg) **Purple cap**	● 3 dose series	≥ 28 days after their second dose. Considered part of the primary series.

*A 3 dose series of Moderna/Spikevax™ (25mcg) vaccine should be preferentially offered to this age group for the extended series due to the shorter 3 dose regimen, instead of 4 doses of Pfizer/Comirnaty™ (3mcg).

Table 2 (Pfizer Additional dose {primary series} recommendation, non-Health Canada approved)

Additional dose recommendations for individuals with 1 or 2 non-Health Canada approved vaccines				**Manitoba Health accepted primary series combinations**
Cohort	**Product**	**Dose**	**Recommended interval**	• Two mRNA vaccines (Pfizer or Moderna) • Two AstraZeneca vaccines • AstraZeneca and one dose of an mRNA vaccine (Pfizer or Moderna) • One dose of Janssen • Three non-Health Canada Approved vaccines • One or two non-Health Canada Approved Vaccines and one dose of an mRNA Vaccine (Pfizer or Moderna) • For moderately to severely immunocompromised ○ Three doses (any combination of AstraZeneca, Pfizer and/or Moderna) • Children 6m to 4 years with 3 doses of a non-Health Canada approved vaccine.
6 months to ≤ 5 years	***Moderna (25mcg) preferred***	● ***Administer one additional dose***	≥ 28 days after their last dose to complete their primary series.	
	Pfizer (3mcg) **Maroon cap**	● administer 2 additional doses	8 weeks apart, starting ≥ 21 days after their last dose to complete their primary series.	
5 to 11 years	Pfizer (10mcg) **Orange cap**	● administer one additional dose	≥ 28 days after their last dose to complete their primary series.	
≥ 12 years	Pfizer (30mcg) **Purple cap**	● administer one additional dose	≥ 28 days after their last dose to complete their primary series.	

Table 3 Manitoba Health recommended mRNA immunization schedule, based on age.

	Approved COVID-19 mRNA vaccine for primary series	**Time between doses of primary series*/# of doses***	**Immunosuppressed: Time between doses of primary series*/# of doses***	**Time between most recent dose and any eligible booster dose**	**Approved COVID-19 mRNA vaccines for booster doses**
Infants and children aged 6 months to 4 years	Moderna/Spikevax™ (25mcg) Or Pfizer/Comirnaty ™ (3mcg)	8 weeks *2 doses (Moderna)* *3 doses (Pfizer)*	4 to 8 weeks between each dose ***3 doses (Moderna)+*** *4 doses (Pfizer)*	Not eligible	Not eligible
Children aged 5 years *	**Pfizer/Comirnaty ™ (10mcg)** or Moderna/Spikevax™ (25mcg)	8 weeks *2 doses*	4 to 8 weeks between each dose *3 doses*	6 months	Pfizer/Comirnaty™ (10mcg) mRNA vaccine
Children aged 6 to 11 years *	**Pfizer/Comirnaty ™ (10mcg)** or Moderna/Spikevax™ (50mcg)	8 weeks *2 doses*	4 to 8 weeks between each dose *3 doses*	6 months	Pfizer/Comirnaty™ (10mcg) mRNA vaccine
Youth aged 12 to 17 years *	**Pfizer/Comirnaty ™ (30mcg)** or Moderna/Spikevax™ (100mcg)	8 weeks *2 doses*	4 to 8 weeks between each dose *3 doses*	6 months	***Pfizer/Comirnaty™ Bivalent*** vaccine ** or Pfizer/Comirnaty ™ (30mcg) or Moderna/Spikevax™ (50/100mcg)
Adults aged 18 to 29 years *	**Pfizer/Comirnaty ™ (30mcg)** or Moderna/Spikevax™ (50mcg/100mcg)	8 weeks *2 doses*	4 to 8 weeks between each dose *3 doses*	6 months	***Pfizer/Comirnaty™ Bivalent*** vaccine ***Moderna/Spikevax™ Bivalent*** vaccine** or Pfizer/Comirnaty ™ (30mcg) or Moderna/Spikevax™ (50mcg/100mcg)
Adults aged 30 years and older	Pfizer/Comirnaty ™ (30mcg) or Moderna/Spikevax™ (50mcg/100mcg)	8 weeks *2 doses*	4 to 8 weeks between each dose *3 doses*	6 months	***Pfizer/Comirnaty™ Bivalent*** vaccine ***Moderna/Spikevax™ Bivalent*** vaccine ** or Pfizer/Comirnaty ™ (30mcg) or Moderna/Spikevax™ (50mcg/100mcg)

+ Moderna/Spikevax™ is the recommended mRNA vaccine for Immunocompromised Infants and children 6 months to 4 years.

*** Pfizer/Comirnaty ™** is the recommended mRNA vaccine for the primary series for individuals 5 to 29 years.

****A bivalent Omicron-containing mRNA COVID-19 vaccine*** is the preferred booster product (there is no evidence that one bivalent vaccine is more effective than the other).

NOTE: Moderna/Spikevax™ **100mcg** is offered as a primary series to individuals age 12 and older and as a booster dose to individuals at increased risk of severe illness. Moderna/Spikevax™ **50mcg** is offered as a booster dose to individuals age 12 and older who are not at risk of severe illness.

Table 4 Storage and handling of Manitoba COVID-19 approved vaccines (Pfizer)

COVID-19 Vaccine Product and Approved Age Indication	Ultra Low Freezer Storage Time (-90ºC to -60ºC)‡	Freezer Storage Time (-25ºC to -15ºC)	Refrigerated Storage Time Before Dilution or Puncture (+2ºC to +8ºC)^	Room Temperature Time Before Dilution or Puncture (+8ºC to +25°C)	After Dilution or Puncture Time (+2ºC to +25ºC)
PFIZER					
Pfizer Pediatric (Comirnaty™) 5-11 years of age **Orange Cap**	12 months from the date of manufacture	Do not store at this temperature	10 weeks within the 12-month shelf life. Document 10-week expiry on carton.	12 hours prior to dilution	Must be used within 12 hours after dilution
Pfizer (Comirnaty™) 12 years of age and older **Purple Cap**	Until expiry date printed on label	2 weeks	1 month prior to dilution	2 hours prior to dilution (including thaw time)	Must be used within 6 hours after dilution
Pfizer (Comirnaty™) 6 months to 5 years **Maroon Cap**	12 months from the date of manufacture	Do not store at this temperature	10 weeks within the 12-month shelf life. Document 10-week expiry on carton.	12 hours prior to dilution	Must be used within 12 hours after dilution
Pfizer (Comirnaty™) *Bivalent* ≥12 years **Grey Cap**	12 months from the date of manufacture	Do not store at this temperature	10 weeks within the 12-month shelf life. Document 10-week expiry on carton.	12 hours prior to puncture. DO NOT DILUTE	Must be used within 12 hours after puncture. DO NOT DILUTE

Note: Most vaccines are distributed to providers at +2ºC to 8ºC (refrigerated temperature). **Thawed or partially thawed vaccines cannot be refrozen.**

- During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.
- Product should be marked with applicable expiry dates based on time in refrigerator and time after puncture to avoid administration errors.

Please refer to the product monographs for all storage and handling guidelines

- Vaccine that is expired or cannot be used if it has reached past the identified timelines are to be removed from storage, deducted from any inventory (if applicable) and returned to MDA for proper disposal following Manitoba's Return Policy and Process (https://www.gov.mb.ca/health/publichealth/cdc/div/docs/vbrpp.pdf
- Regardless of storage condition, vaccine should not be used after 12 months from the date of manufacture printed on the vial and cartons.

Table 5 Bivalent Considerations

COVID-19 Bivalent (Omicron) booster vaccine considerations:

There are two COVID-19 mRNA bivalent Omicron-containing products available in Manitoba. Assisting the client to make an informed decision about which product is best for them can be a complex task. Please use the information provided below to help guide the informed consent process.

Key considerations:

- The bivalent vaccines contain two different mRNA components, based on the original strain and the omicron strain of SARS-CoV-2 virus.
- The bivalent vaccines help boost the immune system, creating more antibodies to fight COVID-19. Research shows they give strong protection from severe illness or hospitalization and lower the risk of symptoms and long-term complications caused by COVID-19 infection.
- Both bivalent products have been authorized for use as a booster dose and are not to be used for a primary series.
- The side effects of the bivalent are similar to the monovalent mRNA vaccines and usually mild.

Eligibility considerations:

- **The bivalent Omicron-containing mRNA vaccines are the preferred booster products for those that are eligible to receive them.**
- NACI recommends that all individuals 12 years of age older and especially those who are at increased risk of severe illness, may be offered a fall COVID-19 booster dose, regardless of the number of booster doses previously received. *NACI recommendations can be viewed here.*
- Everyone 12 years of age and older, who has completed their primary series should be offered a bivalent booster.
- Individuals who already received an mRNA COVID-19 vaccine as a fall booster dose will not be eligible for additional COVID-19 booster doses at this time. This includes the original monovalent vaccine and either bivalent vaccine.

There is no evidence indicating one bivalent vaccine is more effective than the other.

	12 to 17 years	≥ 18 years	Intervals	**Additional considerations:**
Pfizer (Comirnaty™) *Bivalent* ≥12 years	✓	✓	Recommended Interval: 6 months Minimum Interval: 3 months The vaccine intervals are more important than which product the client receives. Those at higher risk should be immunized as early as possible.	• Providers must ensure that the appropriate vaccine is available when offering clinics that include the 12 to 17 age cohort, as they are only eligible to received the Pfizer/Comirnaty™ bivalent product. • If there is no preference stated by the client, consider offering the product that will result in the least wastage. • If the client has a strong preference for one product, do not deny access to it (if they meet the eligibility criteria). Do not engage in a difficult conversation with the client. • If necessary, refer the client to their health care provider for a more comprehensive assessment and conversation about which bivalent product is right for them.
Moderna (Spikevax™) *Bivalent* ≥18 years	✗	✓		