

## QRG template

COVID 19 Vaccine Implementation Task Force	
<b>Clinic Reference</b>	
Title:	<b>COVID-19 Vaccine Pfizer COMIRNATY™ Quick Reference for Immunizers</b>
Area:	<b>Reference for Immunizers</b>
Effective Date:	January 15, 2021 ( <a href="#">Adult formulation</a> ), November 25, 2021 ( <a href="#">Pediatric formulation</a> )
Revised Date:	September, 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](https://www.gov.mb.ca/asset_library/en/covidvaccine/pfizer-biontech-pm.pdf)

#### **Eligibility Criteria:**

Please refer to [Province of Manitoba | Eligibility Criteria \(gov.mb.ca\)](#) for the most up to date information on booster dose eligibility 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: Third dose recommendations: immunocompromised

Table 2: Third dose recommendations: non-Health Canada approved

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

Table 4: Storage and Handling of Manitoba approved COVID-19 vaccines

Product Information	Approved immunization intervals	Presentation	Clinic Setting Considerations	Administration
<b>5 years to ≤ 11 years of age</b>				
<p><b>Primary series:</b> Individuals 5 years to ≤11 years of age: 2 dose regimen of 0.2mL (10 mcg)</p> <p><i>Note: 3<sup>rd</sup> dose may be recommended for some individuals. See table 2</i></p> <p><b>Boosters*:</b> Individuals 6 to 11 years of age: One dose: 0.2ml (10mcg)</p>	<p><b>Primary series intervals</b> <b>Recommended Interval:</b> 8 weeks *</p> <p><b>Authorized Interval:</b> 21 days</p> <p><b>Minimum Interval:</b> 19 days</p> <p><b>Recommended interval for children living in a First Nation community:</b> 21 days</p> <p><b>Booster dose intervals:</b> <b>Recommended Interval:</b> 6 months</p> <p><b>Minimum Interval:</b> *3 months</p>	<p><b>Cap: Orange</b></p> <p><b>Vial volume:</b> 1.3 ml (multidose vial) <b>Requires dilution</b></p> <p>After dilution, one vial contains 10 doses of 0.2 ml. <b>Dose:</b> 10 mcg (0.2ml)</p> <p><b>Inspect vials:</b> After dilution, the vaccine will be a white to off-white suspension. Inspect vials to confirm there are no particulates and no discoloration is observed.</p>	<p><b>Thaw time*:</b> <u>2° to 8°C (Refrigerator):</u> up to 4 hours/carton. <u>15° to 25° C (Room temperature):</u> 30 min</p> <p>Let stand at room temperature 30 min prior to dilution.</p> <p><b>Discard time:</b> Undiluted: 12 hours at room temperature.</p> <p>Once the vial has been diluted/punctured, refrigerate or store at room temperature for maximum 12 hrs, then discard.</p> <p>Thawed vials can be handled in room light conditions.</p>	<p><b>Administered:</b> Intramuscular</p> <p><b>Requires dilution</b> (0.9% Sodium Chloride Injection, USP <b>1.3 mL</b> required for dilution)</p> <p><b>Site:</b> deltoid</p> <p><b>Needle length:</b> 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.</p> <p>Low dead-volume syringes and/or needles should be used to extract 10 doses from a single vial.</p>
*Entire cohort eligible, but <b>recommended</b> for those at high risk of severe outcomes from COVID-19 infection.	*For those who identify as being at increased risk See Table 1 (Recommended mRNA schedule)		*Do not refreeze once thawed	Do not use <b>pediatric formulation</b> to prepare doses for individuals 12 years of age and older.
<b>Potential allergens:</b> 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
<b>≥ 12 years of age and older</b>				
<p><b>Primary Series:</b></p> <p>Individuals ≥ 12 years of age: 2 dose regimen of 0.3ml (30 mcg)</p> <p><i>Note: 3<sup>rd</sup> dose may be recommended for some individuals. See table 2</i></p> <p><b>Booster doses:</b></p> <p>Individuals ≥ 12 years of age: Dose: 0.3ml (30 mcg)</p>	<p><b>Primary series Intervals</b></p> <p><b>Recommended Interval:</b> 8 weeks *</p> <p><b>Authorized Interval:</b> 21 days</p> <p><b>Minimum Interval:</b> 19 days</p> <p><b>Booster dose intervals:</b></p> <p><b>Recommended Interval:</b> 6 months</p> <p><b>Minimum Interval:</b> *3 months</p>	<p><b>Cap: Purple</b></p> <p><b>Vial volume:</b> 0.45 ml (multidose vial)</p> <p><b>Requires dilution</b></p> <p>After dilution, one vial contains 6 doses of 0.3ml</p> <p><b>Dose:</b> 30 mcg (0.3ml)</p> <p><b>Inspect vials:</b> After dilution, the vaccine will be a white to off-white suspension. Inspect vials to confirm there are no particulates and no discoloration is observed.</p>	<p><b>Thaw time*:</b> <u>2° to 8°C (Refrigerator):</u> up to 3 hours/carton. <u>15° to 25° C (Room temperature):</u> 30 min</p> <p>Let stand at room temperature 30 min prior to dilution.</p> <p>Must be diluted within 2 hours of exposure to room temperature.</p> <p><b>Discard time:</b> Undiluted: 12 hours at room temperature.</p> <p>Once the vial has been diluted/punctured, refrigerate or store at room temperature for maximum 6 hrs, then discard.</p> <p>Thawed vials can be handled in room light conditions.</p>	<p><b>Administered:</b> Intramuscular</p> <p><b>Requires dilution</b> (0.9% Sodium Chloride Injection, USP <b>1.8 mL</b> required for dilution)</p> <p><b>Site:</b> deltoid</p> <p><b>Needle length:</b> 5/8" to 1 1/2" Clinical judgement should be used when selecting needle length for IM injections. Consider clients weight, age, gender and muscle mass.</p> <p>Low dead-volume syringes and/or needles should be used to extract 6 doses from a single vial.</p>
	*For those who identify as being at increased risk See Table 1 (Recommended mRNA schedule)		*Do not refreeze once thawed	
<b>Potential allergens:</b> Polyethylene glycol (PEG), Tromethamine (trometamol or Tris) Product is latex and preservative free				

### Recommendations on COVID-19 Immunization Doses for the Primary 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™ (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.
- 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.

**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 (Third dose recommendations, immunocompromised)**

Third dose recommendations for those moderately to severely immunocompromised			
Cohort	Product	Dose	Recommended interval
5 to 11 years	Orange cap	10 mcg (0.2ml)	≥ 28 days after their second dose. Considered part of the primary series.
≥ 12 years	Purple cap	30 mcg (0.3ml)	≥ 28 days after their second dose. Considered part of the primary series.

**Table 2 (Third dose recommendations, non-Health Canada approved)**

Third dose recommendations for individuals with 1 or 2 non-Health Canada approved vaccines				Manitoba Health accepted primary series combinations
5 to 11 years	Orange cap	10mcg (0.2ml)	≥ 28 day interval after last dose to complete their primary series.	<ul style="list-style-type: none"> <li>• Two mRNA vaccines (Pfizer or Moderna)</li> <li>• Two AstraZeneca vaccines</li> <li>• AstraZeneca and one dose of an mRNA vaccine (Pfizer or Moderna)</li> <li>• One dose of Janssen</li> <li>• Three non-Health Canada Approved vaccines</li> <li>• One or two non-Health Canada Approved Vaccines and one dose of an mRNA Vaccine (Pfizer or Moderna)</li> <li>• For moderately to severely immunocompromised                             <ul style="list-style-type: none"> <li>○ Three doses (any combination of AstraZeneca, Pfizer and/or Moderna)</li> </ul> </li> </ul>
≥ 12 years	Purple cap	30 mcg (0.3ml)	≥ 28 day interval after last dose to complete their primary series.	

**Table 3 (Manitoba Health recommended mRNA immunization schedule based on age)**






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

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



^ Pfizer/Comirnaty™ is the only vaccine approved for booster dose in this age group.

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**

COVID-19 Vaccine Product and Approved Age Indication	Ultra Low Freezer Storage Time (-90°C to -60°C)‡	Freezer Storage Time (-25°C to -15°C)	Refrigerated Storage Time Before Dilution or Puncture (+2°C to +8°C)^	Room Temperature Time Before Dilution or Puncture (+8°C to +25°C)	After Dilution or Puncture Time (+2°C to +25°C)
<b>MODERNA</b>					
<b>Moderna (Spikevax™)</b>  6 years of age and older <b>Red Cap</b>	Do not store at this temperature	Until expiry date on vial or identified extended expiry date: <a href="https://modernacovid19global.com/ca/health-product-risk-11jan2022-en.pdf">https://modernacovid19global.com/ca/health-product-risk-11jan2022-en.pdf</a>	30 days	24 hours No dilution required	Must be used within 24 hours after first puncture
<b>Moderna (Spikevax™)</b>  6 months to 5 years <b>Royal Blue Cap</b>	Do not store at this temperature	Until expiry date on vial or identified extended expiry date. Stored in the original carton to protect from light	30 days	24 hours No dilution required	Must be used within 24 hours after first puncture
<b>Moderna (Spikevax™)</b>  Bivalent <b>Blue Cap/Green Label</b>	Do not store at this temperature	Store 9 months at this temperature	30 days	24 hours	19 hours after first puncture
<b>PFIZER</b>					
<b>Pfizer (Comirnaty™)</b>  5-11 years of age <b>Orange Cap</b>	12 months from the date of manufacture	Do not store at this temperature	10 weeks	12 hours prior to dilution	Must be used within 12 hours after dilution
<b>Pfizer (Comirnaty™)</b>  12 years of age and older <b>Purple Cap</b>	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

**Table 4 Storage and handling of Manitoba COVID-19 approved vaccines cont.**

Non-mRNA vaccines					
<b>Novavax (Nuvaxovid™)</b>  18 years of age and older  <b>Blue Cap</b>	Do not store at this temperature	Do not store at this temperature	Maximum of 9 months, not exceeding the expiry on the vial/label	Should remain stored at 2°C to 8°C before first puncture  No dilution required	Must be used within 6 hours after first needle puncture
<b>Janssen</b>  18 years of age and older  <b>Blue Cap</b>	Do not store at this temperature	Until expiry date printed on the vial and carton	11 months, not exceeding the expiry date on the vial/label	12 hours  No dilution required	After first puncture it must be used within: <ul style="list-style-type: none"> <li>• 6 hours if stored between +2°C to +8°C</li> <li>• 3 hours if stored between +9°C to +25°C</li> </ul>

‡ Expiry dates may be extended. Monitor for Health Canada announcements that may affect the expiry dates.  
 ^ Length of time to be stored in refrigerator before puncture or dilution until being discarded, unless the manufacturer's expiry date occurs before that time.

**Note:** Most vaccines are distributed to providers at +2°C to 8°C (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>