Manitoba Health

Vaccine Clinic Resource for Immunizers

Title:	**COVID-19 Vaccine Pfizer COMIRNATY™ Quick Reference Guide**
Formulations	**Monovalent**- Infant, Pediatric and Adult **Bivalent**- Pediatric and Adult
Effective Date:	October 7, 2022 (Bivalent formulation), October 21, 2022 (Infant formulation), December 1, 2022 (12+ monovalent formulation) December 9 (Pediatric bivalent)
Approver:	Final

Disclaimer: *this Quick Reference is not intended to replace other product specific vaccine references. The document is intended as 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.*

COVID-19 Vaccine Resources:

Product Monographs: Province of Manitoba | Resources for Health Care Providers- product monographs (gov.mb.ca)
Storage and Handling: storage-handling-chart.pdf (gov.mb.ca)

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

Manitoba COVID-19 mRNA Immunization Schedule:
Province of Manitoba | COVID-19 mRNA Immunization Schedule (gov.mb.ca)

Canadian Immunization Guide:
For additional guidance on special populations: COVID-19 vaccine: Canadian Immunization Guide- Vaccination of Specific Populations - Canada.ca
For information on allergies/contraindications/precautions: COVID-19 vaccine: Canadian Immunization Guide -Contraindications and Precautions - Canada.ca

Fact Sheets:
For information on vaccine risk and intended benefits, refer to the Province of Manitoba | Resources for the Public COVID-19 Fact Sheets (gov.mb.ca)

Summary of document tables:
Table 1: Recommendations on COVID-19 Immunization for the Primary Series
Table 2: Recommendations on COVID-19 Immunization Booster doses
Table 3: Additional Primary Series Dose Recommendations: Immunocompromised (moderately to severely)
Table 4: Additional Dose Recommendations: non-Health Canada Approved COVID-19 Vaccines

Manitoba Health

Monovalent	Pfizer COMIRNATY™ Infant formulation: 6 months to less than 5 years of age

<table>
<tr><th colspan="2">Product Recommendations</th><th>Approved Intervals</th><th>Presentation</th><th>Storage and Handling</th><th>Administration</th></tr>
<tr><td>Primary Series</td><td>Regimen: 3 dose series

Dose: 0.2ml (3 mcg)

NACI recommends children 6 months to less than 5 years 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).

An additional dose is required for those moderately to severely immunocompromised (See Table 3)

• 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.</td><td>Recommended Interval:
8 weeks between doses

Authorized Interval:
Between dose 1 and 2: 21 days

Minimum Interval:
Between dose 1 and 2: 19 days

Between dose 2 and 3: 52 days</td><td rowspan="2">Maroon cap and label

Vial volume: 0.4 ml (multidose vial)

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

After dilution, one vial contains 10 doses of 0.2 ml.

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.

Low dead-volume syringes and/or needles should be used to extract 10 doses from a single vial.</td><td rowspan="2">Thaw time:
<u>2◦ to 8◦C (Refrigerator):</u>
up to 2 hours/carton.
<u>15◦ to 25◦ C (Room temperature):</u>
30 min

Discard time:
<u>Undiluted:</u>
12 hours at room temperature.

<u>Diluted:</u>
Refrigerate or store at room temperature for maximum 12 hours.

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

Do not refreeze once thawed</td><td rowspan="2">Route: Intramuscular

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><tr><td rowspan="2">Young children (12 months to 3 years)</td><td>Deltoid</td><td>5/8” to 1”</td></tr><tr><td>Anterolateral thigh</td><td>At least 1”</td></tr><tr><td>Children 3+</td><td>Deltoid</td><td>5/8” to 1”</td></tr></table>
Note: Concurrent administration of COVID-19 and non-COVID-19 vaccines (including live and non-live vaccines) is authorized for all age cohorts.</td></tr>
<tr><td>Booster Dose</td><td>Not approved for this age group</td><td>Not applicable</td></tr>
<tr><td colspan="6">Product is latex and preservative free
Potential allergens: Polyethylene glycol (PEG), Tromethamine (trometamol or Tris)
Individuals who have a known allergy to Tromethamine (trometamol or Tris), should not be immunized with COVID-19 vaccines containing Tromethamine (trometamol or Tris).
Individuals who report an allergy to contrast material (CT dye), including gadolinium, can be immunized with vaccines containing Tromethamine (trometamol or Tris). They should be observed for 30 minutes post immunization.</td></tr>
<tr><td colspan="6"><u>NOTE</u>: 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).</td></tr>
</table>

Manitoba Health

Monovalent	Pfizer COMIRNATY™ Pediatric formulation: 5 years to less than 12 years of age

Product Recommendations		Approved Intervals	Presentation	Storage and Handling	Administration
Primary Series	**Regimen**: 2 dose series **Dose**: 0.2mL (10 mcg) Pfizer is the recommended mRNA vaccine for the primary series for individuals 5 to less than 30 years. *An additional dose is required for those moderately to severely immunocompromised (See **Table 3**)*	**Recommended Interval:** 8 weeks **Authorized Interval:** 21 days **Minimum Interval:** 19 days	Orange cap and label **Vial volume:** 1.3 ml (multidose vial) **Requires dilution** (0.9% Sodium Chloride Injection, USP **1.3 mL** required for dilution) After dilution, one vial contains 10 doses of 0.2 ml. **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. *Low dead-volume syringes and/or needles should be used to extract 10 doses from a single vial.*	**Thaw time:** 2◦ to 8◦C (Refrigerator): up to 4 hours/carton. 15◦ to 25◦ C (Room temperature): 30 min **Discard time:** Undiluted: 12 hours at room temperature. Diluted: Refrigerate or store at room temperature for maximum 12 hrs. Once drawn up, administer immediately and no later than 12 hours after dilution. **Do not refreeze once thawed**	**Route:** Intramuscular AGE / SITE / NEEDLE LENGTH 5 years and older / Deltoid / 1” **Optional needle length:** 5/8” to 1 ½” Clinical judgement should be used when selecting needle length for IM injections. Consider clients weight, age and muscle mass. **Optional site:** Anterolateral thigh can be used if deltoid site is not an available site (ie: multiple injections).
Booster Dose	**Regimen**: 1 dose **Dose**: 0.2mL (10 mcg) The pediatric Pfizer bivalent formulation is recommended for the booster dose in this age group and should be used as the default booster option unless the monovalent is specifically requested. Entire cohort eligible, but recommended for those at high risk of severe outcomes from COVID-19 infection. **Recommendations on COVID-19 Immunization Booster Doses**: for further information about booster dose recommendations and administration. (See **Table 2**)	**Recommended Interval**: 6 months **Minimum Interval**: 6 months			

Product is latex and preservative free
Potential allergens: Polyethylene glycol (PEG), Tromethamine (trometamol or Tris)
*Individuals who have a known allergy to Tromethamine (trometamol or Tris), should **not** be immunized with COVID-19 vaccines containing Tromethamine (trometamol or Tris).*
Individuals who report an allergy to contrast material (CT dye), including gadolinium, can be immunized with vaccines containing Tromethamine (trometamol or Tris). They should be observed for 30 minutes post immunization.

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).

Manitoba Health

<table>
<tr><th colspan="2">Monovalent</th><th colspan="5">Pfizer COMIRNATY™: 12 years of age and older</th></tr>
<tr><th colspan="2">Product Recommendations</th><th>Approved Intervals</th><th>Presentation</th><th>Storage and Handling</th><th>Administration</th></tr>
<tr><td>Primary Series</td><td>Regimen: 2 dose series

Dose: 0.3ml (30 mcg)

Pfizer is the recommended mRNA vaccine for the primary series for individuals 5 to less than 30 years

An additional dose is required for those moderately to severely immunocompromised (See Table 3)</td><td>Recommended Interval:
8 weeks

Authorized Interval:
21 days

Minimum Interval:
19 days</td><td rowspan="2">Grey cap and label

Vial volume: 2.25 ml
(6 doses of 0.3ml in a multidose vial)

Does NOT require dilution

Inspect vials to confirm there are no particulates and no discolouration is observed.

Low dead-volume syringes and/or needles should be used to extract 6 doses from a single vial.</td><td rowspan="2">Thaw time:
<u>2◦ to 8◦C (Refrigerator):</u>
up to 4 hours/carton.
<u>15◦ to 25◦ C (Room temperature):</u>
30 min

Discard time:
12 hours at room temperature after first puncture.

Do not refreeze once thawed</td><td rowspan="2">Route: Intramuscular

<table><tr><th>AGE</th><th>SITE</th><th>NEEDLE LENGTH</th></tr><tr><td>5 years and older</td><td>Deltoid</td><td>1”</td></tr></table>
Optional needle length:
5/8” to 1 ½”
Clinical judgement should be used when selecting needle length for IM injections. Consider clients weight, age and muscle mass.

Optional site:
Anterolateral thigh can be used if deltoid site is not an available site (ie: multiple injections).</td></tr>
<tr><td>Booster Dose</td><td>Regimen: 1 or 2 doses*

Dose: 0.3ml (30 mcg)

*Recommendations on COVID-19 Immunization Booster Doses: for further information about booster dose recommendations including eligibility for an additional dose. (See Table 2)</td><td>Recommended Interval: 6 months

Minimum Interval:
6 months</td></tr>
<tr><td colspan="6">Product is latex and preservative free
Potential allergens: Polyethylene glycol (PEG), Tromethamine (trometamol or Tris)
Individuals who have a known allergy to Tromethamine (trometamol or Tris), should not be immunized with COVID-19 vaccines containing Tromethamine (trometamol or Tris).
Individuals who report an allergy to contrast material (CT dye), including gadolinium, can be immunized with vaccines containing Trometha mine (trometamol or Tris). They should be observed for 30 minutes post immunization.</td></tr>
<tr><td colspan="6"><u>NOTE</u>: 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).</td></tr>
</table>

Manitoba Health

Bivalent	Pfizer COMIRNATY™ Pediatric formulation: 5 years to less than 12 years of age

Product Recommendations		Approved Intervals	Presentation	Storage and Handling	Administration
Primary Series	Not for use as primary series	Not applicable	**Orange cap and label** *Label states "Original and Omicron BA.4/5."* **Vial volume:** 1.3 ml (multidose vial) **Requires dilution (**0.9% Sodium Chloride Injection, USP **1.3 mL** required for dilution) After dilution, one vial contains 10 doses of 0.2 ml. **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. *Low dead-volume syringes and/or needles should be used to extract 10 doses from a single vial.*	**Thaw time:** 2◦ to 8◦C (Refrigerator): up to 4 hours/carton. 15◦ to 25◦ C (Room temperature): 30 min **Discard time:** Undiluted: 12 hours at room temperature. Diluted: Refrigerate or store at room temperature for maximum 12 hrs. Once drawn up, administer immediately and no later than 12 hours after dilution. **Do not refreeze once thawed**	**Route:** Intramuscular AGE: 5 years and older; SITE: Deltoid; NEEDLE LENGTH: 1" **Optional needle length:** 5/8" to 1 ½" Clinical judgement should be used when selecting needle length for IM injections. Consider clients weight, age and muscle mass. **Optional site:** Anterolateral thigh can be used if deltoid site is not an available site (ie: multiple injections)
Booster Dose	**Regimen**: 1 dose **Dose**: 0.2ml (10 mcg) Entire cohort eligible, but recommended for those at high risk of severe outcomes from COVID-19 infection. **Recommendations on COVID-19 Immunization Booster Doses**: for further information about booster dose recommendations and administration. (See **Table 2**)	**Recommended Interval**: 6 months **Minimum Interval**: 6 months			

Product is latex and preservative free
Potential allergens: Polyethylene glycol (PEG), Tromethamine (trometamol or Tris)
*Individuals who have a known allergy to Tromethamine (trometamol or Tris), should **not** be immunized with COVID-19 vaccines containing Tromethamine (trometamol or Tris).*
Individuals who report an allergy to contrast material (CT dye), including gadolinium, can be immunized with vaccines containing Tromethamine (trometamol or Tris). They should be observed for 30 minutes post immunization.

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).

Manitoba Health

<table>
<tr><th colspan="2">Bivalent</th><th colspan="4">Pfizer COMIRNATY™: 12 years of age and older</th></tr>
<tr><th colspan="2">Product Recommendations</th><th>Approved Intervals</th><th>Presentation</th><th>Storage and Handling</th><th>Administration</th></tr>
<tr><td>Primary Series</td><td>Not for use as primary series</td><td>Not applicable</td><td rowspan="2">Grey cap and Label
Label states “Original and Omicron BA.4/5.”

Vial volume: 2.25 ml (6 doses in a multidose vial)

Does NOT require dilution

Low dead-volume syringes and/or needles should be used to extract 6 doses from a single vial.

Inspect vials to confirm there are no particulates and no discolouration is observed.</td><td rowspan="2">Thaw time:
<u>2◦ to 8◦C (Refrigerator):</u>
up to 6 hours/carton.
<u>15◦ to 25◦ C (Room temperature):</u>
30 min

Discard time:
12 hours at room temperature after first puncture.

Thawed vials and filled syringes can be handled in room light conditions

Do not refreeze once thawed</td><td rowspan="2">Route: Intramuscular

<table><tr><th>AGE</th><th>SITE</th><th>NEEDLE LENGTH</th></tr><tr><td>5 years and older</td><td>Deltoid</td><td>1”</td></tr></table>
Optional needle length:
5/8” to 1 ½”
Clinical judgement should be used when selecting needle length for IM injections. Consider clients weight, age and muscle mass.

Optional site:
Anterolateral thigh can be used if deltoid site is not an available site (ie: multiple injections)</td></tr>
<tr><td>Booster Dose</td><td>Regimen: 1 or 2 doses*

Dose: 0.3ml (30mcg)

* Recommendations on COVID-19 Immunization Booster Doses: for further information about booster dose recommendations including eligibility for an additional dose (See Table 2)</td><td>Recommended Interval: 6 months

Minimum Interval: 6months</td></tr>
<tr><td colspan="6">Product is latex and preservative free
Potential allergens: Polyethylene glycol (PEG), Tromethamine (trometamol or Tris)
Individuals who have a known allergy to Tromethamine (trometamol or Tris), should not be immunized with COVID-19 vaccines containing Tromethamine (trometamol or Tris).
Individuals who report an allergy to contrast material (CT dye), including gadolinium, can be immunized with vaccines containing Tromethamine (trometamol or Tris). They should be observed for 30 minutes post immunization.</td></tr>
<tr><td colspan="6"><u>NOTE</u>: 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).</td></tr>
</table>

Manitoba Health

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

TABLE 1: Recommendations on COVID-19 Immunization for the Primary Series:

- Everyone 6 months of age and older are eligible to receive a primary series.
- The date the first vaccine is 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.
- Children who will turn from 4 to 5 years of age between 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.
- Individuals age 5 to less than 30 years are recommended to receive Pfizer for their primary series to minimize the rare potential risk of myocarditis/pericarditis. (Note: this risk is unknown in the 5-11-year age group, but has been documented in the 12-30-year age group).
- Preferably, a person who received a first dose of an mRNA vaccine (Moderna or Pfizer) 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.
    - 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 (Moderna or Pfizer).
    - 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 an additional dose in the primary series (see Table 3). 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.
- Bivalent products have been authorized for use as a booster dose and are not to be used for a primary series.

TABLE 2: Recommendations on COVID-19 Immunization Booster doses:

- Everyone 5 years of age and older, who has completed their primary series should be offered a fall 2022 booster dose.
- ***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). The monovalent products can be administered as a booster dose to individuals who request it.
- The recommended interval for booster doses is 6 months between the most recent dose (primary series, previous booster dose) and a recommended booster as vaccine effectiveness increases with a longer duration between doses.
- 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.
- **The following individuals are eligible to receive a spring booster dose in 2023: Individuals 65 years and older; Residents of Long-Term Care (LTC), Assisted Living (ASL) or supportive housing facilities; Adults 18 years and older who are moderately to severely immunocompromised; and Indigenous individuals 45 years and older regardless of place of residence.**
- For individuals not covered in the spring 2023 booster dose criteria listed above, health care providers may offer a bivalent vaccine to individuals who are at high risk of severe infection and have previously received a monovalent booster during the fall 2022 campaign. This requires a prescription if given outside a physician's office and must be given a minimum of 6 months after the last dose.
- It is expected that there will be a fall booster program in 2023. **It is important to take into consideration that receiving a spring 2023 booster could affect the timing of eligibility for a fall 2023 booster dose as a 6-month interval between doses is anticipated.**

Manitoba Health

TABLE 3: Additional Primary Series Dose Recommendations: Moderately to Severely Immunocompromised[1]			
Cohort	**Product**	**Dose**	**Recommended interval**
6 months to less than 5 years	***Moderna (25mcg) preferred**** Blue cap	***3 dose series***	At least 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 less than 12 years	Pfizer (10mcg) **Orange cap**	3 dose series	At least 28 days after their second dose. Considered part of the primary series.
12 years and older	Pfizer (30mcg) **Grey cap**	3 dose series	At least 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).

Moderna (**100mcg)** may be offered (based on clinical judgement) as a primary series to individuals age 12 and older and as a booster dose to individuals at increased risk of severe illness.

NOTE: For eligible individuals 18 years and older unwilling or unable to receive an mRNA vaccine, Novavax/Nuvaxovid can be used for the additional dose.

[1]**For the purposes of COVID-19 vaccine recommendations, the following individuals are considered moderately to severely immunocompromised due to a medical condition and/or treatment:**

- are receiving active chemotherapy (or immunotherapy) for cancer;
- have received a solid organ transplant and are currently receiving chemotherapy or other immunosuppressive therapy;
- were born with moderate or severe dysfunction of their immune system;
- are living with untreated or advanced HIV-AIDS; or
- are taking certain medications that severely affect the immune system.

The following people should talk to their doctor to see whether they are considered to be immunocompromised:

- receiving hemodialysis or peritoneal dialysis;
- are on the list to receive a solid organ transplant; or
- have a ventricular assist device (VAD).

TABLE 4: Additional Dose Recommendations for Individuals who received 1 or 2 non-Health Canada Approved COVID-19 Vaccines			
Cohort	Product	Dose	Recommended Interval
6 months to less than 5 years	***Moderna (25mcg) preferred***	Blue cap ***Administer one additional dose***	At least 28 days after their last dose to complete their primary series.
	Pfizer (3mcg) **Maroon cap**	Administer 2 additional doses	
5 to less than 12 years	Pfizer (10mcg) **Orange cap**	Administer one additional dose	At least 28 days after their last dose to complete their primary series.
12 years and older	Pfizer (30mcg) **Grey cap**	Administer one additional dose	At least 28 days after their last dose to complete their primary series.

Manitoba Health accepted primary series combinations:

- 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 less than 5 years
  - 3 doses of a non-Health Canada approved vaccine.