

# COVID-19 Vaccine – mRNA


## Pfizer-BioNTech Original (Non-Bivalent) – Ultra frozen Vaccine (Comirnaty)

Revision Date: April 21, 2023

### Rationale for Update:

- Removed references to Moderna Spikevax Original for primary series as vaccine is no longer available in Alberta.

*This policy is evergreen and will be updated as new information becomes available.*

Please consult the Product Monograph <sup>1</sup> for further information about the vaccine.	
<b>COVID-19 mRNA Original (Non-Bivalent) Vaccine (Ultra Frozen Vaccine)</b>	
Adult Formulation 12 years of age and older – Dilution NOT Required	
	
<b>Manufacturer</b>	Pfizer-BioNTech
<b>Licensed use</b>	Primary series: 12 years of age and older A booster dose: 16 years of age and older at least 6 calendar months after completion of the primary series
<b>Composition/Platform Vaccine Type</b>	<ul style="list-style-type: none"><li>mRNA (new technology) – nucleoside-modified messenger RNA (modRNA) encoding the viral spike glycoprotein (S)</li><li>Formulated in lipid nanoparticles (LNPs)</li><li>No adjuvants or preservatives</li></ul>
<b>Indications for use of vaccine</b>	12 years of age and older. <b>Note:</b> <ul style="list-style-type: none"><li>A complete series with an mRNA COVID-19 vaccine is preferentially recommended for individuals in the authorized age group without contraindications to the vaccine.</li><li>Due to the lower risk of myocarditis with the Pfizer-BioNTech COVID-19 vaccine compared to Moderna COVID-19 vaccine, National Advisory Committee on Immunization (NACI) preferentially recommends Pfizer-BioNTech COVID-19 original (non-bivalent) vaccine for individuals 5 to 29 years of age to start and/or complete their primary series.</li><li>The Pfizer-BioNTech Original (non-bivalent) COVID-19 vaccine is no longer available as a booster dose. The Pfizer-BioNTech Omicron-containing bivalent mRNA COVID-19 vaccine is the preferred booster product, and, therefore, is the only mRNA COVID-19 booster currently offered.</li></ul>
<b>Dose</b>	0.3 mL (30 mcg)
<b>Route</b>	<ul style="list-style-type: none"><li>Intramuscular injection in the deltoid muscle.</li></ul>

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<p><b>Schedule</b></p> <p><i>See below Schedule for Individuals with certain Immunocompromising conditions</i></p>	<p>(Vastus lateralis can be used as an alternate if required.)</p> <p><b>Primary series 2 doses<sup>1</sup></b></p> <ul style="list-style-type: none"> <li>❖ Dose 1: day 0</li> <li>❖ Dose 2: 8 weeks after dose 1</li> </ul> <p>Optimal spacing between dose 1 and dose 2 is 8 weeks<sup>2</sup></p> <ul style="list-style-type: none"> <li>• Data shows that extending the interval between the first and second dose by several weeks leads to even higher immune responses and better protection against COVID-19 infection that is also expected to last longer.</li> <li>• As such protection provided by COVID-19 vaccines may be further improved when the interval between the first and second doses are extended.</li> <li>• Emerging Canadian safety surveillance data suggest an extended interval between the first and second dose may reduce the risk of myocarditis/pericarditis following the second dose of an mRNA COVID-19 vaccine.</li> <li>• When choosing to use a longer dose interval, the risk of infection between doses needs to be considered based on the extent of local transmission, and person's risk of exposure to the virus. Individuals can consult with their health care provider if they have questions about when to get the second dose.</li> </ul> <p><b>Note:</b></p> <ul style="list-style-type: none"> <li>• A shortened interval between dose 1 and dose 2 of 21 days as per product monograph may be considered in certain situations: required for travel, work requirement, increased risk for infection based on local transmission and the degree of individual risk of exposure.</li> <li>• Minimum spacing between dose 1 and 2 is 19 days and is required for a dose to be considered valid.</li> <li>• In general, regardless of the time between doses, interruption of a vaccine series does not require restarting the series.<sup>2</sup></li> </ul>
<p><b>Schedule for Individuals with certain Immunocompromising conditions</b></p>	<p><b>Primary series 3 doses<sup>1</sup></b></p> <ul style="list-style-type: none"> <li>❖ Dose 1: day 0</li> <li>❖ Dose 2: 28 days after dose 1</li> <li>❖ Dose 3: 8 weeks after dose 2</li> </ul> <ul style="list-style-type: none"> <li>• It is recommended that individuals with certain immunocompromising conditions be immunized with a primary series of three doses of an mRNA COVID-19 vaccine. This is to provide stronger protection for those who may have a suboptimal immune response to vaccines. An mRNA vaccine should be administered except in the event of contraindication or refusal.</li> <li>• It is recommended that the interval between dose 1 and dose 2 be 28 days and the interval between dose 2 and dose 3 be 8 weeks. <ul style="list-style-type: none"> <li>○ The interval between dose 2 and dose 3 is recommended to be 8 weeks because emerging evidence from the general population indicates that a longer interval will likely result in a better immune response and duration of protection.</li> <li>○ However, there is heterogeneity among those who are moderately to severely immunocompromised, and risks from COVID-19, as well as the likelihood of a reduced response to vaccines, will vary depending on the immunocompromising condition. Thus, a shortened interval no less than 28 days may be considered for those with increased risk of exposure and greater severity of immunodeficiency based on their clinician's recommendation.</li> </ul> </li> </ul>

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- Specific Immunocompromising conditions that make an individual eligible for a third dose:<sup>2</sup>
  - Solid organ transplant recipients — pre-transplant and post-transplant
  - Hematopoietic stem cell transplants recipients — pre-transplant and post-transplant while in immunosuppressed state (post-HSCT individuals are generally considered to be immunocompetent after 3 years as long as they are not on immunosuppressive drugs)
  - Individuals with malignant hematologic disorders and non-hematologic malignant solid tumors prior to receiving or receiving active treatment which includes chemotherapy, targeted therapies, and immunotherapy or having received previous COVID-19 vaccines while on active treatment (does not include individuals receiving solely hormonal therapy, radiation therapy or a surgical intervention).
  - Individuals with chronic kidney disease on peritoneal dialysis or hemodialysis.
  - Individuals receiving chimeric antigen receptor (CAR)-T-cell therapy.
  - Individuals on:
    - long term high-dose systemic steroid treatment (prednisone equivalent of  $\geq 2$  mg/kg/day or 20 mg/day if weight  $> 10$  kg, for  $\geq 14$  days), or
    - alkylating agents, or
    - Individuals on anti-B-cell therapies – including anti-CD19, anti-CD20, anti-CD22 and anti-CD52 monoclonal antibodies (such as rituximab, ocrelizumab, and ofatumumab), or
    - antimetabolites (e.g. methotrexate, azathioprine, mycophenolate), or
    - tumor-necrosis factor (TNF) inhibitors (e.g., adalimumab, certolizumab, etanercept, golimumab, infliximab), or
    - other agents that are significantly immunosuppressive at clinicians' discretion
  - HIV-infected individuals without viral suppression or those with acquired immunodeficiency syndrome (AIDS).
  - Individuals with moderate to severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome).

**Note:**

- Documentation of immunocompromising conditions is not required. Individuals who identify themselves as meeting at least one of the criteria above could be offered the 3 dose primary series.
- Immunization for immunocompromised individuals should occur at a time when the individual is most likely to mount an immune response. Physician consultation is recommended regarding the timing of immunization (initiation and interval) based on the individual's treatment and unique circumstances.
- Hematopoietic stem cell transplant (HSCT) recipients who received COVID-19 vaccine pre-transplant are eligible to restart their COVID-19 vaccine series beginning at least 3 months post-transplant. Consultation with their HSCT physician is not necessary as long as the initial clearance letter has been received to proceed with inactivated vaccines.
- CAR T-cell therapy recipients without a prior history of HSCT who received COVID-19 vaccine pre-CAR T-cell therapy are eligible to restart their COVID-19 vaccine series, beginning at least 3 months post-CAR T-cell therapy.

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	<p>Consultation with their physician is not necessary as long as a clearance letter has been received to proceed with inactivated vaccines.</p> <ul style="list-style-type: none"> <li>For HSCT recipients whose post-HSCT vaccine series were interrupted by CAR T-cell therapy, see the following HSCT guidance: <ul style="list-style-type: none"> <li><a href="#">Principles of Immunization in Hematopoietic Stem Cell Transplant Recipients and Solid Organ Transplant Recipients</a></li> <li><a href="#">Immunization for Adult HSCT Recipients</a></li> <li><a href="#">Immunization for Child HSCT Recipients</a></li> </ul> </li> </ul>		
<p><b>Interval between previous COVID-19 infection and COVID-19 immunization</b></p>	<p>For individuals with a history of COVID-19 infection the following guidance is provided on suggested intervals between infection and COVID-19 immunization.<sup>2</sup></p> <p><b>Note:</b></p> <ul style="list-style-type: none"> <li>These suggested intervals are based on immunological principles and expert opinion, and may change as evidence on COVID-19, variants of concern (VOCs), and COVID-19 vaccines emerge. When considering whether or not to administer vaccine doses following the suggested intervals outlined in this table, biological and social risk factors for exposure (e.g., local epidemiology, circulation of VOCs, living settings) and risk of severe disease should also be taken into account. These intervals are a guide and clinical discretion is advised. Individuals can be immunized at less than the recommended intervals from infection upon request.</li> <li>For individuals who have not had any previous doses, they may receive their first dose after acute symptoms of COVID-19 have resolved and they are no longer infectious, or they may follow these suggested intervals (with the exception of those with MIS-C who should wait at least 90 days).</li> </ul>		
	<p>Infection prior to initiation or completion of a primary COVID-19 immunization series</p>	<p>Individuals <b>without</b> certain immunocompromising conditions AND no history of multisystem inflammatory syndrome in children (MIS-C)</p>	<p>8 weeks after a positive test.</p>
		<p>Individuals <b>with</b> certain immunocompromising conditions (as listed above) AND no history of MIS-C</p>	<p>4 to 8 weeks after a positive test.</p>
		<p>History of MIS-C (regardless of immunocompromised status)</p>	<p>Receive the vaccine when clinical recovery has been achieved or at least 90 days since the onset of MIS-C, whichever is longer.</p>

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<p><b>Contraindications</b></p>	<ul style="list-style-type: none"> <li>• Known severe hypersensitivity to any component of the vaccine.<sup>1</sup></li> <li>• Two non-medicinal ingredients in the vaccine that have been associated with allergic reactions in other products <ul style="list-style-type: none"> <li>○ Polyethylene glycol (PEG). The potential allergen may be found in bowel preparation products for colonoscopy, laxatives, cough syrup, cosmetics, contact lens care solutions, skin products and some food and drinks.<sup>2,3</sup></li> <li>○ Tromethamine (trometamol or Tris) – component found in contrast media, oral and parenteral medications.<sup>2</sup></li> </ul> </li> </ul> <p>Anaphylaxis to previous dose of COVID-19 mRNA vaccine may not be an absolute contraindication. See <a href="#">COVID-19 Immunization for Individuals with Allergies and Other Health Conditions</a> for recommendations.</p>
<p><b>Precautions</b></p>	<ul style="list-style-type: none"> <li>• Individuals who have had a serious allergic reaction to another vaccine, drug or food should talk to their health care provider before receiving the vaccine.<sup>2,3</sup></li> <li>• Individuals receiving anticoagulant therapy or those with a bleeding disorder that would contraindicate intramuscular injection should not be given the vaccine unless the potential benefit clearly outweighs the risk of administration.<sup>1</sup></li> <li>• Administration should be postponed in individuals suffering from acute severe febrile illness.<sup>1,2</sup></li> <li>• Immunization of children with a previous history of MIS-C should be postponed until clinical recovery has been achieved or until it has been 90 days or greater since diagnosis, whichever is longer.</li> </ul>
<p><b>Myocarditis</b></p>	<ul style="list-style-type: none"> <li>• Cases of myocarditis and/or pericarditis following immunization with an mRNA COVID-19 vaccine (Pfizer-BioNTech COVID-19 vaccine or Moderna COVID-19 vaccine) have been reported during post-authorization use in Canada and internationally, including from Israel, the United States, and Europe. However, the risk is considered rare.</li> <li>• Available information indicates that cases of myocarditis and pericarditis: <ul style="list-style-type: none"> <li>○ occur more commonly after the second dose,</li> <li>○ more often in adolescents and young adults (12 to 29 years of age),</li> <li>○ more often in males, and</li> <li>○ more frequently following Moderna COVID-19 vaccine than Pfizer-BioNTech COVID-19 vaccine.</li> </ul> </li> <li>• Typically, onset of symptoms begins within a week after the receipt of an mRNA COVID-19 vaccine. The majority of cases are mild and individuals tend to recover quickly and investigation into long-term outcomes is ongoing.</li> <li>• It is unknown if individuals with a history of previous myocarditis and/or pericarditis are at higher risk of vaccine associated myocarditis and/or pericarditis. <ul style="list-style-type: none"> <li>○ Generally, deferral of COVID-19 immunization is not required for those with a prior history of myocarditis or pericarditis that is unrelated to COVID-19 mRNA vaccines.</li> <li>○ If these individuals have questions or concerns about their prior history of myocarditis or pericarditis and immunization, it is recommended that individuals consult with their clinician. However, consultation with a clinician is not required to receive COVID-19 vaccines.</li> </ul> </li> <li>• Individuals with a history compatible with pericarditis within 6 weeks of receiving a dose of an mRNA COVID-19 vaccine, who either had no cardiac workup or who had normal cardiac investigations, can be re-immunized when they are symptom free and at least 90 days have passed since previous immunization.<sup>2</sup></li> </ul>

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	<ul style="list-style-type: none"> <li>• In most circumstances, further doses of mRNA COVID-19 vaccines should be deferred among people who experienced myocarditis (with or without pericarditis) within 6 weeks of receiving a previous dose of an mRNA COVID-19 vaccine.<sup>2</sup> <ul style="list-style-type: none"> <li>○ However, further mRNA doses may be offered if individuals with confirmed myocarditis or pericarditis with abnormal cardiac investigation choose to receive another dose of vaccine after discussing the risks and benefits with their clinician. If another dose of vaccine is offered, the Pfizer-BioNTech vaccine should be offered due to the lower reported rate of myocarditis and/or pericarditis following the Pfizer-BioNTech 30mcg vaccine.</li> <li>○ Informed consent should discuss the unknown risk of recurrence of myocarditis and/or pericarditis following additional doses of Pfizer-BioNTech COVID-19 vaccine in individuals with a history of confirmed myocarditis and/or pericarditis after a previous dose of mRNA COVID-19 vaccine.</li> </ul> </li> <li>• Anyone receiving an mRNA COVID-19 vaccine should be informed of the risk of myocarditis and pericarditis and advised to seek medical attention if they develop related symptoms including shortness of breath, chest pain, or the feeling of a rapid or abnormal heart rhythm.</li> <li>• Healthcare professionals are advised to consider the possibility of myocarditis and/or pericarditis in their differential diagnosis if individuals present with chest pain, shortness of breath, palpitations or other signs and symptoms of myocarditis and/or pericarditis following immunization with an mRNA COVID-19 vaccine.</li> </ul>
<p><b>Immunocompromised and Auto-Immune Disorders</b></p>	<ul style="list-style-type: none"> <li>• Participants in the COVID-19 vaccine clinical trials only included individuals who were not immunosuppressed, such as those with stable infection with human immunodeficiency virus (HIV), and those not receiving immunosuppressive therapy during the trial.</li> <li>• Participants with autoimmune conditions who were not immunosuppressed were not excluded from trials, however, they constitute a very small proportion of trial participants and represent a very narrow range of autoimmune conditions.</li> <li>• Real-world data in these individuals has not detected any safety signals, however, there is evidence of a diminished immune response in individuals who are immunocompromised and those with auto-immune disorders who are receiving immunosuppressive therapy. The type of immunosuppressive therapy or condition affected the immune response to COVID-19 vaccines.</li> <li>• COVID-19 vaccine can be offered to individuals in the eligible group who are immunosuppressed due to disease or treatment and those with an auto-immune disorder. <ul style="list-style-type: none"> <li>○ It is recommended that individuals consult with their primary health care provider or medical specialist for any vaccine related questions.</li> <li>○ However, consultation with a primary health care provider or medical specialist is not required to receive COVID-19 vaccine.</li> </ul> <p>Exceptions:</p> <ul style="list-style-type: none"> <li>▪ SOT clients require consultation with their primary health care provider or medical specialist prior to receiving COVID-19 vaccine.</li> <li>▪ HSCT clients do not require consultation as long as the initial clearance letter has been received to proceed with inactivated vaccines.</li> </ul> <p><u>Additional resources:</u></p> <ul style="list-style-type: none"> <li>• <a href="#">COVID-19 Scientific Advisory Group Rapid Evidence Report.</a></li> </ul> </li> </ul>

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	<ul style="list-style-type: none"> <li>• <a href="#">Advisory Committee on Immunization Practices (ACIP) interim recommendations for the use of Pfizer-BioNTech and Moderna COVID-19 vaccines</a></li> </ul>
<b>Pregnancy</b>	<ul style="list-style-type: none"> <li>• COVID-19 vaccines can be safely offered at any stage of pregnancy.<sup>2</sup></li> <li>• The safety and efficacy of Pfizer BioNTech COVID-19 vaccine in pregnant women has not yet been established in the clinical trials,<sup>1</sup> however preliminary data on mRNA vaccines administered in pregnancy is now available from post marketing surveillance with no safety signals detected.<sup>4</sup></li> <li>• COVID-19 vaccine can be offered to pregnant individuals in the eligible group as they are more at risk for severe illness from COVID-19 compared with non-pregnant individuals.<sup>5</sup> <ul style="list-style-type: none"> <li>○ Evidence to date shows that COVID-19 immunization during pregnancy is safe and does not increase risk for miscarriage, stillbirth, low birth weight, preterm birth, NICU admission, or other adverse pregnancy/birth outcomes.<sup>2</sup></li> <li>○ It is recommended that individuals consult with their primary health care provider or obstetrician for any vaccine related questions or concerns.</li> <li>○ However, consultation with a primary health care provider or obstetrician is not required to receive COVID-19 vaccine.</li> </ul> </li> </ul> <p><u>Additional resource:</u> <a href="#">Society of Obstetricians and Gynecologists of Canada Statement on COVID-19 Immunization in Pregnancy.</a></p>
<b>Lactation</b>	<ul style="list-style-type: none"> <li>• It is unknown whether Pfizer BioNTech COVID-19 Vaccine is excreted in human milk as breastfeeding individuals were excluded from the initial trials. A risk to the newborns/infants cannot be excluded.<sup>1,2</sup></li> <li>• However, based on how these vaccines work, COVID-19 vaccines are not expected to be a risk to lactating individuals or their breastfed newborns/infants.<sup>5</sup></li> <li>• COVID-19 vaccine should be offered to individuals in the eligible group who are breastfeeding. <ul style="list-style-type: none"> <li>○ It is recommended that individuals consult with their primary health care provider or medical specialist for any vaccine related questions or concerns.</li> <li>○ However, consultation with a primary health care provider or medical specialist is not required to receive COVID-19 vaccine.</li> </ul> </li> </ul>
<b>Other Considerations</b>	<ul style="list-style-type: none"> <li>• Individuals presenting for immunization do not need to be tested for previous COVID-19 infection.</li> <li>• It is not recommended that serology testing be completed to determine if an immune response to the COVID-19 vaccine has been mounted in individuals. Serology testing should not be used as evidence to inform whether vaccine doses have been effective.</li> <li>• Immunization of individuals who may be currently infected with SARS-CoV-2 is not known to have a detrimental effect on the illness.</li> <li>• Individuals with COVID-19-like symptoms should not go to an immunization/venue in order to minimize the risk of COVID-19 transmission.</li> </ul>
<b>Administration with Other Products</b>	<ul style="list-style-type: none"> <li>• COVID-19 vaccines may be co-administered with, or at any time before or after other vaccines (including, live, inactivated, adjuvanted, or unadjuvanted vaccines) to individuals 6 months of age and older.<sup>2</sup></li> <li>• Currently there is no data on the impact of the COVID-19 mRNA vaccines on tuberculin skin testing or IGRA (QFT) test results. There is a theoretical risk that COVID-19 vaccines may temporarily affect cell-mediated immunity, resulting in false-negative tuberculin skin testing or IGRA (QFT) test results.<sup>2</sup></li> </ul>

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	<ul style="list-style-type: none"> <li>○ In the absence of data, and acknowledging the importance of both timely tuberculosis testing and immunization, immunization with COVID-19 vaccines can take place at any time before, after or at the same visit as the TST or IGRA test.<sup>2</sup></li> <li>○ However, repeat tuberculin skin testing or IGRA (at least 4 weeks post-COVID-19 immunization) of individuals with negative TST or IGRA results for whom there is high suspicion of latent tuberculosis may be considered in order to avoid missing persons with TB infection.<sup>2</sup></li> <li>● Deferral of COVID-19 immunization is not recommended for individuals who have received anti-SARS-CoV-2 monoclonal antibodies or convalescent plasma provided for treatment or prophylaxis of COVID-19 just because they received these pharmacological interventions. This applies to people who received these before receiving any COVID-19 vaccine dose or between doses. <ul style="list-style-type: none"> <li>- A study among nursing home residents and staff demonstrated that recipients of a SARS-CoV-2 monoclonal antibody (bamlanivimab), mounted a robust immune response to mRNA immunization, regardless of age, risk category or vaccine type.<sup>9</sup></li> <li>- Although antibody response was numerically lower in people who received monoclonal antibodies, they were still considered to be high and the clinical significance of the reduction is unknown.<sup>9</sup></li> <li>- There was no correlation between interval to COVID-19 immunization and neutralizing titres in recent monoclonal antibody recipients.<sup>9</sup></li> <li>- Intervals between previous COVID-19 infection and COVID-19 immunization outlined in this document would still apply to individuals who got the monoclonal antibodies or convalescent plasma for their infection.</li> </ul> </li> <li>● Individuals who are to receive Evusheld (tixagevimab and cilgavimab) as pre-exposure prophylaxis should wait at least 2 weeks following COVID-19 immunization to minimize interference.</li> </ul> <p><b>Note:</b></p> <ul style="list-style-type: none"> <li>● Timing of administration and potential interference between COVID-19 vaccine and monoclonal products not used for treatment or prophylaxis of COVID-19 infection are currently unknown and the primary health care provider or medical specialist should be consulted on a case-by-case basis.</li> <li>● mRNA COVID-19 vaccines may be given at any time before or after an immunoglobulin preparation (including Rhlg) or blood product not specific to COVID-19 treatment has been administered. There is no recommended minimum interval between these products and COVID-19 vaccine.</li> </ul>
<p><b>Program Notes</b></p>	<ul style="list-style-type: none"> <li>● December 9, 2020 - licensed for use in Canada</li> <li>● December 16, 2020 - implemented in Alberta</li> <li>● January 13, 2021 – interval between dose 1 and dose 2 extended to 42 days except for LTC/DSL residents.</li> <li>● March 10, 2021 –interval between dose 1 and dose 2 extended up to 4 months for all populations</li> <li>● April 21, 2021 - Exceptions to extended interval to include SOT, HSCT, and individuals with malignant hematologic disorders and non-hematologic malignant solid tumors receiving specific types of active treatment, and individuals on anti-CD20 monoclonal antibodies.</li> <li>● April 26, 2021 - Eligibility to include unlicensed use in children turning 12 to 15 years of age this calendar year with high-risk underlying health conditions as defined in Phase 2B of Alberta’s COVID-19 immunization program.</li> </ul>

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- May 4, 2021 - Updated considerations for pregnancy, lactation, and individuals 12 to 15 years of age.
- May 5, 2021 – Licensure updated to include individuals 12 to 15 years of age.
- May 20, 2021 - Updated to include storage of thawed undiluted vials at 2°C to 8°C from 5 days to 31 days.
- May 28, 2021 – Exceptions to extended interval expanded to include individuals with chronic kidney disease on peritoneal dialysis or hemodialysis.
- June 14, 2021 - Spacing between administration of COVID-19 vaccine and other vaccines changed to 14 days (from 28 days).
  - Removed recommendation to delay pregnancy by 28 days or more after the administration of COVID-19 vaccine.
- June 16, 2021 – updated interchangeability section.
- July 6, 2021 – Updated to incorporate safety information from Health Canada on myocarditis/pericarditis.
  - Removed scheduling information for extended interval (4 months) between dose 1 and 2 and exceptions for extended interval.
- August 3, 2021 - Updated information on myocarditis/pericarditis.
- August 30, 2021- Updated information on additional doses for immunocompromised, residents in senior congregate living facilities and for travel.
- September 8, 2021 - Updated recommendations for co-administration of COVID-19 vaccines and other inactivated vaccines.
- September 20, 2021 - Updated to align with NACI recommendations for immunocompromising conditions eligible for additional dose of COVID-19 vaccine.
- October 6, 2021 - Updated 'third dose' eligibility to include individuals 75 years of age and older and FNMI people 65 years of age and older.
  - Updated recommendations for co-administration of COVID-19 vaccines with all other vaccines.
- October 25, 2021 – Updated to specify the minimum interval between monoclonal antibodies/convalescent plasma used for treatment of COVID-19 infection and COVID-19 vaccines.
- November 8, 2021 - Updated 'third dose' eligibility to include individuals 70 years of age and older, FNMI people 18 years of age and older, individuals 18 years of age and older who received only a viral vector vaccine series, and frontline HCWs with an interval of less than 8 weeks between dose 1 and dose 2.
- November 17, 2021 - Updated the "Other Considerations" section to state that individuals with a history of lab confirmed COVID-19 infection who have no contraindications can be provided COVID-19 vaccine as soon as their isolation period is over.
  - Licensed use updated as per November 9, 2021 product monograph – booster doses licensed for 18 years and older.
- November 26, 2021 - Updated to include preferential recommendation for Pfizer-BioNTech COVID-19 vaccine for individuals 12 years to 29 years of age due to a lower risk of myocarditis following immunization with the Pfizer-BioNTech vaccine compared to Moderna in this age group.
  - Interval between dose 1 and dose 2 updated to align with NACI's recommended optimal spacing of 8 weeks.
- December 6, 2021 - Updated booster dose eligibility to include all adults 18 years of age and older in a phased approach starting with those 60 years of age and older.
- December 15, 2021 – Expanded booster dose eligibility for health care workers.
  - Updated myocarditis information.

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- December 17, 2021 - Updated wording with respect to interchangeability.
- December 21, 2021 - Interval for third (booster) doses changed from at least 6 months to at least 5 months after last dose of the primary series for all individuals 18 years of age and older.
- January 20, 2022 - Updated booster dose eligibility to include individuals 18 years of age and older with certain Immunocompromising conditions.-
- February 14, 2022 - Updated to incorporate NACI recommendation on re-immunization following myocarditis.
  - Clarified wording on individuals with history of COVID-19 infection.
  - Adolescents 12 to 17 years of age with underlying health conditions and immunocompromising conditions eligible for booster dose.
  - First Nations, Metis and Inuit Individuals 12 to 17 years of age eligible for a booster dose.
- March 2, 2022 - Updated to incorporate NACI interim guidance on suggested interval between previous COVID-19 infection and COVID-19 immunization.
- Mar 14, 2022 - Updated booster dose eligibility to include all individuals 12-17 years of age
- April 12, 2022 - Updated to incorporate second booster dose eligibility and additional dose eligibility for travel purposes.
  - Included link to 'COVID-19 Immunization for Individuals with Allergies and Other Health Conditions.'
- June 1, 2022 – Updated to include recommendation for immunization post CAR-T cell therapy, extended storage time in an ultra-frozen state and to indicate that a second booster dose will correspond to a fifth dose for certain immunocompromised individuals.
- July 19, 2022 – Updated to expand second booster dose eligibility to include all individuals 18 years of age and older, updated timing between administration of anti SARS-CoV-2 monoclonal antibodies or convalescent plasma and COVID-19 immunization, and addition of new product formulation (Gray Cap) that does not require dilution.
- October 24, 2022 – Updated booster dose recommendations, updated recommendations on timing of tuberculin skin testing/interferon gamma release assay and COVID-19 immunization. Updated pregnancy and breastfeeding recommendations. Removed sections.
- December 1, 2022 - Updated to remove purple cap formulation as this product is no longer available.
- March 01, 2023 – Removed booster dose recommendations as no longer offering product as a booster.
- April 21, 2023 - Removed references to Moderna Spikevax Original for primary series as vaccine is no longer available in Alberta.

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## References

- <sup>1</sup> Pfizer-BioNTech. (updated 2021 November 9). COVID-19 mRNA Vaccine, Suspension for Intramuscular Injection *Product Monograph*. <https://covid-vaccine.canada.ca/info/pdf/pfizer-biontech-covid-19-vaccine-pm1-en.pdf>
- <sup>2</sup> National Advisory Committee on Immunization. (2021). Canadian Immunization Guide (Evergreen ed.). Ottawa, ON: Public Health Agency of Canada <https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-4-active-vaccines/page-26-covid-19-vaccine.html>

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