Vaccine Medical Directive and Delegation
Comirnaty (Pfizer BioNTech) COVID-19 Vaccine

DELEGATED PROCEDURE	Delegation of Authority to: ☒ Prescribe a drug ☐ Sell a drug
ORDER TO	☒ Administer ☐ Dispense ☐ Sell
AUTHORIZING MD	Dr. Penny Sutcliffe, Medical Officer of Health
AUTHORIZED IMPLEMENTERS	Public Health Sudbury & Districts Public Health Nurses, Registered Nurses, Registered Practical Nurses, graduates of an accredited Nursing Program in Ontario, post-secondary nursing students, medical students of an accredited Medical Program in Ontario, Midwives, Radiation Therapists, Respiratory Therapists, Physician Assistants, Pharmacists and Paramedics who have completed their Certification of Competence Module. Paramedic students from Collège Boréal and Cambrian College who have received formal didactic and practical education in IM, medication administration, and sharp safety, in a formative and summative evaluation process, following the paramedic NOCP's (National Occupational Competency Profile). This was completed in a supervised setting with certified faculty from Collège Boréal and Cambrian College. Second year RPN students from Collège Boréal and Cambrian College who have received formal didactic and practical education in IM, medication administration, and sharp safety, in a formative and summative evaluation process, as per Standards of Practice College of Nurses. This was completed in a supervised setting with certified faculty from Collège Boréal and Cambrian College. Pharmacy Technicians who have completed an approved injection course through the College of Pharmacists and who are working with a regulated health professional who can obtain informed consent and provide patient education may perform the act of injection under this medical directive.
CLINICAL INDICATIONS/ PURPOSE	Comirnaty (Pfizer BioNTech) COVID-19 Vaccine (COVID-19 mRNA Vaccine) for the prevention of coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 12 years of age and older in whom contraindications are not present.[1]
SITUATIONAL CONDITIONS	• Informed consent. • Absence of contraindication(s). • In accordance with $COVAX_{ON}$ schedules logic.
CONTRAINDICATIONS	Comirnaty (Pfizer BioNTech) COVID-19 Vaccine (COVID-19 mRNA Vaccine) is contraindicated for use by implementers authorized under this medical directive for the following individuals:

	• Individuals with a **history of a severe immediate (≤ 4 hours following vaccination) allergic reaction (e.g., anaphylaxis)** after previous administration of an mRNA COVID-19 vaccine, re-vaccination may be offered with the same vaccine or the same mRNA platform if a risk assessment deems that the benefits outweigh the potential risks for the individual and if informed consent is provided[2]. Individuals should consult with an allergist/immunologist or another appropriate physician prior to re-vaccination[4]. Refer to the Warnings and Precautions section for more specific details. • Individuals with a **previous history of allergy to an mRNA vaccine or any component of the COVID-19 vaccine**, where consultation with an allergist or other appropriate physician precludes further vaccination with an mRNA vaccine[2]. Until clinically assessed and advised to receive the vaccine, administration of the vaccine is contraindicated. Referral to a MD or NP is recommended.[3] Refer to the Warnings and Precautions section below for information on administration of mRNA vaccine to individuals with severe allergies who have been assessed by a MD or NP. • Individuals **displaying current or recent history of chest pain or shortness of breath** should not be offered the COVID-19 vaccine. Refer to Warnings and Precautions section below for information on administration of an mRNA vaccine to individuals displaying these symptoms.[3] • Individuals who had **an episode of myocarditis (with or without pericarditis) within the 6 weeks following a previous administration of an mRNA vaccine** should not receive the vaccine. This includes any person who had an abnormal cardiac investigation including ECG, elevated troponins, echocardiogram or cardiac MRI after a dose of an mRNA COVID-19 vaccine.[2] Individuals who have a history of myocarditis unrelated to mRNA COVID-19 vaccination should consult their clinical team for individual considerations and recommendations.[2] Refer to the Warnings and Precautions section below for information on administration of COVID-19 vaccine to individuals who experienced an episode of myocarditis or pericarditis after previous administration of an mRNA vaccine who have been assessed by a MD or NP. • **Children with a previous history of multi-inflammatory syndrome (MIS-C)** unrelated to any previous COVID-19 vaccination, vaccination should be postponed until clinical recovery has been achieved or until it has been ≥ 90 days since diagnosis, whichever is longer.[3]
WARNINGS AND PRECAUTIONS	The use of Pfizer Comirnaty (Pfizer BioNTech) COVID-19 Vaccine may be permitted, or must be deferred, for individuals in accordance with the following: **Acute Illness** ***Current infection with SARS-CoV-2*** Vaccination of individuals who may be currently infected with SARS-CoV-2 is not known to have a detrimental effect on the illness. Vaccination should be deferred in symptomatic individuals with confirmed or suspected SARS-CoV-2 infection, or those with respiratory symptoms, to minimize the risk of COVID-19 transmission at an immunization clinic/venue.[2] As a precautionary measure and in light of the need to be able to monitor for COVID-19 vaccine adverse events without potential confounding from symptoms of COVID-19 or other co-existing illnesses, people should wait until all symptoms of an acute illness are resolved before vaccinating with a COVID-19 vaccine.[2]

	Current chest pain or shortness of breath Individuals displaying current or recent symptoms of chest pain or shortness of breath should defer vaccination until they can consult with their health care provider for individual considerations and recommendations. **Individuals presenting with severe symptoms should be directed to the emergency department or instructed to call 9-1-1**.[3] **Hypersensitivity and allergies** ***Allergic reaction to a previous dose of an mRNA vaccine*** Individuals with a history of a severe, immediate (≤ 4h following vaccination) allergic reaction (e.g., anaphylaxis) to a previous dose of an mRNA COVID-19 vaccine, revaccination may be offered with the same vaccine or the same mRNA platform if a risk assessment deems that the benefits outweigh the potential risks for the individual and if informed consent is provided. Consultation with an allergist or other appropriate physician should be sought prior to re-vaccination. If re-vaccinated, vaccine administration should be done in a controlled setting with expertise and equipment to manage anaphylaxis. Individuals should be observed for at least 30 minutes after re-vaccination.[2] ***Confirmed allergies to a component of a COVID-19 vaccine*** Ingredients of authorized COVID-19 vaccines that have been associated with allergic reactions within the Comirnaty (Pfizer BioNTech) Vaccine include polyethylene glycol [PEG] only (purple cap formulation). In individuals with a confirmed severe, immediate (≤4h following exposure) allergy (e.g., anaphylaxis) to a component of a specific COVID-19 vaccine or its container (e.g., PEG), consultation with an allergist is recommended before receiving the specific COVID-19 vaccine. In individuals with a serious PEG allergy in whom mRNA vaccination is precluded based on a consultation with an allergist or other appropriate physician: for these individuals in the authorized age group without contraindications to the vaccine, Novavax Nuvaxovid may be preferred.[2] **Mild to moderate immediate allergic reactions to a COVID-19 vaccine or a vaccine excipient** In individuals with mild to moderate immediate allergic reactions (defined as limited in the scope of symptoms and involvement of organ systems or even localized to the site of administration) to a previous dose of mRNA COVID-19 vaccine or any of its components, re-vaccination may be offered with the same vaccine or the same platform (i.e., mRNA). Assessment by a physician or nurse with expertise in immunization may be warranted prior to re-immunization.[2] Most instances of anaphylaxis to a vaccine begin within 30 minutes after administration of the vaccine. Therefore, if re-vaccination is chosen, an extended period of observation post-vaccination of **at least** 30 minutes should be provided for the aforementioned individuals.[2] Individuals with known allergies to components of the vaccines may speak with an appropriate physician or NP for evaluation. This assessment will enable the development of a vaccination care plan which may include receiving the vaccine under the supervision of your physician. Documentation of the discussion with the physician/NP may be provided to the clinic and can include a vaccination care plan (including what types of parameters the clinic should meet to provide safe vaccination administration, such as availability of advanced medical care to manage anaphylaxis), details/severity of the previous allergic episode(s), confirm that appropriate counselling on the safe administration of vaccine was provided, and include the date, the clinician's name, signature and contact

information as well as the individual's name and date of birth[4]. Referral and consultation support for Physicians and Nurse Practitioners is available through Ontario's eConsult Service.[3]

Individuals meeting the above criteria will be referred to Health Sciences North (HSN) for vaccination in a controlled setting. Individuals who have had an allergic reaction within 4 hours and/or anaphylaxis that occurred with a vaccine or injectable medication that does not contain a component or cross-reacting component of the COVID-19 vaccines can receive the COVID-19 vaccine followed by observation for a minimum of 30 minutes.[2,]

Individuals with a history of significant allergic reactions and/or anaphylaxis to any food, drug, venom, latex, or other allergens not related to the COVID-19 vaccine can receive the COVID-19 vaccine followed by observation for a minimum of 15 minutes. Individuals with allergy issues like allergic rhinitis, asthma and eczema can receive the vaccine followed by observation for a minimum of 15 minutes.[2]

Autoimmune conditions and immunodeficiencies
Moderately to severely immunocompromised individuals in the authorized age group who are immunosuppressed due to disease or treatment including stem cell therapy, Hematopoietic Stem Cell Transplant (HSCT) and chimeric antigen receptor T (CAR-T)-cell therapy, chemotherapy, immune checkpoint inhibitors, monoclonal antibodies (e.g., rituximab) and other targeted agents (e.g., CD4/6 inhibitors, PARP inhibitors, PARP inhibitors, anti-CD20, CD19, CD22 targeting antibodies, or BiTEs, etc.).) should be offered a 3-dose primary series plus booster doses of the vaccine. These individuals are **strongly encouraged to speak with their treating health care provider** regarding the timing of vaccination in relation to therapy for their underlying health condition and/or treatment modification in view of possible decreased vaccine effectiveness with the use of immunosuppressive therapy.[2,3,4]

It is recommended that re-vaccination with a new COVID-19 vaccine primary series be initiated post-transplantation for hematopoietic stem cell transplant (HSCT), hematopoietic cell transplants (HCT) (autologous or allogeneic) and recipients of CAR-T-cell therapy given the loss of immunity following therapy or transplant. Optimal timing for re-vaccination should be determined on a case-by-case basis in consultation with the clinical team.[4] Person requesting revaccination in these circumstances should consult with their health care provider/specialist regarding the optimal timeline for re-vaccination.[3]

All other individuals in the authorized age group with autoimmune conditions, immunodeficiency conditions or those immunosuppressed due to disease or treatment should be offered the vaccine. **These individuals may choose to consult with their health care provider prior to vaccination** (for example, to discuss immunosuppressive medication management/timing in relation to their vaccination).[2,3,4]

Hematologic
Individuals taking long-term anticoagulation (e.g., warfarin or heparin therapy) are not considered to be at higher risk of bleeding complications following immunization and may be safely immunized without discontinuation of their anticoagulation therapy. In individuals with bleeding disorders, the condition should be managed prior to immunization to minimize the risk of bleeding.[2]

Myocarditis and Pericarditis

All vaccine recipients

All individuals receiving mRNA COVID-19 vaccine should be informed of the risk of myocarditis and pericarditis and advised to seek medical attention immediately if they develop symptoms including chest pain, shortness of breath, palpitations (pounding or heart racing), or feeling of rapid or abnormal heart rhythm in the week following vaccination.[2,3] **As a precaution, Pfizer-BioNTech is preferentially recommended for persons 12 – 29 years of age.[3]**

Individuals with a history of myocarditis unrelated to mRNA COVID-19 vaccination

Individuals who have a history of myocarditis unrelated to mRNA COVID-19 vaccination should consult their health care provider for individual considerations and recommendations. If the diagnosis is remote and they are no longer followed clinically for cardiac issues, they should receive the vaccine.[2]

Individuals with confirmed myocarditis (with or without pericarditis) after a dose of an mRNA COVID-19

In most circumstances, and as a precautionary measure until more information is available, individuals with a diagnosed episode of myocarditis (with or without pericarditis) within 6 weeks of receipt of a previous dose of an mRNA COVID-19 vaccine should defer further doses of the vaccine. This includes any person who had an abnormal cardiac investigation including electrocardiogram (ECG), elevated troponins, echocardiogram, or cardiac MRI after a dose of an mRNA vaccine.[2]

Some individuals 12 years of age and older with confirmed myocarditis (with or without pericarditis) after a dose of an mRNA COVID-19 vaccine may choose to receive another dose of vaccine after discussing the risk and benefit with their healthcare provider.[2,3] Individuals can be offered the next dose once they are symptom free and at least 90 days have passed since vaccination.[3]

If another dose of vaccine is offered, they should be offered Pfizer 30 mcg due to the lower reported rate of myocarditis and/or pericarditis following the Pfizer-BioNTech 30mcg vaccine compared to the Moderna 100 mcg vaccine. Informed consent should include discussion about the unknown risk of recurrence of myocarditis and/or pericarditis following receipt of 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, as well as the need to seek immediate medical assessment and care should symptoms develop.[2,3]

Diagnosis uncertain

In situations where there is uncertainty regarding **myocarditis** diagnosis, discussion should occur with an appropriate physician or nurse practitioner on potential options for (re)immunization with the same or alternative COVID-19 vaccine, including a risk-benefit analysis for the individual. The individual qualifies for a medical exemption if the physician or nurse practitioner has determined that the individual is unable to receive any COVID-19 vaccine. Those with a history compatible with **pericarditis** and who either had no cardiac workup or had normal cardiac investigations, can be re(immunized) once they are symptom free and at least 90 days has passed since vaccination.[2,3]

Bell's Palsy
Very rare reports of Bell's Palsy (facial paralysis and facial paresis) following vaccination with COVID-19 mRNA vaccines have been reported.[1,3] This condition is typically temporary with sudden onset of symptoms which generally start improving after a few weeks. The exact cause of Bell's Palsy is not known; however it is believed to be the result of swelling and inflammation of the nerve that controls muscles on the face.[3] Currently available information is insufficient to determine a causal relationship with the Comirnaty vaccine as noted as a post-market adverse reaction in the Pfizer BioNTech (Comirnaty) product monograph.[1]

Individuals who experience a combination of the following symptoms after vaccination should seek medical attention: uncoordinated movement of the muscles that control facial expression, loss of feeling in the face, headache, tearing from the eye, drooling, lost of sense of taste on the front of the tongue, hypersensitivity to sound in one ear and/or inability to close an eye on one side of the face.[3]

Guillain-Barre Syndrome (GBS)
Individuals with a past history of GBS unrelated to COVID-19 vaccination should receive an mRNA COVID-19 vaccine.[2] Individuals who developed GBS after a previous dose of an authorized COVID-19 vaccine may receive an mRNA vaccine for subsequent dose(s) after consultation with their health care provider (i.e., if the benefits outweigh the risk and informed consent is provided).[2] To date, no increased risk of GBS has been identified following vaccination with an mRNA COVID-19 vaccine. The risk of GBS recurrence after COVID-19 vaccination amongst those with a past history of GBS appears to be low.[2]

Adverse Reactions
Reactions are generally mild to moderate in intensity and of limited duration.[3]

Very common and common side effects include: localized redness/erythema, swelling and or pain at the injection site, fatigue, headache, muscle pain, chills, joint pain, fever, nausea/vomiting.

Uncommon reactions include swollen lymph nodes.

Rare or very rare adverse events include pericarditis/myocarditis.

Drug: Drug Interactions
Vaccines
COVID-19 vaccines may be given at the same time as, or any time before or after, other vaccines, including live, non-live, adjuvanted or unadjuvanted vaccines.[2,3]

Tuberculin skin testing (TST) or Interferon gamma release assay (IGRA)
There is a theoretical risk that mRNA or viral vector vaccines may temporarily affect cell-mediated immunity, resulting in false-negative TST/IGRA test results. If TB skin testing/IGRA test is required, it should be administered and read before immunization or delayed for at least 4 weeks after vaccination. Vaccination with COVID-19 vaccines may take place at any time after all steps of TST

	has been completed.[2] In cases of urgency the test should be performed, with re-testing at least 4 weeks post-immunization where there is a high index of suspicion of TB infection.[2] ***Blood Products and Human Immunoglobulin*** COVID-19 vaccines should not be given concurrently with anti-SARS-CoV-2 monoclonal antibodies. Administration of these products concurrently may result in decreased effectiveness of the COVID-19 vaccine and/or anti SARS-CoV-2 monoclonal antibodies. Anti SARS-CoV-2 monoclonal antibodies have high affinity for the spike protein expressed by COVID-19 vaccines, which could prevent the production of antibodies stimulated by the vaccine, or binding of vaccine antigen to the monoclonal antibody may neutralize the antibody.[2] ***Oral Analgesics and Antipyretics*** Prophylactic oral analgesics or antipyretics (e.g., acetaminophen or ibuprofen) should not be routinely used before or at the time of vaccination, but their use is not a contraindication to vaccination.[2] There is currently no evidence of benefit from administration of oral analgesics for the prevention of immunization injection pain or systemic reactions.[2] Oral analgesics or antipyretics may be considered for the management of adverse events (e.g., pain or fever, respectively), if they occur after vaccination.[2] ***Drug: Food Interactions*** None listed **Pregnancy and Breastfeeding** Compared to non-pregnant persons, SARS-CoV-2 infection in pregnancy may increase the risk of complications requiring hospitalization and intensive care, as well as poorer pregnancy outcomes including premature birth, stillbirth, and caesarian delivery.[2] All pregnant and breastfeeding individuals in the authorized age group are eligible and should receive all recommended doses of a COVID-19 vaccine (including booster doses) as soon as possible. The Society of Obstetricians and Gynaecologists of Canada recommend COVID-19 vaccination during pregnancy and in any trimester and while breastfeeding, if no contraindications exist. While all available COVID-19 vaccines approved in Canada can be used during pregnancy and breastfeeding, preference is given to the use of mRNA vaccinations during pregnancy as more data on safety and efficacy on pregnancy is available for these vaccines.[2,3] COVID-19 vaccines can be safely given to breastfeeding individuals and recent data shows that mRNA from vaccines do not transfer into breast milk. Anti-COVID-19 antibodies produced by the breastfeeding person have been shown to transfer through the milk and provide protection to the infant. The vaccines are safe for the breastfeeding person and should be offered to those eligible for vaccination.[2,4] Those that are trying to become pregnant do not need to avoid pregnancy after vaccination with an mRNA vaccine.[2]
PHYSICIAN'S ORDER	Comirnaty (Pfizer BioNTech) COVID-19 Vaccine (COVID-19 mRNA Vaccine) in accordance with Tables 1, 2, 3 and 4 below.

Some general principles regarding the Comirnaty (Pfizer BioNTech) Vaccine Schedule:

- Pfizer BioNTech COVID-19 Vaccine is the preferred vaccine for individuals 12-29 years of age.
- Either Moderna or Pfizer vaccines may be used as a booster dose regardless of which COVID-19 vaccine was used in the primary series.[4] The following principles are authorized without individual providing informed consent*:
    - Individuals in Ontario **aged 12-17 years of age** are recommended to receive Pfizer-BioNTech COVID-19 vaccine for their booster dose series.[4]
    - Individuals in Ontario **aged 18 years of age and older** are recommended to receive a first booster of an mRNA vaccine for their booster series.[4]
- The intervals listed in Tables 1, 2, 3, and 4 below may change as listed for individuals with a previous or current SARS-CoV-2 infection. Refer to Table 5 for suggested intervals between previous SARS-CoV-2 infection and COVID-19 vaccination.[3]
- For those vaccinated outside of Ontario or Canada please refer to the most current version of the COVID-19 Vaccine Administration guidance document.[3]

Table 1: Primary Series for Immunocompetent Individuals[3]
This table is to be referenced for all immunocompetent adults and adolescents 12 years of age and older.

- When the first dose in a series is an mRNA vaccine, the same mRNA vaccine product should be offered for the subsequent dose(s) if readily available. If unavailable another mRNA product recommended for that age group can be considered interchangeable and should be offered to complete the series. Where a different product is used to complete the vaccine series, the second dose should be given at the recommended interval.[3]
- An 8-week interval between the first and second dose of mRNA vaccine should be provided as a longer interval between doses is associated with higher vaccine effectiveness and potentially lower risk of myocarditis/pericarditis.[2]

<table>
<tr><th>Schedule: Primary Series (Eligible and Recommended)</th><th>First Dose</th><th>Second Dose: Recommended[A] and Minimum[B] Intervals</th></tr>
<tr><td>Schedule: 2 dose primary series

Eligible: Individuals 12+

Recommended: Individuals 12+</td><td>0.3mL (30mcg) IM</td><td>0.3mL (30mcg) IM in accordance with the following product-specific intervals:
<table>
<tr><th>Vaccine for first dose</th><th>Interval Between First and Second Dose</th></tr>
<tr><td>Pfizer (Pediatric Formulation)</td><td>Recommended: 8 weeks/56 days
Minimum: 19 days with informed consent*</td></tr>
<tr><td>Pfizer (Adult Formulation)</td><td>Recommended: 8 weeks/56 days
Minimum: 19 days with informed consent*</td></tr>
<tr><td>Moderna</td><td>Recommended: 8 weeks/56 days
Minimum: 21 days with informed consent*</td></tr>
<tr><td>Astra Zeneca (1 dose)</td><td>Recommended: To complete the primary series: 8 weeks/56 days
Minimum: 28 days with informed consent*</td></tr>
</table>
</td></tr>
</table>

		Janssen	Not applicable – primary series is complete. Any additional doses would be considered booster doses.
		Novavax	**Recommended:** 8 weeks/56 days **Minimum:** 21 days with informed consent*
		Medicago	**Recommended:** 8 weeks/56 days **Minimum:** 21 days with informed consent*

[A] Recommended interval refers to the Ministry of Health recommendation that longer intervals between the first and second doses of COVID-19 vaccines result in more robust and durable immune response and higher vaccine effectiveness. Recommended intervals between doses must be adhered to for the purposes of this directive.

[B] Minimum interval is the Health Canada authorized interval. Although the recommended intervals between doses are always advised, shorter intervals may be considered in the context of local epidemiology and compassionate care (i.e., travel to provide palliative care, prior to a scheduled medical procedure or starting immunosuppressive treatments, etc.). When requested by the client and with informed consent minimum intervals may be used between **dose 1 and dose 2** after assessment of risk/benefit.

***Informed consent = advising client of recommended interval and that greater interval= greater protection.

Table 2: Primary Series for Immunocompromised Individuals[3]

This table is to be referenced for all moderately to severely immunocompromised individuals 12 years of age and older.

Moderately to severely immunocompromised individuals include:[6]

- Individuals receiving dialysis (hemodialysis or peritoneal dialysis).
- Active treatment (e.g., chemotherapy/targeted therapy/immunotherapy) for solid tumour/hematologic malignancy.
- Receipt of solid-organ transplant and taking immunosuppressive therapy.
- Receipt of chimeric antigen receptor (CAR)-T-cell therapy or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy).
- Moderate to severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome).
- Individuals with HIV with prior AIDS defining illness or prior CD4 count ≤ 200/mm3 or prior CD4 fraction ≤ 15% or (in children 5-11 years) perinatally acquired HIV infection.
- *Active treatment* with the following categories of immunosuppressive therapies: anti-B cell therapies (monoclonal antibodies targeting CD19, CD20 and CD22), high-dose systemic corticosteroids (refer to the CIG for suggested definition of high dose steroids), alkylating agents, antimetabolites, or tumor-necrosis factor (TNF) inhibitors and other biologic agents that are significantly immunosuppressive. Refer to the most current version of the COVID-19 Vaccine Booster Recommendations document for the definition of *active treatment*.[4]

Eligibility:

Self-attestations are accepted. No referral required for severely to moderately immunocompromised 56 day recommended interval. Clinic must confirm severely to moderately immunocompromised status to ensure correct dosing provided. Referrals are needed for:

- Shorter interval for eligible Immunocompromised Third Dose (extended primary series) (e.g., 28 days).
- Exact timing identified by a Health Care Provider.[3,4]

Individuals requiring a referral must present with a completed referral form (English/French) from a HCP/specialist or pharmacist. Alternatively, individuals may present a prescription for their medication which is to be cross-referenced with Table 3 of the COVID-19 Vaccine Booster Recommendations[4] document for confirmatory purposes. Confirmation of dosage from the client is sufficient verification of dose if it is not on the prescription.

Schedule: Primary Series (Eligible and/or Recommended)	**First Dose**	**Second Dose: Recommended[A] and Minimum[B] Intervals**	**Third Dose: Recommended[A] and Minimum[B] Intervals**
Schedule: 3 dose primary series **Eligible:** Individuals 12+ **Recommended:** Individuals 12+	0.3mL (30mcg) IM	**Dose:** 0.3mL (30mcg) IM **Recommended:** Refer to Table 1 for recommended intervals **Minimum:** Refer to Table 1 for minimum intervals	**Dose:** 0.3mL (30mcg) IM **Recommended:** 8 weeks/56 days after second dose **Minimum:** 28 days after second dose with informed consent and with a referral from their Health Care Provider* (however an interval longer than 28 days is likely to result in a better immune response with exact timing to be decided with treating provider)

[A] Recommended interval refers to the Ministry of Health recommendation that longer intervals between the first and second doses of COVID-19 vaccines result in more robust and durable immune response and higher vaccine effectiveness. Recommended intervals between doses must be adhered to for the purposes of this directive.

[B] Minimum interval is the Health Canada authorized interval. Although the recommended intervals between doses are always advised, shorter intervals may be considered in the context of local epidemiology and compassionate care (i.e., travel to provide palliative care, prior to a scheduled medical procedure or starting immunosuppressive treatments, etc.). When requested by the client and with informed consent minimum intervals may be used between **dose 1 and dose 2** after assessment of risk/benefit.

*Informed consent = advising client of recommended interval and that greater interval= greater protection.

Table 3: Booster Doses for all Immunocompetent Individuals[3]

A first booster is recommended based on ongoing risk of infection due to waning immunity, the ongoing risk of severe illness from COVID-19, the societal disruptions that results from transmission of infections, and the adverse impacts on health system capacity from the COVID-19 pandemic.

The term “second booster dose” corresponds to a fourth dose among eligible immunocompetent individuals, as they have a recommended 2-dose primary series. Although, healthy individuals aged 18 to 59 years old are now eligible to receive a second booster 5 months/140 days after their first booster, these individuals continue to have protection against severe disease more than 6 months after their first dose.[4]

Individuals who are at higher risk of severe disease from COVID-19 infection and are **recommended** to get the **second booster** dose as soon as they become eligible, include:[3]

- Individuals 60 years of age and older
- First Nation, Inuit and Metis individuals, and their non-Indigenous household members 18 years of age and older
- Residents of a long-term care home, retirement home, or Elder Care Lodge and older adults living in other congregate settings that provide assisted-living and health services

Population (Eligible and/or Recommended)	**Third Dose / First Booster: Recommended[A] and Minimum[B] Intervals**	**Fourth Dose/ Second Booster: Recommended[A] and Minimum[B] Intervals**
Immunocompetent individuals 12-17 years of age ○ **First Booster:** recommended ○ **Second Booster:** not eligible	**Dose:** 0.3mL (30mcg) IM **Eligible:** 12-17 years of age **Recommended:** 1st booster dose 6 months/186 days after second dose **Minimum:** 1st booster dose 3 months/84 days after second dose with informed consent*	**Dose:** NA **Eligible:** not eligible to receive second booster dose **Recommended:** NA **Minimum:** NA

	Immunocompetent individuals 18 years of age and older including: • 2-dose primary series Astra Zeneca vaccine recipients • 1-dose primary series Janssen vaccine recipients • 2-dose primary series Novavax vaccine recipients2-dose primary series Medicago vaccine recipients **First Booster** ○ **Recommended**: Individuals 18+ **Second Booster** ○ **Eligible:** Individuals 18+ ○ **Recommended:** Individuals 18+ at higher risk of severe disease (see above)	**Dose:** 0.3mL (30mcg) IM **Recommended:** 1st booster dose 5 months/140 days after second dose.[3] For residents of Long-Term Care Homes, Retirement Homes, Elder Care Lodges and older adults living in other congregate settings are recommended to receive their first booster ≥ 3 months/84 days after the last dose of their primary series.[9] **Minimum:** 1st booster dose 3 months/84 days after second dose with informed consent*	**Dose:** 0.3mL (30mcg) IM **Recommended:** 2nd booster dose 5 months/140 days after second dose.[3] Residents of Long-Term Care Homes, Retirement Homes, Elder Care Lodges and older adults living in other congregate settings are recommended to receive their second booster ≥ 3 months/84 days after their first booster.[6] **Minimum:** 2nd booster dose 3 months/84 days after second dose with informed consent*

[A] Recommended interval refers to the Ministry of Health recommendation that longer intervals between the first and second doses of COVID-19 vaccines result in more robust and durable immune response and higher vaccine effectiveness. Recommended intervals between doses must be adhered to for the purposes of this directive.

[B] Minimum interval is the Health Canada authorized interval. Although the recommended intervals between doses are always advised, shorter intervals may be considered in the context of local epidemiology and compassionate care (i.e., travel to provide palliative care, prior to a scheduled medical procedure or starting immunosuppressive treatments, etc.). When requested by the client and with informed consent minimum intervals may be used between **dose 1 and dose 2** after assessment of risk/benefit.

***** Informed consent = advising client of recommended interval and that greater interval= greater protection.

Table 4: Booster Doses for all Immunocompromised Individuals[3]

A first booster is recommended based on ongoing risk of infection due to waning immunity, the ongoing risk of severe illness from COVID-19, the societal disruptions that results from transmission of infections, and the adverse impacts on health system capacity from the COVID-19 pandemic. For individuals who received a 3 dose primary series (e.g., moderately to severely immunocompromised individuals, individuals who received COVID-19 vaccines not authorized by Health Canada), the first booster would be considered a fourth dose.

The term "second booster dose" corresponds to a fifth dose among eligible immunocompromised individuals, or individuals who have received COVID-19 vaccines not authorized by Health Canada as they have a recommended 3-dose primary series.

Individuals who are at higher risk of severe disease from COVID-19 infection include moderately to severely immunocompromised individuals and are **recommended** to get the second booster dose as soon as they become eligible.[3]

Population (Eligible and/or Recommended)	**Fourth Dose / First Booster: Recommended[A] and Minimum[B] Intervals**	**Fifth Dose/ Second Booster: Recommended[A] and Minimum[B] Intervals**
Moderately to severely immunocompromised individuals 12-17 years of age ○ **First Booster:** recommended ○ **Second Booster:** recommended	**Dose:** 0.3mL (30mcg) IM **Eligible:** 12-17 years of age **Recommended:** 1st booster dose 6 months/168 days after third dose **Minimum:** 1st booster dose 3 months/84 days after third dose with informed consent*	**Dose:** 0.3mL (30mcg) IM **Eligible:** not eligible to receive second booster dose **Recommended:** 2nd booster dose 6 months/168 days after first booster dose **Minimum:** 2nd booster dose 3 months/84 days after third dose with informed consent*
Moderately to severely immunocompromised individuals 18 years of age and older including: • 2-dose primary series Astra Zeneca vaccine recipients • 1-dose primary series Janssen vaccine recipients • 2-dose primary series Novavax vaccine recipients • 2-dose primary series Medicago vaccine recipients ○ **First Booster:** recommended ○ **Second Booster:** recommended	**Dose:** 0.3mL (30mcg) IM **Recommended:** 1st booster dose 5 months/140 days after third dose **Minimum:** 1st booster dose 3 months/84 days after third dose with informed consent*	**Dose:** 0.3mL (30mcg) IM **Recommended:** 2nd booster dose 5 months/140 days after first booster **Minimum:** 2nd booster dose 3 months/84 days after first booster with informed consent*

[A] Recommended interval refers to the Ministry of Health recommendation that longer intervals between the first and second doses of COVID-19 vaccines result in more robust and durable immune response and higher vaccine effectiveness. Recommended intervals between doses must be adhered to for the purposes of this directive.

[B] Minimum interval is the Health Canada authorized interval. Although the recommended intervals between doses are always advised, shorter intervals may be considered in the context of local epidemiology and compassionate care (i.e., travel to provide palliative care, prior to a scheduled medical procedure or starting immunosuppressive treatments, etc.). When requested by the client and with informed consent minimum intervals may be used between **dose 1 and dose 2** after assessment of risk/benefit.

*Informed consent = advising client of recommended interval and that greater interval= greater protection.

Table 5: Suggested Intervals Between Previous SARS-CoV-2 Infection and COVID-19 Vaccination[3]

Ontario, in alignment with NACI, continues to recommend that COVID-19 vaccines should be offered to individuals with previous SARS-CoV-2 infection without contraindications to the vaccine. Below are suggested intervals between previous SARS-CoV-2 infection and COVID-19 vaccination.

Infection Timing Relative to COVID-19 Vaccination	**Population**	**Suggested Interval Between Infection** and Vaccination**
Infection prior to completion or initiation of primary vaccination series.	Individuals 12 years of age and older who are immunocompetent and with no previous history of multisystem inflammatory syndrome in children (MIS-C)	Receive the vaccine 8 weeks after symptom onset or positive test (if asymptomatic)
	Individuals 12 years of age and older who are moderately to severely immunocompromised and with no history of multisystem inflammatory syndrome (MIS-C)	Receive the vaccine dose 4 to 8 weeks after symptom onset or positive test (if asymptomatic)
	Individuals 12 years of age and older with a previous history of multisystem inflammatory syndrome MIS-C (regardless of immunocompromised status)	Receive the vaccine dose when clinical recovery has been achieved or ≥ 90 days since the onset of MIS-C, whichever is longer
Infection after primary series but before first booster dose and/or second booster dose	Individuals currently eligible for booster dose(s)	3 months after symptom onset or positive test (if asymptomatic). If they are 12 to 17 years old, as per the recommended interval for the booster dose, at least 6 months (168 days) should

			have passed after completing the primary series before receiving their booster dose.

** A previous infection with SARS-CoV-2 is defined as:

- A COVID-19 case confirmed by a molecular (e.g., PCR) or rapid antigen test, or
- Symptomatic AND a household contact of a confirmed COVID-19 case.[3]

Note: When considering whether or not to administer vaccine doses following the suggested intervals outlined in the table, biological and social risk factors for exposure (local epidemiology, circulation of VODs, living settings) and severe disease should also be taken into account. There intervals are a guide and clinical discretion is advised. A longer interval between infection and vaccination may result in a better immune response. [3]

OBSERVATION PERIOD	Vaccine recipients should be kept under observation for at least 15 minutes after immunization; 30 minutes is a preferred interval when there is a specific concern about a possible vaccine reaction.[1]
PREPARATION OF VACCINE	**Reconstitution:** Remove a thawed vial of Comirnaty (Pfizer BioNTech) COVID-19 Vaccine from the refrigerator and allow it to come to room temperature OR if using a frozen vial of Comirnaty (Pfizer BioNTech) COVID-19 Vaccine, thaw for 30 minutes at room temperature.[1] Prior to dilution, invert the thawed vaccine vial gently 10 times to mix (do not shake).[1] Obtain sterile 0.9% Sodium Chloride Injection, USP (not bacteriostatic 0.9% Sodium Chloride Injection). Cleanse the vial stopper with a single-use antiseptic swab. Add 1.8 mL of 0.9% Sodium Chloride Injection, USP into the Comirnaty (Pfizer BioNTech) COVID-19 Vaccine vial using a sterile needle 21-gauge or narrower. Equalize vial pressure before removing the needle from the vial by withdrawing 1.8 mL air into the empty diluent syringe. Gently invert the vaccine 10 times to mix (do not shake). Record the date and time of dilution on the Comirnaty (Pfizer BioNTech) COVID-19 Vaccine vial label.[1] Vials at room temperature must be diluted within 2 hours.[1] The diluted product must be used within 6 hours of being reconstituted.[1] After dilution, one vial contains a minimum of 6 doses of 0.3 mL.[1]
ADDITIONAL DOSE FROM A VIAL	Following the dilution of a vial of Comirnaty (Pfizer BioNTech) vaccine with 1.8 mL of diluent (0.9% sodium chloride), the vial contains six (6) x 0.3mL doses of vaccine.[5] • It may be possible to withdraw an additional 0.3mL of the vaccine (i.e.: a 7th dose).[5] • It is recommended that if an additional dose or more of vaccine can be withdrawn from a single vial that it is administered as a valid dose and recorded accordingly in $COVax_{ON}$ or other specified documentation.[5] • Appropriate documentation of the source of these doses needs to be kept for tracking purposes.[5] • There will be no pooling of doses.

VACCINE STORAGE, STABILITY AND DISPOSAL	Refer to the Ministry of Health's General COVID-19 Vaccine Storage and Handling Guidance[5] for guidance on: • Storing, distributing, and/or administering COVID-19 vaccines. • Assessing temperature excursions, including the vaccine return process.
TRANSPORTATION OF VIALS	Refer to Ministry of Health's General COVID-19 Vaccine Storage and Handling Guidance [5] for guidance on the onward transportation of the COVID-19 vaccines beyond the initial point of delivery. This section applies to the distribution of unopened vials of COVID-19 vaccine only. Refer to the Transportation of Diluted Vaccine section below for more information on the transportation of vaccine from opened/punctured vials. Transport refers to taking the vaccine from one site to another using a vehicle on ground, air, or water. Walking the vaccine is not considered transport when it is for a short period (i.e., up to 15 minutes).
TRANSPORTATION OF DILUTED VACCINE	Refer to Chapter 1 Storage and Handling of Pfizer-BioNTech's COVID-19 Vaccines Guidance Document .[7] Once diluted, transportation is recommended in syringes to prevent agitation of the product in an opened vial. This should only be completed when necessary for vaccination and not part of routine practices. The pre-drawn syringes must be: • labelled with the name and dosage of vaccine, • labelled with the exact beyond-use date and time (i.e.: 12* hours from when the vial was first punctured), • labelled with the lot number and initials of preparer, protected with a barrier of bubble wrap or corrugated cardboard (at least 1 inch) to be utilized as a barrier between ice packs and the container with pre-drawn syringes, and • protected from light during transportation with the use of an amber-coloured UV bag with a tamper evident seal.[5] It is recommended that the vaccine is only transported at +2°C to +8°C once. Under exceptional circumstances, based on a risk assessment, the vaccine may be transported at +2°C to +8°C more than once if and per normal process ensure the following:[5] • The cold chain has been properly monitored and documented. • Syringes are packed in order to minimize movement and agitation and transport time does not exceed a maximum of 6 hours of cumulative time. Thawed punctured vials, after dilution, may be stored between 2C to 25C and use d within 24 hours from first puncture. Additional stability data has been provided from the manufacturer which supports an additional 12 hours of cumulative storage in vials or syringes to total 24 hours (12 hours as listed in the product monograph, plus an additional 12 hours excursion time).[7] *Syringe stability: additional stability data from Pfizer supports storage of diluted vaccine in syringes for up to 24 hours in refrigerated temperatures (2C to 8C) and up to 12 hours at room temperature (8C to 25C).[7] Total cumulative time post-dilution cannot exceed 24 hours.[7]

VACCINE PRESENTATION	Comirnaty (Pfizer BioNTech) COVID-19 Vaccine, mRNA presents as a white to off-white frozen suspension for intramuscular injection. It must be diluted prior to administration. The diluted vaccine will be an off-white suspension. Inspect vials to confirm there are no particulates and no discoloration, prior to administration.[1]
VACCINE COMPONENTS	Comirnaty (Pfizer BioNTech) COVID-19 Vaccine, mRNA contains a nucleoside-modified messenger RNA (modRNA) encoding the viral spike glycoprotein (S) of SARS-CoV-2 (original strain) and several non-medicinal ingredients listed below.[1] Each vial must be diluted with 1.8mL of sterile 0.9% Sodium Chloride Injection, USP prior to use to form the vaccine, and contains 6 doses of 0.3 mL after dilution. One 0.3mL dose contains 30 µg mRNA vaccine (embedded in lipid nanoparticles).[1] **Non-medicinal ingredients**: • ALC-0315 = ((4-hydroxybutyl) azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) • ALC-0159 = 2-[(polyethylene glycol*)-2000]-N,N-ditetradecylacetamide • 1,2-distearoyl-sn-glycero-3-phosphocholine • cholesterol • dibasic sodium phosphate dihydrate • monobasic potassium phosphate • potassium chloride • sodium chloride • sucrose • water for injection *Polyethylene glycol (PEG) is found in bowel preparation products for colonoscopy, laxatives, cough syrup, cosmetics, skin care products, and some food and drinks, however, this list is not exhaustive. The vial stopper does not contain natural rubber latex.
REFERENCES	1. Pfizer Canada ULC. Pfizer-BioNTech COVID-19 Vaccine (COVID-19 mRNA Vaccine) Product Monograph. Updated June 1, 2022. 2. National Advisory Committee on Immunization (NACI). COVID-19 vaccine: Canadian Immunization Guide - Canada.ca. 3. Ontario Ministry of Health. COVID-19: Vaccine Administration. Version 5.0, April 29 2022. 4. Ontario Ministry of Health. COVID-19: Vaccine Booster Recommendations. Version 8.3. July 14, 2022. 5. Ontario Ministry of Health. General COVID-19: Vaccine Storage and Handling Guidance. Version 1, March 24, 2022. 6. Ontario Ministry of Health. Staying Up to Date with COVID-19 Vaccines: Recommended Doses. Version 2.0, May 2, 2022 (amended May 24, 2022). 7. Ontario Ministry of Health. Chapter 1: Storage and Handling of Pfizer-BioNTech's COVID-19 Vaccines. Version 1, July 2022.

SIGNATURE AND DATE	Date: July 26, 2022 Revised: May 2022