[Insert Health Care Agency]

MEDICAL DIRECTIVE: Comirnaty® COVID-19 Vaccine (Pfizer-BioNTech)

Original Date: YYYY/MM
Next Review Date: YYYY/MM
Contact Officer: [Insert Agency Contact Officer]

Order/Delegated Procedure

Administer injectable Comirnaty COVID-19 immunizations (Pfizer-BioNTech 30mcg dose).

Recipient Clients

Authorized for use in those 12 years of age and older[2]
Authorized as a booster dose in those 18 years of age and older[2]
Based on advice from Ontario's Vaccine Clinical Advisory Group and NACI, the Ministry of Health is issuing a preferential recommendation for the use of Comirnaty COVID-19 vaccine (Pfizer-BioNTech) for individuals younger than 30 years of age.[9]

Authorized Implementers

Health care providers of [Named Agency] including nurses, nursing students under the supervision of a nurse, and contracted Agency Nurses in good standing with the College of Nurses of Ontario (CNO) and who have completed the required orientation, including a review of related policies, educations training at clinics and observation by the [Agency Designate].

Indications

- Comirnaty (COVID-19 Vaccine, mRNA) is indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS- CoV-2)[1]

Contraindications

Clients are **NOT ELIGIBLE** for Comirnaty COVID-19 vaccine under this medical directive if there is a risk of serious adverse reaction identified during their health assessment:

- A history of anaphylactic reaction to a previous dose of the Comirnaty COVID-19 vaccine [1]
- A history of <u>proven</u> immediate or anaphylactic hypersensitivity to any component of the Comirnaty COVID-19 vaccine or its packaging.[1] Components of the Comirnaty

COVID-19 vaccine are listed in Appendix A.

The vaccine should not be administered in a general vaccine clinic. The client must seek evaluation by an appropriate physician or Nurse Practitioner (NP). Such an assessment is required to assess the method for possible (re)administration of a COVID-19 vaccine.[9]

Documentation after discussion with the health care provider is to be provided at the clinic including a vaccination care plan and **parameters the clinic should meet to provide safe vaccine administration.**[9]

Precautions

- As a precautionary measure, the additional dose of mRNA vaccine should be deferred in individuals who have experienced myocarditis or pericarditis following any preceding dose of an mRNA COVID-19 vaccine until more information is available.[15] The National Advisory Committee on Immunization (NACI), Public Health Ontario (PHO) and The Ministry of Health continue to follow this closely and will update this recommendation as more evidence becomes available.[14]
- Individuals with proven severe allergic reaction (e.g., anaphylaxis) to injectable therapy not related to a component of authorized COVID-19 vaccines (e.g. intramuscular, intravenous, or subcutaneous vaccines or therapies) may be routinely vaccinated and do not need to be assessed. Most instances of anaphylaxis to a vaccine begin within 30 minutes after administration of the vaccine. Therefore, an extended period of observation post-vaccination of 30 minutes should be provided for the aforementioned individuals.[2]
- Individuals with a history of allergy not related to a component of authorized COVID-19 vaccines or other injectable therapy (e.g. foods, oral drugs, insect venom or environmental allergens) can receive COVID-19 vaccines without any special precautions. Individuals should be observed for a minimum of 15 minutes following vaccination.[2]
- Clients with a bleeding disorder should be optimally managed prior to immunization.[2]
- Clients currently experiencing moderate/severe, acute illness should have their vaccination postponed until the illness has resolved.[2]

Additional Special Considerations and Third Dose Eligibility

- COVID-19 vaccines should not be given simultaneously with monoclonal antibodies or convalescent plasma.[2]
- Clients receiving anticoagulant therapy can be immunized if they are optimally managed, and after immunization they should be advised to apply firm pressure to the injection site for 5 to 10 minutes.[2]
- NACI recommends that COVID-19 vaccines may be given concomitantly with, or at

any time before or after, other vaccines, including live, non-live, adjuvanted, or unadjuvanted vaccines.[2]

- If tuberculin skin testing or an 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 tuberculin skin testing have been completed. [2]
- For more information on the administration of COVID-19 vaccines, please refer to the NACI document: Recommendations on the use of COVID-19 vaccines (as current).
    - If this is the individual's second dose and they received the AstraZeneca vaccine for their first dose, ensure the client has read and understood the *COVID-19 Vaccine Information for Individuals who received a First Dose of the AstraZeneca/COVISHEIELD information sheet from the Ministry of Health.*
- For the most current information related to special populations, please refer to the Ministry of Health document: COVID-19 Vaccination Recommendations for Special Populations, December 31, 2021 (or as current).
- For information on third dose eligibility and fourth doses for specific populations, please refer to the Ministry of Health document: COVID-19 Vaccine Third Dose Recommendations, January 13, 2022 (or as current).

Obtaining Consent

Appropriate informed consent must be obtained as per the *Guidelines for Implementing the Order/Delegated Procedure* and the client must NOT have any contraindications.

Guidelines for Implementing the Order/Delegated Procedure

Nurses and nursing students are expected to prepare and administer vaccine(s) to clients in a safe, effective, and ethical manner, and to be accountable for their actions. Nurses and nursing students are expected to meet the CNO's Medication Practice Standard by performing all the administration and verification steps to minimize the chance of error.

Nurses and nursing students are expected to consult with their Manager or designate if unable to perform their nursing duties in a safe and effective manner.

Responsibilities of the nurse and nursing student who implement the intervention include the following:

- Clarify that informed consent has been obtained
- Assess the client to determine whether the specific client conditions and any situational circumstances identified in the directive have been met
- Know the risks to the client of implementing the Order/Delegated

Procedure

- Possess the knowledge, skills and judgement required to implement the directive safely
- Know the predictability of the outcomes of the intervention
- Determine whether management of the possible outcomes is within their practice; if so whether they are competent to provide management of outcomes and if not, whether the appropriate resources are available to assist as required.

Administration of vaccine must be in accordance with the manufacturers' product information monographs and the NACI's Recommendations on the use of COVID-19 vaccine(s).[2]

At all clinics where immunizing agents are administered, the [ ] will be available for consultation.

Agency Designate

Informed Consent

To obtain informed consent, the nurse and/or nursing student must ensure:

- The purpose of the immunization, desired outcome, risks, and benefits are reviewed.
- The client has read and understood the information on the appropriate COVID-19 Vaccine Information Sheet(s). If the client cannot read the sheet, it should be read or explained to them. The nurse must ensure the client has no contraindications to the vaccine as specified in the "Contraindications" section of this Medical Directive and query regarding current health (e.g., immunosuppression) and precautions.
- The client has had the opportunity to ask questions about the vaccine and had these questions answered to their satisfaction.
- The client has provided informed written or verbal consent to the nurse administering vaccine.

Capacity to provide consent

A client can give consent if they understand the information that is being presented to them and appreciate the foreseeable consequences of their decision or lack of decision.

When in doubt about informed consent or a medical condition of the client, do not administer the vaccine and consult with the [ ].

Agency Designate

Comirnaty COVID-19 Vaccine

Dose and Schedule for the Comirnaty COVID-19 Vaccine:

Dose:

- 30 mcg of SARS-CoV-2 spike protein mRNA.

Volume:

- 0.3 mL

Schedule:

- 2 doses
    - Minimum interval 19 days apart
    - Authorized interval 21 days apart
    - Alternate interval 28 days apart [2]
- 3 doses
    - For specific timing of third dose intervals refer to the Ministry of Health document COVID-19 Vaccine Third Dose Recommendations (January 13, 2022 or as current)
- 4 doses
    - For fourth dose eligibility and dose intervals refer to the Ministry of Health document COVID-19 Vaccine Third Dose Recommendations (January 13, 2022 or as current)
    - For rationale and options for vaccine type and dose, refer to table 2 in the aforementioned guidance document.

Preparation and Administration of the Comirnaty COVID-19 Vaccine

Follow the *Injection Technique Policy and Procedure of* [Named Agency] in conjunction with the following resources below.

COVID-19 Vaccine Administration guidance document https://www.health.gov.on.ca/en/pro/programs/publichealth/coronavirus/docs/vaccine/COVID-19_vaccine_administration.pdf with additional information on preparation, dosage forms, strengths, composition, and packaging found in the vaccine product monograph https://covid-vaccine.canada.ca/info/pdf/pfizer-biontech-covid-19-vaccine-pm1-en.pdf

Storage Requirements and Additional Doses from Vaccine Vials
Refer to the Vaccine Storage and Handling guidance document https://www.health.gov.on.ca/en/pro/programs/publichealth/coronavirus/docs/vaccine/vaccine_storage_handling_pfizer_moderna.pdf

Documentation and Communication
Documentation of administered doses into the COVax database post-

vaccination should be completed following the [ ] procedure
Named Agency
and the College of Nurses of Ontario's Documentation Practice Standard.] [6]

Adverse Reactions

The following adverse events have been reported as being common, very common or uncommon after either dose of the Comirnaty COVID-19 vaccine[2]:

Very common: may affect more than 1 in 10 people
- injection site pain
- tiredness
- headache
- muscle pain
- chills
- joint pain
- fever
- diarrhea

Common: may affect more than 1 in 100 and up to 1 in 10 people
- injection site redness
- injection site swelling
- nausea
- vomiting

Uncommon: may affect up to 1 in 100 people
- enlarged lymph nodes
- feeling unwell
- arm pain[1]
- feeling weak or lack of energy/sleepy
- decreased appetite
- excessive sweating
- night sweats[1]

Recommendations for the post-vaccination observation period for other vaccines during the pandemic, such as for influenza vaccine, should continue to be followed.[2] Therefore, advise clients to remain in the post-vaccination waiting area for the length of time as recommended in the National Advisory Committee on Immunization (NACI) *Recommendations on the Duration of the Post-vaccination Observation Period for Influenza Vaccination during the COVID-19 Pandemic*.[4]

Given the urgency to provide booster doses, the 15-minute observation period booster

doses of mRNA vaccines could be waived on a temporary basis during the emergency response to the Omicron variant. A reduced post-vaccination observation period, between 5 -15 minutes could be considered for the administration of third booster doses of COVID-19 vaccine during the pandemic, if specific conditions are met such as past experience with the two previous COVID-19 vaccine doses and other relevant conditions as outlined in the NACI 2020-2021 influenza vaccine advice.[16]

In situations of suspected hypersensitivity or non-anaphylactic allergy to COVID-19 vaccine components, the [Agency Designate] shall be consulted prior to vaccination, to determine the appropriateness of the vaccination, the option of vaccination in a controlled setting and/or the use of an extended post-vaccination observation period.

As per s.38 of the *Health Protection and Promotion Act*, those administering vaccines should ensure that the vaccine recipients are advised to immediately call their doctor/nurse practitioner or go to the nearest hospital emergency department if they develop a reaction that could be related to the vaccine.[5] Specifically, the client should be monitored for:

- Hives
- Swelling of the mouth and throat
- Trouble breathing, hoarseness or wheezing
- High fever (over 40C or 104F)
- Convulsions (seizures)
- A fast heartbeat [1]
- Dizziness and weakness [1]

If a reaction as described above occurs while at an [Named Agency], refer to the *Medical Directive for Anaphylaxis Management or internal policies.*

Adverse events/reactions must be documented, reported to the Renfrew County and District Health Unit.

Approving Physician(s)/Authorizer(s):

NAME: **SIGNATURE:**	**DATE:** YYYY/MM/DD

Appendix A – Components of the Comirnaty COVID-19 Vaccine and its Packaging

For a comprehensive list of components in the vaccine and packaging, please consult the product leaflet or information contained within the product monograph available through Health Canada's Drug Product Database.[2]

Potential non-medicinal ingredients in the vaccine or its container known to cause type 1 hypersensitivity reactions ranging from mild cutaneous reactions to anaphylaxis includes the following (which may not be a complete list):

- polyethylene glycol (PEG)[2]

The full list of non-medical ingredients is as follows:[1]

- 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

Comirnaty COVID-19 Vaccine does not contain any preservatives, antibiotics, adjuvants, or human- or animal-derived materials. The glass vials have a stopper which does not contain natural rubber latex.[1]

Appendix B - Immunosuppression

- Long-term immunosuppressive therapy is used for various disease conditions including cancer, organ transplantation, GVHD following HSCT, and chronic inflammatory conditions (e.g., inflammatory bowel disease, inflammatory arthritis, psoriasis, systemic lupus erythematosus). Therapies include cancer chemotherapy, radiation therapy, long term high-dose steroid treatment (prednisone equivalent of ≥ 2 mg/kg/day or 20 mg/day if weight > 10 kg, for ≥ 14 days), cytotoxic drugs, calcineurin inhibitors, biological response modifiers and antibodies that target lymphocytes.
- In general, if a patient is 3 months post-chemotherapy and the cancer is in remission, or if immunosuppression has been discontinued for at least 3 months (6 months or more for anti-B cell antibodies), the person is no longer considered immunocompromised.
- Individuals living with HIV that are considered immunocompetent can be vaccinated. Individuals with stable Hepatitis B or C infection can also be vaccinated. [8]
- If there is uncertainty regarding whether or not a client qualifies as being immunosuppressed, consult the MOH.

References

1. Product Monograph – Pfizer-BioNTech COVID-19 Vaccine
2. NACI's Recommendations on the use of COVID-19 vaccines
3. NACI's Guidance on the Prioritization of key populations for COVID-19 Vaccine(s)
4. Recommendations on the Duration of the Post-vaccination Observation Period for Influenza Vaccination during the COVID-19 Pandemic
5. Health Protection and Promotion Act
6. College of Nurses of Ontario. Documentation, revised 2008. Toronto, ON: 2019.
7. Ministry of Health and Long-Term Care Guidance document COVID-19 Vaccine-relevant information and planning resources
8. Canadian Immunization Guide, Immunization of Immunocompromised Persons Part 3- Vaccination of Specific Populations.
9. Ministry of Health and Long-Term Care Guidance document: COVID-19 Vaccination Recommendations for Special Populations. Version 9.1 December 31,2021.
10. Ministry of Health and Long-Term Care Guidance document COVID-19 Vaccine: Allergy Form. Version 3.0 March 11, 2021-or as current.
11. Ministry of Health and Long-Term Care Guidance Document: COVID-19: Vaccine Storage and Handling Guidance. Version 7.2 January 5, 2022
12. NACI Rapid Response: Interchangeability of Authorized COVID-19 Vaccines.
13. Ministry of Health Memorandum: Ontario COVID-19 Vaccine Program. August 17, 2021
14. Ministry of Health and Long-Term Care Guidance Document: COVID-19 Vaccine Information Sheet. Version 1.0 December 14, 2021.
15. Chief Medical Officer of Health Statement: Ontario Recommends the use of Pfizer-BioNTech COVID-19 Vaccine for Individuals Aged 18-24 Years Old. September 29, 2021.
16. Ministry of Health Document: COVID-19 Vaccine Third Dose Recommendations, Version 7.0 January 13, 2022 (or as current).