



Pfizer-BioNTech COVID -19 mRNA Vaccine for COVID Immunization Clinic – Medical Directive

Medical Advisory Committee Approved: 05FEB2021

Harmonized

A printed copy of this document may not reflect the current, electronic version on Lakeridge Health's Intranet, 'The Wave.' Any copies of this document appearing in paper form should ALWAYS be checked against the electronic version prior to use.

Authorizing Prescriber(s)

Lakeridge Health (LH) Physician(s) for the COVID Immunization Clinic (CIC), Occupational Health (OH), Safety and Healthy Workplace Department (herein after referred to as Occupational Health) at LH.

Authorized to Whom

Regulated Health Care Providers (RHCP) working in the CIC and/or OH with the knowledge, skill, judgement and training to administer intramuscular (IM) treatments.

Patient Description/Population

Any Lakeridge Health Colleague (LHC) and/or patient, 16 years of age and older, who requires a Pfizer-BioNTech COVID-19 mRNA vaccine.

LHCs include:

- employees,
- privileged staff (physicians, dentists, midwives),
- volunteers,
- board members
- contract workers, and
- students

Any CIC Patient 16 years of age and older who requires a Pfizer- BioNTech COVID-19 mRNA vaccine.

Order and/or Procedure

***** Doses are for LHCs who are 16 years of age or older***.**

1. Provide the patient or LHC with information regarding Pfizer-BioNTech COVID-19 mRNA vaccination.
2. Review the decision form with the patient or LHC to ensure that it has been read, understood and signed.
3. Perform relevant assessment of allergy status, present health and current medications
4. Explain the procedure, the risks, side effects, and precautions found on the consent form
5. Ensure there are no contraindications to the vaccination with the Pfizer-BioNTech COVID-19 mRNA vaccine found on the decision form.

Document Sponsor/Owner Group: Occupational Health, Date Approved 18DEC2020

This material has been prepared solely for the use at Lakeridge Health. Lakeridge Health accepts no responsibility for use of this material by any person or organization not associated with Lakeridge Health. No part of this document may be reproduced in any form for publication without the permission of Lakeridge Health.

6. Administer Pfizer-BioNTech COVID-19 mRNA vaccine, 30 mcg (0.3 mL) IM (deltoid):

- Initial dose (first shot in the series)

AND

- At least 19 days post initial dose (second/last shot of the series).

Note: The preferred interval is 21-28 days, and up to 42 days, as advised by the Ministry of Health of Ontario, in the context of limited vaccine supply. Longer intervals between doses are acceptable (e.g. beyond 42 days), in extenuating circumstances, where the LHC and/or patient could not receive the second dose in the preferred interval.

7. If this is the patient's/LHC second visit, (second/last shot of the series) ensure that the Pfizer -BioNTech mRNA vaccine to be administered is the same as the one received at the initial visit (first/initial shot of the series).

8. Advise the patient/LHC to remain in the vicinity for post injection to monitor for serious adverse reaction:

- 15 minutes (no history of adverse reactions),

OR

- 30 minutes (history of adverse reaction to food, medication, and/or environment (e.g. anaphylaxis to bee stings)

9. Advise the patient/LHC to notify OH or CIC of significant side effects.

Indications to the Implementation of the Directive

Any LHC/patient, 16 years of age and older, who require and have not received the Pfizer-BioNTech COVID-19 mRNA vaccine, have not completed a COVID-19 vaccine series, or have not initiated a vaccine series with a different vaccine product.

Precautions with the following populations:

- Patients/LHC who have a bleeding issue, bruise easily or use a blood-thinning medicine

Contraindications to the Implementation of the Directive

This medical directive must not be implemented in the following circumstances:

- The LHC, patient, Substitute Decision Maker (SDM) and/or guardian refuses to provide verbal consent/assent,
- The LHC/patient is less than 16 years of age,
- Acutely ill,
- LHC/patients exhibiting signs and/or symptoms of anaphylactic hypersensitivity to any of the components of the Pfizer- BioNTech COVID-19 mRNA vaccine or its container, including polyethylene glycol,
- LHC/patients who are symptomatic individuals with confirmed or suspected SARS-CoV-2 infection, or those with symptoms of COVID-19,



Pfizer-BioNTech Covid-19 mRNA Vaccine for COVID Immunization Clinic – Medical Directive

Medical Advisory Committee Approved: 05FEB2021

- LHC/patients who are immunosuppressed due to disease or treatment or those with an autoimmune disorder,
- LHC/patients who have received another vaccine (not a COVID-19 vaccine) in the past 14 days,
- LHC/patients who are or who are planning on becoming pregnant,
- LHC/patients who are breastfeeding.

Any LHC/patient with contraindications within this medical directive will require consultation with the CIC MRP (e.g., LHC or patients who are or who are planning on becoming pregnant, who are breastfeeding, immunocompromised, have an autoimmune disorder or who are less than 16 years of age)

Consent

The RHCP implementing this medical directive must obtain consent/assent.

If the LHC, patient, member of the household/SDM refuses to consent, do not carry out the vaccination and refer them to their Primary Healthcare Practitioner.

Documentation Requirements

In addition to the standard documentation practices, the nurse implementing this directive must document the following in the LHCs or patients, Provincial consent form and retaining that as documentation, and will include:

- The name of this medical directive
- The procedure that was completed
- The name of the implementer
- The date and time (unless documenting electronically)
- Legible signature of implementer including credentials

For example: December 20th, 2020 at 1000, COVID-19 mRNA vaccine administered as per the Occupational Health COVID-19 mRNA Vaccine for COVID Immunization Clinic– Medical Directive, B. Smith, RN.

Review/Evaluation Process

This medical directive will be reviewed every 2 years by Occupational Health

References

Canadian Immunization Guide. OHA/OMA Communicable Disease Surveillance Protocol – Influenza Protocol Product Monographs (all vaccines and stock medications)

COVID-19 Vaccine Lakeridge Health Monograph



**Pfizer-BioNTech Covid-19 mRNA Vaccine for COVID
Immunization Clinic – Medical Directive**

Medical Advisory Committee Approved: 05FEB2021

Ministry of Health. COVID-19 Administration of Pfizer-BioNTech COVID-19 Vaccine.
Version1. December 13, 2020.

PFIZER-BIONTECH COVID-19 Vaccine Product Monograph. COVID-19 mRNA Vaccine,
Suspension for Intramuscular Injection

Government of Ontario (2017). Regulated health professions act, 1991S.O. 1992, chapter
18. Retrieved from <https://www.ontario.ca/laws/statute/91r18>