Vaccine Medical Directive and Delegation
Novavax (Nuvavax) 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	Novavax (Nuvaxovid) COVID-19 Vaccine (recombinant protein subunit) for the prevention of coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older in whom contraindications are not present.[1] The recombinant protein subunit COVID-19 vaccine Novavax Nuvaxovid may be offered to individuals in the authorized age group without contraindications to the vaccine who are not able or willing to receive an mRNA COVID-19 vaccine.[3]
SITUATIONAL CONDITIONS	• Informed consent. • Absence of contraindication(s). • In accordance with $COVAX_{ON}$ schedules logic.
CONTRAINDICATIONS	Novavax (Nuvaxovid) is contraindicated for use by implementers authorized under this medical directive for the following individuals: • Individuals who have had a severe immediate (≤ 4 hours following vaccination) allergic reaction (e.g., anaphylaxis) after previous administration of COVID-19 vaccine, or any component of the COVID-19 vaccine, until clinically assessed and advised to receive the vaccine. Referral to a MD or NP is recommended. 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. [5] • In general, an allergy to a component of a specific vaccine or its container is considered a contraindication. Polysorbate 80 is found in Novavax Nuvaxovid and is a potential allergen that has been associated with allergic reactions in other products. These reactions have occurred rarely and ranged from mild cutaneous reactions to anaphylaxis.

WARNINGS AND PRECAUTIONS	The use of Novavax (Nuvaxovid) COVID-19 Vaccine may be permitted, or must be deferred, for individuals in accordance with the following: **Acute Illness** Vaccination should be deferred in individuals with symptoms of SARS-CoV-2 infection, or those with respiratory symptoms until symptoms are completely resolved to minimize the risk of transmission of infection at an immunization clinic and to avoid attributing any complications resulting from infection to vaccine related AEFI. Symptomatic and asymptomatic individuals who have been advised to self-isolate due to COVID-19 exposure should defer vaccination until their isolation period is over. 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**. **Hypersensitivity and allergies** A component of the Novavax Nuvaxovid vaccine that may cause type 1 hypersensitivity reactions is Polysorbate 80. Allergic reactions to Polysorbate 80 are rare. Polysorbate 80 is found in products such as medical preparations (e.g., vitamin oils, tablets, and anticancer agents) or cosmetics.[3] For individuals with serious polyethylene glycol (PEG) allergy or previous serious allergic reaction to an mRNA vaccine precluding vaccination with mRNA vaccines, Novavax Nuvaxovid may be the preferred product for vaccination, based on consultation with an allergist or other appropriate physician or nurse practitioner. [3] **Autoimmune conditions and immunodeficiencies** The safety and efficacy of Novavax (Nuvaxovid) have not been established in these groups. **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 (NACI). In individuals with bleeding disorders, the condition should be managed prior to immunization to minimize the risk of bleeding.[2,3,4] **Myocarditis and Pericarditis** Cases of myocarditis and/or pericarditis have been reported following the administration of Novavax (Nuvaxovid) including two teenage males who had myocarditis shortly after receiving a second dose of vaccine. The clinical course for both was mild and resolved completely. Further studies are underway. [1] Based on advice from Ontario's Vaccine Clinical Advisory Group, the Ministry of Health is issuing a preferential recommendation for the use of Pfizer-BioNTech COVID-19 vaccine for individuals 12-29 years of age. In the context of adequate Pfizer-BioNTech COVID-19 vaccine supply, the preferential recommendation for the use of Pfizer-BioNTech COVID-19 vaccine for individuals 12-29 years of age is anticipated to reduce the rare number of events of myocarditis/pericarditis in Ontario.[3] 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.

Some people with confirmed myocarditis and/or pericarditis may choose to receive another dose of vaccine after discussing the risks and benefits with their healthcare provider. Individuals can be revaccinated once they are symptom free and at least 90 days has passed since vaccination. If another dose of vaccine is offered, they should be offered the Pfizer-BioNTech 30 mcg vaccine 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. [3]

Adverse Reactions
Very common and common side effects after administration of Novavax (Nuvaxovid) COVID-19 Vaccine are injection site pain, fatigue, headache, muscle pain, chills, joint pain, nausea/vomiting. Older vaccine recipients experienced lower frequencies of events.

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.[3]

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. 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
The safety and efficacy of Novavax (Nuvaxovid) have not been established in these groups. [3]

PHYSICIAN'S ORDER

Novavax (Nuvaxovid) COVID-19 Vaccine (recombinant protein subunit)

NACI continues to preferentially recommend the use of mRNA COVID-19 vaccines for most people due to the excellent protection they provide against severe illness and hospitalization and their well-known safety profiles. The Novavax Nuvaxovid vaccine is a new COVID-19 vaccine option for people who have been unable, due to contraindications or are not willing to receive an mRNA COVID-19 vaccine.[3]

Table 1: Immunocompetent Individuals

Population	Schedule	First Dose	Second Dose	Third dose

Individuals 18 years of age and older Pfizer-BioNTech COVID vaccine is preferred for individuals 12-29 years of age. Out of province/country [D]	2 dose primary series	0.5 mL (5 mcg) IM	0.5 mL (30 mcg) IM in accordance with the following product-specific intervals[A,B] At a minimum of 21 days – NACI suggests 8 weeks between doses.[3] **Vaccine for first dose** / **Vaccine for second dose** / **Recommended and minimum intervals between Doses [A,B]** mRNA vaccine[1,3] / Recommended interval 8-12 weeks[1] Novavax / Recommended interval 8 – 12 weeks. Astra Zeneca / Novavax / Recommended interval 8 – 12 weeks[1] For intervals following previous SARS-CoV-2 infection see E	Recommended interval 6 months (168 days) after second dose[1] Can be given as a booster dose 10 – 12 weeks after a primary series of Astra Zeneca or Pfizer. [C,1]	

[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.

[C] The Novavax Nuvaxovid COVID-19 vaccine may be offered as a booster dose to people without contraindications who are not able or unwilling to receive an mRNA vaccine, regardless of which COVID-19 vaccines were received in the primary series. NACI continues to preferentially recommend that booster doses of a mRNA COVID -19 vaccine should be offered to individuals without contraindications to the vaccine. Informed consent should include a discussion about what is known and unknown about the benefits and potential risks of the use of the Novavax Nuvaxovid vaccine as a booster dose. [3]

[D] For those vaccinated outside of Ontario or Canada please refer to and follow Provincial Guidance [5]

E [3]

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 5 years of age and older who are not considered moderately to severely immunocompromised 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 5 years of age and older who are moderately to severely immunocompromised and with no previous history of MIS-C	Receive the dose 4- 8 weeks after symptom onset or positive test if asymptomatic
	Individuals 5 years of age and older with a previous history of 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 – 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 the booster dose

A previous infection with SARS-COV-2 is defined as:

- Confirmed by a molecular (e.g PCR or rapid antigen test) or
- Symptomatic AND a household contact of a confirmed COVID-19 case.

Immunocompromised Individuals
There is currently no data to support the efficacy and safety of Novavax (Nuvaxovid) in individuals who are immunocompromised due to disease or treatment. [3]

Interruption of a vaccine series resulting in a greater than suggested interval between doses does not require restarting the series since a delay between doses does not result in reduced protection.[2]

Reconstitution:
There is no diluent. The Novavax Nuvaxovid COVID-19 vaccine must not be reconstituted, mixed with other medicinal products, or diluted.[3]
Before administering a dose of vaccine, carefully mix the contents of the multi-dose vial by swirling gently in an upright position for 10 seconds. **Do not shake**. [3]

Observation Period
A 15-minute observation period is recommended. [2]

DOSE FROM A VIAL	A vial of Novavax (Nuvaxovid) contains 10 doses of 0.5 mL. • There will be no pooling of doses.
VACCINE STORAGE, STABILITY AND DISPOSAL [1, 23]	**Storage Prior to Use:** The unopened NUVAXOVID multidose vials are stored refrigerated between 2° to 8°C (36° to 46°F) for a maximum of 9 months. Store in the original carton to protect from light. **Storage of Punctured vials** Chemical and physical in-use stability has been demonstrated from the time of first needle puncture to administration for 6 hours at 2°C to 25°C.

	NUVAXOVID does not contain a preservative. Store the opened vial between 2°C to 25°C for up to 6 hours
TRANSPORTATION OF VIALS	Refer to the Ministry of Health's COVID-19: Vaccine Storage and Handling Guidance (version 7.4 –March 24, 2022, or most current)[4] 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.
TRANSPORTATION OF VACCINE	Refer to Ontario Ministry of Health, COVID-19: Vaccine Storage and Handling Guidance:[4] The vaccines should be transported prior to puncture, but in the event that transport of a punctured vial or pre-drawn syringe is required to provide access to vaccination or prevent wastage the following should be followed/considered: • Adherence to the must use by date/timing of the product following first puncture of a vial: Novavax 6 hours post first puncture stored between +2oC to +25oC • A pre-filled syringe is stable for 6 hours between 2˚C and 25˚C • The number of times an opened vial or pre-drawn syringe is transported should be minimized to prevent risk of product microbial contamination and adherence to the must use by date/timing • A barrier of bubble wrap or corrugated cardboard (at least 1 inch) may be utilized as a barrier between ice packs and the container with the vial or pre-drawn syringes.[4] • The vial or syringe(s) should be packed to cushion it and to protect it from agitation • The cold chain has been properly monitored and documented • The vial or syringe(s) should be packed appropriately in a conditioned cooler (transport container) at +2oC to +8oC and the temperature monitored during transport The vial or pre-drawn syringes should be labelled with the name and dosage of vaccine, exact beyond-use date, and time (i.e.: 6 hours from when the vial was first punctured), lot number and initials of preparer, facility name and phone number. Transport time is a maximum of 6 hours cumulative.
VACCINE PRESENTATION	Colourless to slightly yellow, clear to mildly opalescent suspension free of particles provided in a clear multidose glass vial with a rubber stopper and a blue flip-off top. Each multidose vial contains 10 doses each of 0.5 mL.
VACCINE COMPONENTS	Medicinal ingredients: 5 micrograms of purified SARS-CoV-2 recombinant spike protein as the active substance.[2] **Non-medicinal ingredients**: • Disodium hydrogen phosphate heptahydrate • Sodium dihydrogen phosphate monohydrate • Sodium chloride • Polysorbate 80 • Sodium hydroxide • Hydrochloric acid • Water for injection The Matrix-M adjuvant contains cholesterol, phosphatidylcholine, potassium dihydrogen phosphate, disodium hydrogen phosphate dihydrate, sodium chloride, and potassium chloride.[2] *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.[2] The vial stopper does not contain natural rubber latex. [2]

REFERENCES	1. NACI Recommendations on the use of Novavax (NUVAXOVID) COVID-19) vaccine. February 17, 2022. 2. Nuvaxovid Product Monograph. February 17, 2022. 3. COVID-19 Vaccine Administration. Version 5.0. April 27, 2022. 4. COVID-19: Vaccine Storage and Handling Guidance. Version 7.4. March 24, 2022. 5. COVID-19 Guidance for Individuals Vaccinated Outside of Ontario/Canada. V 4.0 March 24, 2022. 6. COVID-19 Vaccination Recommendations for Special Populations. V 9.1 December 31, 2021.
SIGNATURE AND DATE	Date: May 2, 2022

R: April 2022