Vaccine Medical Directive and Delegation
Janssen (Johnson & Johnson) 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	Janssen COVID-19 Vaccine (SARS-CoV-2 Vaccine [Ad26.COV2. S, recombinant]) is indicated for active immunization for the prevention of coronavirus disease-2019 (COVID-19) caused by SARS-CoV-2 virus in individuals 18 years and older. Janssen COVID-19 Vaccine is a single dose viral vector vaccine. There is a preferential recommendation for the use of mRNA COVID-19 vaccines in all authorized age groups due to better effectiveness of mRNA vaccines and the rare risk of certain serious adverse events with viral vector vaccines, such as VITT. A viral vector COVID-19 vaccine may be offered to individuals in the authorized age group without contraindications to the vaccine only when all other authorized COVID-19 vaccines are contraindicated.[3] Informed consent should include discussion about the risk and symptoms of Vaccine-Induced Thrombotic Thrombocytopenia (VIIT) as well as the need to seek immediate medical care should symptoms develop.[4] Refer to the warning and precautions section for further information and list of symptoms. Anyone receiving any authorized viral vector COVID-19 vaccine should be informed of the risks associated with viral vector vaccines (Vaccine-Induced Thrombotic Thrombocytopenia (VIIT), Capillary Leak Syndrome (CLS), and Guillain-Barré Syndrome (GBS) and be advised to seek medical attention if they develop signs and symptoms suggestive of these

	conditions.[4] Refer to the warning and precautions section for further information and list of symptoms.
SITUATIONAL CONDITIONS	• Informed consent. • Absence of contraindication(s)**.** • In accordance with $COVAX_{ON}$ schedules logic.
CONTRAINDICATIONS	Janssen COVID-19 Vaccine is contraindicated for use by implementers authorized under this medical directive for the following: • Actively receiving monoclonal antibody therapy or convalescent plasma therapy for the treatment or prevention of COVID-19. • Individuals who have experienced major venous and/or arterial thrombosis with thrombocytopenia following vaccination with any vaccine.[2] • Individuals who have a history of capillary leak syndrome (CLS).[2] • Individuals who have experienced/who think they have experienced a previous cerebral venous sinus thrombosis (CVST) with thrombocytopenia or who have experienced heparin-induced thrombocytopenia (HIT).[2] • 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, should seek evaluation by an appropriate physician or nurse practitioner. Such an assessment is required to assess the method for possible (re)administration of a COVID-19 vaccine. [(2)]until clinically assessed and advised to receive the vaccine.
WARNINGS/ PRECAUTIONS	The use of Janssen 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.[2,3] 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.[2,3] 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** Individuals who have had a severe, immediate (≤ 4h following vaccination) allergic reaction or anaphylaxis to a previous dose of a COVID-19 vaccine or to any of its components or its container should **seek evaluation by an appropriate physician or Nurse Practitioner (NP) as vaccination with an mRNA vaccine can be safely performed in these individuals.** Such an assessment is required to assess the method for possible (re)administration of a COVID-19 vaccine. Vaccination with an mRNA vaccine can be safely administered to individuals with severe, immediate allergic reactions to ingredients or components of the vaccine under supervision of an appropriate physician. Individuals with known allergies to components of the mRNA vaccines should 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 a physician. The allergens included in the vaccine include polyethylene glycol (PEG), tromethamine (trometamol or Tris), and polysorbate 80.

	* **Documentation** of the discussion with the physician/NP must be provided to the clinic and 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. Referral and consultation support for Physicians and Nurse Practitioners is available through Ontario's eConsult Service.[5] 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.[2,3,4] 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.[1,2,3,4] **Autoimmune conditions and immunodeficiencies** 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 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.[2,3,4,5] 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.[4,5] Person requesting re-vaccination in these circumstances should present a completed referral form (English/French) from a health care provider/specialist outlining the optimal timeline for re-vaccination. 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).[2,3,4,5] **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]

As per NACI, anyone receiving any authorized viral vector COVID-19 vaccine should be informed of the risks associated with viral vector vaccines including Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT), Capillary Leak Syndrome (CLS), and Guillain-Barre syndrome (GBS) following viral vector COVID-19 vaccines (NACI, 2021) and be advised to seek medical attention if they develop signs and symptoms suggestive of these conditions.

Rare cases of serious thrombosis (blood clots) and thrombocytopenia (low platelets): VITT (Vaccine-Induced Immune Thrombotic Thrombocytopenia)
A combination of thrombosis and thrombocytopenia (TTS), in some cases accompanied by bleeding, that resembles HIT (heparin-induced thrombocytopenia) have been observed very rarely following vaccination with Janssen COVID-19 Vaccine. This includes severe cases at unusual sites such as cerebral venous sinus thrombosis (CSVT) and splanchnic vein thrombosis, as well as arterial thrombosis, with thrombocytopenia.[2]

Health Canada has assessed the available data on the reported events and has determined that the benefits of the Janssen COVID – 19 vaccine outweigh the risks of thrombosis and thrombocytopenia. [2]

Individuals receiving the Janssen COVID-19 vaccine should be advised to seek immediate medical attention for symptoms of thromboembolism and/or early signs of thrombocytopenia within 3-4 weeks following vaccination, some cases had a fatal outcome, and no specific risk factors have been identified at this time.[3]

Symptoms to monitor for include: shortness of breath, chest pain, leg swelling or pain, persistent abdominal pain, skin bruising (other than at the site of vaccination) or petechiae (red or purple spots or blood blisters under the skin); and neurological symptoms such as sudden onset of severe headaches, persistent or worsening headaches, blurred vision, double vision, confusion or seizures, difficulty speaking or moving a part of the body, particularly those persisting or occurring approximately 4 days to 3-4 weeks after vaccination.[2]

Capillary leak syndrome (CLS)
A small number of reports of CLS have been reported following vaccination. CLS is a very rare, serious condition that causes fluid leakage from small blood vessels (capillaries), resulting in swelling mainly in the arms and legs, low blood pressure, thickening of the blood and low blood levels of albumin (an important blood protein). Individuals with a history of CLS should not be vaccinated with viral vector COVID-19 vaccine.[3]
Immune thrombocytopenia (ITP)
Cases of ITP with very low platelet levels (<20, 000 per uL) have been reported very rarely after vaccination with Janssen and AstraZeneca COVID-19 vaccines, usually within the first four weeks after receiving Janssen COVID-19 vaccine. This included cases with bleeding and cases with fatal outcome. Some of these cases occurred in individuals with a history of ITP. If an individual has a history of ITP, the risks of developing low platelets should be considered before vaccination, and platelet monitoring is recommended after vaccination. [2]

Venous Thromboembolism (VTE)

VTE has been observed rarely following vaccination with the Janssen COVID-19 Vaccine. In individuals with a pre-existing increased risk for thromboembolism, the possible increased risk of VTE with vaccine use should be considered. [2]

Guillain-Barré syndrome (GBS)
There have been a small number of reports of people developing GBS after receiving a COVID-19 viral vector vaccine. GBS is a rare but potentially serious immune-mediated neurologic disorder that results in pain or numbness, muscle weakness, and paralysis in severe cases. Most people fully recover from GBS, but some have residual deficits or symptoms and rarely, fatal cases can occur. Individuals with past history of GBS should receive an authorized mRNA vaccine. When authorized mRNA COVID-19 vaccines are contraindicated or inaccessible, individuals may receive an authorized viral vector vaccine after consultation with their health care provider.3,[4]

Adverse Reactions
Very common and common side effects include pain, swelling or redness/erythema at the injection site, fatigue, headache, muscle pain, chills, joint pain, nausea/vomiting, and fever.[2] Uncommon side effects include lymphadenopathy. Rare or very rare events include Vaccine-Induced Thrombotic Thrombocytopenia (VIIT), Capillary Leak Syndrome (CLS), and Guillain-Barré Syndrome (GBS).[3]

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]

TST/IGRA
There is a theoretical risk that COVID-19 vaccines may temporarily affect cell-mediated immunity, resulting in false-negative TST/IGRA results. If TB skin testing/IGRA is required, it should be administered and read before immunization or delayed for at least 4 weeks after vaccination. Vaccination with COVID-19 vaccine may take place at any time after TST has been completed. In cases of urgency the test should be performed, with re-testing 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 simultaneously with monoclonal antibody therapy or convalescent plasma therapy for the treatment or prevention of COVID-19 disease.[2] To date, there is insufficient evidence on the receipt of both a COVID-19 vaccine and any monoclonal antibodies or convalescent plasma for treatment or prevention of non-COVID-19 disease. Therefore, timing of administration and potential interference between these two products are currently unknown and expert clinical opinion should be sought on a case-by-case basis.[2,3,4]

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

All pregnant individuals in the authorized age group are eligible and recommended to be vaccinated as soon as possible, at any stage in pregnancy, as COVID-19 infection during pregnancy can be severe (increased risk for hospitalization, ICU admission, mechanical ventilation, and death compared to non-pregnant individuals) and the benefits of vaccination outweigh the risks. Vaccination may be considered at any gestational age, including the first trimester. While pregnant individuals were not included in Phase III trials for COVID-19 vaccines, real-world safety data for hundreds of thousands of pregnant individuals that have received COVID-19 vaccines are now available and did not reveal any safety signals.[2,4,5]

COVID-19 vaccines can be safely given to breastfeeding individuals, and recent data shows that mRNA from vaccines does 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.[2,4,5]

PHYSICIAN'S ORDER

Janssen COVID-19 Vaccine is given in accordance with the table below:

Population	Schedule	Dose	Recommendations for an Additional Dose
Individuals 18 years of age and older Out of Province/Country [B]	Primary series consists of a single dose of vaccine	0.5 mL IM	A booster dose of a mRNA vaccine should be given at least 3 months (84 days) after the Janssen vaccine. [(3] For suggested intervals between previous COVID-19 infection and COVID-19 vaccination see [A3]

*Booster dose of a viral vector vaccine should only be considered when an mRNA vaccine is contraindicated or inaccessible.[2] Direction from the Medical Officer of Health is required.

[A] If infection occurred prior to completion or initiation of primary vaccination series:

1. Individuals 5 years of age and older who are not considered moderately to severely immunocompromised and with no history of MIS-C – should receive the vaccine 8 weeks after symptoms or positive test (if asymptomatic)
2. Individuals 5 years of age and older who are moderately to severely immunocompromised and with no previous history of MIS-C – should receive the vaccine 4 -8 weeks after symptom onset or positive test (if asymptomatic)
3. Individuals 5 years of age and older with a previous history of MIS-C (regardless of immunocompromised status) – should receive the vaccine when clinical recovery has been achieved or > 90 days since the onset of MIS-C, whichever is longer. [2]

[B] For those vaccinated outside of Ontario or Canada please refer to and follow Provincial Guidance [8]

Administration

Prior to withdrawing a dose of vaccine from the vial, carefully mix the contents by swirling gently in an upright position for 10 seconds. Do not shake.[1]

ADDITIONAL DOSE FROM A VIAL

It is recommended that if an additional 0.5 mL dose(s) of vaccine can be withdrawn from a single vial beyond the number of doses listed in the Product Monograph, that it is administered as a valid dose and recorded accordingly in $COVax_{ON}$ or other specified documentation. There should be no pooling of vials. [6]

VACCINE STORAGE, STABILITY AND DISPOSAL

For a limited time, Janssen COVID-19 vaccines are being dispatched in Canada with EU English-only labels on vials and cartons. Information pertaining to the vaccine's Drug Identification number (DIN), name and address of the Canadian DIN holder, name and address of the Canadian importer and distributer, storage, and expiry date instructions are not provided on the label. Therefore, information pertaining to the storage of Janssen found in this document should be followed.[6]

	Storage prior to use The vaccine can be stored and/or transported frozen at -25°C to -15°C. The expiry date for storage at -25°C to -15°C is printed on the vial and carton after "EXP". The vaccine can also be transported at 2°C to 8°C for a single period of 6 months, not exceeding the original expiry date.(2) **Thawing vaccine** Thaw in refrigerated temperatures at +2°C to +8°C. When stored frozen at -25°C to -15°C a carton of 10 vials will take approximately 13 hours to thaw. Individual vials will take approximately 2 hours to thaw in refrigerated temperatures. Do not re-freeze once thaw.[6] Thaw at room temperature. When stored frozen at -25°C to -15°C a carton of 10 vials or individual vials should be thawed at room temperature up to +25°C. A carton of 10 vials will take approximately 4 hours to thaw.[6] Individual vials will take approximately 1 hour to thaw. The vaccine (unpunctured vial) is stable for a total of 12 hours at +9°C to +25°C. This is not a recommended storage condition or shipping condition but may guide decisions for use in case of temporary temperature excursions. Do not re-freeze once thaw.[6] **Storage After First Puncture of the Vaccine Vial** After the first dose has been withdrawn, the vial/filled syringe can be held at 2°C to 8°C for up to 6 hours or at room temperature (maximally 25°C) for up to 3 hours, after the first puncturing of the vial. Discard if vaccine is not used within this time.[6] Maximum hold times for these two temperatures are not cumulative. The vaccine cannot be held at room temperature for 3 hours and then refrigerated for another 6 hours. If the 3-hour time limit at room temperature is not reached, the punctured vial may be transported to a refrigerated storage at +2°C to +8°C for the remaining 3 hours.[6]

TRANSPORTATION OF DILUTED VACCINE	Opened or punctured vials of Janssen should not be transported. A single dose of Janssen vaccine should only be transported when in a syringe.[6]
	• The vaccine does not contain a preservative, therefore special attention should be paid to handling and packaging of the syringe to prevent contamination.
	• The syringe should be protected from light.
	• There should be a tamper-evident seal on the pre-drawn syringe or container during transport between locations.
	• The pre-drawn syringes and the container should be labeled, identifying information to prevent errors during storage, dispensing, transport, and use. Container and pre-drawn labeling components should include:
	  ○ Name and dosage of vaccine.
	  ○ Facility name and phone number.
	  ○ Quantity of syringes.
	  ○ The exact beyond-use date and time (i.e., 6 hours from when the Janssen vaccine vial was first punctured).
	  ○ Lot number.
	  ○ Initials of the preparer.
	• The syringe should be packed appropriately in a conditioned cooler (transport container) at +2°C to +8°C and the temperature monitored during transport. Note: The vaccine in the syringe can be at ambient temperature, at a maximum of +25°C for up to 3 hours.
	• 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 pre-drawn syringes. This is to

	prevent direct contact between pre-drawn syringes and the cooling agent that may cause the vaccine to freeze or deviate from appropriate cold chain. • The syringe should be packed to cushion it and to protect it from agitation. • **Drawn up vaccine must be administered within 6 hours from the time the vial was first punctured if stored** at +2°C to +8°C or within 3 hours when held at room temperature, maximally at +25°C.
TRANSPORTATION OF VIALS	Insulated containers should be packed according to the guidance provided in ministry guidance on vaccine storage and handling for refrigerated vaccines.[2] • Transport in the largest configuration wherever possible (e.g., box), avoiding individual vial distribution, while considering the minimum number of doses needed at the onwards location to avoid wastage. • Prevent movement in the cooler by surrounding with dunnage (padding material) inside the container to minimize product movement during transport. • If transport is conducted at vial level, the vial should be placed in insulation and bubble wrap or similar padding to protect the product (e.g., wrap the vial in bubble wrap and place it into a medication/pill bottle). • Do not pack vaccine that is at +2°C and +8°C with frozen vaccine vials. • Do not allow thawed vaccine to come into contact with any frozen packs added to maintain temperature. • Keep the vaccine vials upright. • Protect the vials from light. The total transportation time should be no greater than 12 hours. If the transportation is by road and air, limits of 3 hours by air and 9 hours by road should be adhered to.[2] • Do not transport the vaccine at room temperature.
VACCINE PRESENTATION	Colourless to slightly yellow, clear to very opalescent suspension provided in a multiple dose vial of 5 doses of 0.5 mL. Inspect the vials visually for foreign particulate matter and/or discoloration prior to administration. If either of these conditions exists, the vaccine should not be administered.[1]
VACCINE COMPONENTS	Janssen COVID-19 Vaccine contains an Adenovirus type 26 (Ad26) vectored COVID-19 vaccine encoding the SARS-CoV-2 Spike (S) protein in a stabilized conformation (replication-incompetent, recombinant) and the following non-medicinal ingredients:[1] **Non-medicinal ingredients**: • 2-hydroxypropyl-β-cyclodextrin (HBCD) • Citric acid monohydrate • Ethanol • Hydrochloric acid • Polysorbate-80 • Sodium chloride • Sodium hydroxide • Trisodium citrate dihydrate • Water for injection The vial does not contain latex.[1]
REFERENCES	1. Janssen Inc. Janssen COVID 19 Vaccine Product Monograph. November 23, 2021. 2. Ontario Ministry of Health. COVID-19 Vaccine Administration. Version 4.0. March 24, 2022. 3. COVID-19 Vaccine Third Dose Recommendations. Version 8.0. March 24, 2022. 4. National Advisory Committee on Immunization (NACI): Recommendations on the Use of COVID-19 Vaccine(s). Updated March 30, 2022. 5. COVID-19 Vaccine Recommendations for Special Populations. Version 9.1. December 31, 2021.

	6. COVID-19 Vaccine Storage and Handling Guidance. Version 7.4 March 24, 2022 7. Janssen COVID-19 Vaccine Information Sheet. Ontario Ministry of Health. Version 1.0. December 2, 2021. 8. COVID 19 Vaccine Guidance for Individuals Vaccinated Outside of Ontario/Canada. V 4.0 March 24, 2022.
SIGNATURE AND DATE	Date: April 8, 2022

R: April 2022