Vaccine Medical Directive and Delegation
JCOVDEN™ (Janssen) COVID-19 Vaccine

DELEGATED PROCEDURE	Delegation of Authority to: ☒ Prescribe a drug ☐ Sell a drug
ORDER TO	☒ Administer ☐ Dispense ☐ Sell
AUTHORIZING MD	Dr. Imran Khan, Public Health Physician
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	JCOVDEN™ (COVID-19 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 in whom contraindications are not present. JCOVDEN™ is a viral vector vaccine.[3] 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.[3] JCOVDEN™ COVID-19 vaccine may be offered to individuals without contrainidcations to the vaccine and who are in the authorized age group, **only when all other authorized COVID-19 vaccines are contraindicated**.[2,3] A booster dose of JCOVDEN™ COVID-19 vaccine may be offered to individuals without contraindications to the vaccine and who are in the authorized age group when all other authorized COVID-19 vaccines are contraindicated. There is very limited evidence on the use and effectiveness of an additional dose of viral vector COVID-19 vaccine.[2]

SITUATIONAL CONDITIONS	• Informed consent with discussion of risks/benefits including (refer to the warnings and precautions section for a summary of risks). • Absence of contraindication(s)**.** • In accordance with $COVAX_{ON}$ schedules logic.
CONTRAINDICATIONS	JCOVDEN™ is contraindicated for use by implementers authorized under this medical directive for the following: • Individuals who have experienced thrombosis (venous and/or arterial thrombosis) with thrombocytopenia [Thrombosis with Thrombocytopenia Syndrome (**TTS)**] following vaccination with viral vector vaccines.[2,3] • Individuals who have a history of capillary leak syndrome (CLS).[2,3] • Individuals who developed Immune thrombocytopenia (ITP) following vaccination with viral vector COVID-19 vaccines.[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) to a component of a specific COVID-19 vaccine or its container. Re-vaccination may be offered with the same vaccine 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. Refer to the warnings and precautions section for more specific details.[2] More appropriate vaccine products may be available for immunization. • Individuals **displaying current or recent history of chest pain or shortness of breath** should not be offered the COVID-19 vaccine. They should be advised to consult a health care provider and be directed to the emergency department or call 911 if symptoms are severe.[2]
WARNINGS/ PRECAUTIONS	The use of JCOVDEN™ may be permitted, or must be deferred, for individuals in accordance with the following: **Acute Illness** ***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.[3] ***Previous SARS-CoV-2 Infection*** Refer to Table 1 (page 7) for recommended intervals between COVID-19 infection and vaccination. NOTE: there is no data regarding the safety and efficacy of vaccination with viral vector vaccines after previous SARS-CoV-2 infection.[3] **Hypersensitivity and allergies** Severe Immediate Allergy

In Individuals with a confirmed severe, immediate (within 4 hours following exposure) allergy (anaphylaxis) to a component of a specific COVID-19 vaccine or its container, consultation with an allergist is recommended before receiving that specific COVID-19 vaccine.[3]

Known Allergies to Vaccine Components

Individuals with known allergies to components of the vaccine should speak with an appropriate physician or NP for evaluation*.[2] This assessment will enable the development of a vaccination care plan which may include receiving the vaccine under the supervision of a physician.[2] A potential allergen included in the vaccine is polysorbate 80.[2]

* **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.[2]

Individuals meeting the above criteria will be referred to Health Sciences North (HSN) for vaccination in a controlled setting.

Other Allergies:

- Those with a proven severe allergic reaction (e.g. anaphylaxis) to injectable therapy not related to a component of the COVID-19 vaccines may be routinely vaccinated with COVID-19 vaccine with a 30 minute observation period.[3]
- Those with a history of allergy not related to the COVID-19 vaccine or other injectable therapy (e.g. food, oral drugs, insect venom or environmental allergies) may be routinely immunized with COVID-19 vaccine with a 15 minute observation period.[3]

Autoimmune conditions and Immunocompromised Persons

JCOVDEN™ may be offered to eligible individuals with an autoimmune condition only when all other authorized COVID-19 vaccines are contraindicated. Safety data in not available.[3]

JCOVDEN™ may be offered to eligible individuals with an autoimmune condition only when all other authorized COVID-19 vaccines are contraindicated. Safety data in not available.[3]

Informed consent should include a discussion that there is currently limited evidence on the use of JCOVDEN™ vaccine in persons with autoimmune conditions and in immunocompromised persons.[3]

Hematologic

In individuals with bleeding disorders, the condition should be managed prior to immunization to minimize the risk of bleeding.[3]

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.[3] In individuals with bleeding disorders, the condition should be managed prior to immunization to minimize the risk of bleeding.[3]

Thrombosis with Thrombocytopenia Syndrome (TTS)
Very rare cases of serious blood clots or thrombosis (at unusual sites such as cerebralvenous sinus thrombosis, splanchnic vein thrombosis, as well as arterial thrombosis) associated with thrombocytopenia have been reported following vaccination with viral vector COVID-19 vaccines. Symptoms include shortness of breath, chest pain, leg swelling, abdominal pain, onset of severe headache, persistent/worsening headache, blurred vision, confusion/seizure, skin bruising or petechiae.[3] Individuals with TTS should not receive further doses of viral vector vaccines.[3]

There is no evidence that individuals with previous cerebral venous sinus thrombosis (CVST) with thrombocytopenia not related to a viral vector vaccine or people with previous heparin-induced thrombocytopenia (HIT) not related to a viral vector vaccine are at increased risk of VITT compared to other individuals after receiving a viral vector vaccine. However, similar to other individuals, an mRNA vaccine is preferred.[3]

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)
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.[3] Individuals should seek immediate medical attention if they develop symptoms such as unexplained bleeding, unexplained bruising, or small purplish spots beyond the site of vaccination.[3]

Venous Thromboembolism (VTE)
In individuals with a pre-existing increased risk for thromboembolism, the possible increased risk of VTE with vaccine use should be considered.[3] Individuals should seek immediate medical attention if they develop symptoms such as shortness of breath, chest pain, leg pain, leg swelling or persistent abdominal pain following vaccination.[3]

Transverse Myelitis (TM)
Rare reports of inflammation of the spinal cord causing weakness in the arms or legs, sensory symptoms or problems with bladder or bowel function have been reported post-vaccination. Seek medical attention if symptoms develop.[1]

Guillain-Barré syndrome (GBS)
Individuals with past history of GBS unrelated to COVID-19 vaccination should receive an authorized mRNA vaccine. When authorized mRNA COVID-19 vaccines are

contraindicated, individuals may receive an authorized viral vector vaccine after weighing the risks/benefits and in consultation with their health care provider.[3]

Multisystem Inflammatory Syndrome in Children or Adults (MIS-C or MIS-A)
JCOVDEN™ is not authorized for use in children. For adults with previous history of MIS-A, vaccination should be postponed until clinical recovery has been achieved or until it has been ≥ 90 days since their diagnosis, whichever is longer.[3]

Myocarditis/Pericarditis
Individuals with a history of mycocarditis unrelated to COVID-19 vaccination should consult their clinical team for individual considerations and recommendations. If the diagnosis is reomote and they are no longer followed clinically for cardiac issues, they should receive COVID-19 vaccine.[3]

Summary of Risks Associate with Viral Vector Vaccines
As per NACI, anyone receiving any authorized viral vector COVID-19 vaccine should be informed of the risks associated with viral vector vaccines including Thrombosis with Thrombocytopenia Syndrome (TTS) and Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT), Immune thrombocytopenia (ITP), Capillary Leak Syndrome (CLS), and Guillain-Barre syndrome (GBS) following viral vector COVID-19 vaccines and be advised to seek medical attention if they develop signs and symptoms suggestive of these conditions.[3]

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 Thrombosis with Thrombocytopenia Syndrome (TTS) including Vaccine-Induced Thrombotic Thrombocytopenia (VIIT), Capillary Leak Syndrome (CLS), Immune thrombocytopenia (ITP), Venous Thromboembolisme (VTE), Transverse Myelitis (TM) and Guillain-Barré Syndrome (GBS).[3]

Drug: Drug Interactions
<u>Vaccines</u>
JCOVDEN™ 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]

<u>TST/IGRA</u>
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.[3]

<u>Blood Products and Human Immunoglobulin</u>
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.[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.[3]

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.[2,3] Vaccination with an mRNA vaccine is preferred.[2,3]

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.[2,3]

JCOVDEN™ may be offered to eligible individuals who are pregnant or breastfeeding when all other authorized COVID-19 vaccines are contraindicated.[3]

PHYSICIAN'S ORDER

JCOVDEN™: given in accordance with the table below, the clinical indications, contraindications and warnings and precautions listed above, and Table 1 below.

Population	Schedule	Dose	Booster Doses*
Individuals 18 years of age and older	Primary series consists of a single dose of vaccine	0.5 mL IM	0.5 mL at least 2 months after the 1st dose.

*Booster dose of a viral vector vaccine should only be considered when all other COVID-19 vaccines are contraindicated.[2] Direction from the Medical Officer of Health is required.
For those vaccinated outside of Ontario or Canada please refer to the current Vaccine Administration Guidance document for further information.

<table>
<tr><td></td><td>Table 1: Suggested Intervals Between Previous SAS-CoV-2 Infection and Vaccination with JCOVDEN™ for Eligible Persons:

<table>
<tr><th>Infection Timing Relevant to Vaccination</th><th>Population</th><th>Interval</th></tr>
<tr><td rowspan="2">Infection prior to initiation of primary vaccination</td><td>Immunocompetent</td><td>2 months (56 days) after symptom onset or positive test if asymptomatic</td></tr>
<tr><td>Moderately to severely immunocompromised</td><td>1 to 2 months (28 to 56 days) after symptom onset or positive test if asymptomatic</td></tr>
<tr><td rowspan="2">Infection after primary series and prior to booster dose</td><td>Immunocompetent</td><td>6 months (168 days) after symptom onset or positive test if asymptomatic. A minimum of 3 months (84 days) may be used with informed consent</td></tr>
<tr><td>Individuals who are at high risk as outlined in the current booster dose eligibility algorithm</td><td>3 months (84 days) after symptom onset or positive test if asymptomatic.</td></tr>
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<tr><td>OBSERVATION PERIOD</td><td>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.[2]</td></tr>
<tr><td>PREPARATION OF VACCINE</td><td>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]</td></tr>
<tr><td>ADDITIONAL DOSE FROM A VIAL</td><td>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. [4]</td></tr>
<tr><td>VACCINE STORAGE, STABILITY AND DISPOSAL</td><td>Refer to the Ontario Ministry of Health, Chapter 3: Storage and Handling of Chapter 3: Storage and Handling of Janssen COVID-19 Vaccines, Version 3.0 – Oct 13, 2022 for guidance on:
Storing, distributing and/or administering COVID-19 vaccines.
Assessing temperature excursions, including the vaccine return process.</td></tr>
<tr><td>TRANSPORTATION OF VACCINE</td><td>Refer to the Ontario Ministry of Health, Chapter 3: Storage and Handling of Janssen COVID-19 Vaccines, Version 3.0 – Oct 13, 2022 for complete information on the transporation of COVID-19 vaccine.

Transportation
Single syringe
In exceptional circumstances it is recommended that the vaccine be transported in a single syringe over a punctured vial, to prevent agitation of the product in a 7unctured vial.[4]

Drawn up vaccine must be administered within 6 hours from the time of first puncture if stored between +2°C to +8°C or at room temperature for up to 3 hours (max 25 °C) after first puncture of the vial.[4]</td></tr>
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	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.[4] The vaccine package is to be protected from light and cushioned to protect it from agitation.[4] Unpunctured vial It is preferrable to transport an unpunctured vial. Unpunctured vials may be transported/are stable between +9°C to +25°C for up to 12 hours.[4] Transport time vaccine movement should not exceed 12 hours of cumulative time.[4] If the syringe being transported is from a vial that was previously transported at fridge temperature, then the total transportation time minus the time in the syringe (drawn up dose) and the transport time of the vial must be considered.[4]
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	JCOVDEN™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. JCOVDEN™COVID 19 Vaccine Product Monograph. October 27, 2022 2. Ontario Ministry of Health. COVID-19 Vaccine Guidance. Version 3.1 November 7, 2022. 3. Public Health Agency of Canada. Canadian Immunization Guide. COVID-19 Vaccine Chapter. Updated Oct/22. Accessed Nov 3/22. 4. Ontario Ministry of Health. COVID-19 Vaccine Storage and Handling Guidance. Chapter 3: Janssen Jcovden. Version 2 – September 26, 2022.
SIGNATURE AND DATE	Date: November 14, 2022

R: Nov/2022