

Updated: Executive Officer Notice: Administration of Publicly Funded COVID-19 Vaccines in Ontario Pharmacies – Eligibility

Effective September 1st, 2022

Certain eligible pharmacies can administer publicly funded injectable COVID-19 vaccines to eligible individuals (see Pharmacy Eligibility below).

The purpose of this Executive Officer (EO) Notice (Administration of the Publicly Funded COVID-19 Vaccines in Ontario Pharmacies – **Eligibility**), the EO Notice: Administration of the Publicly Funded COVID-19 Vaccines in Ontario Pharmacies – **Billing**, and the accompanying Questions and Answers (Qs & As) documents, are to set out the terms and conditions for a participating pharmacy's submission of claims for payment (claims) for administering injectable COVID-19 vaccines to eligible individuals. Each document is a ministry policy that pharmacy operators must comply with under section 3.2 of the Health Network System (HNS) Subscription Agreement for Pharmacy Operators. Participating pharmacies must comply with all of the terms and conditions set out in the EO Notices and Qs & As. It is a condition of participating that participating pharmacies offer first, second and third or booster doses to all eligible groups, provided that there is sufficient supply of the vaccines.

The two (2) EO Notices and the accompanying Qs & As documents are <u>not</u> intended to describe a pharmacy operator's obligations in respect of administering injectable COVID-19 vaccines under applicable legislation, other agreements with the Province of Ontario, or policies of the Ontario College of Pharmacists (OCP). Pharmacy operators with questions about their legal obligations outside of the HNS Subscription Agreement should refer to the applicable legislation, other agreement, or OCP policy as appropriate.

This EO Notice (Administration of the Publicly Funded COVID-19 Vaccines in Ontario Pharmacies – **Eligibility**) replaces the previous EO notice on the same topic respecting the administration of publicly funded COVID-19 vaccines in Ontario pharmacies that was effective August 8th, 2022.



Pharmacy eligibility

In order to be eligible to submit claims for administering a publicly funded COVID-19 vaccine, a pharmacy operator (also referred to in this document as a "participating pharmacy") must be selected to participate by the ministry and meet the following requirements:

- Have a valid HNS Subscription Agreement with the ministry
- Have a valid agreement¹ with the ministry respecting COVID-19 vaccine administration and the use of the Provincial COVID-19 vaccine solution (the "COVID-19 Vaccine Agreement"); and
- Enrolled in the 2021-22 Universal Influenza Immunization Program (UIIP)².*

This eligibility criteria may be updated from time to time. Please refer to the <u>ministry</u> <u>website</u> for the most recent version of this notice.

*Due to the rapid spread of the Omicron variant and to increase access to vaccination services to as many eligible individuals as possible, as of January 13, 2022, the ministry opened enrollment in the COVID-19 vaccination program to pharmacies that are not enrolled in the 2021-22 UIIP on an exceptional and temporary basis. Pharmacies that are interested in administering publicly funded COVID-19 vaccines but not currently enrolled in the 2021-22 UIIP should email the ministry at: <u>OPDPInfoBox@ontario.ca</u> with their store name, address and ON Provider #. In addition to having a valid HNS Subscription Agreement and a valid COVID-19 Vaccine Agreement, such pharmacies will be required to pass an inspection by their local public health unit (PHU), including a cold chain inspection, and comply with all storage and handling guidelines for vaccines. Please note that conducting inspections will be at the sole discretion of the local PHUs and their resources and timelines. Pharmacies that are administering COVID-19 vaccines must also apply for the 2022-23 UIIP.

Patient eligibility

The following rules apply to the interpretation of the eligibility criteria in **Tables 1, 2, 3 and 4** below for any vaccine dose.

¹ A valid agreement is in respect of a particular pharmacy operator operating at a specific pharmacy location. Where a pharmacy is sold, or where a pharmacy operator relocates, a new COVID-19 Vaccine Agreement is required to reflect the new pharmacy operator or location.

² Enrollment in the UIIP is in respect of a particular pharmacy operator operating at a specific pharmacy location. Where a pharmacy is sold, or where a pharmacy operator relocates, new enrollment in the UIIP is required to reflect the new pharmacy operator or location.



An individual is eligible to receive a publicly funded COVID-19 vaccine if they live, work, or study in Ontario or they are visiting Ontario from another province / territory or another country, and if they meet the applicable eligibility criteria in the tables below. For all vaccine doses, when eligibility is defined by age, individuals must be the respective age of eligibility on the day of the vaccine administration.

Individuals who received a COVID-19 vaccine outside of Ontario or Canada who contact their local Public Health Unit will have their COVID-19 vaccine history verified and uploaded into the COVAX_{ON} system. Depending on how many doses and which vaccines were previously administered (please refer to the <u>COVID-19 Vaccine Information Guidance</u> located on the <u>ministry's website</u>), pharmacies may administer an additional dose of an mRNA vaccine, if required to complete the vaccine series, in alignment with the ministry's guidance "<u>Staying Up to Date with COVID-19 Vaccination</u>".

Informed consent is required to administer any COVID-19 vaccine to an eligible individual.

Ontario recommends mRNA vaccines as the preferred vaccine for all individuals. However, individuals 18 and older who have contraindications such as a confirmed allergy to components of the mRNA vaccines or who are not able or willing to receive an mRNA vaccine may receive the Novavax, Inc. COVID-19 vaccine (Nuvaxovid[™]) or the Medicago Inc. COVID-19 vaccine (Covifenz®) if they do not have a contraindication to the Nuvaxovid or Covifenz® vaccine. A viral vector vaccine (Janssen or AstraZeneca / COVISHIELD vaccine) should only be offered to individuals 18 and older without contraindications to the viral vector vaccine when all other authorized COVID-19 vacines are contraindicated, with informed consent. The Province has a limited supply of Nuvaxovid[™], MODERNA 0.10mg/mL (DIN 02527685), Covifenz® and viral vector vaccines. Specifically regarding Covifenz®, the supply is uncertain. Pharmacies should work with their public health unit to determine how eligible individuals (as defined below) can receive these vaccines³.

Based on advice from the Ontario Immunization Advisory Committee (OIAC), and in alignment with <u>NACI</u>, the Ministry of Health has issued a **preferential recommendation for the use of Pfizer-BioNTech COVID-19 vaccine for individuals 5-29.** This recommendation stems from an observed increase in the number of reports in Ontario of myocarditis/pericarditis following vaccination with Moderna relative to Pfizer-BioNTech in the 18-29 year old age group, particularly among males. Although risk of myocarditis/pericarditis with the Moderna (50 mcg) vaccine in children 6 to 11 years of age is unknown, with a primary series in adolescents and young adults the rare risk of myocarditis/pericarditis with Moderna (100 mcg) was higher than with Pfizer-BioNTech (30 mcg). See <u>COVID-19 Vaccine Administration</u> for more details on administering to special populations.

³ For more information on COVID-19 vaccines refer to ministry guidance: COVID-19 Vaccine Administration



The use of Pfizer-BioNTech Comirnaty vaccine (10 mcg) is preferred to the Moderna (25 mcg) for those 5 years of age. However, per NACI, Moderna (25 mcg) may be offered to children who are 5 years of age as an alternative to the Pfizer-BioNTech vaccine (10 mcg), with informed consent and discussion of risks and benefits with the child's healthcare provider.

Although the lower concentration (0.10mg/mL) format of the Moderna COVID-19 vaccine can be used to administer a 50mcg dose for children aged 6 to 11 years or to those 18+ as a booster, due to limited vaccine supply, this format is reserved for completing a primary series for infants/children aged 6 months to 5 years at this time.

Residents of long-term care homes, residents of retirement homes, and elderly persons living in other congregate settings (e.g. assisted-living facilities, naturally occurring congregate retirement settings/seniors apartment buildings, congregate settings for people with developmental disabilities, mental health and addictions issues, etc.) who meet the eligibility criteria in the tables below are only eligible to receive a pharmacy-administered vaccine dose when pharmacy staff administer the dose at the long-term care home, retirement home or other congregate setting. Staff, support workers, essential caregivers, volunteers and contractors who are working at the long-term care home, retirement home or other congregate settings are also eligible for pharmacy-administered vaccine doses either at the pharmacy or when the pharmacy staff visit the home / congregate setting, provided that they meet the applicable eligibility criteria in the tables below. Pharmacies must coordinate any vaccine administration at a long-term care home, retirement home or congregate setting with the local public health unit and the proprietor of the home/setting.

Individuals attending Pharmacy Mobile Clinics are subject to the eligibility requirements set out below where applicable. For more information refer to Pharmacy Qs+As Question 48.

Table 1 – Eligibility for first* or single dose administration**

Vaccine Product

COVID-19 vaccine MODERNA 0.10mg/mL (DIN 02527685)

Eligibility Criteria for First Dose Administration

• Children who are 6 months to 5 years of age.

Note: Although those 6 to 11 years of age are also eligible to use this dosage format⁴, at this time the Province has a limited supply of the MODERNA (0.10mg/mL) vaccine. Pharmacies should work with their public health unit to determine which eligible individuals (as defined above) should receive the vaccine.

Vaccine Product

⁴ For dosing information, see the most recent version of the Executive Officer Notice: Administration of Publicly Funded COVID-19 Vaccines in Ontario Pharmacies – Billing, available <u>here</u>.



• Pediatric Pfizer-BioNTech COVID-19 vaccine, orange cap (DIN 02522454)

Eligibility Criteria for First Dose Administration

• Children who are 5 to 11 years of age.

Vaccine Product

- Pfizer-BioNTech COVID-19 (12+ formulation) vaccine, purple cap (DIN: 02509210);
- Pfizer-BioNTech COVID-19 (12+ formulation) vaccine, grey cap (DIN: 02527863);

Eligibility Criteria for First Dose Administration

Individuals who are 12 years of age or older

Vaccine Product

• COVID-19 vaccine MODERNA 0.20mg/mL (DIN: 02510014)

Eligibility Criteria for First Dose Administration

Individuals who are 6 years of age or older⁴

Vaccine Product

• Nuvaxovid[™] COVID-19 vaccine (DIN: 02525364)

Eligibility Criteria for First Dose Administration

Individuals who are 18 years of age or older and who do not have contraindications to Nuvaxovid and:

- have contraindications such as a confirmed allergy to components of the mRNA vaccines, if the individual has been assessed by an appropriate physician / nurse practitioner and the pharmacy has received a completed <u>COVID-19 Vaccination</u>: <u>Allergy Form</u> prior to administrating the Nuvaxovid[™] vaccine; or
- are otherwise not able or willing to receive to receive an mRNA vaccine

Note: at this time the Province has a limited supply of the Nuvaxovid[™] vaccine. Pharmacies should work with their public health unit to determine how eligible individuals (as defined above) can receive this vaccine.

Vaccine Product

- COVISHIELD COVID-19 vaccine (DIN: 02512947)
- COVID-19 vaccine AstraZeneca (PIN: 09857655)
- Janssen COVID-19 VACCINE (DIN 02513153)

Eligibility Criteria for First or Single Dose Administration

Individuals who are 18 years of age or older and who:

 have contraindications to all other COVID-19 vaccines funded by Ontario, such as a confirmed allergy, if the individual has been assessed by an appropriate physician / nurse practitioner and the pharmacy has received a completed <u>COVID-19 Vaccination: Allergy Form</u> prior to administrating the AstraZeneca / COVISHIELD / Janssen vaccine



Note: at this time the Province has a limited supply of AstraZeneca / COVIDSHIELD and Janssen vaccines. Pharmacies should work with their public health unit to determine how eligible individuals (as defined above) can receive these vaccines.

Vaccine Product

• Covifenz® COVID-19 Vaccine (DIN: 02521326)

Eligibility Criteria for First Dose Administration

Individuals who are 18 to 64 years of age or older and who do not have contraindications to Covifenz® and:

- have contraindications such as a confirmed allergy to components of the mRNA vaccines, if the individual has been assessed by an appropriate physician / nurse practitioner and the pharmacy has received a completed <u>COVID-19 Vaccination</u>: <u>Allergy Form</u> prior to administrating the Covifenz® vaccine; or
- are otherwise not able or willing to receive to receive an mRNA vaccine

Note: at this time the Province has a limited and uncertain supply of the Covifenz® vaccine. Pharmacies should work with their public health unit to determine how eligible individuals (as defined above) can receive this vaccine.

Table 2 – Eligibility for second dose administration**

The following rules apply to the interpretation of the eligibility criteria in Table 2 below.

Persons who received a first dose of the AstraZeneca/COVISHIELD vaccine (a viral vector vaccine) are recommended to receive an mRNA vaccine (Pfizer-BioNTech (12+ formulation) or Moderna) for their second dose, unless contraindicated. People who experienced a severe immediate allergic reaction after a first dose of an mRNA COVID-19 vaccine can safely receive future doses of the same or another mRNA COVID-19 vaccine after consulting with an appropriate physician / nurse practitioner. See <u>NACI's</u> recommendations on the use of COVID-19 vaccines for more information (see Table 2 below). According to the National Advisory Committee on Immunization (<u>NACI</u>) recommendations, an mRNA vaccine is preferred as the second dose for individuals who received a first dose of the AstraZeneca/COVISHIELD vaccine, based on emerging evidence of a potentially better immune response from this mixed vaccine schedule and to mitigate the potential risk of Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT) associated with viral vector vaccines.

Persons age 18+ may receive two doses of the Nuvaxovid[™] vaccine or a mixed primary series (one dose of the Nuvaxovid[™] vaccine and one dose of another COVID-19 vaccine). If a person will be receiving a mixed primary series with the Nuvaxovid[™] vaccine, obtaining the person's informed consent should include a discussion of the benefits and potential



risks given the currently limited data on the effectiveness and safety of mixed schedules with the Nuvaxovid[™] vaccine.

Persons age 18 to 64 years of age may receive two doses of the Covifenz® vaccine or a mixed primary series (one dose of the Covifenz® vaccine and one dose of another COVID-19 vaccine). If a person will be receiving a mixed primary series with the Covifenz® vaccine, obtaining the person's informed consent should include a discussion of the benefits and potential risks given the currently limited data on the effectiveness and safety of mixed schedules with the Covifenz® vaccine.

Persons who received a first dose of an mRNA vaccine (Pfizer-BioNTech) or Moderna) should be offered the same mRNA vaccine for their second dose, unless the same mRNA vaccine is not readily available* or the vaccine used for the first dose is unknown, in which case, another mRNA vaccine can be considered interchangeable and should be offered to complete the vaccine series. Note: An mRNA vaccine followed by a second AstraZeneca vaccine is not an acceptable interchangeable vaccine series unless the individual has a contraindication to the mRNA vaccines. * Note, readily available means easily available at the time of vaccination without delay or vaccine wastage.

Persons who received an mRNA or Nuvaxovid[™] or Covifenz® vaccine for their first dose should receive their second dose 8 weeks after the first dose. Persons who received the AstraZeneca /COVISHIELD vaccine for their first dose should receive their second dose at least 8 weeks after the first dose. There is emerging evidence 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. See <u>NACI's statement</u> for more information. Ontario strongly recommends patients wait 8 weeks after receiving their first dose before getting a second dose. However, individuals can receive their second dose earlier than 8 weeks if required, with informed consent. The appropriate <u>minimum</u> dose interval should be determined from the product monograph of the vaccine used for the first dose.

For more information refer to the Q&A for Health Care Providers on Mixed COVID-19 mRNA Vaccine Schedules available <u>here</u>, and the COVID-19 Vaccine Administration Guidance available <u>here</u>.

The use of Pfizer-BioNTech Comirnaty vaccine (10 mcg) is preferred to the Moderna (25 mcg) for those 5 years of age. However, per NACI, Moderna (25 mcg) may be offered to children who are 5 years of age as an alternative to the Pfizer-BioNTech vaccine (10 mcg), with informed consent and discussion of risks and benefits with the child's healthcare provider.

Although the lower concentration (0.10mg/mL) format of the Moderna COVID-19 vaccine can be used to administer a 50mcg dose for children aged 6 to 11 years or to those 18+ as



a booster, due to limited vaccine supply, this format is reserved for completing a primary series for infants/children aged 6 months to 5 years at this time.

Table 2 – Eligibility for second dose administration**

(please review preamble to Table 2)

Vaccine Product

• COVID-19 vaccine MODERNA 0.10mg/mL (DIN 02527685)

Eligibility Criteria for Second Dose Administration

Children who are 6 months to 5 years old who received their first dose with the Moderna 0.10mg/mL vaccine may receive their second dose with the Moderna 0.10mg/mL vaccine if:

- 8 weeks have passed since their first dose with the Moderna 0.10mg/mL vaccine; or
- less than 8 weeks have passed since their first dose, provided that the interval between doses is consistent with the product monograph of the vaccine used for the individual's first dose and the individual or their substitute decision maker has provided informed consent to a shorter interval.

Note: Although those 6 to 11 years of age are also eligible to use this dosage format, at this time the Province has a limited supply of the MODERNA (0.10mg/mL) vaccine. Pharmacies should work with their public health unit to determine which eligible individuals (as defined above) should receive the vaccine.

Vaccine Product

• Pediatric Pfizer-BioNTech COVID-19 vaccine, orange cap (DIN 02522454)

Eligibility Criteria for Second Dose Administration

Children who are 5 to 11 years old who received their first dose with the Pfizer vaccine may receive their second dose with the Pediatric Pfizer vaccine if:

- 8 weeks have passed since their first dose with the Pfizer vaccine; or
- less than 8 weeks have passed since their first dose, provided that the interval between doses is consistent with the product monograph of the vaccine used for the individual's first dose and the individual or their substitute decision maker has provided informed consent to a shorter interval.

Vaccine Product

- Pfizer-BioNTech COVID-19 (12+ formulation) vaccine, purple cap (DIN: 02509210);
- Pfizer-BioNTech COVID-19 (12+ formulation) vaccine, grey cap (DIN: 02527863);
- COVID-19 vaccine MODERNA 0.20mg/mL (DIN: 02510014) (age 6 and older)

Eligibility Criteria for Second Dose Administration



Individuals who received their first dose of AstraZeneca/COVISHIELD vaccine may receive one of the mRNA vaccines (Pfizer (12+ formulation) or Moderna) as their second dose if:

- at least 8 weeks have passed since their first dose; or
- less than 8 weeks have passed since their first dose, provided that the interval between doses is consistent with the product monograph of the vaccine used for the individual's first dose and the individual or their substitute decision maker has provided informed consent to a shorter interval.

Individuals who received their first dose of an mRNA vaccine (Pfizer or Moderna) may receive one of the mRNA vaccines (Pfizer (12+ formulation) or Moderna (age 6 and older)) as their second dose if:

- 8 weeks have passed since their first dose; or
- less than 8 weeks have passed since their first dose, provided that the interval between doses is consistent with the product monograph of the vaccine used for the individual's first dose and the individual or their substitute decision maker has provided informed consent to a shorter interval.

Vaccine Product

• Nuvaxovid[™] COVID-19 vaccine (DIN: 02525364)

Eligibility Criteria for Second Dose Administration

Individuals who are at least 18 years old and who do not have contraindications to Nuvaxovid[™] and:

- have contraindications such as a confirmed allergy to components of the mRNA vaccines or a viral vector vaccine for their first dose (i.e., severe allergic reaction or anaphylaxis to that vaccine as assessed by an appropriate physician / nurse practitioner and documented in a <u>COVID-19 Vaccination: Allergy Form</u>); or
- who are otherwise not able or willing to receive an mRNA vaccine may receive their second dose with Nuvaxovid[™] if recommended and if:
 - 8 weeks have passed since their first dose with the Pfizer-BioNTech vaccine, the Moderna vaccine, or the Nuvaxovid[™] vaccine;
 - at least 8 weeks have passed since their first dose with the AstraZeneca / COVISHIELD vaccine; or
 - less than 8 weeks have passed since their first dose, provided that the interval between doses is consistent with the product monograph of the vaccine used for the individual's first dose and the individual or their substitute decision maker has provided informed consent to a shorter interval.

Note: at this time the Province has a limited supply of the Nuvaxovid[™] vaccine. Pharmacies should work with their public health unit to determine how eligible individuals (as defined above) can receive the vaccine.



Vaccine Product

- COVISHIELD COVID-19 vaccine (DIN: 02512947)
- COVID-19 vaccine AstraZeneca (PIN: 09857655)

Eligibility Criteria for Second Dose Administration

Individuals who are at least 18 years old and who have contraindications such as a confirmed allergy to components of the mRNA vaccines OR who received the Pfizer-BioNtech (12+ formulation) or Moderna mRNA vaccine for their first dose and had a severe allergic reaction or anaphylaxis to that vaccine as assessed by an appropriate physician / nurse practitioner and documented in a <u>COVID-19 Vaccination: Allergy Form</u>, may receive their second dose with a viral vector vaccine (for example, AstraZeneca / COVISHIELD vaccine) if recommended and if:

- 8 weeks have passed since their first dose with the Pfizer-BioNTech vaccine, the Moderna vaccine or the Nuvaxovid[™] vaccine;
- at least 8 weeks have passed since their first dose with the AstraZeneca / COVISHIELD vaccine; or
- less than 8 weeks have passed since their first dose, provided that the interval between doses is consistent with the product monograph of the vaccine used for the individual's first dose and the individual or their substitute decision maker has provided informed consent to a shorter interval.

Note: at this time the Province has a limited supply of viral vector vaccines. Pharmacies should work with their public health unit to determine how eligible individuals (as defined above) can receive the vaccine.

Vaccine Product

• Covifenz® COVID-19 Vaccine (DIN: 02521326)

Eligibility Criteria for Second Dose Administration

Individuals who are 18 to 64 years of age or older and who do not have contraindications to Covifenz® and:

- have contraindications such as a confirmed allergy to components of the mRNA vaccines, if the individual has been assessed by an appropriate physician / nurse practitioner and the pharmacy has received a completed <u>COVID-19 Vaccination</u>: <u>Allergy Form</u> prior to administrating the Covifenz® vaccine; or
- are otherwise not able or willing to receive to receive an mRNA vaccine

Note: at this time the Province has a limited and uncertain supply of the Covifenz® vaccine. Pharmacies should work with their public health unit to determine how eligible individuals (as defined above) can receive this vaccine.



Table 3 – Eligibility for third or booster dose administration**

For more information on third doses or boosters, refer to the ministry's <u>COVID-19 Vaccine</u> <u>Booster Recommendations</u> Guidance for information.

The following rules apply to the interpretation of the eligibility criteria in Table 3 below.

- The Pfizer-BioNTech and Moderna COVID-19 vaccines have been <u>authorized for use</u> by Health Canada as a booster dose after completion of the primary series in individuals 5 years of age and older and 18 years of age and older, respectively. A booster dose with an mRNA vaccine is recommended for eligible individuals, to obtain stronger and longer-lasting protection regardless of which vaccine was used in the primary series. Note: At this time, only the Pediatric Pfizer BioNTech COVID-19 vaccine, orange cap (10mcg) is authorized as a booster dose for children aged 5 – 11 years.
- The OIAC has recommended the Pfizer-BioNTech and Moderna COVID-19 vaccines as a booster dose after completion of the primary series in youth 5 to 29 years of age, with a preferential recommendation for Pfizer-BioNTech in youth aged 12 to 29 years. For children aged 5 to 11 years, only the Pediatric Pfizer BioNTech COVID-19 vaccine, orange cap (10mcg) is authorized as a booster.
- Individuals who received AstraZeneca/COVISHIELD COVID-19 vaccine for their first and second dose are recommended to receive an mRNA vaccine for their third or booster dose(s).
- People who experienced a severe immediate allergic reaction after a first dose of an mRNA COVID-19 vaccine can safely receive future doses of the same or another mRNA COVID-19 vaccine after consulting with an appropriate physician / nurse practitioner. See <u>NACI's recommendations on the use of COVID-19 vaccines</u> for more information.
- As per guidance from <u>NACI</u>⁵ and Ontario Immunization Advisory Committee (OIAC), a booster dose of Nuvaxovid[™] may be offered to individuals age 18 and over, who do not have a contraindication to Nuvaxovid[™] and are not able or willing to receive an mRNA vaccine, regardless of which COVID-19 vaccines were received in the primary series. A booster dose of a viral vector vaccine should only be offered when all other authorized COVID-19 vaccines are contraindicated. If a person will be receiving Nuvaxovid[™] vaccine as a booster dose, obtaining the person's informed consent should include, as applicable, a discussion of the benefits and potential risks given the currently limited data on the effectiveness and safety of mixed schedules with the Nuvaxovid[™] vaccine and that this vaccine is not currently authorized for use as a booster dose in Canada. If an individual needs to receive a third or booster dose of a viral vector vaccine, informed consent should include discussion about the

⁵ Nuvaxovid[™] COVID-19 vaccine is currently not authorized by Health Canada for use as a booster dose in Canada.



lack of evidence on the use of an additional dose of viral vector COVID-19 vaccine and the increased risk of Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT), Capillary Leak Syndrome (CLS), and Guillain-Barre syndrome (GBS) following viral vector COVID-19 vaccines (<u>NACI, 2021</u>). Only individuals who are at least 18 years old can receive a third or booster dose with a viral vector vaccine. Covifenz® is not currently authorized for use as a booster dose in Canada.

- At this time the Province has a limited supply of Nuvaxovid[™], Moderna (0.10mg/mL), Covifenz[®] and viral vector vaccines. Specifically regarding Covifenz[®], the supply is uncertain. Pharmacies should work with their public health unit to determine how eligible individuals (as defined above) can receive the vaccine.
- The Janssen COVID-19 vaccine series involves a single dose. However, individuals
 who received the single dose Janssen vaccine are eligible for a supplementary or
 booster dose in accordance with this section. References in this section to
 individuals who have already received a two dose series of a COVID-19 vaccine
 shall be interpreted to include individuals who received the single dose Janssen
 vaccine. In addition, for immunocompromised individuals who received the single
 dose Janssen vaccine, references in this section to a third dose shall be interpreted
 to mean a second dose.
- Persons who received a second dose of an mRNA vaccine (Pfizer-BioNTech or Moderna) should be offered the same mRNA vaccine for their third or booster dose, unless the same mRNA vaccine is not readily available* or the vaccine used for the second dose is unknown, in which case, another mRNA vaccine can be considered interchangeable and should be offered. *Note, readily available means easily available at the time of vaccination without delay or vaccine wastage.
- Residents of long-term care homes, residents of retirement homes, elderly living in other congregate living settings and immunocompromised individuals are recommended to receive the full dose of either Moderna (100 mcg) or Pfizer-BioNTech (12+ formulation or 30 mcg) for third or booster doses. ⁶ Note: For children ages 5-11 who are immunocompromised, the pediatric Pfizer-BioNTech (10mcg) vaccine should be given as the third dose for a 3-dose primary series. For children ages 6 months 5 years of age who are immunocompromised, the Moderna 0.10mg/mL vaccine should be given as the third dose for a 3-dose primary series.
- For individuals in all other population groups noted in Table 3 who are receiving a booster dose with an mRNA vaccine see the following dose information:
 - Moderna (0.20mg/mL): the full dose (100 mcg) is recommended for adults 70 years of age or older, while a half dose (50 mcg) is recommended for those less than 70 years of age however, a 100 mcg dose may be preferred, based on clinical discretion.

⁶ See <u>NACI's recommendation</u> and ministry 3rd Dose Recommendation <u>Guidance</u> for more details.



- Pfizer-BioNTech (12+ formulation): the full dose (30 mcg) is recommended for all booster doses.⁷
- If an individual 18 years of age or older received doses out of province⁸ but is considered to be fully vaccinated in Ontario, they are eligible for a booster dose if at least 3 months (84 days) have passed since their last dose. If an individual 5 to 17 years of age received doses out of province but is considered to be fully vaccinated in Ontario, they are eligible for a booster dose if at least 6 months (168 days) have passed since their last dose.

Table 3 – Eligibility for third or booster⁹ dose administration**

(please review preamble to Table 3)

Vaccine Product: 3-Dose Series

- Pediatric Pfizer-BioNTech COVID-19 vaccine, orange cap (DIN 02522454)
- Pfizer-BioNTech COVID-19 (12+ formulation) vaccine, purple cap (DIN: 02509210)
- Pfizer-BioNTech COVID-19 (12+ formulation) vaccine, grey cap (DIN: 02527863);
- COVID-19 vaccine MODERNA 0.10mg/mL (DIN: 02527685)
- COVID-19 vaccine MODERNA 0.20mg/mL (DIN: 02510014)
- Nuvaxovid[™] COVID-19 vaccine (DIN: 02525364)
- COVISHIELD COVID-19 vaccine (DIN: 02512947)
- COVID-19 vaccine AstraZeneca (PIN: 09857655)
- Janssen COVID-19 VACCINE (DIN 02513153)
- Covifenz® COVID-19 Vaccine (DIN: 02521326)

Eligibility Criteria for Third Dose Administration (for those who are immunocompromised and require a three-dose vaccine series)

3rd Dose for Immunocompromised Individuals

- Individuals 6 months of age and older (or 18 years of age and older, in the case of Nuvaxovid[™] or viral vector vaccines; or 18 to 64 years of age, in the case of Covifenz[®]) from the following moderately to severely immunocompromised population groups that present with a referral letter from their health care provider OR are taking an immunosuppressant medication listed <u>here</u>, if at least 2 months (56 days) have passed since receiving their second dose or at an interval of at least 28 days as directed in writing by a health care provider:
 - Individuals receiving dialysis (hemodialysis or peritoneal dialysis)

⁷ Ibid

⁸ For more information refer to COVID-19 Guidance for Individuals Vaccinated Outside of Ontario/Canada

⁹ At this time, no individual will receive more than 4 COVID-19 vaccine doses (2-dose primary vaccine series plus 2 booster doses) unless they qualify to repeat the entire COVID-19 vaccine series, as noted in Table 4.



- Individuals receiving active¹⁰ treatment (e.g., chemotherapy, targeted therapies, immunotherapy) for solid tumour or hematologic malignancies
- o Recipients of solid-organ transplant and taking immunosuppressive therapy
- Recipients of chimeric antigen receptor (CAR)-T-cell therapy or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy).
- Individuals with moderate to severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome).
- Individuals with HIV with prior AIDS defining illness or prior CD4 count ≤ 200/mm3 or prior CD4 fraction ≤ 15% or (in children 5-11 years) perinatally acquired HIV infection.
- Individuals receiving active treatment with the following categories of immunosuppressive therapies: anti-B cell therapies¹¹ (monoclonal antibodies targeting CD19, CD20 and CD22), high-dose systemic corticosteroids (refer to the <u>Canadian Immunization Guide</u> for suggested definition of high dose steroids), alkylating agents, antimetabolites, or tumor-necrosis factor (TNF) inhibitors and other biologic agents that are significantly immunosuppressive.

Note: Pharmacists may verify whether a patient is eligible for a 3rd dose of a COVID-19 vaccine based on the patient's use of an immunosuppressant medication listed <u>here</u> by referring to a patient's recent prescription label or prescription receipt or their medication profile. If an individual presents a prescription of a medication that is not listed <u>here</u>, they should be directed to their health care provider to receive a referral form/letter for a third dose of the COVID-19 vaccine.

Vaccine Product: Boosters

- Pediatric Pfizer-BioNTech COVID-19 vaccine, orange cap (DIN 02522454);
- Pfizer-BioNTech COVID-19 (12+ formulation) vaccine, purple cap (DIN: 02509210);
- Pfizer-BioNTech COVID-19 (12+ formulation) vaccine, grey cap (DIN: 02527863);
- COVID-19 vaccine MODERNA 0.20mg/mL (DIN: 02510014)
- Nuvaxovid[™] COVID-19 vaccine (DIN: 02525364)
- COVISHIELD COVID-19 vaccine (DIN: 02512947)
- COVID-19 vaccine AstraZeneca (PIN: 09857655)
- Janssen COVID-19 VACCINE (DIN 02513153)

Eligibility Criteria for Booster Dose Administration

¹⁰ Active treatment includes patients who have completed treatment within 3 months. Active treatment is defined as chemotherapy, targeted therapies, immunotherapy, and excludes individuals receiving therapy that does not suppress the immune system (e.g. solely hormonal therapy or radiation therapy). See Ontario Health/Cancer Care Ontario's <u>Frequently</u> <u>Asked Questions</u> for more information.

¹¹ Active treatment for patients receiving B-cell depleting therapy includes patients who have completed treatment within 12 months



Eligibility for 1st Booster Dose: (for those who received a two-dose series or three-dose series)

- All individuals aged 18 years and older are eligible for a booster dose, if at least 3 months (84 days) have passed since completing a primary COVID-19 vaccine series
- Individuals aged 5 to 17 years, are eligible for a booster dose, if at least 6 months (168 days) have passed since completing a primary COVID-19 vaccine series, including those who are moderately to severely immunocompromised who have completed a 3-dose primary vaccine series¹²), (see above 3rd Dose for Immunocompromised Individuals).
 - Note: With informed consent, individuals aged 5 to 17 years may receive their booster dose in less than 6 months (168 days) as long as 3 months have passed since completing their primary COVID-19 vaccine series.
 - Only the Pediatric Pfizer-BioNTech COVID-19 vaccine (orange cap) is authorized as a booster dose for individuals aged 5 to 11 years.

Eligibility for 2nd Booster Dose: (for those who received a two or three-dose series plus one booster)¹³

- Residents of long-term care homes, retirement homes, Elder Care Lodges and older adults living in other congregate settings providing assisted-living and health services (see this <u>guidance document</u> for examples) may receive a second booster (**fourth dose**), if at least three months, or 84 days, have passed since the individual's first booster (third dose).
- Individuals aged 18 years and older may receive a second booster (fourth dose), if at least five months (140 days), have passed since the individual's first booster (third dose).
 - Note: With informed consent, individuals aged 18 years and older may receive their second booster dose in less than 5 months as long as 3 months have passed since they received their first booster (third dose).
- Immunocompromised individuals who have completed a three-dose primary series and received a first booster dose are eligible for a second booster dose (i.e. a 5th dose) if they are:
 - age 12 to 17 years and at least 6 months (168 days) have passed since the individual's first booster (fourth dose)
 - age 18 years and older and at least 5 months (140 days) have passed since the individual's first booster (fourth dose)
 - Note: With informed consent, immunocompromised individuals age 12+ may receive their second booster dose in less than the 6 or 5 months, as

¹² Individuals (12 years of age and older) who were receiving active treatment necessitating a three dose primary series, are eligible for a booster dose, even if not receiving active treatment currently.

¹³ Eligibility is based on the recommendations from the Ontario Immunization Advisory Committee and the Ministry.



applicable, as long as 3 months have passed since they received their first booster (fourth dose).

Table 4 – Eligibility to repeat COVID-19 vaccine series

It is recommended that a re-vaccination with a repeat COVID-19 vaccine primary series plus booster (if applicable) 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.¹⁴ Optimal timing for re-immunization should be determined on a case-by-case basis in consultation with the clinical team.

Vaccine Product

- Pediatric Pfizer-BioNTech COVID-19 vaccine, orange cap (DIN 02522454);
- Pfizer-BioNTech COVID-19 (12+ formulation) vaccine, purple cap (DIN: 02509210);
- Pfizer-BioNTech COVID-19 (12+ formulation) vaccine, grey cap (DIN: 02527863);
- COVID-19 vaccine MODERNA 0.10mg/mL (DIN: 02527685)
- COVID-19 vaccine MODERNA 0.20mg/mL (DIN: 02510014)
- Nuvaxovid™ COVID-19 vaccine (DIN: 02525364
- COVISHIELD COVID-19 vaccine (DIN: 02512947)
- COVID-19 vaccine AstraZeneca (PIN: 09857655)
- Janssen COVID-19 VACCINE (DIN 02513153)
- Covifenz® COVID-19 Vaccine (DIN: 02521326)

Eligibility Criteria for re-vaccination series

Individuals who already received a primary COVID-19 vaccine series (plus booster dose, if applicable) and who receive hematopoietic stem cell transplants (HSCT), hematopoietic cell transplants (HCT) (autologous or allogeneic), and recipients of CAR-T-cell therapy, due to the loss of immunity following therapy or transplant.

Re-vaccination series including first, second, and third dose intervals based on a referral letter from a health care provider.

If applicable a booster dose may be administered if at least 3 months (84 days) have passed since completing re-vaccination with a complete COVID-19 vaccine series.

* See Executive Officer Notice dated May 11, 2021 regarding the Ministry of Health's direction to pause the administration of first doses of publicly funded AstraZeneca / COVISHIELD COVID-19 vaccines in Ontario pharmacies, available <u>here</u>.

¹⁴ As per the <u>Canadian Immunization Guideline</u>, HSCT recipients should be viewed as vaccine naïve (i.e. never immunized) and require re-immunization after transplant.



**See the most recent version of the Executive Officer Notice: Administration of Publicly Funded COVID-19 Vaccines in Ontario Pharmacies – Billing for age restrictions for the vaccines based on the applicable product monographs, available <u>here</u>.

Pharmacies should be informed and stay current with the vaccine's official indications in accordance with Health Canada's approved product monograph, including information regarding recommended dosing as per the product monograph. Ontario is funding third and booster doses, based on recommendations of NACI, the Chief Medical Officer of Health and other health experts as noted in <u>ministry guidance</u> and guidance from <u>NACI</u> and the OIAC.

This eligibility criteria may be updated from time to time. Please refer to the <u>ministry</u> <u>website</u> for the most recent version of this notice and for details of the provincial rollout plan, please visit the <u>ministry's website</u>.

Prior EO Notices

- Executive Officer Notice: Administration of Publicly Funded COVID-19 vaccines in Ontario Pharmacies, effective March 10, 2021.
- Executive Officer Notice: Administration of Publicly Funded COVID-19 vaccines in Ontario Pharmacies – Eligibility, effective March 22, 2021.
- Executive Officer Notice: Administration of Publicly Funded COVID-19 vaccines in Ontario Pharmacies Eligibility, effective April 1, 2021.
- Executive Officer Notice: Administration of Publicly Funded COVID-19 vaccines in Ontario Pharmacies Eligibility, effective April 19, 2021.
- Executive Officer Notice: Administration of Publicly Funded COVID-19 vaccines in Ontario Pharmacies Eligibility, effective April 30, 2021.
- Executive Officer Notice: Administration of Publicly Funded COVID-19 vaccines in Ontario Pharmacies Eligibility, effective May 6, 2021.
- Executive Officer Notice: Pause of the Administration of First Doses of Publicly Funded AstraZeneca / COVISHIELD COVID-19 Vaccines in Ontario Pharmacies (May 11, 2021)
- Executive Officer Notice: Administration of Publicly Funded COVID-19 vaccines in Ontario Pharmacies Eligibility, effective May 13, 2021.
- Executive Officer Notice: Administration of Publicly Funded COVID-19 vaccines in Ontario Pharmacies Eligibility, effective May 18, 2021.
- Executive Officer Notice: Administration of Second Doses for Individuals who received First Dose of AstraZeneca / COVISHIELD COVID-19 Vaccines in Ontario Pharmacies (May 21, 2021)
- Executive Officer Notice: Administration of Publicly Funded COVID-19 vaccines in Ontario Pharmacies Eligibility, effective May 23, 2021.



- Executive Officer Notice: Administration of Publicly Funded COVID-19 vaccines in Ontario Pharmacies Eligibility, effective May 31, 2021.
- Executive Officer Notice: Administration of Publicly Funded COVID-19 vaccines in Ontario Pharmacies Eligibility, effective June 4, 2021.
- Executive Officer Notice: Administration of Publicly Funded COVID-19 vaccines in Ontario Pharmacies Eligibility, effective June 14, 2021.
- Executive Officer Notice: Administration of Publicly Funded COVID-19 vaccines in Ontario Pharmacies Eligibility, effective June 17, 2021.
- Executive Officer Notice: Administration of Publicly Funded COVID-19 vaccines in Ontario Pharmacies Eligibility, effective June 25, 2021.
- Executive Officer Notice: Administration of Publicly Funded COVID-19 vaccines in Ontario Pharmacies Eligibility, effective July 5, 2021.
- Executive Officer Notice: Administration of Publicly Funded COVID-19 vaccines in Ontario Pharmacies Eligibility, effective August 18, 2021.
- Executive Officer Notice: Administration of Publicly Funded COVID-19 vaccines in Ontario Pharmacies Eligibility, effective September 1, 2021.
- Executive Officer Notice: Administration of Publicly Funded COVID-19 vaccines in Ontario Pharmacies Eligibility, effective September 8, 2021.
- Executive Officer Notice: Administration of Publicly Funded COVID-19 vaccines in Ontario Pharmacies Eligibility, effective October 1, 2021.
- Executive Officer Notice: Administration of Publicly Funded COVID-19 vaccines in Ontario Pharmacies Eligibility, effective October 8, 2021.
- Executive Officer Notice: Administration of Publicly Funded COVID-19 vaccines in Ontario Pharmacies Eligibility, effective November 3, 2021.
- Executive Officer Notice: Administration of Publicly Funded COVID-19 vaccines in Ontario Pharmacies Eligibility, effective November 25, 2021.
- Executive Officer Notice: Administration of Publicly Funded COVID-19 vaccines in Ontario Pharmacies Eligibility, effective December 2, 2021.
- Executive Officer Notice: Administration of Publicly Funded COVID-19 vaccines in Ontario Pharmacies Eligibility, effective December 17, 2021.
- Executive Officer Notice: Administration of Publicly Funded COVID-19 vaccines in Ontario Pharmacies Eligibility, effective December 20, 2021.
- Executive Officer Notice: Administration of Publicly Funded COVID-19 vaccines in Ontario Pharmacies Eligibility, effective January 13, 2022.
- Executive Officer Notice: Administration of Publicly Funded COVID-19 vaccines in Ontario Pharmacies Eligibility, effective February 18, 2022.
- Executive Officer Notice: Administration of Publicly Funded COVID-19 vaccines in Ontario Pharmacies Eligibility, effective March 25, 2022.



- Executive Officer Notice: Administration of Publicly Funded COVID-19 vaccines in Ontario Pharmacies Eligibility, effective April 5, 2022.
- Executive Officer Notice: Administration of Publicly Funded COVID-19 vaccines in Ontario Pharmacies – Eligibility, effective May 2, 2022.
- Executive Officer Notice: Administration of Publicly Funded COVID-19 vaccines in Ontario Pharmacies Eligibility, effective July 14, 2022.
- Executive Officer Notice: Administration of Publicly Funded COVID-19 vaccines in Ontario Pharmacies Eligibility, effective July 28, 2022.
- Executive Officer Notice: Administration of Publicly Funded COVID-19 vaccines in Ontario Pharmacies Eligibility, effective August 8, 2022.

Additional Information:

For pharmacy billing:

Please call ODB Pharmacy Help Desk at: 1-800-668-6641

For COVID-19 vaccine rollout in pharmacy:

Please email the ministry at: <u>OPDPInfoBox@ontario.ca</u>

For Ministry COVID-19 Vaccine-Relevant Information and Planning Resources

Please access this website

For all other Health Care Providers and the Public:

Please call ServiceOntario, Infoline at 1-866-532-3161 TTY 1-800-387-5559. In Toronto, TTY 416-327-4282.