

Updated: Executive Officer Notice: Administration of Publicly Funded COVID19 Vaccines in Ontario Pharmacies – Eligibility

Effective November 25, 2021

Certain eligible pharmacies can administer publicly funded injectable COVID-19 vaccines to eligible Ontarians (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 Ontarians. 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.

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 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 November 3rd, 2021.

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 agreement 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).

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

Patient eligibility

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

An individual is eligible to receive a publicly funded COVID-19 vaccine if they live, work, or study in Ontario or they are here for an extended stay, and if they meet the applicable eligibility criteria in the tables below.

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 system. Depending on how many doses and which vaccines were previously administered (please refer to the COVID-19 Guidance for Individuals Vaccinated outside of Ontario/Canada located on the ministry's website), pharmacies may administer an additional dose of an mRNA vaccine if required to complete the vaccine series, in alignment with the ministry's guidance "Who is considered to be fully vaccinated in Ontario".

Following a thorough review of the current global and Canadian experience and <u>provincial</u> vaccine safety surveillance data, Ontario recommends the Pfizer-BioNTech vaccine (12+ formulation) for youth ages 12 -17. This preferential recommendation stems from the fact that there is more experience to date with this vaccine in this age group, and there is the possibility of a lower rate of myocarditis and/or pericarditis with Pfizer-BioNTech in this age group.

Ontario also recommends the Pfizer- BioNTech vaccine (12+ formulation) as the preferred vaccine for 18-24 year olds. This <u>recommendation</u> is based on advice from Ontario's



Vaccine Clinical Advisory Group and stems from an observed, important increase in the number of reports in Ontario of pericarditis/myocarditis following vaccination with the Moderna vaccine relative to the Pfizer-BioNTech vaccine in the 18-24 year old age group, particularly among males. Further information on trends in myocarditis/pericarditis following mRNA vaccines in Ontario are summarized in an enhanced epidemiologic summary from Public Health Ontario. In the context of adequate Pfizer-BioNTech vaccine supply, this preferential recommendation for the use of Pfizer-BioNTech vaccine in 18-24 year-olds is anticipated to reduce the rare number of events of myocarditis/pericarditis in Ontario.

Informed consent is required for those age 12 to 24 who wish to receive the Moderna vaccine, as it is whenever administering a vaccine.

Table 1 – Eligibility for first dose administration*

Vaccine Product	Eligibility Criteria for First Dose Administration
Pediatric Pfizer- BioNTech COVID-19 vaccine (DIN 02522454)	Children who are 5 to 11 years of age at the time of the vaccination and individuals turning 5 years of age any time during 2021.***
Pfizer-BioNTech COVID-19 (12+ formulation) vaccine (DIN: 02509210)	Individuals who are 12 years of age or older at the time of vaccination***
COVID-19 vaccine MODERNA (DIN: 02510014)	Individuals who are 12 years of age or older at the time of vaccination. Note: Informed consent is required for those age 12 to 24 who wish to receive the Moderna vaccine, as it is in other cases.
COVISHIELD COVID- 19 vaccine (DIN: 02512947) and COVID-19 vaccine AstraZeneca (PIN:	Individuals who are 18 years of age or older at the time of vaccination and who have contraindications such as a confirmed allergy to components of the mRNA vaccines, if th individual has been assessed by an allergist / immunologist and the pharmacy has received a completed COVID-19 Vaccination: Allergy Form prior to administrating a viral vector vaccine (for example, AstraZeneca / COVISHIELD vaccine).
09857655)	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 these vaccines.

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) should usually receive an mRNA vaccine (Pfizer-BioNTech (12+ formulation) or Moderna) for their second dose, unless contraindicated (see Table 2 below). According to the National Advisory Committee on Immunization (NACI) recommendations, an mRNA vaccine is now 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 who received a first dose of an mRNA vaccine (Pfizer-BioNTech (12+ formulation) 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 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 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 NACI's statement 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 minimum 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 here, and the COVID-19 Vaccine Administration Guidance available here.



Children who are 11 years of age and received the Pfizer-BioNTech (12+ formulation) vaccine (30mcg dose) as their first dose under Ontario's extended eligibility (2009 birth year, now no longer in place***) are recommended to complete the vaccine series with the product authorized for their age at the time of the second dose (i.e. Pfizer-BioNTech pediatric formulation of 10mcg if 11 years old; Pfizer 12+ formulation of 30mcg if 12 years old).

Vaccine Product	Eligibility Criteria for Second Dose Administration
COVISHIELD COVID- 19 vaccine (DIN: 02512947) and COVID-19 vaccine AstraZeneca (PIN: 09857655)	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 allergist / immunologist / specialist and documented in a COVID-19 Vaccination: Allergy Form , 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 or the Moderna 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 a viral vector vaccines. Pharmacies should work with their public health unit to determine how eligible individuals (as defined above) can receive the vaccine.



Pediatric Pfizer-
BioNTech COVID-19
vaccine (DIN 02522454)

Children who are less than 12 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.

Pfizer-BioNTech COVID-19 (12+ formulation) vaccine (DIN: 02509210)

and

COVID-19 vaccine MODERNA (DIN: 02510014) 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) 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.

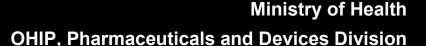




Table 3 – Eligibility for third or booster dose administration****

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

- Only mRNA vaccines (Pfizer-BioNTech (12+ formulation) or Moderna) are being
 offered to eligible persons for third or booster doses, unless the person had an
 adverse effect from the injection (AEFI) as assessed by a relevant specialist; OR a
 severe allergic reaction or anaphylaxis to a mRNA vaccine as assessed by an
 allergist / immunologist and documented in a COVID-19 Vaccination: Allergy Form,
 in which case the third or booster dose may be a viral vector vaccine if the allergist /
 immunologist / specialist determines an additional dose is required.
- Informed consent for an additional dose of viral vector vaccine should include discussion about the lack of evidence on the use of an additional dose of viral vector COVID-19 vaccine in immunocompromised populations and the increased risk of VITT, Capillary Leak Syndrome (CLS), and Guillain-Barre syndrome (GBS) following viral vector COVID-19 vaccines (NACI, 2021).
- 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.
- Persons who received a second dose of an mRNA vaccine (Pfizer-BioNTech (12+
 formulation) 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 (65 years
 of age and older) 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. ¹
- For individuals in all other population groups noted in Table 3 (i.e. elderly living in the community, health care workers, members of Indigenous communities, and recipients of a complete viral vector vaccine series), who are receiving a booster dose the following is recommended:
 - Moderna: 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.

¹ 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.²

Vaccine Product	Eligibility Criteria for Third or Booster Dose Administration
Pfizer-BioNTech COVID-19 (12+ formulation) vaccine (DIN: 02509210) COVID-19 vaccine MODERNA (DIN: 02510014)	 3rd Dose for Immunocompromised Individuals Individuals 12 years of age and older 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 here, 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 active³ treatment (e.g., chemotherapy, targeted therapies, immunotherapy) for solid tumour or hematologic malignancies 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 stage 3 or advanced untreated HIV infection and those with acquired immunodeficiency syndrome. Individuals receiving active treatment with the following categories of immunosuppressive

² Ibid

³ 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 Asked Questions</u> for more information.



therapies: anti-B cell therapies⁴ (monoclonal antibodies targeting CD19, CD20 and CD22), high-dose systemic corticosteroids (refer to the Canadian Immunization Guide 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 here 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 here, they should be directed to their health care provider to receive a referral form/letter for a third dose of the COVID-19 vaccine.

Booster dose for Long-Term Care Home and Retirement Home Residents and Elderly Living in Other Congregate Settings

- Residents of long-term care homes as identified by the local public health unit and the long-term care home, if at least 6 months (168 days) have passed since receiving their second dose and the vaccine is administered at the long-term care home ****
- Residents of retirement homes as identified by the local public health unit and the retirement home, if at least 6 months (168 days) have passed since receiving their second dose.****
- Elderly, (those 65 years of age and older) 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.) as identified by the local public health unit and the congregate

⁴ Active treatment for patients receiving B-cell depleting therapy includes patients who have completed treatment within 12 months



setting, if at least 6 months (168 days) have passed since receiving their second dose.⁵

At this time, claims for booster doses for residents of long-term care homes, residents of retirement homes, and elderly persons living in other congregate settings may only be submitted to the HNS when pharmacies administer the booster doses at the long-term care home, retirement home, or congregate setting where the resident lives as per arrangements with local public health units.

Booster dose for other population groups:

- Elderly (those 70 years of age and older, born in 1951 or earlier) living in the community if at least 6 months (168 days) have passed since receiving their second dose
- Health Care Workers who received their second dose of the COVID-19 vaccine if at least 6 months (168 days) have passed since receiving their second dose. Health Care Workers⁶ include:
 - Any <u>regulated health professionals</u> and any staff member, contract worker, student/trainee, registered volunteer, or other designated essential caregiver currently working in-person in a health care organization, including workers that are not providing direct patient care and are frequently in the patient environment (i.e. cleaning staff, research staff, other administrative staff).
 - Workers providing health care service or direct patient service in a congregate, residential or community setting outside of a health care organization
- All First Nations, Inuit and Métis individuals, and non-Indigenous individuals who share a household with a First Nations, Inuit or Métis individual, if at least 6

⁵ Refer to the COVID-19 3rd Dose Recommendations Guidance Document

⁶ Refer to the complete list of Healthcare workers in the COVID-19 3rd Dose Recommendations <u>Guidance</u> <u>Document</u>



- months (168 days) have passed since receiving their second dose.
- Individuals who received two doses of either the AstraZeneca or COVISHIELD COVID-19 vaccine (i.e. a Viral Vector Vaccine Series), if at least 6 months (168 days) have passed since receiving their second dose.
- Individuals who received one dose of the Janssen / Johnson & Johnson COVID-19 vaccine (i.e. a Viral Vector Vaccine Series), if at least 6 months (168 days) have passed since receiving their first dose.
- * 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 here.
- **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 here.
- *** Pharmacies should be informed and stay current with the vaccine's official indications in accordance with Health Canada's approved product monograph. The Pfizer-BioNTech COVID-19 vaccine (12+ formulation) is currently indicated for use in individuals 12 years of age and older. However, Ontario had previously extended eligibility for the Pfizer-BioNTech COVID-19 vaccine (12+ formulation) to all children born in 2009 to allow administration to more people at that time. This extended eligibility for the 12+ formulation is no longer in place and individuals who are 11 years old at the time of vaccination are only eligible to receive the pediatric formulation. The Pediatric Pfizer-BioNTech COVID-19 vaccine is currently indicated for use in individuals 5 to 11 years of age. However, Ontario is extending eligibility for the Pediatric Pfizer-BioNTech COVID-19 vaccine to children born in 2016.

**** The province will begin offering third or booster doses of a mRNA COVID-19 vaccine at recommended intervals to specific population groups. See ministry guidance available here for more information.

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 for select vulnerable populations, based on recommendations of NACI, the Chief Medical Officer of Health and other health experts as noted in ministry guidance and guidance from NACI.



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</u>'s website.

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 1st, 2021.
- Executive Officer Notice: Administration of Publicly Funded COVID-19 vaccines in Ontario Pharmacies Eligibility, effective October 8th, 2021.
- Executive Officer Notice: Administration of Publicly Funded COVID-19 vaccines in Ontario Pharmacies Eligibility, effective November 3rd, 2021.

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: OPDPInfoBox@ontario.ca

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.