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

Effective October 1, 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 **not** 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 September 8, 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 ministry 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.

Following a thorough review of the current global and Canadian experience and provincial vaccine safety surveillance data, Ontario recommends the Pfizer-BioNTech vaccine for youth ages 12-17 (including those turning 12 in 2021). 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 as the preferred vaccine for 18-24 year olds. This recommendation 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.

Table 1 – Eligibility for first dose administration*

Vaccine Product	Eligibility Criteria
Pfizer-BioNTech COVID-19 vaccine (DIN: 02509210)	Individuals who are 12 years of age or older at the time of vaccination or any time during 2021***
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.
COVISHIELD COVID-19 vaccine (DIN: 02512947) and COVID-19 vaccine AstraZeneca (PIN: 09857655)	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 the individual has been assessed by an allergist / immunologist and the pharmacy has received a completed COVID-19 Vaccination: Allergy Form prior to administrating the COVISHIELD / AstraZeneca vaccine. Note: at this time the Province has a limited supply of AstraZeneca/COVISHIELD vaccine. Pharmacies should work with their public health unit to determine how eligible individuals (as defined above) can receive the 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 may receive either AstraZeneca/COVISHIELD vaccine or an mRNA vaccine (Pfizer-BioNTech or Moderna) for their second dose, unless contraindicated. According to 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 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.

- Where a different product is used to complete the mRNA vaccine series, the appropriate minimum dose interval should be determined from the product monograph of the mRNA vaccine used for the first dose (21 days where the Pfizer-BioNTech vaccine was used for the first dose, and 28 days where the Moderna vaccine was used for the first dose). Note that an interval of 28 days for Pfizer may be considered for operational feasibility. 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 Series Second Dose Eligibility Quick Reference available here.

Vaccine Product	**Eligibility Criteria**
COVISHIELD COVID-19 vaccine (DIN: 02512947) and COVID-19 vaccine AstraZeneca (PIN: 09857655)	• Individuals who received AstraZeneca/COVISHIELD vaccine for their first dose and choose to receive the AstraZeneca/COVISHIELD vaccine for their second dose may receive their second dose at least 8 weeks after their first dose, unless they are eligible for an earlier second dose based on the exception below. • Exception: individuals with certain health conditions as documented in a letter from a health care provider, as more particularly described here, may receive the second dose as early as 4 weeks. • 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 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 the AstraZeneca / COVISHIELD vaccine if: at least 21 days

	have passed since their first dose with the Pfizer-BioNTech vaccine; ▪ at least 28 days have passed since their first dose with the Moderna vaccine; or ▪ at least 8 weeks have passed since their first dose with the AstraZeneca / COVISHIELD vaccine. • Note: at this time the Province has a limited supply of AstraZeneca/COVISHIELD vaccine. Pharmacies should work with their public health unit to determine how eligible individuals (as defined above) can receive the vaccine.
Pfizer-BioNTech COVID-19 vaccine (DIN: 02509210) and COVID-19 vaccine MODERNA (DIN: 02510014)	• Individuals who received their first dose of AstraZeneca/COVISHIELD vaccine and choose to receive one of the mRNA vaccines (Pfizer or Moderna) as their second dose may receive their second dose at least 8 weeks after their first dose, unless they are eligible for an earlier second dose based on the exception below. • Exception: individuals with certain health conditions as documented in a letter from a health care provider, as more particularly described here, may receive their second dose as early as 4 weeks. --- • Individuals who received their first dose of an mRNA vaccine (Pfizer or Moderna) may receive their second dose at an interval of up to 16 weeks, unless they are eligible for an earlier second dose based on the following rules. As of October 1, 2021: • Individuals who are 12 years of age or older, if: ▪ at least 21 days have passed since their first dose with the Pfizer-BioNTech vaccine; or ▪ at least 28 days have passed since their first dose with the Moderna vaccine.

	• Individuals who are turning 12 years of age at any time during 2021, if at least 21 days have passed since their first dose. These individuals are only eligible to receive a second dose of the Pfizer BioNTech vaccine.*** • Note: While individuals age 12 to 24 are eligible to receive the Moderna COVID-19 vaccine, Ontario recommends using the Pfizer-BioNTech vaccine for ages 12-24 (including those turning 12 in 2021). Informed consent is required for those age 12 to 24 who wish to receive the Moderna vaccine.

Table 3 – Eligibility for third dose administration**

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

- Only mRNA vaccines (Pfizer-BioNTech or Moderna) are being offered to eligible persons for third 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 dose may be the AstraZeneca / COVISHIELD vaccine if the allergist / immunologist / specialist determines a third dose is required.
- Informed consent for an additional dose of viral vector vaccine (i.e.,AstraZeneca/ COVISHIELD 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 AstraZeneca/COVISHIELD vaccine. 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 or Moderna) should be offered the same mRNA vaccine for their third 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.

Vaccine Product	Eligibility Criteria
Pfizer-BioNTech COVID-19 vaccine (DIN: 02509210) COVID-19 vaccine MODERNA (DIN: 02510014)	As of August 18, 2021: • Residents of higher-risk retirement homes[1] as identified by the local public health unit and the retirement home, if at least 5 months have passed since receiving their second dose and the vaccine is administered at the retirement home **** At this time, claims for third doses for residents of higher-risk retirement homes may only be submitted to the HNS when pharmacies administer third doses at the resident's retirement home as per arrangements with local public health units. As of September 8, 2021: • Individuals from certain immunocompromised population groups (but see updated eligibility criteria for these groups, effective September 14, 2021, below) As of September 14, 2021: • Individuals from the following moderately to severely immunocompromised population groups that present with a referral letter from their health care provider, if at least 2 months have passed since receiving their second dose or at an interval of at least 28 days as directed by the health care provider****: o Individuals receiving active[2] treatment (e.g., chemotherapy, targeted therapies, immunotherapy) for solid tumour or hematologic malignancies o Recipients of solid-organ transplant and taking immunosuppressive therapy

[1] The list of higher-risk retirement homes will be sent to pharmacies through their ONEMail account.
[2] 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 Frequently Asked Questions for more information.

	○ 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 therapies: anti-B cell therapies[3] (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. **** As of September 17, 2021: • Residents of long-term care homes as identified by the local public health unit and the long-term care home, if at least 5 months have passed since receiving their second dose and the vaccine is administered at the long-term care home **** At this time, claims for third doses for residents of long-term care homes may only be submitted to the HNS when pharmacies administer the third doses at the resident's long-term care home as per arrangements with local public health units.

***** 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.

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

**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 is currently indicated for use in individuals 12 years of age and older. However, Ontario is extending eligibility for the Pfizer-BioNTech COVID-19 vaccine to children born in 2009. Ontario has closely monitored data from Alberta and British Columbia in making this decision, and these provinces have offered the Pfizer vaccine to youth born in 2009 for several months with no risks identified.

**** The province will begin offering third doses of a mRNA COVID-19 vaccine to specific immunocompromised population groups and residents of long-term care homes, high-risk retirement homes and elder care lodges. 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. At this time, the recommended dosing in the product monographs consists of a two dose series for both Pfizer and Moderna mRNA vaccines. Ontario is funding third doses for select vulnerable populations, based on recommendations of the Chief Medical Officer of Health and other health experts as noted in ministry guidance.

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

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.