

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

Effective October 13, 2023

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

The purpose of this Executive Officer (EO) Notice: Administration of Publicly Funded COVID-19 Vaccines in Ontario Pharmacies (EO Notice), and the accompanying Frequently Asked Questions (FAQs) document, is 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 of Health (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 Notice and FAQs.

The EO Notice and the accompanying FAQs document 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 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 replaces the previous EO Notice: Administration of Publicly Funded COVID-19 Vaccines in Ontario Pharmacies that was effective September 26th, 2023.

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 authorized 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
- Be enrolled in the current 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.

Individual Eligibility

The following rules apply to the interpretation of the eligibility criteria in Appendices A and B for any COVID-19 vaccine dose (see pages 10 to 13).

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 age and interval (Appendix A, pp. 10-12) and dosing (Appendix B, p. 13) eligibility criteria for a vaccine. 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.

To align with National Advisory Committee on Immunization (NACI) and the product monographs, as of Fall 2023, the Ontario Ministry of Health (MOH) is moving away from using the terms 'primary series' and 'booster dose(s)'. This document refers to an individual's vaccination status as 'not previously vaccinated' and 'previously vaccinated' (refer to the most up to the date version of the COVID-19 Vaccine Guidance for additional details).

As of Fall 2023, all individuals receiving a COVID-19 vaccine are recommended to receive an XBB formulation. The COVID-19 XBB formulation is the preferred product for individuals not previously vaccinated.

Vaccine schedule recommendations differ based on the number of previous doses received and immune status. Please see Appendix A (pp. 10-12) for the recommended vaccination schedule. Informed consent is required to administer any COVID-19 vaccine to an eligible individual.

Please refer to the most up to date version of <u>COVID-19 Vaccine Guidance</u> for detailed information on vaccine recommendations, recommendations for moderately to severely

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.



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immunocompromised individuals, recommendations regarding re-vaccination with a new COVID-19 vaccine series post transplantation, out of province vaccines etc.



Claims for Payment

- There is no cost to eligible patients who receive the COVID-19 vaccine when administered at a pharmacy.
- For each valid claim submitted, a pharmacy will receive \$13.00 as payment for providing the following services:
 - Providing the patient with details of the process and answering any questions related to the vaccination.
 - Obtaining the consent of the patient or their substitute decision-maker prior to vaccine administration
 - Administering the COVID-19 vaccine.
 - Providing the patient with proper monitoring and written vaccine information as well as after-care instructions following vaccine administration.
 - Providing the patient with a written receipt of the vaccination with the pharmacy contact information after the vaccine is administered (see Pharmacy Documentation Requirements section below); a pharmacy may wish to issue an electronic receipt as well. (Note: a written receipt can be printed from COVAX_{ON}).
 - Complying with any requirements to access and use the Provincial COVID-19 Vaccine Solution-COVAX_{ON} under the COVID-19 Vaccine Agreement.
- Pharmacies may access personal protective equipment (PPE) from the ministry's dedicated supply, if needed, to administer the COVID-19 vaccine. The ministry's supply of PPE must ONLY be used to support the activity of pharmacies administering the publicly funded COVID-19 vaccine.
- The table in Appendix B lists the publicly funded COVID-19 vaccines that are available to pharmacies and are billable, including any restrictions on administering the vaccine (e.g., age groups).

Exclusions and Restrictions

- If a patient does not have a valid Ontario health card number, pharmacy staff can still
 administer the publicly funded COVID-19 vaccine, provided that the patient provides an
 alternate identification confirming their name and date of birth. In such cases,
 pharmacies must use the proxy patient ID: 79999 999 93.
- Administration of non-publicly funded COVID-19 vaccines that are privately purchased by the pharmacy does not qualify for payment.



- Vaccine administration must occur at the location of the participating pharmacy premises, unless otherwise indicated. The pharmacy is permitted to administer publicly funded vaccines supplied by their distributor in a nearby location (e.g., an adjacent pharmacy parking lot) and retirement homes, elderly congregate settings, long-term care homes, or mobile clinic locations as long as they are able to ensure adherence to public safety and relevant Ministry policy / direction (including infection prevention and control measures), the COVID-19 Vaccine Agreement, and any Ontario College of Pharmacist (OCP) standards, polices or guidelines. See the most recent version of the accompanying FAQs for more information.
- The role of pharmacists, pharmacy students, interns or pharmacy technicians administering the COVID-19 vaccine in initiatives led by other authorized organizations that have entered into COVID-19 Vaccine Agreements with the Ministry (e.g., public health units or hospitals that organize mass immunization clinics) that are not billed through the HNS is excluded from this notice.
- A pharmacist's recommendation to a prescriber that a patient should receive a COVID-19 vaccine is not a billable service under the Pharmaceutical Opinion Program

Billing Procedures - Summary

- Claims for administering the publicly funded COVID-19 vaccine can only be submitted electronically using the HNS (see "Billing Procedures - Detailed" below).
 No manual paper claims will be accepted unless 3 intervention codes are required in order to process the claim.
- The Part A pharmacist who administers the vaccine or who is overseeing other
 pharmacy staff administering the vaccine must be identified in the prescriber field on
 the claim. Each claim must include the Drug Identification Number (DIN)
 corresponding to the publicly funded COVID-19 vaccine that was administered to the
 eligible individual (see table in Appendix B).
- The person submitting the claim must ensure that the eligible individual's date of birth, Ontario health number and name (as it appears on the health card / document) are included in the claim. Failure to do so – especially for non-Ontario Drug Benefit (ODB) Program recipients – may impact the ability to submit future claims for these individuals.
 - For eligible individuals without an Ontario health number, pharmacies must use the proxy patient ID: 79999 999 93 (see below for further details).

Billing Procedures – Detailed



The claim submission follows the usual process (See <u>Section 5.1</u> of the Ontario Drug Program Reference Manual) for submitting claims in the HNS with the following additional information:

Fields required for all claims for pharmacist administered COVID-19 vaccines

ODB recipients and non-ODB recipients

- Intervention code 'PS': (Professional Care Services)
- Drug Identification Number (DIN): as per the publicly funded COVID-19 vaccine administered (see Appedix B)
- Valid Pharmacist ID
- Professional fee: \$13.00

Additional fields required for non-ODB recipients with an Ontario health number

When submitting a claim for an eligible individual who does not have ODB coverage, submit the following additional information:

- Patient Gender: 'F' = female; 'M' = male
- Patient Date of Birth: Valid YYYYMMDD
- Patient's Ontario Health number
- Intervention codes:
 - o PS: Professional Care Services
 - ML: Established eligibility coverage (i.e., 1 day of the Plan 'S' coverage)
- Carrier ID: 'S'
- Drug Identification Number (DIN): as per the publicly funded COVID-19 vaccine administered
- Valid Pharmacist ID

Additional fields required for non-ODB recipients without an Ontario health number

When submitting a claim for an eligible individual who does not have an Ontario health number, submit the following additional information:

- First Name: Patient's first name
- Last Name: Patient's last name
- Patient Gender: 'F' = female; 'M' = male
- Patient Date of Birth: Valid YYYYMMDD
- Proxy patient ID: 79999 999 93
- Intervention codes:
 - o PS: Professional Care Services
 - o PB: Name entered is consistent with card
- Valid Pharmacist ID



Payment for epinephrine auto-injector for emergency treatment after administration of the COVID-19 vaccine

If there is an adverse event resulting immediately after pharmacy staff administers a publicly funded COVID-19 vaccine, the ministry will reimburse pharmacies for the acquisition cost of the epinephrine auto-injector up to the total amount reimbursed.

Emergency treatment must take place in the pharmacy or where the vaccine was administered, for example an adjacent pharmacy parking lot, retirement home, long-term care home, other congregate setting, or mobile clinic location, if applicable.

The claim submission process is the same as the one followed for the publicly funded UIIP. Refer to Section 6.15 of the Ontario Drug Program Reference Manual for billing information.

Pharmacy Documentation Requirements

Pharmacies must keep a record of every dose of publicly funded COVID-19 vaccine administered.

Pharmacists shall keep records consistent with their obligations under the *Pharmacy Act,* 1991, the *Drug and Pharmacies Regulation Act*, the COVID-19 Vaccine Agreement, and any instructions or guidelines provided by the OCP or the ministry.

For purposes of post-payment verification, pharmacy records related to claims for administering a publicly funded COVID-19 vaccine must be maintained in a readily available format for the purpose of ministry inspection for a minimum of 10 years from the last recorded pharmacy service provided to the patient, or until 10 years after the day on which the patient reached or would have reached the age of 18 years, whichever is longer.

Overpayments due to inappropriate claim submissions are subject to recovery.

Pharmacy documentation must be maintained in a readily retrievable format and record requirements are:

- Record of name and address of patient.
- Record of patient's Ontario health number or alternate ID with contact information if applicable.
- Record of name of vaccine administered, dose (including half-dosing if applicable), lot number, expiry date, time, date, route and site of administration.
- Record of pharmacy name, pharmacy address and name and signature of individual who administered the vaccine.
- Record of location of administration (inside pharmacy, pharmacy parking lot or within the retirement home, elderly congregate setting, long-term care home or location of a mobile clinic if applicable)



- Evidence of the provision of a written and electronic (if applicable) record (post administration) of the COVID-19 immunization record to the patient, which includes the pharmacy's contact information and date and time for the second scheduled dose at the same pharmacy location. Note: date and time of the second dose may be hand-written on the written record provided to the patient.
- Record of any serious adverse events following immunization that result in the administration of epinephrine, and the circumstances relating to the administration of the substance.
- Records documenting compliance with any requirements to access and use the Provincial COVID-19 Vaccine Solution-COVAXON under the COVID-19 Vaccine Agreement. Note: All respective health care providers whether pharmacist, intern, registered pharmacy student, pharmacy technician or other health care provider must identify themselves as the vaccinator in the COVAX_{ON} system and on the vaccine receipt provided to the patient.

Prior EO Notices

Updates relating to this Executive Officer Notice were, prior to April 6, 2023, communicated as two (2) separate EO Notices (Administration of the Publicly Funded COVID-19 Vaccines in Ontario Pharmacies – **Eligibility**; Administration of the Publicly Funded COVID-19 Vaccines in Ontario Pharmacies – **Billing**) on the effective dates listed below.

EO Notices in 2023							
March 6	April 6	July 7	September 26	October 13			
	EO Notices in 2022						
January 13	April 7	July 28	September 12	November 8			
February 18	May 2	August 8	September 26	December 21			
March 25	July 14	September 1	October 17				
	EO Notices in 2021						
March 10	May 11	June 4	September 1	December 2			
March 22	May 13	June 14	September 8	December 17			
April 1	May 18	June 17	October 1	December 20			
April 19	May 21	June 25	October 8				
April 30	May 23	July 5	November 3				
May 6	May 31	August 18	November 25				



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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:

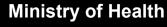
Please call ServiceOntario, Infoline at 1-866-532-3161 TTY 1-800-387-5559. In Toronto, TTY 416-327-4282.



Appendix A: Moderna or Pfizer XBB mRNA COVID-19 vaccine schedule based on immunization history and immune status (adapted from Table 1 in the COVID-19 Vaccine Guidance)

A: For those NOT moderately to severely immunocompromised

Age	Immunization History ¹	Recommended Number of XBB Doses and Interval ² Between Doses				
		Moderna XBB Schedule ³	Pfizer XBB Schedule			
6 months – 4 years	3 or more doses	N/A	 1 dose Recommended: 168 days from last dose Minimum: 84 days from last dose⁴ 			
	2 doses	Recommended: 168 days from last dose Minimum: 84 days from last dose ⁴	Recommended: 56 days from last dose Minimum: 28 days from last dose (if 2 nd dose was Moderna) 56 days from last dose (if 2 nd dose was Pfizer)			
	1 dose	Recommended: 56 days from last dose Minimum: 28 days from last dose	2 doses Recommended: 56 days from last dose and between doses Minimum: 28 days from last dose (if 1st dose was Moderna) and between doses If 1st dose was Pfizer: 21 days between dose 1 & 2 56 days between dose 2 & 3			
	0 doses	Recommended: 56 days between doses Minimum: 28 days between doses	 3 doses Recommended: 56 days between doses Minimum: 21 days between dose 1 & 2 56 days between dose 2 & 3 			
5 years +	2 or more doses	 1 dose Recommended: 168 days from last dose Minimum: 84 days from last dose⁴ 				
	1 dose	Recommended: 56 days from last dose Minimum: 28 days from last dose (if 1st dose was Moderna) 21 days from last dose (if 1st dose was Pfizer)				
	0 doses	1 dose				





B: For those moderately to severely immunocompromised

Age	Immunization History⁵	Recommended Number of XBB Doses and Interval ⁶ Between Doses			
		Moderna XBB ⁷	Pfizer XBB		
6 months – 4 years	4 or more doses	N/A	1 dose Recommended: 168 days from last dose Minimum: 84 days from last dose ⁸		
	3 doses	 1 dose Recommended: 168	 1 dose Recommended: 56 days from last dose Minimum: 28 days from last dose (if 3rd dose was Moderna) 56 days from last dose (if 3rd dose was Pfizer) 		
	2 doses	 1 dose Recommended: 56 days from last dose Minimum: 28 days from last dose Moderna preferred⁹ 	 2 doses Recommended: 56 days from last dose and between doses Minimum: 28 days from last dose (if 2nd dose was Moderna) If 2nd dose was Pfizer 56 days between dose 2 & 3 56 days between dose 3 & 4 		
	1 dose	2 doses Recommended: 56 days from last dose and between doses Minimum: 28 days from last dose and between doses Moderna preferred9	 3 doses Recommended: 56 days from last dose and between doses Minimum: 28 days from last dose (if 1st dose was Moderna) If 1st dose was Pfizer 21 days between dose 1 & 2 56 days between dose 2 & 3 56 days between dose 3 & 4 		
	0 doses	3 doses • Recommended: 56 days between doses • Minimum: 28 days between doses Moderna preferred9	4 doses Recommended: 56 days between doses Minimum: 21 days between dose 1 & 2 56 days between dose 2 & 3 56 days between dose 3 & 4		



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5 years +	3 or more doses	1 dose				
		Recommended: 168 days from last dose				
		Minimum: 84 days from last dose ⁸				
	2 doses	1 dose				
		Recommended: 56 days from last dose				
		Minimum:				
		 28 days from last dose (if 2nd dose was Moderna) 				
		 21 days from last dose (if 2nd dose was Pfizer) 				
	1 dose	2 doses				
		Recommended: 56 days from last dose and between doses				
		Minimum:				
		 Moderna: 28 days from last dose (if 1st dose was Moderna) and between doses 				
		 Pfizer: 21 days from last dose (if 1st dose was Pfizer) and between doses 				
	0 doses	2 doses				
		Recommended: 56 days between doses				
		Minimum:				
		 Moderna: 28 days between doses 				
		o Pfizer: 21 days between doses				

¹ Refers to the doses of non-XBB COVID-19 vaccine that were previously received.

² Recommended intervals are based on NACI recommendations. A longer interval between doses of a COVID-19 vaccine, results in a more robust and durable immune response and higher vaccine effectiveness. The minimum interval is the shortest interval at which the product should be given and is outlined in the product monographs.

³ For individuals **6 months – 4 years**, this column assumes that all previous non-XBB doses were all Moderna vaccines. If one or more dose was Pfizer, follow the Pfizer XBB Schedule.

⁴ Per NACI, a shorter interval (3 to < 6 months) may be used to support fall program implementation

⁵Refers to the doses of non-XBB COVID-19 vaccine that were previously received.

⁶ Recommended intervals are based on NACI recommendations. A longer interval between doses of a COVID-19 vaccine, results in a more robust and durable immune response and higher vaccine effectiveness. The minimum interval is the shortest interval at which the product should be given and is outlined in the product monographs.

⁷ For individuals 6 months – 4 years, this column assumes that all previous non-XBB doses were all Moderna vaccines. If one or more dose was Pfizer, follow the Pfizer XBB Schedule.

⁸ Per NACI, a shorter interval (3 to < 6 months) may be used to support fall program implementation.

⁹ The ministry preferentially recommends the Moderna XBB vaccine over the Pfizer XBB vaccine for individuals 6 months – 4 years who are moderately to severely immunocompromised. This product preference reflects acceptability and feasibility considerations for implementing a 3 dose (Moderna) vs. 4 dose (Pfizer) series and greatly likelihood of series completion in high-risk individuals, with fewer doses required in the Moderna schedule.

Appendix B: COVID-19 Vaccines Available for Use in Ontario (adapted from COVID-19 Vaccine Guidance)

COVID-19 Formulations	Moderna	Moderna Bivalent (BA.4/5)	Moderna XBB	Pfizer- BioNTech <i>XBB</i>	Pfizer- BioNTech <i>Bivalent</i>	Pfizer- BioNTech <i>XBB</i>	Pfizer- BioNTech <i>Bivalent</i>	Pfizer- BioNTech <i>XBB</i>	Novavax
Cap and Label Colour									
	Royal blue cap and purple label	Blue cap and grey label	Royal blue cap and coral blue label	Maroon cap and label	Orange cap and label	Blue cap and label	Grey cap and label	Grey cap and label	Royal blue cap
DIN Number	02527685	02532352	02541270	02541866	02533197	02541858	02531461	02541823	02525364
Age Eligibility Criteria	(i) 6 months to 5 years (ii) 6 to 11 years	(i) 6 months - 5 yrs (off label) (ii) 6 - 11 yrs (iii) ≥12 yrs	(i) 6 months - 4 yrs (ii) 5-11 yrs (iii) 12 yrs+	6 months – 4 years	5 - 11 yrs	5 – 11 yrs	12 yrs+	12 yrs+	12 yrs+ (primary series) 18 yrs+ (booster doses)
Vial Concentration	0.1 mg/mL	0.1 mg/mL	0.1 mg/mL	0.015 mg/mL	0.05 mg/mL	0.03 mg/mL	0.1 mg/mL	0.1 mg/mL	0.01 mg/mL
Dose/ Volume	(i) 25 mcg/0.25mL (ii) 50 mcg/0.5 mL	(i) 25 mcg/0.25mL (ii) 25 mcg/0.25mL (iii) 50 mcg/0.5mL	(i) 25 mcg/0.25 mL (ii) 25 mcg/0.25 mL (iii) 50 mcg/0.5 mL	3 mcg/ 0.2 mL	10 mcg/ 0.2 mL	10 mcg/ 0.3 mL	30 mcg/ 0.3mL	30 mcg/ 0.3mL	5 mcg/ 0.5 mL
Dilution	None	None	None	2.2 mL/vial	1.3 mL/vial	None	None	None	None
Vaccine Type	Monovalent mRNA	Bivalent mRNA	Monovalent mRNA	Monovalent mRNA	Bivalent mRNA	Monovalent mRNA	Bivalent mRNA	Monovalent mRNA	Protein Subunit Vaccine
Use	Unvaccinated and previously vaccinated individuals	Unvaccinated (off- label) and previously vaccinated individuals	Unvaccinated and previously vaccinated individuals	Unvaccinated and previously vaccinated individuals					