Ontario

Ministry of Health

COVID-19 Vaccine Guidance

Version 7.0 – July 7, 2023

Summary of Changes

- Bivalent mRNA vaccines to be used for primary series initiation or completion in individuals 6 months and older (page 3, 4, 5 and 26).
- Removal of the COVID-19 Janssen vaccine as an available vaccine option (page 6).
- Individuals 5 years and older should consider delaying receipt of a COVID-19 vaccine booster until Fall 2023 (page 9-10).
- Expanded indication of bivalent Moderna BA.4/5 to include individuals 6-17 years for use as a booster (page 26).
- Addition of Vaccine Preparation and Administration section (page 23).
- Update of Appendix C: Vaccinator Infographic (page 27-28).

This guidance provides basic information only. This document is not intended to provide or take the place of medical advice, diagnosis or treatment, or legal advice.

In the event of any conflict between this guidance document and any applicable emergency orders, or directives issued by the Minister of Health, Minister of Long-Term Care, or the Chief Medical Officer of Health (CMOH), the order or directive prevails.

- Please check the Ministry of Health (MOH) COVID-19 website regularly for updates to this document

This document can be used as a reference for vaccine clinics and vaccine administrators to support COVID-19 immunization. Complementary resources include the individual vaccine product monographs, the COVID-19: Vaccine Storage and Handling Guidance and the COVID-19 Vaccine: Canadian Immunization Guide.

Evidence on vaccine effectiveness for COVID-19 vaccines currently authorized for use in Canada continues to evolve. For up to date information on vaccine efficacy and effectiveness, please consult the National Advisory Committee on Immunization (NACI) statements and publications on the Government of Canada webpage.

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Table 1: Interim recommendations[1] for bivalent COVID-19 mRNA vaccines based on age, dosage, and schedule

Age	Recommended Intervals[2]	Minimum Intervals
6 months - 4 years	**Primary Series** Bivalent Moderna (25 mcg) • 2nd dose, 56 days after 1st dose	**Primary Series** Bivalent Moderna (25 mcg) • 2nd dose, 28 days after 1st dose
	Booster Doses – not eligible	
5-11 years	**Primary Series** Bivalent Pfizer-BioNTech (10 mcg)/ Bivalent Moderna (25 mcg) • 2nd dose, 56 days after 1st dose	**Primary Series** Bivalent Pfizer-BioNTech (10 mcg)/ Bivalent Moderna (25 mcg) • 2nd dose, 28 days after 1st dose
	Booster Doses: Bivalent Pfizer-BioNTech (10 mcg)[3]/Bivalent Moderna (25 mcg) 6 months (168 days) after last dose or confirmed SARS-CoV-2 infection	
12 years +	**Primary Series** Bivalent Pfizer-BioNTech (30 mcg)[4]/ Bivalent Moderna (50 mcg) • 2nd dose, 56 days after 1st dose	**Primary Series** Bivalent Pfizer-BioNTech (30 mcg)/ Bivalent Moderna (50 mcg) • 2nd dose, 28 days after 1st dose
	Booster Doses Bivalent Pfizer-BioNTech (30 mcg)/ Bivalent Moderna (50 mcg) • 6 months (168 days)[5] after last dose or confirmed SARS-CoV-2 infection	**Booster Doses** Bivalent Pfizer-BioNTech (30 mcg) • 3 months (84 days) after last dose or confirmed SARS-CoV-2 infection Bivalent Moderna (50 mcg) • 4 months (112 days) after last dose or confirmed SARS-CoV-2 infection
Immuno-compromised 6 months+	**An additional dose is required to complete the primary series.** The recommended interval is 56 days (minimum 28 days) from the 2nd dose.	

[1] Interim recommendations as per NACI to use bivalent mRNA vaccines off-label to initiate or complete the primary series. Informed consent is always required for vaccines under the Health Care Consent Act and express consent is required when a vaccine is being offered off-label. Bivalent mRNA vaccines continue to be recommended for use as booster doses.

[2] Longer intervals between the first and second doses of COVID-19 vaccines result in more robust and durable immune response and higher vaccine effectiveness.

[3] Bivalent Pfizer (10 mcg) is the only authorized bivalent booster for those 5 years of age.

[4] Bivalent Pfizer is preferred for those 12-29 years initiating or completing the primary series due to lower risk of myocarditis and/or pericarditis.

[5] The recommended interval is 6 months; however, vaccine administrators may use their clinical discretion to decide on administration prior to the 6-month interval.

Table 2: Interim recommendations[1] for bivalent COVID-19 mRNA vaccine product preferences by age and immune status

	Age	Product Preference (mcg/mL)
Primary Series	6 months to 4 years	Bivalent Moderna (25 mcg/0.25 mL) is the recommended and only bivalent product for this age group[6]
	5 to 11 years[7]	No preference between bivalent Pfizer-BioNTech (10 mcg/0.2 mL) or bivalent Moderna (25 mcg/0.25 mL)
	12 to 29 years[8]	Bivalent Pfizer-BioNTech (30 mcg/0.3 mL)
	30 years and older[7]	No preference between bivalent Pfizer-BioNTech (30 mcg/0.3 mL) or bivalent Moderna (50 mcg/0.5 mL)
Booster Doses	6 months to 4 years	Not eligible for booster doses
	5 years	Bivalent Pfizer-BioNTech (10 mcg/0.2 mL) is the only authorized bivalent product for this age group
	6 to 11 years	No preference between bivalent Pfizer-BioNTech (10 mcg/0.2 mL) or bivalent Moderna (25 mcg/0.25 mL)
	12 years and older	No preference between bivalent Pfizer-BioNTech (30 mcg/0.3 mL) or bivalent Moderna (50 mcg/0.5 mL)

[6] Currently, there is no bivalent Pfizer product available in Canada for individuals 6 months to 4 years of age.

[7] Individuals 6 months and older who are moderately to severely immunocompromised may benefit from a primary series with bivalent Moderna (25 mcg in 6 months-11 years, 50 mcg in those 12 years and older) compared to bivalent Pfizer (10 mcg in 5 -11 years, 30 mcg in those 12 years and older).

[8] For individuals 12 to 29 years of age, bivalent Pfizer (30 mcg) vaccine is preferred due to the lower risk of myocarditis and/or pericarditis, however, for some moderately to severely immunocompromised individuals, administration of the bivalent Moderna (50 mcg) may be considered based on individual clinician judgement and informed consent.

Ontario's COVID-19 Vaccine Program

Ontario's COVID-19 vaccine program aims to ensure as many Ontarians as possible are up to date with their COVID-19 vaccines for the purposes of protecting individuals against **severe** COVID-19 disease, including hospitalization and death.

At this time, the seasonality of COVID-19 is not known, and it has not yet been determined whether people will need a COVID-19 booster at a set time period (e.g., every 6 months). This guidance outlines current recommendations for 'staying up to date', based on age and health status.

Health equity remains a cornerstone and a priority of Ontario's COVID-19 vaccine program. Sustained culturally safe and community centred efforts need to be prioritized to:

1. Ensure ongoing access to vaccines for Indigenous, racialized, and marginalized populations disproportionately affected by COVID-19 due to disparities in the Social Determinants of Health including systemic barriers to accessing health care; and
2. promote people remaining up to date with their COVID-19 vaccines – both for primary series and booster doses.

Primary Series Recommendations

1. **NACI recommends bivalent Omicron-containing mRNA COVID-19 vaccines (i.e., Bivalent Pfizer-BioNTech or Bivalent Moderna) be used to initiate or complete the primary series for all individuals 6 months and older**, without contraindications to the vaccine, as outlined in Table 1 and 2. These recommendations are interim and were made considering only the currently available bivalent mRNA COVID-19 vaccines, which are authorized for use as a primary series. Future recommendations will consider new product options as regulatory decisions are made. Consistent with NACI recommendations on vaccine interchangeability, regardless of which product is offered to start a primary series, the previous dose should be counted; the series should be continued and not restarted. If a primary series is started with an original mRNA vaccine, a bivalent Omicron-containing vaccine can be used to complete the series. If a primary series is started with a bivalent Omicron-containing mRNA vaccine and the same product is not readily available to complete the series, another bivalent Omicron-containing mRNA vaccine

may be used to complete the series. **Bivalent products available in Ontario include bivalent Pfizer BA.4/5 and bivalent Moderna BA.4/5.** Bivalent Moderna BA.4/5 is the only bivalent Moderna product available in Ontario, as bivalent Moderna BA.1 has been fully phased out. Please see Table 1 for more information on product recommendations by age, dosage and schedules (recommended and minimum intervals).

2. **Novavax COVID-19 vaccine (protein subunit vaccine)** may be offered to individuals who are 12 years and older, without contraindications to the vaccine, who are not able or willing to receive an mRNA COVID-19 vaccine.
3. **Astra Zeneca, Medicago and Janssen COVID-19 vaccines are no longer being used in Ontario**.

A longer interval between doses of a COVID-19 vaccine, for both primary series and booster doses, results in a more robust and durable immune response and higher vaccine effectiveness. A longer interval between doses may also be associated with lower risk of myocarditis and/or pericarditis in adolescents and young adults. See the Canadian Immunization Guide for more information. Additionally, individuals with a confirmed SARS-CoV-2 infection should also delay vaccination to ensure appropriate vaccine efficacy (Table 3). These intervals are a guide and clinical discretion is advised.

Primary Series Recommendations for Moderately to Severely Immunocompromised Individuals

- **An extended primary series is recommended for certain moderately to severely immunocompromised individuals** 6 months of age and older with the aim of enhancing the immune response to vaccination and establishing an adequate level of protection for individuals who may develop a sub-optimal immune response to the standard two dose primary series. An extended primary series constitutes administration of an additional dose to complete the primary series. See the COVID-19 chapter in the Canadian Immunization Guide: Immunocompromised persons for more information.
    - As per NACI, moderately to severely immunocompromised individuals 6 months to 4 years may be offered a primary series that includes an additional dose of an mRNA COVID-19 vaccine (3 doses), whereas moderately to severely immunocompromised individuals 5 years and older should receive a primary series that includes an additional dose of an mRNA COVID-19 vaccine (3 doses).

  - Individuals **6 months and older who are moderately to severely immunocompromised may benefit from a primary series with bivalent Moderna** (25 mcg in 6 months-11 years and 50 mcg in those 12 years and older) compared to bivalent Pfizer (10 mcg in 5 -11 years and 30 mcg in those 12 years and older).
  - For **individuals 12 to 29 years of age**, **the bivalent Pfizer (30 mcg) vaccine is preferred** due to the lower risk of myocarditis and/or pericarditis, however, for some moderately to severely immunocompromised individuals, administration of the bivalent Moderna (50 mcg) may be considered based on individual clinician judgement and informed consent.

- An extended primary series is recommended for the following populations:
  - Individuals receiving dialysis (hemodialysis or peritoneal dialysis)
  - Recipients of solid-organ transplant and taking immunosuppressive therapy
  - Individuals receiving active treatment[9] (e.g., chemotherapy, targeted therapies, immunotherapy) for solid tumour or hematologic malignancies
  - 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)
  - HIV with AIDS-defining illness in last 12 months before starting vaccine series, or severe immune compromise with CD4 count <200 cells/uL or CD4 percentage <15%, or without HIV viral suppression
  - Individuals receiving active treatment with the following categories of immunosuppressive therapies: anti-B cell therapies[10] (monoclonal

[9] 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.

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

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 (Appendix D).

- It is recommended that re-vaccination with a new COVID-19 vaccine primary series 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.[11] Optimal timing for re-immunization should be determined on a case-by-case basis in consultation with the clinical team. For additional information on organ transplantation, consult the Canadian Society of Transplantation statement on COVID-19 vaccination.
- For additional information on rheumatic diseases, consult the Canadian Rheumatology Association statement on COVID-19 vaccination.
- For additional information on inflammatory bowel disease, consult the Canadian Association of Gastroenterology statement on COVID-19 vaccination.
- For additional information on immunodeficiency conditions, consult the COVID-19 resources on the Canadian Society of Allergy and Clinical Immunology webpage.
- For frequently asked questions about COVID-19 vaccines and adult cancer patients, consult Cancer Care Ontario.

The safety and efficacy of the Novavax COVID-19 vaccine has not been established in individuals who are immunocompromised due to disease or treatment. As such, eligible individuals who **choose to be immunized with the Novavax COVID-19 vaccine should be informed that there is currently limited evidence for use of these vaccines in this population.** Individual clinical discretion should be used when offering an additional dose of Novavax to immunocompromised individuals as part of an extended primary series.

[11] As per the Canadian Immunization Guide, HSCT recipients should be viewed as vaccine naïve (i.e., never immunized) and require re-immunization after transplant.

Booster Doses Recommendations and Staying Up to Date

Individuals 5 years and older should consider delaying receipt of a COVID-19 vaccine booster until Fall 2023.

Staying Up to Date[12]

- For those **6 months – 4 years**, means having a completed primary series. Booster doses are not currently recommended for this age group.
- For those **5 years and older,** means completion of the primary series and receipt of the currently recommended booster dose.

Booster doses are recommended for all eligible populations based on the ongoing risk of infection due to waning immunity, the ongoing risk of severe illness from COVID-19, the societal disruption that results from transmission of infections, risk of post-COVID condition or post-acute COVID syndrome (PCC), and the adverse impacts on health system capacity from the COVID-19 pandemic.

Individuals are recommended to receive a bivalent mRNA COVID-19 vaccine for their booster doses due to the strong protection offered and well-established safety and effectiveness data (CIG, 2022). The bivalent COVID-19 vaccines currently available in Ontario target the original COVID-19 virus and the BA.4/5 Omicron sub-variants.

A booster dose should be offered 6 months (168 days) after a previous COVID-19 vaccination or confirmed SARS-CoV-2 infection.[13] While the recommended interval is 6 months, vaccine administrators can use their use their clinical discretion based on individual circumstances. The closer the timing is to the optimal 6-month interval, the better; evidence shows that the antibody response is higher with longer intervals between infection and vaccination and between vaccine doses.

[12] This definition is based on NACI recommendations for COVID-19 vaccine booster doses, however, is subject to change as the COVID-19 pandemic evolves.

[13] A confirmed SARS-CoV-2 infection is characterized by positive result obtained using a molecular (e.g., PCR) or Health Canada approved rapid antigen test OR symptomatic disease compatible with COVID-19 AND a household exposure to a confirmed COVID-19 case.

Population-Level Recommendations

- Currently, there are no booster products authorized by Health Canada for **infants and children 6 months to 4 years;** these individuals are not eligible for a booster dose at this time.
- **Effective the week of July 7th, 2023, individuals 5 years and older** should consider delaying receipt of a COVID-19 vaccine booster until Fall 2023. Receiving a booster dose in the Fall, as respiratory season commences, will maximize protection against COVID-19 when peak circulation of the virus is expected. The decision to receive a booster dose prior to Fall 2023 may be appropriate for certain individuals based on their unique health status and personal situation. Individuals should be encouraged to speak with their health care provider.

Booster doses of Novavax COVID-19 vaccine (protein subunit vaccine) may be offered to individuals who are 18 years and older without contraindications to the vaccine and who are not able or willing to receive an mRNA COVID-19 vaccine. As part of informed consent, individuals who are not able or willing to receive an mRNA vaccine should be made aware of the long-term effectiveness and safety data that is available for the mRNA vaccine products as compared to the other authorized COVID-19 vaccines (CIG, 2022).

Co-Administration

Individuals 6 months and older, may receive a COVID-19 vaccine simultaneously with (i.e., same day), or at any time before or after non-COVID-19 vaccines (including live and non-live vaccines). Informed consent should include a discussion of the benefits and risks given the limited data available on administration of COVID-19 vaccines at the same time as, or shortly before or after, other vaccines. If vaccines must be co-administered, immunization on separate limbs is recommended, however if the same limb must be used, the injection sites should be separated by at least 2.5 cm (1 inch).

The exception to this is the Imvamune® vaccine provided for mpox. If vaccine timing can be planned, it is recommended to wait at least 4 weeks before or after administration of an Imvamune® vaccine. However, the administration of Imvamune® as pre- or post-exposure vaccination should not be delayed in an individual who has recently received a COVID-19 vaccine. These suggested waiting periods are precautionary but may help prevent erroneous attribution of an AEFI to one particular vaccine or the other. Please refer to Mpox Vaccine (Imvamune®) Guidance for Health Care Providers.

Studies to assess safety and immunogenicity of concurrent administration of COVID-19 vaccines with other vaccines are ongoing.

Recommended Intervals Between Previous SARS-CoV-2 Infection and COVID-19 Vaccination

The Ontario Ministry of Health, in alignment with NACI, continues to recommend that COVID-19 vaccines should be offered to individuals with previous SARS-CoV-2 infection without contraindications to the vaccine. Below are suggested intervals between previous SARS-CoV-2 infection and COVID-19 vaccination.

Table 3: Suggested Intervals between SARS-CoV-2 Infection and COVID-19 Vaccination

SARS-CoV-2 Infection timing relative to COVID-19 vaccination	Population	Recommended Interval
Infection prior to completion or initiation of primary series	Individuals 6 months and older who are not considered moderately to severely immunocompromised and with no previous history of multisystem inflammatory syndrome in children and adults (MIS-C and MIS-A)	8 weeks (56 days) after symptom onset or positive test (if asymptomatic)
	Individuals 6 months and older who are moderately to severely immunocompromised and with no previous history of MIS-C and MIS-A	4 to 8 weeks (28 to 56 days) after symptom onset or positive test (if asymptomatic)
	Individuals 6 months and older with a history of MIS-C and MIS-A (regardless of immunocompromised status)	Receive vaccine dose when clinical recovery has been achieved or ≥90 days since the diagnosis of MIS-C and MIS-A, whichever is longer

SARS-CoV-2 Infection timing relative to COVID-19 vaccination	Population	Recommended Interval
Infection after primary series	Individuals currently eligible for booster dose(s)	Receive vaccine dose 6-months (168 day) after previous COVID-19 infection (characterized by positive test or after having symptoms post contact with someone who had a positive test)[14].

*A previous infection with SARS-CoV-2 is defined as:

- Confirmed SARS-CoV-2 infection using a molecular (e.g., PCR) or Health Canada-approved rapid antigen test; or
- Symptomatic disease compatible with COVID-19 **AND** a household exposure to a confirmed COVID-19 case.

These suggested intervals are based on immunological principles and expert opinion, and may change as evidence on COVID-19, variants of concern (VOCs), and COVID-19 vaccines emerge. When considering whether or not to administer vaccine doses according to the intervals outlined in this table, biological and social risk factors for exposure (e.g., local epidemiology, circulation of VOCs, living settings) and risk of severe disease should also be taken into account. These intervals are a guide and clinical discretion is advised.

In accordance with provincial guidance, individuals who have symptoms of COVID-19 or other infectious agents should self-isolate, including COVID-19 vaccine clinics, until the following criteria are met:

- Symptoms have been improving for at least 24 hours (or 48 hours if nausea, vomiting and/or diarrhea were present)
- No fever
- There has not been development of additional symptoms

[14] Please refer to the Booster Doses Recommendations and Staying Up to Date section for guidance on current booster recommendations.

These suggested waiting times are intended to minimize the risk of transmission of COVID-19 and other respiratory or gastrointestinal pathogens at an immunization venue and to enable monitoring for COVID-19 vaccine adverse events following immunization (AEFI) without potential confounding from symptoms of COVID-19 or other co-existing illnesses.

COVID-19 Vaccine Precautions & Population Specific Considerations

See the COVID-19 Vaccine: Canadian Immunization Guide's section on Contraindications and Precautions for recommendations for individuals with bleeding disorders, immune thrombocytopenia, venous thromboembolism, thrombosis with thrombocytopenia syndrome, myocarditis and/or pericarditis following vaccination, Guillain-Barré syndrome and Bell's palsy.

Myocarditis & Pericarditis following vaccination with an mRNA COVID-19 vaccine

There have been Canadian and international reports of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining around the heart) following vaccination with COVID-19 mRNA vaccines. Global experience to date has indicated that the majority of reported cases have responded well to conservative therapy (rest, treatment with non-steroidal anti-inflammatory drugs (NSAIDS)) and tend to recover quickly. Symptoms have typically been reported to start within one week after vaccination. Cases of myocarditis/pericarditis following COVID-19 mRNA vaccination occur more commonly in adolescents and young adults (12 to 29 years), more often after the second dose and more often in males than females. Safety surveillance data from the US suggests that the risk of myocarditis or pericarditis is lower in children 5 to 11 years following monovalent Pfizer-BioNTech (10 mcg) vaccination compared to adolescents and young adults (who received a monovalent Pfizer-BioNTech 30 mcg dose). Among children 5 to 11 years, very rare cases were most often reported following dose 2 and among males. Post-market safety surveillance is ongoing (NACI, 2022). Providers are encouraged to consult the enhanced epidemiologic surveillance summary from Public Health Ontario for trends and risk of myocarditis/pericarditis following mRNA vaccines in Ontario.

NACI continues to strongly recommend that a complete series with an mRNA COVID-19 vaccine be offered to all eligible individuals in Canada, including those 5 years and older.

The benefits of vaccination with COVID-19 vaccines continue to outweigh the risks of COVID-19 illness and related, possibly severe outcomes for all age groups.

- Anyone receiving an authorized mRNA COVID-19 vaccine should be informed of the risk of myocarditis and pericarditis, and advised to seek medical attention if they develop symptoms including chest pain, shortness of breath, palpitations (pounding or heart racing), or feeling of rapid or abnormal heart rhythm (NACI).

In most circumstances, and as a precautionary measure until more information is available, individuals with a diagnosed episode of myocarditis (with or without pericarditis) within 6 weeks of receipt of a previous dose of an mRNA COVID-19 vaccine should defer further doses of the vaccine. This includes any person who had an abnormal cardiac investigation including electrocardiogram (ECG), elevated troponins, echocardiogram or cardiac MRI after a dose of an mRNA vaccine. This is a precaution based on recommendations issued by the National Advisory Committee on Immunization (NACI) in the Canadian Immunization Guide. NACI, Public Health Ontario (PHO), and the Ontario Ministry of Health (MOH) are following this closely and will update this recommendation as more evidence becomes available.

- In situations where there is uncertainty regarding **myocarditis** diagnosis, discussion should occur with an appropriate physician or nurse practitioner on potential options for (re)immunization with the same or alternative COVID-19 vaccine, including a risk-benefit analysis for the individual. Those with a history compatible with pericarditis and who either had no cardiac workup or had normal cardiac investigations, can receive the next dose once they are symptom free and at least 90 days has passed since vaccination.
- Some people with confirmed myocarditis with or without pericarditis may choose to receive another dose of vaccine after discussing the risks and benefits with their health care provider. Individuals can be offered the next dose once they are symptom free and at least 90 days has passed since vaccination. If another dose of vaccine is offered, they should be offered the bivalent Pfizer-BioNTech (30 mcg) vaccine due to the lower reported rate of myocarditis and/or pericarditis when offered as part of the primary series. Informed consent should include discussion about the unknown risk of recurrence of myocarditis and/or pericarditis following receipt of additional doses, as well as the need to seek immediate medical assessment and care should symptoms develop.
    - For more information consult Public Health Ontario's Myocarditis and Pericarditis Following COVID-19 mRNA Vaccines resource.

- Interim clinical guidance and an algorithm for the identification and management of myocarditis and pericarditis following mRNA COVID-19 vaccination in children is available from the Hospital for Sick Children.
- A clinical framework is also available from the Canadian Journal of Cardiology Myocarditis and Pericarditis following COVID-19 mRNA Vaccination: Practice Considerations for Care Providers

Multi-Inflammatory Syndrome in Children or in Adults (MIS-C/A) following vaccination with an mRNA COVID-19 vaccine

Children and adolescents with SARS-CoV-2 infection are at risk of multisystem inflammatory syndrome in children (MIS-C), a rare but serious syndrome that can occur several weeks following SARS-CoV-2 infection. Very rare cases of MIS-C/A (multisystem inflammatory syndrome in children and in adults) have been reported following vaccination with COVID-19 mRNA vaccines in Canada and internationally among individuals aged 12 years and older. However, on October 29, 2021, the European Medical Association Pharmacovigilance Risk Assessment Committee (EMA-PRAC) issued a statement that there is currently insufficient evidence on a possible link between mRNA COVID-19 vaccines and very rare cases of MIS-C/A.

For children or adults with a previous history of MIS-C or MIS-A, respectively, unrelated to any previous COVID-19 vaccination, vaccination should be postponed until clinical recovery has been achieved or until it has been ≥ 90 days since diagnosis, whichever is longer.

Bell's palsy following vaccination with an mRNA COVID-19 vaccine

Very rare cases of Bell's palsy (typically temporary weakness or paralysis on one side of the face) have been reported following vaccination with COVID-19 mRNA vaccines (Pfizer-BioNTech or Moderna) in Canada and internationally among individuals 12 years and older. Bell's palsy is an episode of facial muscle weakness or paralysis. The condition is typically temporary. Symptoms appear suddenly and generally start to improve after a few weeks. The exact cause is unknown. It's believed to be the result of swelling and inflammation of the nerve that controls muscles on the face.

Symptoms of Bell's palsy may include:

- uncoordinated movement of the muscles that control facial expressions, such as smiling, squinting, blinking or closing the eyelid
- loss of feeling in the face

- headache
- tearing from the eye
- drooling
- lost sense of taste on the front two-thirds of the tongue
- hypersensitivity to sound in the one ear
- inability to close an eye on one side of the face

Individuals should seek medical attention if they develop symptoms of Bell's palsy following receipt of mRNA COVID-19 vaccines. Health care providers should consider Bell's palsy in their evaluation if the patient presents with clinically compatible symptoms after an mRNA COVID-19 vaccine. Investigations should exclude other potential causes of facial paralysis.

History of Allergies

See the COVID-19 Vaccine: Canadian Immunization Guide for information on vaccination for all individuals with allergies (including those with allergic reactions to previous doses of any COVID-19 vaccine, or vaccine components).

People who experienced a severe immediate allergic reaction after a 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 allergist/immunologist or another appropriate physician. See the CIG for more information. As per the Canadian Society of Allergy and Clinical Immunology, individuals with a suspected history of adverse reactions to tromethamine, including suspected history of systemic allergic reactions to radiocontrast media and ketorolac, may receive vaccines containing tromethamine (CSACI, 2023).

Individuals with known allergies to components of the vaccines may speak with an appropriate physician or nurse practitioner (NP) for evaluation. This assessment will enable the development of a vaccination care plan which may include receiving the vaccine under the supervision of your physician. Documentation of the discussion with the physician/NP may be provided to the immunizing clinic and can include a vaccination care plan, including the parameters the clinic should meet to provide safe vaccination administration, such as availability of advanced medical care to manage anaphylaxis); details/severity of the previous allergic episode(s); confirmation that appropriate counselling on the safe administration of vaccine has been provided; and the date, the clinician's name, signature and contact information, as well as the individual's name and date of birth.

Symptoms, either current or displayed recently, of chest pain or shortness of breath

- Vaccine should not be offered to persons displaying current or recent history of chest pain or shortness of breath.

  Persons displaying current or recent history of chest pain or shortness of breath should consult with a health care provider prior to vaccination and/or if symptoms are severe, should be directed to the emergency department or instructed to call 911.

Side effects

COVID-19 vaccines, like medicines and other vaccines, may cause side effects. In clinical trials, most of the side effects experienced were mild to moderate, and usually resolved within a few days. Please see the individual product monographs for a complete list of reported side effects.

History of Fainting/Dizziness or Fear of Needles

Individuals with a history of fainting/dizziness, or fear of injections/needles can safely receive the COVID-19 vaccine. Considerations may include:

- Immunize while seated to reduce injuries due to fainting,
- If considered high-risk, immunize while lying down.
- These individuals may bring a support person.
- CARD (C-Comfort, A-Ask, R-Relax, D-Distract) is an evidence-based framework that can help with vaccination. See CARD resources to support immunization

Pregnant or Breastfeeding

COVID-19 vaccination during pregnancy is effective at protecting pregnant individuals against severe COVID-19 disease, hospitalization, and ICU admission from COVID-19 infection, as well as intubation and mortality in those with severe disease. Pregnant or breastfeeding individuals should receive all recommended COVID-19 vaccine doses as soon as they are able. In addition, to protecting the pregnant individual, the benefits of immunization during pregnancy for the fetus have also been well-documented. Protective antibodies are transferred to the fetus transplacentally, resulting in increased protection for the infant during the early postnatal period (CIG, 2023).

Recommendations for vaccination during pregnancy and/or breastfeeding:

- A **COVID-19 vaccine may be offered at any stage of the pregnancy (i.e., in any trimester).**
- COVID-19 vaccines may be **co-administered** with other vaccines recommended during pregnancy or while breastfeeding.
- NACI **strongly recommends** that individuals who are pregnant or breastfeeding who have not yet begun or completed the **primary series** should be offered the recommended doses to complete the primary series.
- Pregnant and breastfeeding individuals are also encouraged to be up to date with booster doses.

There have been no serious safety concerns with receiving an mRNA COVID-19 vaccination during pregnancy or lactation. Pregnant or breastfeeding individuals experience the same rates of expected local and systemic adverse events as individuals who are not pregnant and/or breastfeeding. Vaccination during pregnancy does not increase risk of miscarriage, stillbirth, low birth weight, preterm birth, NICU admission or other adverse pregnancy/birth outcomes. Similarly, studies have not found any negative impact of vaccination on the child being fed human milk or on milk production or excretion.

For additional resources, individuals who are pregnant and/or breastfeeding can access the Provincial Council for Maternal and Child Health's decision making tool, the Society of Obstetricians and Gynaecologists of Canada Statement on COVID-19 Vaccination in Pregnancy, Canadian Immunization Guide and the NACI Updated guidance on COVID-19 vaccines for individuals who are pregnant or breastfeeding.

Adverse Events Following Immunization

An **adverse event following immunization (AEFI)** is defined as any unexpected medical occurrence (e.g., unfavourable or unintended sign, abnormal laboratory finding, symptom or disease) following administration of an active immunizing agent (CIG, 2023). This event does not necessarily have a causal relationship with the use of a vaccine.

Guidance on reporting adverse events following immunization (AEFI) for health care providers

- Health care providers administering vaccines are required to inform vaccine recipients or their parent/guardian of the importance of reporting adverse events following immunization (AEFIs) to a health care provider in accordance with Section 38 of the *Health Protection and Promotion Act* (HPPA). Vaccine recipients or their parent/guardian may also contact their local public health unit to ask questions or to report an AEFI.
- Specified health care providers (e.g., physicians, nurses and pharmacists) are required under s.38(3) of the HPPA to report AEFIs to their local public health unit. Reports should be made using the Ontario AEFI Reporting Form.
- See Public Health Ontario's vaccine safety webpage and Fact Sheet – Adverse Event Following Immunization Reporting For Health Care Providers In Ontario for additional guidance.
- The Ontario Ministry of Health in collaboration with Public Health Ontario monitors reports of AEFIs. This monitoring is done in collaboration with the Public Health Agency of Canada and Health Canada.

All health care providers administering vaccines must be familiar with the anaphylaxis protocols for their clinic sites and ensure availability of anaphylaxis management kits. For additional information please visit the Public Health Ontario resource on the Management of Anaphylaxis Following Immunization in the Community and the Canadian Immunization Guide.

Those administering vaccines should ensure that vaccine recipients or their parents/guardians are advised to notify clinic staff, or if they have left the clinic, call their doctor/nurse practitioner or go to the nearest hospital emergency department if they develop any of the following symptoms:

- Hives
- Swelling of the face, throat or mouth
- Altered level of consciousness/serious drowsiness
- Trouble breathing, hoarseness or wheezing
- High fever (over 40°C or 104°F)
- Convulsions or seizures
- Other serious reactions (e.g., "pins and needles" or numbness)

A reduced post-vaccination observation period, between 5 to 15 minutes may be considered for the administration of booster dose(s) of COVID-19 vaccine during the pandemic, if specific conditions are met such as the client's past experience with COVID-19 vaccine doses and other relevant conditions as outlined in the NACI 2020-2021 influenza vaccine advice. This would be an exception to usual immunization guidance (i.e., a 15 minute post-vaccination observation period) and this approach could be used in specific settings (i.e., mass immunization clinic, primary care clinics, pharmacies) at this time on a temporary basis, weighing the risks of a reduction in observation period (e.g., small increased risk of delayed identification of an adverse event that may require immediate medical attention) and reducing risk of SARS-CoV-2 transmission where physical distancing cannot be maintained and allowing more individuals to be immunized in a given time period.

Out of Province Vaccines

If an individual has completed the primary series with a **Health Canada approved COVID-19 vaccine and/or non-Health Canada approved vaccine listed on the World Health Organization's (WHO) COVID-19 Vaccine Emergency Use Listing** (EUL) (Appendix A) according to the recommended schedule, their primary vaccine series is considered complete. Individuals 5 years of age and older who have completed the primary series with either a Health Canada or WHO EUL COVID-19 primary vaccine series are eligible for a bivalent mRNA COVID-19 booster dose if 6 months have passed since their last vaccine dose or confirmed SARS-CoV-2 infection[13].

Individuals 5 years and older should consider delaying receipt of a COVID-19 vaccine booster until Fall 2023.

If an individual has completed or partially completed their primary series with a vaccine that is neither Health Canada approved nor WHO EUL, **additional doses of a Health Canada approved will be required to complete their primary vaccine series, unless the individual has received 3 doses of this vaccine**, in which case, their primary series is considered complete**.**

To complete the primary series:

- **Immunocompetent or immunocompromised** (5 years and older): 3 OOP vaccines – do not need any additional Health Canada approved doses.
- **Immunocompetent** (5 years and older)**:** who received either one or two doses of an OOP vaccine, administer **one** Health Canada approved dose

- **Immunocompromised** (5 years and older): need a total of three vaccine doses to complete the series:
    - Received one OOP vaccine: need **two** Health Canada approved vaccines
    - Received two OOP vaccines: need **one** Health Canada approved vaccine

It is recommended to administer Health Canada approved dose(s) at a recommended 56-day interval since the previous dose or at a minimum of 28 days in order to complete the primary series.

If this scenario arises for an individual who is 6 months to 4 years, contact the COVID-19 guidance team at the MOH for further clinical direction.

Individuals who have received COVID-19 vaccines outside of Ontario or Canada should contact their local public health unit to have their COVID-19 immunization record documented in COVaxON. Proof of immunization[15] (e.g., an immunization record, proof of vaccination certificate) is required to verify the COVID-19 vaccine product received out of province.[16] PHUs are responsible for documenting immunization information for individuals who have received COVID-19 vaccine doses outside of Ontario into COVaxON. See the COVaxON job aid and functionality change communications for more information.

COVID-19 Vaccine Errors and Deviations

***Please note: PHAC and OIAC have not yet updated the following documents to reflect NACI's interim recommendations on use of bivalent mRNA COVID-19 vaccines for use in the primary series**.

For guidance on managing COVID-19 vaccine administration errors and deviations, please see the Government of Canada's Planning guidance for immunization clinics for COVID-19 vaccines: Managing vaccine administration errors or deviations and the Ontario Immunization Advisory Committee's (OIAC) Recommendations: Management of Age-Related COVID-19 Vaccine Administration Errors .

[15] See Canadian Immunization Guide section on Immunization records.

[16] The Canadian Immunization Guide outlines that vaccination should only be considered valid if there is written documentation of vaccine administration.

Where there is conflict between the two resources above, please refer to OIAC recommendations. For inadvertent immunization errors and deviations that are not addressed in the documents linked above and/or that involve multiple errors or have additional complexity, health care providers are encouraged to contact their local public health unit (PHU) for further advice.

The local PHU should be notified, and vaccine administration errors or deviations should be handled and reported in accordance with both the site (if non-PHU) and PHU procedures.

- Vaccine administration errors and deviations that should be escalated to the Ministry of Health include those that may result in public safety concerns, cause misinformation, serious adverse events or death to any person; where large volumes of vaccine doses have been impacted or wasted; or where there is inadvertent administration of exposed and/or expired vaccine to a large number of patients. When in doubt, err on the side of caution and notify the Ministry of Health. For all issues that are escalated to the Ministry of Health, please report these per the following protocol: Email the Ministry of Health Communications team (media.moh@ontario.ca) and the Implementation team (covid.immunization@ontario.ca), with the following header:
- Incident Report for [PHU/Site] on [Date]:
    - Description of Incident
    - Date of Incident:
    - Location of Incident:
    - Type of Incident:
    - Administration error or deviation:
    - Description of Incident:
    - Summary of action and steps taken to-date:
    - Next steps:

If an inadvertent vaccine administration error or deviation results in an adverse event following immunization (AEFI), complete Ontario's AEFI reporting form, including details of the error or deviation. The completed AEFI form should be submitted to your local PHU.

Vaccine Preparation and Administration

See the individual vaccine product monographs for step-by-step directions on administration (i.e., thawing prior to dilution, dilution, and preparation) and information on packaging types and expiry dates.

It is important that proper sized syringes are chosen to ensure the correct volume is accurately drawn up. Refer to the Canadian Immunization Guide, Table 3: Needle selection guidelines for assistance in selecting appropriate needle length and gauge. Safety engineered needles must be used for vaccine administration as required under O. Reg. 474/07 made under the Occupational Health and Safety Act.

Information on vaccine storage and handling, stability and disposal can be found in the COVID-19: Vaccine Storage and Handling Guidance document and in the individual chapter for each vaccine product:

Chapter 1: Storage and Handling of Pfizer-BioNTech's COVID-19 Vaccines.

Chapter 2: Storage and Handling of Moderna COVID-19 Vaccines

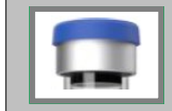
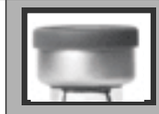
Chapter 4: Storage and Handling of Novavax's COVID-19 Vaccine

Appendix A: COVID-19 Vaccines Accepted for Completion of the Primary Series

	Manufacturer	Vaccine Name & Product Monograph	Vaccine Type	Authorized Population	Authorized Dose	Minimum number of Dose(s) and Minimum Interval
Health Canada Authorized	Pfizer-BioNTech	Pfizer-BioNTech Comirnaty	Messenger ribonucleic acid (mRNA)	**Primary Series:** 6 mos +	See Appendix B	**Monovalent:** 2 doses, 19 days apart (3 doses for individuals 6 months – 4 years) **Bivalent:** 2 doses, 28 days apart
	Moderna	Moderna Spikevax	Messenger ribonucleic acid (mRNA)	**Primary Series:** 6 mos +	See Appendix B	**Monovalent:** 2 doses, 28 days apart **Bivalent:** 2 doses, 28 days apart
	Novavax	Novavax Nuvaovid	Recombinant protein subunit, Adjuvanted	**Primary Series:** 12 yrs +	0.5 mL (5 mcg of recombinant protein)	2 doses, 21 days apart
	Johnson & Johnson	Janssen Jcovden	Non-replicating viral vector (Ad26)	**Primary Series:** 18 yrs + **No longer in use in Ontario**	0.5 mL (5 x 10^{10} viral particles)	Single dose
	AstraZeneca	AstraZeneca Vaxzevria	Non-replicating viral vector (ChAd)	**Primary Series:** 18 yrs + **No longer in use in Ontario**	0.5 mL (5 x 1010 viral particles)	2 doses, 28 days apart
	Medicago Inc.	Medicago Covifenz	Virus-like particle, recombinant	**Primary Series:** 18 yrs + **No longer in use in Ontario**	0.5 mL (3.75 mcg SARS-CoV-2 recombinant spike protein)	2 doses, 21 days apart

	Manufacturer	Vaccine Name & Product Monograph	Vaccine Type	Authorized Population	Authorized Dose	Minimum number of Dose(s) and Minimum Interval
World Health Organization (WHO) Emergency Use Listing (EUL)	Bharat Biotech, India	COVAXIN	Whole Inactivated Coronavirus	**Primary Series:** 18 yrs + (6-17 yrs for restricted use in emergency situation)	6 mcg / 0.5 mL	2 doses, 28 days apart
	CanSinoBio	CONVIDECIA	Adenovirus Type 5 Vector	**Primary Series**: individuals aged 18-59 yrs	4 x 10^{10} viral particles / 0.5 mL	single dose
	Serum Institute of India	COVISHIELD	Adenovirus Vector	**Primary Series**: 18 yrs +	5 x 10^{10} viral particles / 0.5 mL	2 doses, 28 days apart
	Serum Institute of India	COVOVAX	Protein Subunit	**Primary Series:** 7 yrs +	5 mcg / 0.5 mL	2 doses, 21 days apart
	SinoPharm / Beijing Institute of Biological Products (BIBP)	COVILO	Whole inactivated Coronavirus	**Primary Series:** 18 yrs+	3.9-10.4U / 0.5 mL	2 doses, 21 days apart
	Sinovac	CoronaVac	Whole inactivated Coronavirus	**Primary Series:** 3 yrs+	3 mcg / 0.5 mL (equivalent to 600 SU per dose)	2 doses, 28 days apart
	SK Bioscience Co.	SKYCovione	Recombinant Protein Subunit	**Primary Series**: individuals aged 18-65 yrs		2 doses, 28 days apart

Appendix B: mRNA Vaccines Approved for Use in Canada [17]

COVID-19 Formulations	Moderna	Moderna *Bivalent (BA.4/5)*	Pfizer-BioNTech	Pfizer-BioNTech	Pfizer-BioNTech *Bivalent (BA.4/5)*	Pfizer-BioNTech	Pfizer-BioNTech *Bivalent*
Cap and Label Colour							
	Royal blue cap and purple label	**Blue cap and grey label**	**Maroon cap and label**	**Orange cap and label** !	**Orange cap and label** !	**Grey cap and label** !	**Grey cap and label** !
Authorized Age Group	(i) 6 months to 5 years (ii) 6 to 11 years	(i) 6 months to 5 years (off label) (ii) 6 to 11 years (iii) ≥12 years	6 months to 4 years	5 to 11 years	5 to 11 years	≥12 years	≥12 years
Vial Concentration	0.1 mg/mL	0.1 mg/mL	0.015 mg/mL	0.05 mg/mL	0.05 mg/mL	0.1 mg/mL	0.1 mg/mL
Dose/ Volume	(i) 25 mcg/0.25mL (ii) 50 mcg/0.5 mL	(i) 25 mcg/0.25mL (ii) 25 mcg/025mL (iii) 50 mcg/0.5mL	3 mcg/0.2mL	10 mcg/0.2mL	10 mcg/ 0.2mL	30 mcg/0.3mL	30 mcg/0.3mL
Dilution	None	None	2.2 mL/vial	1.3 mL/vial	1.3mL/vial	None	None
Primary Series / Booster	Primary Series	Primary Series (off-label) & Booster	Primary Series	Primary Series	Primary Series (off-label) & Booster	Primary Series	Primary Series (off-label) & Booster
Product Monograph	Moderna PM	Moderna Bivalent PM	Pfizer-BioNTech PM	Pfizer-BioNTech PM	Pfizer-BioNTech Bivalent PM	Pfizer-BioNTech PM	Pfizer-BioNTech Bivalent PM

[17] Adapted from Manitoba Health.

! Please use caution: Both monovalent and bivalent Pfizer-BioNTech vials have the same cap and label colour. They also have the same vial concentration. Ensure the correct product is used.

Appendix C: Vaccinator Infographic

Primary Series

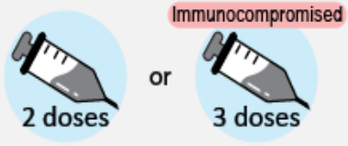
Most individuals need two doses of a COVID-19 Vaccine (mRNA, Novavax[1]) to complete a primary series. Immunocompromised individuals are recommended to receive an additional dose to complete their primary series. Individuals 6 months and older are recommended to complete their primary series using a bivalent mRNA vaccine.

Primary Series Intervals Between Doses: Recommended: **56 days** Minimum: **28 days**

Primary Series for Individuals Aged 6 Months–4 Years

SPIKEVAX/MODERNA

Bivalent BA.4/5
Age: 6 months–4 years
Dilute: NO
Dose: 25 mcg/0.25 mL



Booster Doses

Booster doses have not been approved for children aged 6 months–4 years.

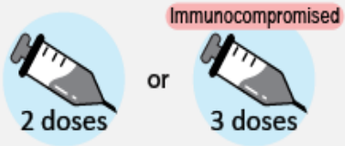
Primary Series for Children Aged 5-11 Years[2]

COMIRNATY/PFIZER

Bivalent BA.4/5
Age: 5-11 years
Dilute: With 1.3 mL
Dose: 10 mcg/0.2 mL

SPIKEVAX/MODERNA

Bivalent BA.4/5
Age: 5-11 years
Dilute: NO
Dose: 25 mcg/0.25 mL



Mixing Doses

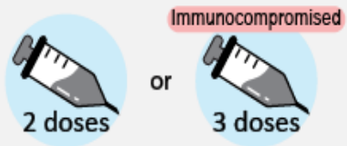
Individuals aged 5-11 years may be administered vaccine products interchangeably, using the correct dose for their age.

Booster Doses

Primary Series for Individuals Aged 12 Years and Older[2,3]

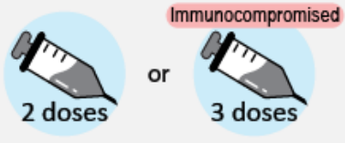
COMIRNATY/PFIZER

Bivalent BA.4/5
Age: 12+ years
Dilute: NO
Dose: 30 mcg/0.3 mL



SPIKEVAX/MODERNA

Bivalent BA.4/5
Age: 12+ years
Dilute: NO
Dose: 50 mcg/0.5 mL



Mixing Doses

Individuals aged 12 years and older may be administered vaccine products interchangeably, using the correct dose for their age.[5]

Booster Doses

This document can be used as a reference for vaccine clinics and vaccine administrators to support COVID19 immunization and is not intended take the place of medical advice, diagnosis or treatment, or legal advice. In the event of conflict between this document and any applicable emergency orders, or directives issued by the Minister of Health, Minister of Long-Term Care, or the Chief Medical Officer of Health, the order or directive prevails. Check the Ministry of Health COVID-19 website for updates to COVID-19 Vaccine Guidance.

[1]Novavax may be offered as a primary series to individuals who are aged 12 years and older and as a booster dose to individuals 18 years and older without contraindications to the vaccine who are not able or willing to receive an mRNA COVID-19 vaccine. Informed consent is required.

[2]A previous infection with SARS-CoV-2 is defined as: Confirmed by a molecular (e.g., PCR) or rapid antigen test; or Symptomatic AND a household contact of a confirmed COVID-19 case.

[3]Individuals 5 years and older who are immunocompromised may benefit from receiving a bivalent Moderna dose rather than a bivalent Pfizer dose.

Booster Doses
Effective July 7th, 2023, individuals 5 years and older should consider delaying receipt of COVID-19 booster dose until fall 2023. Receiving a booster dose in the fall, as respiratory season commences, will maximize protection against COVID-19 outcomes when peak circulation of the virus is expected. The decision to receive a booster dose prior to fall 2023 may be appropriate for certain individuals based on their unique health status and personal situation. Individuals should be encouraged to speak with their health care provider.

Booster Dose Interval: Recommended six months since last dose or confirmed COVID-19[4]

Boosters for Children Aged 5-11 Years

COMIRNATY/PFIZER

Bivalent BA.4/5
Age: 5-11 years
Dilute: With 1.3ml
Dose: 10mcg/0.2ml

SPIKEVAX/MODERNA

Bivalent BA.4/5
Age: 6-11 years
Dilute: NO
Dose: 25mcg/0.25ml

Boosters for Individuals Aged 12 Years and Older

COMIRNATY/PFIZER

Bivalent BA.4/5
Age: 12+ years
Dilute: NO
Dose: 30mcg/0.3ml

SPIKEVAX/MODERNA

Bivalent BA.4/5
Age: 12-17 years
Dilute: NO
Dose: 50mcg/0.5ml

[4]A confirmed SARS-CoV-2 infection is characterized by positive result obtained using a molecular (e.g., PCR) or Health Canada approved rapid antigen test OR symptomatic disease compatible with COVID-19 AND a household exposure to a confirmed COVID-19 case.

For guidance on managing COVID-19 vaccine administration errors and deviations, please see the Government of Canada's Planning guidance for immunization clinics for COVID-19 vaccines: Managing vaccine administration errors or deviations and the Ontario Immunization Advisory Committee's (OIAC) Recommendations: Management of Age-Related COVID-19 Vaccine Administration Errors . Where there is conflict between the two resources above, please refer to OIAC recommendations. ***Please note that these resources have not yet been updated to reflect the interim NACI recommendations.***

Appendix D: List of Immunosuppressive Medications

Please note that although **proof of immune status is no longer required to receive an additional primary series dose.** The below list is included for reference but may not be comprehensive.

Class	Generic Name(s)	Brand Name(s)
Steroids (>20 mg per day of prednisone or equivalent for at least 2 weeks)	• Prednisone	
	• dexamethasone	• Decadron
	• methylprednisolone	• DepoMedrol • SoluMedrol • Medrol
Antimetabolites	• cyclophosphamide	• Procytox
	• leflunomide	• Arava
	• methotrexate	• Trexall • Metoject • Otrexup • Rasuvo • Rheumatrex
	• azathioprine	• Imuran
	• 6- mercaptopurine (6-MP)	• Purinethol
	• mycophenolic acid	• Myfortic
	• mycophenolate mofetil	• Cellcept
Calcineurin inhibitors/mTOR kinase inhibitor	• tacrolimus	• Prograf • Advagraf • Envarsus PA
	• cyclosporine	• Neoral • Gengraf • Sandimmune
	• sirolimus	• Rapamune
JAK (Janus kinase) inhibitors	• baricitinib	• Olumiant
	• tofacitinib	• Xeljanz
	• upadacitinib	• Rinvoq

Class	Generic Name(s)	Brand Name(s)
Anti-TNF (tumor necrosis factor)	• adalimumab	• Humira • Amgevita • Hadlima • Hulio • Hyrimoz • Idacio
	• golimumab	• Simponi
	• certolizumab pegol	• Cimzia
	• etanercept	• Enbrel • Brenzys • Erelzi
	• infliximab	• Remicade • Avsola • Inflectra • Remsima • Renflexis
Anti-Inflammatory	• Sulfasalazine	• Salazopyrin • Azulfidine
	• 5-Aminosalicylic Acid (ASA)/mesalamine	• Pentasa
Anti-CD20	• Rituximab	• Rituxan • Ruxience • Riximyo • Truxima • Riabni
	• ocrelizumab	• Ocrevus
	• ofatumumab	• Kesimpta
IL-1 RA (interleukin-1 receptor antagonist)	• anakinra	• Kineret
	• canakinumab	• Ilaris
Anti-IL6	• tocilizumab	• Actemra
	• sarilumab	• Kevzara
Anti-IL12/IL23	• ustekinumab	• Stelara
Anti-IL17	• secukinumab	• Cosentyx
	• ixekizumab	• Taltz
Anti-ILI7R	• brodalumab	• Siliq
Anti-BlyS	• belimumab	• Benlysta
Anti-IL23	• guselkumab	• Tremfya
	• risankizumab	• Skyrizi
Selective T-cell costimulation blocker	• abatacept	• Orencia
S1PR (sphingosine 1-phosphate receptor) agonist	• fingolimod	• Gilenya
	• siponimod	• Mayzent
	• ozanimod	• Zeposia
Phosphodiesterase inhibitors	• Apremilast	• Otezla
Anti-integrin	• vedolizumab	• Entyvio