

Ministry of Health

Medical Exemptions to COVID-19 Vaccination

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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) <u>COVID-19 website</u> regularly for updates to this document, list of symptoms, other guidance documents, Directives and other information.

Background

This document is intended to assist physicians/specialists and nurse practitioners in evaluating contraindications or precautions to COVID-19 vaccination that may warrant a medical exemption. A contraindication is a situation where a vaccine should not be given as the risks outweigh any potential therapeutic benefit. A precaution is condition that may increase the risk of an adverse event following immunization (AEFI) or compromise the ability of the vaccine to produce an immune response, which may result in deferral of immunization; however, there may be circumstances where the benefits of vaccination outweigh the potential risks from vaccination associated with the condition or where reduced immunogenicity still benefits immunocompromised individuals (Canadian Immunization Guide). In general, there are very few actual contraindications to available COVID-19 vaccines that would qualify as medical exemptions and most individuals can safely receive COVID-19 vaccines.



This document in based on recommendations from <u>Canada's National Advisory</u> <u>Committee on Immunization (NACI)</u> and expert clinician advice, prepared in consultation with Public Health Ontario and several specialist physicians with expertise in AEFIs.

As the context and evidence on COVID-19 vaccines evolves, this guidance will be updated and individuals with medical exemptions should be periodically reevaluated by their nurse practitioner/physician/specialist as new evidence and new vaccine products become available.

Reasons for Medical Exemption

Individuals who have experienced serious adverse events following COVID-19 immunization and those with certain medical conditions that may affect their response to immunization should be referred to an allergist/immunologist or specialist based on their adverse event/medical condition, for further assessment. This should include a detailed patient history, assessment of adverse event/medical condition and specialist investigations/diagnosis, individualized risk-benefit analysis, and recommendations/options for immunization. For serious or rare AEFIs, individuals should be thoroughly investigated to determine if the event can be attributed to an alternative etiology. Referral and specialist consultation support for physicians and nurse practitioners is available through Ontario's eConsult Service, OTN Hub, and the Special Immunization Clinic (SIC) Network. In many instances, safe administration of subsequent doses of COVID-19 vaccine is possible under the management of an allergist/immunologist. True medical exemptions are expected to be infrequent and should be supported by expert consultation.



Table 1: Summary of conditions and/or adverse events following immunization (AEFI) that may qualify for a medical exemption to COVID-19 vaccination

1. Pre-existing Condition(s)	Management
Severe allergic reaction or anaphylaxis to a component of a COVID-19 vaccine	 Qualifies for medical exemption only if: Allergy was documented and evaluated by an allergist/immunologist; AND Discussion with allergist/immunologist has occurred on potential options for immunization with the same or alternative COVID-19 vaccine; AND Allergist/immunologist has determined that the individual is unable to receive any COVID-19 vaccine.
Myocarditis prior to initiating an mRNA COVID-19 vaccine series (individuals aged 12-17 years old)	 As per NACI, individuals aged 12-17 years old with history of myocarditis unrelated to mRNA COVID-19 vaccination should consult their clinical team for individual considerations and recommendations.¹ Qualifies for medical exemption if: Discussion with relevant specialist on potential options for immunization with an mRNA COVID-19 vaccine or alternative; AND Relevant specialist has determined that the individual is unable to receive any COVID-19 vaccine.

¹ As per <u>NACI</u> if the diagnosis with myocarditis is remote and they are no longer followed by a medical professional for cardiac issues, they should receive an mRNA COVID-19 vaccine.



2. Contraindications to Initiating an AstraZeneca/ COVISHIELD COVID-19 Vaccine Series ²	Management
History of capillary leak syndrome (CLS)	 Series should be completed with an mRNA vaccine. Qualifies for medical exemption if: Individual has medical exemption to completing their vaccine series with an mRNA vaccine.
History of cerebral venous sinus thrombosis (CVST) with thrombocytopenia	 Series should be completed with an mRNA vaccine. Qualifies for medical exemption if: Individual has medical exemption to completing their vaccine series with an mRNA vaccine.
History of heparin-induced thrombocytopenia (HIT)	 Series should be completed with an mRNA vaccine. Qualifies for medical exemption if: Individual has medical exemption to completing their vaccine series with an mRNA vaccine.
History of major venous and/or arterial thrombosis with thrombocytopenia following any vaccine	 Series should be completed with an mRNA vaccine. Qualifies for medical exemption if: Individual has medical exemption to completing their vaccine series with an mRNA vaccine.

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² As of May 11th, 2021 Ontario has <u>paused</u> the rollout and administration of first doses of the AstraZeneca /COVISHIELD COVID-19 vaccine. At this time, first doses should only be given in extenuating circumstances (i.e. on the recommendation of an allergist/immunologist where a confirmed allergy exists or other contraindication to mRNA vaccination).



3. Adverse Events Following COVID-19 Immunization ³	Management
Severe allergic reaction or anaphylaxis following a COVID-19 vaccine	 Qualifies for medical exemption if: Allergy was documented and evaluated by an allergist/immunologist; AND Discussion with allergist/immunologist has occurred on potential options for (re)immunization with the same or alternative COVID-19 vaccine; AND Allergist/immunologist has determined that the individual is unable to receive any COVID-19 vaccine.
Thrombosis with thrombocytopenia syndrome (TTS)/VITT ⁴ following the Astra Zeneca/COVISHIELD COVID-19 vaccine	 Series should be completed with an mRNA vaccine. Qualifies for medical exemption only if: Individual has medical exemption to completing their vaccine series with an mRNA vaccine
Myocarditis or Pericarditis following a mRNA COVID-19 vaccine	 Qualifies for medical exemption if: Myocarditis/pericarditis was diagnosed after medical evaluation (e.g. ER physician, relevant specialist). In situations where there is uncertainty regarding myocarditis/pericarditis diagnosis, discussion should occur with relevant specialist on potential options for (re)immunization with the same or alternative COVID-19 vaccine. The individual qualifies for a medical exemption if the relevant specialist has determined that the individual is unable to receive any COVID-19 vaccine.

³ AEFI is defined as any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the use of a vaccine.

⁴ Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT).



Serious adverse event following COVID-19 immunization (e.g. results in hospitalization, persistent or significant disability/incapacity)	 Qualifies for medical exemption if: Event has been medically evaluated; AND Discussion has occurred with a relevant specialist (e.g., allergist/immunologist, SIC network, Medical Officer of Health, etc.) on the individual's risks and benefits of potential options for immunization with the same or alternative COVID-19 vaccine; AND Relevant specialist has determined that the individual is unable to receive any COVID-19 vaccine.
4. Actively receiving monoclonal antibody therapy OR convalescent plasma therapy for the treatment or prevention of COVID-19	Qualifies for time-limited medical exemption while they are actively receiving therapy

1. Pre-existing Condition(s)

History of severe allergic reaction or anaphylaxis to any component of a COVID-19 vaccine

Individuals who have had a severe allergic reaction (e.g. anaphylaxis) to any component of a COVID-19 vaccine or its container should not routinely be offered that COVID-19 vaccine. These individuals require an assessment from an allergist/immunologist to determine whether the vaccine is contraindicated or may be safely administered under controlled conditions supported by the allergist/immunologist. A COVID-19 vaccine of a different vaccine platform may also be offered for immunization on the recommendation of the allergist/immunologist. A medical exemption may be issued only if discussion has occurred with the allergist/immunologist on potential options for immunization with the same or alternative COVID-19 vaccine, including a risk-benefit analysis for the individual, and the allergist/immunologist has determined that the individual is unable to receive any COVID-19 vaccine.



For a comprehensive list of components in the vaccine and packaging, please consult the product leaflet or information contained within the product monograph available through Health Canada's Drug Product Database.

History of Myocarditis prior to initiating a mRNA COVID-19 vaccine series

Individuals who have a history of myocarditis unrelated to mRNA COVID-19 vaccination should consult their clinical team for individual considerations and recommendations. Individuals previously diagnosed with myocarditis, whose diagnosis is considered remote and are no longer followed by a medical professional for cardiac issues should receive the vaccine. This is a precaution for individuals aged 12-17 years old based on recommendations issued by the National Advisory Committee on Immunization (NACI). A medical exemption may be issued only if discussion has occurred with a relevant specialist regarding potential options for immunization with an mRNA COVID-19 vaccine or alternative, and the specialist has determined that the individual is unable to receive any COVID-19 vaccine.

2. Contraindications to Initiating an AstraZeneca/COVISHIELD COVID-19 Vaccine Series

NOTE: As of May 11, 2021, Ontario has paused the rollout and administration of first doses of the AstraZeneca/COVISHIELD vaccine. At this time, first doses should only be given in extenuating circumstances (i.e. on the recommendation of an allergist/immunologist where a confirmed allergy exists or other contraindication to mRNA vaccination).

History of capillary leak syndrome (CLS)

Individuals who have experienced episodes of capillary leak syndrome (CLS) should not receive the AstraZeneca/COVISHIELD COVID-19 vaccine. Very rare cases of capillary leak syndrome (CLS) have been reported following immunization with the AstraZeneca/COVISHIELD COVID-19 vaccine. This is a contraindication to receiving the AstraZeneca/COVISHIELD COVID-19 vaccine. An authorized COVID-19 vaccine using a different platform (i.e. mRNA) should be offered for immunization. A medical



exemption may be issued only if an mRNA COVID-19 vaccine is contraindicated for the individual.

History of cerebral venous sinus thrombosis (CVST) with thrombocytopenia

Individuals who have experienced a previous CVST with thrombocytopenia should not receive the AstraZeneca/COVISHIELD COVID-19 vaccine. This is a contraindication to receiving the AstraZeneca/COVISHIELD COVID-19 vaccine. An authorized COVID-19 vaccine using a different platform (i.e. mRNA) should be offered for immunization. A medical exemption may be issued only if an mRNA COVID-19 vaccine is contraindicated for the individual.

History of heparin-induced thrombocytopenia (HIT)

Individuals who have experienced a HIT should not receive the AstraZeneca/COVISHIELD COVID-19 vaccine. This is a contraindication to receiving the AstraZeneca/COVISHIELD COVID-19 vaccine. An authorized COVID-19 vaccine using a different platform (i.e. mRNA) should be offered for immunization. A medical exemption may be issued only if mRNA COVID-19 vaccine is contraindicated for the individual.

History of major venous and/or arterial thrombosis with thrombocytopenia following any vaccine

Individuals who have experienced major venous and/or arterial thrombosis with thrombocytopenia following vaccination with any vaccine should not receive the AstraZeneca/COVISHIELD COVID-19 vaccine. This is a contraindication based on recommendations issued by Ontario's Vaccine Clinical Advisory Group on Immunization. An authorized COVID-19 vaccine using a different platform (i.e. mRNA) should be offered for immunization. A medical exemption may be issued only if an mRNA COVID-19 vaccine is contraindicated for the individual.



3. Adverse Events Following Immunization (AEFI) with COVID-19 vaccine

Severe Allergic Reaction or Anaphylaxis following a COVID-19 vaccine

Individuals who have had a severe allergic reaction (e.g., anaphylaxis) to a previous dose of a COVID-19 vaccine should not routinely be offered a COVID-19 vaccine of the same vaccine platform. This event is a contraindication to routine COVID-19 vaccination with the same vaccine. These individuals require an assessment of the event from an allergist/immunologist, who may determine whether the vaccine may be administered and a method for possible safe (re)administration of a COVID-19 vaccine. An authorized COVID-19 vaccine using a different platform may also be offered. A medical exemption may be issued if discussion has occurred with the allergist/immunologist on potential options for (re)immunization with the same or alternative COVID-19 vaccine, including a risk-benefit analysis for the individual, and the allergist/immunologist has determined that the individual is unable to receive any COVID-19 vaccine.

Other allergies

Individuals with other types of non-severe allergies can safely receive COVID-19 vaccines as outlined in the MOH's <u>Vaccination Recommendations for Special Populations</u>. These allergies do not on their own constitute the grounds for a medical exemption. For more information on the management of individuals with allergies please see the MOH's <u>Vaccination Recommendations for Special Populations</u>.

Thrombosis with thrombocytopenia syndrome (TTS)/VITT following AstraZeneca/COVISHIELD COVID-19 vaccine

Individuals who have experienced a major venous or arterial thrombosis with thrombocytopenia following vaccination with AstraZeneca/COVISHIELD COVID-19 vaccine are contraindicated to receiving another dose of the same vaccine. An authorized COVID-19 vaccine using a different platform (i.e. mRNA) should be offered for subsequent immunization. A medical exemption may be issued only if



they have a medical exemption to completing their series with an mRNA COVID-19 vaccine.

Myocarditis/Pericarditis following mRNA COVID-19 vaccination

Individuals with a diagnosed episode of myocarditis and/or pericarditis after receipt of their first dose of an mRNA COVID-19 vaccine should defer their second dose in the vaccination series until more information and guidance is available. This is a precaution based on recommendations issued by the National Advisory Committee on Immunization (NACI). 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. A medical exemption may be issued if myocarditis/pericarditis was diagnosed after medical evaluation (e.g. ER physician, relevant specialist). In situations where there is uncertainty regarding myocarditis/pericarditis diagnosis, discussion should occur with a relevant specialist on potential options for (re)immunization with the same or alternative COVID-19 vaccine, including a risk-benefit analysis for the individual. The individual qualifies for a medical exemption if the specialist has determined that the individual is unable to receive any COVID-19 vaccine.

Serious Adverse Event Following COVID-19 Immunization (AEFI)

Individuals who experience a <u>serious adverse event following immunization</u> (AEFI) (e.g. hospitalization, persistent or significant disability/incapacity) with a COVID-19 vaccine should be medically assessed by a relevant specialist, and the event should be reported to their local public health unit (PHU). This may include clinical syndromes such as Guillain-Barré Syndrome (GBS). The <u>Health Protection and Promotion Act (HPPA)</u> mandates reporting of AEFIs by healthcare providers who administer immunizations (e.g., registered nurses, pharmacists, and physicians).

AEFI reports received by PHUs are investigated, assessed, and documented according to provincial surveillance guidelines, as required by the Ontario Public Health Standards (OPHS). For serious AEFIs, this includes referral to relevant specialist for diagnosis/management and expert assessment for recommendation for subsequent immunization (e.g. the Special Immunization Clinic (SIC) Network, allergist/immunologist, etc.). This assessment will include a detailed assessment of



the adverse event including specialist investigations and diagnosis, and assessment for alternative etiology for the event. Discussion with the patient should then consider the event and the personal and epidemiological context (in terms of risk of COVID-19 infection) for the patient and the risks and benefits regarding recommendations/options for immunization. The individual qualifies for a medical exemption if the relevant specialist (e.g., allergist/immunologist, SIC network, Medical Officer of Health, etc.) determines that the individual is unable to receive any COVID-19 vaccine after the event has been medically evaluated AND a discussion has occurred on the individual's risks and benefits of potential options for immunization with the same or alternative COVID-19 vaccine

There are very few serious AEFIs that would result in a medical exemption to COVID-19 vaccination.

4. Actively receiving monoclonal antibody or convalescent plasma therapy for the treatment or prevention of COVID-19 disease

Individuals who are actively receiving monoclonal antibody or convalescent plasma therapy for the treatment or prevention of COVID-19 disease should not receive a COVID-19 vaccine (NACI). This is a time-limited (temporary) precaution. COVID-19 vaccines may be administered to these individuals once therapy is discontinued, with the timing of administration and potential for immune interference evaluated on a case-by-case basis by an immunologist/relevant specialist. A medical exemption may be issued only if the individual is actively receiving therapy.

Documentation

Documentation of a medical exemption must be provided by either a physician or a nurse practitioner (note: A nurse practitioner is a registered nurse who holds an extended certificate of registration under the Nursing Act, 1991). The exemption must clearly indicate the reason why the individual cannot be vaccinated against COVID-19 (i.e., clear medical information that supports the exemption).

The physician's or registered nurse in the extended class's information is complete by including:



- Name and contact information of the physician or registered nurse in the extended class;
- Logo or letterhead identifying the physician or registered nurse in the extended class;
- Statement that there is a medical reason for the individual's exemption from being fully vaccinated against COVID-19; and
- Any effective time-period for the medical reason which includes the date the patron is seeking access to the business or organization.