

Ministry of Health

# Medical Exemptions to COVID-19 Vaccination

Version 2.0, December 31, 2021

## Highlights of changes

- Detailed time-limited medical exemption for individuals who are on immunosuppressive therapies that may require alternate timing of their vaccine.
- People who experienced a severe immediate allergic reaction after a first dose of any COVID-19 vaccine may be able to receive future doses of an mRNA COVID-19 vaccine.
- Janssen vaccine contraindications and adverse events following immunization are included.

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, list of symptoms, other guidance documents, Directives and other information.
- Please refer to the Medical and Clinical Trial Exemptions: Guidance for Issuing and Entering Records into COVaxON for information on entering exemption records into COVax and obtaining patient consent for the purpose.
  - If you require a copy of this Medical and Clinical Trial Exemptions guidance or sample template, please contact your Public Health Unit, the Ministry of Health, or your Regulatory College.

## 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 a 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 Health Canada authorized COVID-19 vaccines that would qualify as medical exemptions and most individuals can receive COVID-19 vaccines. Only individuals with contraindications to mRNA and viral vector vaccines qualify for medical exemption.

This document is based on recommendations from [Canada's National Advisory Committee on Immunization \(NACI\)](#) 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 re-evaluated by their nurse practitioner/physician/specialist as emerging 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 immune response to immunization should be referred to an appropriate physician or nurse practitioner based on their adverse event/medical condition for further assessment. This should include a detailed patient history, assessment of the adverse event/medical condition and investigations/diagnosis, individualized risk-benefit analysis, and recommendations/options for future 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 appropriate physician or nurse practitioner. True medical exemptions are expected to be infrequent and should be supported by expert consultation.

**Tables 1-4: 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)**

Condition/AEFI	Management
<p>Myocarditis prior to initiating an mRNA COVID-19 vaccine series (individuals aged 12-17 years old)</p>	<ul style="list-style-type: none"> <li>• As per <a href="#">NACI</a>, individuals aged 12-17 years old with a history of myocarditis unrelated to mRNA COVID-19 vaccination should consult their clinical team for individual considerations and recommendations.<sup>1</sup></li> <li>• Qualifies for medical exemption if:               <ul style="list-style-type: none"> <li>○ Discussion with appropriate physician or nurse practitioner has occurred on potential options for immunization with an mRNA COVID-19 vaccine or alternative; AND</li> <li>○ Physician or nurse practitioner has determined that the individual is unable to receive any COVID-19 vaccine.</li> </ul> </li> </ul>
<p>Severe allergic reaction (including anaphylaxis) to a component of a COVID-19 vaccine</p>	<ul style="list-style-type: none"> <li>• Qualifies for medical exemption only if:               <ul style="list-style-type: none"> <li>○ Allergy was documented by an appropriate physician or nurse practitioner; AND</li> <li>○ Discussion with an appropriate physician or nurse practitioner has occurred on potential options for immunization; AND</li> <li>○ Physician or nurse practitioner has determined that the individual cannot receive any COVID-19 vaccine with currently available mitigation strategies.</li> </ul> </li> </ul> <p><b>Note:</b> True medical exemptions are expected to be infrequent. In most instances, safe administration of subsequent doses of the COVID-19 vaccine is possible under the management of an appropriate physician or nurse practitioner.</p>

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

## 2. Contraindications to Initiating an AstraZeneca or Janssen COVID-19 Vaccine Series

Condition/AEFI	Management
History of capillary leak syndrome (CLS)	<ul style="list-style-type: none"> <li>• Series should be completed with an mRNA vaccine.</li> <li>• Qualifies for medical exemption if:               <ul style="list-style-type: none"> <li>○ Individual has medical exemption to completing their vaccine series with an mRNA vaccine.</li> </ul> </li> </ul>
History of cerebral venous sinus thrombosis (CVST) with thrombocytopenia	<ul style="list-style-type: none"> <li>• Series should be completed with an mRNA vaccine.</li> <li>• Qualifies for medical exemption if:               <ul style="list-style-type: none"> <li>○ Individual has medical exemption to completing their vaccine series with an mRNA vaccine.</li> </ul> </li> </ul>
History of heparin-induced thrombocytopenia (HIT)	<ul style="list-style-type: none"> <li>• Series should be completed with an mRNA vaccine.</li> <li>• Qualifies for medical exemption if:               <ul style="list-style-type: none"> <li>○ Individual has medical exemption to completing their vaccine series with an mRNA vaccine.</li> </ul> </li> </ul>
History of major venous and/or arterial thrombosis with thrombocytopenia following any vaccine	<ul style="list-style-type: none"> <li>• Series should be completed with an mRNA vaccine.</li> <li>• Qualifies for medical exemption if:               <ul style="list-style-type: none"> <li>○ Individual has medical exemption to completing their vaccine series with an mRNA vaccine.</li> </ul> </li> </ul>

### 3. Adverse Events Following COVID-19 Immunization<sup>2</sup>

Condition/AEFI	Management
<p>Thrombosis with thrombocytopenia syndrome (TTS)/VITT<sup>3</sup> following the AstraZeneca or Janssen COVID-19 vaccine</p>	<ul style="list-style-type: none"> <li>• Subsequent immunization should be completed with an mRNA vaccine.</li> <li>• Qualifies for medical exemption only if:               <ul style="list-style-type: none"> <li>○ Individual has medical exemption to completing their vaccine series with an mRNA vaccine.</li> </ul> </li> </ul>
<p>Myocarditis or Pericarditis following an mRNA COVID-19 vaccine</p>	<ul style="list-style-type: none"> <li>• Qualifies for medical exemption if:               <ul style="list-style-type: none"> <li>○ Myocarditis/pericarditis was diagnosed after medical evaluation (e.g., ER physician, relevant specialist).</li> </ul> </li> <li>• In situations where there is uncertainty regarding myocarditis/pericarditis diagnosis, discussion should occur with appropriate physician or nurse practitioner on potential options for (re)immunization with the same or alternative COVID-19 vaccine. The individual qualifies for a medical exemption if the physician or nurse practitioner has determined that the individual is unable to receive any COVID-19 vaccine.</li> </ul>

<sup>2</sup> 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.

<sup>3</sup> Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT).

Condition/AEFI	Management
<p>Severe allergic reaction (including anaphylaxis) following a COVID-19 vaccine</p>	<ul style="list-style-type: none"> <li>• Qualifies for medical exemption if:               <ul style="list-style-type: none"> <li>○ Allergy was documented by an appropriate physician or nurse practitioner; AND</li> <li>○ Discussion with appropriate physician or nurse practitioner has occurred on potential options for (re)immunization; AND</li> <li>○ Physician or nurse practitioner has determined that the individual cannot receive any COVID-19 vaccine with currently available mitigation strategies.</li> </ul> </li> </ul> <p><b>Note:</b> True medical exemptions are expected to be infrequent. In most instances, safe administration of subsequent doses of the COVID-19 vaccine is possible under the management of an appropriate physician or nurse practitioner.</p>
<p>Serious adverse event following COVID-19 immunization (e.g., results in hospitalization, persistent or significant disability/incapacity)</p>	<ul style="list-style-type: none"> <li>• Qualifies for medical exemption if:               <ul style="list-style-type: none"> <li>○ Event has been medically evaluated; AND</li> <li>○ Discussion has occurred with an appropriate physician or nurse practitioner (e.g., 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</li> <li>○ Physician or nurse practitioner has determined that the individual is unable to receive any COVID-19 vaccine.</li> </ul> </li> </ul>

#### 4. Other

Condition/AEFI	Management
<p>Actively receiving monoclonal antibody therapy OR convalescent plasma therapy for the treatment or prevention of COVID-19</p>	<ul style="list-style-type: none"> <li>• Qualifies for time-limited medical exemption while they are actively receiving therapy.</li> </ul>
<p>Actively receiving or recently completed immunosuppressing therapy anticipated to significantly blunt vaccine response</p>	<ul style="list-style-type: none"> <li>• Qualifies for time-limited medical exemption if:               <ul style="list-style-type: none"> <li>○ Appropriate physician or nurse practitioner has recommended that the individual defer vaccination to a later point to optimize immune response to COVID-19 vaccination; AND</li> <li>○ The individual is actively receiving or recently completed one or more of the following immunosuppressives:                   <ul style="list-style-type: none"> <li>▪ Anti-CD20 – vaccination deferral of up to 6 months following completion of therapy is recommended</li> <li>▪ Anti-thymocyte globulin – vaccination deferral of up to 1 month is recommended following completion of therapy</li> <li>▪ Chimeric Antigen Response (CAR) T-cell therapy - vaccination deferral of up to 3 months is recommended following completion of therapy</li> <li>▪ Hematopoietic stem cell transplant – vaccination deferral of up to 3 months is recommended following completion of therapy</li> <li>▪ Prednisone <math>\geq 1\text{mg/kg}</math> – vaccination deferral of up to 1 month is recommended following completion of therapy</li> </ul> </li> </ul> </li> </ul>

## 1. Pre-existing Condition(s)

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

Individuals aged 12 – 17 years old 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 clinically by a medical professional for cardiac issues should receive the vaccine. This guidance is issued by the [National Advisory Committee on Immunization \(NACI\)](#). A medical exemption may be issued only if discussion has occurred with an appropriate physician or nurse practitioner regarding potential options for immunization with an mRNA COVID-19 vaccine or alternative, and the physician or nurse practitioner has determined that the individual cannot receive any COVID-19 vaccine.

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

Individuals with a confirmed severe, immediate ( $\leq 4$ h following exposure) allergy (e.g., anaphylaxis) to a component of a specific COVID-19 vaccine or its container (e.g., PEG), are recommended to consult with an appropriate physician or nurse practitioner before receiving the specific COVID-19 vaccine. Individuals who are allergic to tromethamine (found in the Moderna COVID-19 vaccine) should be offered the Pfizer-BioNTech COVID-19 vaccine which does not contain this excipient. Individuals who are allergic to polysorbates (found in viral vector vaccines), should be offered an mRNA vaccine. A medical exemption may be issued only if discussion has occurred with the appropriate physician or nurse practitioner on options for immunization with the COVID-19 vaccine, including a risk-benefit analysis for the individual, and the physician or nurse practitioner has determined that the individual cannot 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](#).

## **2. Contraindications to Initiating an AstraZeneca or Janssen COVID-19 Vaccine Series**

### **History of capillary leak syndrome (CLS)**

Individuals who have experienced episodes of capillary leak syndrome (CLS) should not receive the AstraZeneca or Janssen COVID-19 vaccine. Very rare cases of capillary leak syndrome (CLS) have been reported following immunization with the AstraZeneca COVID-19 vaccine. This is a contraindication to receiving the AstraZeneca or Janssen 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 or Janssen COVID-19 vaccine. This is a contraindication to receiving the AstraZeneca or Janssen 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 or Janssen COVID-19 vaccine. This is a contraindication to receiving the AstraZeneca or Janssen 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 or Janssen 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**

#### **Thrombosis with thrombocytopenia syndrome (TTS)/VITT following AstraZeneca or Janssen COVID-19 vaccine**

Individuals who have experienced a major venous or arterial thrombosis with thrombocytopenia following vaccination with AstraZeneca or Janssen COVID-19 vaccine are contraindicated to receiving the AstraZeneca or Janssen 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 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. The individual qualifies for a medical exemption if the physician or nurse practitioner has determined that the individual is unable to receive any COVID-19 vaccine.

#### **Severe Allergic Reaction or Anaphylaxis following a COVID-19 vaccine**

In individuals with a history of a severe, immediate ( $\leq 4$ h following vaccination) allergic reaction (e.g., anaphylaxis) after previous administration of an mRNA COVID-19 vaccine, re-vaccination (i.e. administration of a subsequent dose in the series when indicated) may be offered with the same vaccine or the same mRNA platform if a risk assessment deems that the benefits outweigh the potential risks for the individual and if informed consent is provided. The risk of a severe immediate allergic reaction after re-immunization appears to be low and no long-term morbidity has been associated with re-vaccination.

- Consultation with an allergist may be sought prior to re-vaccination.
- If re-vaccinated, vaccine administration should be done in a controlled setting with expertise and equipment to manage allergic reactions. Individuals should be observed for at least 30 minutes after re-vaccination. For example, a longer period of observation is warranted for individuals exhibiting any symptom suggestive of an evolving AEFI at the end of the 30 minute observation period.

For those with a previous history of allergy to an mRNA vaccine, re-vaccination with an mRNA vaccine is preferred over a viral vector vaccine due to the better effectiveness and immunogenicity of mRNA vaccines and the possible adverse effects specifically associated with viral vector vaccines (e.g., Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT), capillary leak syndrome, and Guillain-Barré Syndrome).

In individuals with a history of a severe, immediate ( $\leq 4$ h following vaccination) allergic reaction (e.g., anaphylaxis) after previous administration of a viral vector COVID-19 vaccine, re-vaccination may be offered with an mRNA platform if a risk assessment deems that the benefits outweigh the potential risks for the individual and if informed consent is provided. If re-vaccinated, individuals should be observed for at least 30 minutes after re-vaccination.

A medical exemption may be issued if discussion has occurred 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, and the physician or nurse practitioner has determined that the individual cannot receive any COVID-19 vaccine with the currently available mitigation strategies.

### **Other allergies**

Individuals with other types of non-severe allergies can receive COVID-19 vaccines as outlined in the MOH's [Vaccination Recommendations for Special Populations](#). 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 [Vaccination Recommendations for Special Populations](#).

## Serious Adverse Event Following COVID-19 Immunization (AEFI)

Individuals who experience a [serious adverse event following immunization](#) (AEFI) (e.g., hospitalization, persistent or significant disability/incapacity) with a COVID-19 vaccine should be medically assessed by an appropriate physician or nurse practitioner, 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 [Health Protection and Promotion Act \(HPPA\)](#) 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 an appropriate physician or nurse practitioner for diagnosis/management and expert assessment for recommendation for subsequent immunization (e.g., the Special Immunization Clinic (SIC) Network, immunologist, etc.). This assessment will include a detailed assessment of the adverse event including 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 appropriate physician or nurse practitioner (e.g., 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. Other

### **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 appropriate physician or nurse practitioner. A medical exemption may be issued only if the individual is actively receiving therapy.

### **Actively receiving or recently completed immunosuppressing therapy anticipated to significantly blunt vaccine response**

Individuals who are actively receiving or recently completed an immunosuppressive therapy listed in the table below may be advised by their physician or nurse practitioner to defer COVID-19 vaccination to a later point to optimize immune response to the COVID-19 vaccine and minimize delays in management of their underlying condition. This is a time-limited (temporary) precaution. The recommended maximum deferral duration following completion of specific therapies is listed in the table below.

COVID-19 vaccines may be administered to these individuals once therapy is discontinued, with timing of administration evaluated on a case-by-case basis by an appropriate physician or nurse practitioner. Discussion with the patient should then consider their medical condition and the personal and epidemiological context (in terms of risk of COVID-19 infection) for the patient and the risks and benefits regarding timing and recommendations/options for immunization. A time-limited medical exemption may be issued only if the appropriate physician or nurse practitioner has recommended that the individual defer COVID-19 vaccination to a later point to optimize their immune response.

**Table 5: Recommended COVID-19 vaccination deferral duration following completion of specific therapies**

<b>Immunosuppressive Therapy</b>	<b>Recommended Maximum Deferral Duration Following Completion of Therapy</b>
Anti-CD20	6 months
Anti-thymocyte globulin	1 month
Chimeric antigen response (CAR) t-cell therapy	3 months
Hematopoietic stem cell transplant	3 months
Prednisone $\geq 1\text{mg/kg}$	1 month