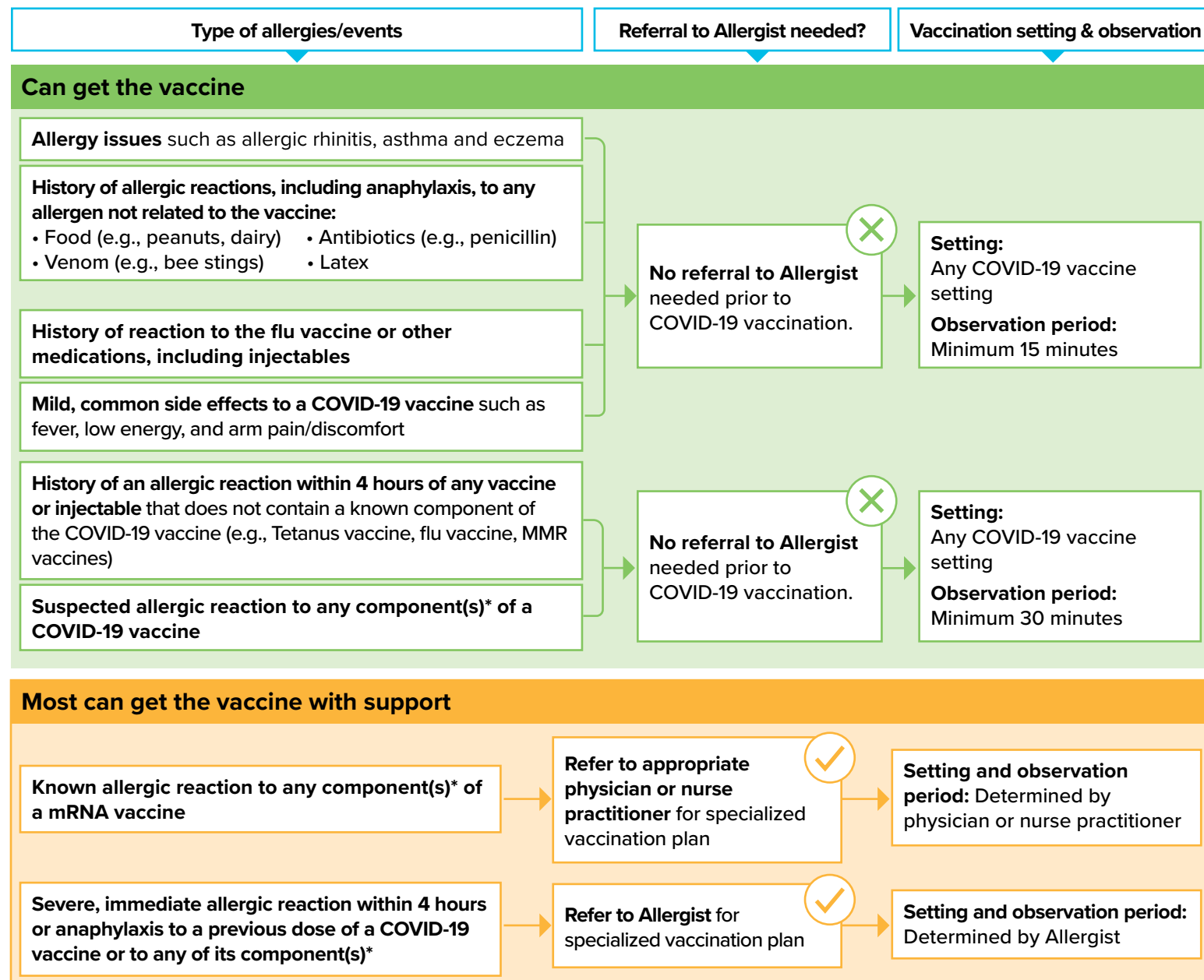


Pathways to COVID-19 Vaccination for Patients with Allergies:

Support tool for primary care physicians developed in partnership with the OMA Section on Allergy

This tool reflects the current evidence, guidance and recommendations for COVID-19 vaccination in patients 6 months and older with allergies, which has evolved since COVID-19 vaccines were first introduced.



? What allergic reactions are suitable for referral to Allergists?

Referrals to Allergists should only include patients with systemic symptoms including but not limited to changes or compromise in their airway, breathing or circulation. Possible symptoms can include angioedema/diffuse hives, wheezing, hypotension, tachycardia and loss of consciousness.

Immunization stress-related responses frequently mimic allergic reactions. These responses can include flushing, sensation of throat symptoms without objective findings, hypertension and tachycardia. These do not need referrals and may simply require patients to have an extended observation period with their next dose.

i A note on medical exemptions

- Allergists estimate that 95% of their patients who have a severe allergic reaction to dose 1 or any of its components can safely get a second dose.
- Exemptions will only be given if an assessment by an Allergist finds the patient's type of reaction CANNOT be mitigated (most can be). Please note to your patients that exemptions are very rarely given on grounds of a COVID-19 vaccine allergy.

* Components of COVID-19 vaccines that could be potential allergens include polyethylene glycol (PEG), tromethamine (trometamol or Tris) and polysorbate 80.



Common questions about allergies and the COVID-19 vaccines

What constitutes an allergic reaction?

An allergic reaction can include acute, localized reactions at the site of the injection, such as hives and angioedema. It can also include more severe, systemic reactions such as anaphylaxis.

Should I refer to an Allergist for all vaccine reactions?

No. A referral to an Allergist is not appropriate for the following non-allergic events:

- History of myocarditis, if still clinically followed
- Uncertainty around diagnosis of myocarditis after mRNA vaccination



Refer to or eConsult with appropriate physician or nurse practitioner

- Non-allergic neurological conditions with objective deficits observed on exam, such as Guillain-Barré Syndrome (GBS)
- Isolated neurological symptoms after first dose, such as numbness, tingling, aphasia, tinnitus and other stroke-like symptoms



Refer to or eConsult with Neurology if screening neurologic exam is abnormal or there is high index of suspicion for a vaccine-related, adverse neurologic event

- Mild, common side effects to a COVID-19 vaccine such as fever, low energy and arm pain/discomfort
- Isolated itching or rash/swelling localized to the injection site four hours or more after COVID-19 vaccination
- History of pericarditis with no or normal cardiac investigations after mRNA vaccination
- History of myocarditis if not clinically followed



No referral to specialist required

Can any other conditions look like an allergic reaction?

Immunization stress-related responses are far more common than allergic reactions and can include flushing, sensation of throat symptoms without objective findings, hypertension and tachycardia. These patients can receive their next dose with an extended observation period (30 minutes).

If you are unsure what your patient is experiencing, you can use [Ontario eConsult](#) or the [Ontario Telemedicine Network \(OTN\)](#) to consult with an Allergist.

What should I advise for patients with an allergic reaction that occurs more than 4 hours after vaccination?

It depends on the nature of the reaction a patient has experienced. For instance, patients with symptoms not likely to impact their next vaccine dose will likely not need a referral, provided symptoms fully resolve. If you are unsure of what to advise, you can use [Ontario eConsult](#) or the [Ontario Telemedicine Network \(OTN\)](#) to consult with an Allergist.

Do patients with COVID-19 vaccine allergies need documentation stating they consulted with an Allergist before getting their next dose?

Yes, most patients who had a severe allergic reaction, including anaphylaxis, or an allergic reaction within 4 hours of receiving a component of the vaccine or a previous dose will receive a specialized vaccination plan for future doses. They need to bring this vaccination plan, the details/severity of previous reaction(s), and proof of counselling with an Allergist to the vaccination site to receive their next dose.

What common over-the-counter drugs or household products have polyethylene glycol (PEG), polysorbate, or tromethamine?

PEG, which is all the Pfizer-BioNTech Comirnaty and Moderna Spikevax vaccines, and in the Medicago Covifenz vaccine in trace amounts, is also commonly found in over-the-counter medications (for example,

cough syrup, laxatives), prescription medications, bowel preparation products for colonoscopies, skin care products, dermal fillers, cosmetics, contact lens solution and ultrasound gel.

Polysorbate 80, which is in the AstraZeneca Vaxzevria, Novavax Nuvaxovid, Medicago Covifenz and Janssen (Johnson & Johnson) Jcovden vaccines, is also commonly found in cosmetics and medical preparations (for example, vitamin oils, tablets, anti-cancer agents).

Tromethamine (trometamol or Tris), which is in all Moderna Spikevax vaccines and in most Pfizer-BioNTech Comirnaty vaccines, is also commonly found in some medications and in CT and MRI contrast dyes. However, most allergic reactions to CT and MRI contrast dyes are not caused by tromethamine. The Canadian Society for Allergy and Clinical Immunology (CSACI) states that there are no concerns with getting the COVID-19 vaccine for those with a history of CT dye reactions.



Please note that while common over-the-counter and household products contain these ingredients found in COVID-19 vaccines, the amounts are exponentially higher than what is given in the vaccine. This means those with documented and even severe allergies to these products may safely receive COVID vaccines or alternatively be offered a different type of vaccine product.

Do patients with suspected allergies to component(s) of a COVID-19 vaccine need to be referred to an Allergist?

No. In accordance with guidance from the National Advisory Committee on Immunization (NACI), patients with a suspected but unproven allergy to a vaccine component can be vaccinated without an assessment for the suspected allergy. Patients can be vaccinated in any setting, but the recommended observation period should be extended to a minimum of 30 minutes.



Common questions about allergies and the COVID-19 vaccines (continued)

Reporting adverse events

Physicians and other healthcare providers have a duty to report adverse reactions following immunization (AEFIs) to the local public health unit within 7 days. The local public health unit will investigate the event and the medical officer of health will provide recommendations on next steps. Learn more about the [AEFI reporting process](#) and access the [AEFI reporting form](#).

Can allergen immunotherapy (allergy shots) be given at the same time as the COVID-19 vaccine?

The Canadian Society for Allergy and Clinical Immunology (CSACI) recommends that a subcutaneous immunotherapy injection and the COVID-19 vaccine be given on separate days, ideally 72 hours apart, to make it easier to tell which injection may have caused any adverse reactions.

Similarly, the American Academy of Allergy, Asthma & Immunology recommends not to give the two shots within 48 hours of each other.

Can the Mantoux test be given at the same time as the COVID-19 vaccine?

Yes. According to the Vaccine Recommendations and Guidelines of the Advisory Committee on Immunization Practices (ACIP), inactive vaccines like the COVID-19 vaccines do not interfere with Mantoux tuberculosis test results.

Can my patient who had a reaction to the flu vaccine or other drugs with polysorbates get an mRNA vaccine?

Yes. These patients should be offered an mRNA vaccine (Pfizer-BioNTech Comirnaty or Moderna Spikevax), which does not include polysorbates.

Polysorbates are found in viral vector vaccines.

Will my patients benefit from taking anti-histamines or other allergy medications ahead of getting the COVID-19 vaccine?

Antihistamines do not appear to treat or prevent anaphylaxis.

If antihistamines are being taken regularly for other health conditions, they can be continued.

If a patient was advised to take an antihistamine before an upcoming vaccination, there is also no evidence that this will decrease vaccine efficacy. This class of medications can be continued and vaccination can proceed.

Is there a need to test for allergies to vaccine components prior to vaccination?

No, evidence does not support allergy testing for vaccine components prior to vaccination. Such testing has unknown sensitivity/specificity in predicting severe allergic reactions.

Note that allergies to components of a COVID-19 vaccine are extremely rare.

Are all vaccination sites equipped to handle a serious allergic reaction?

Yes, all vaccine settings have trained staff and can respond to serious allergic reactions if needed.

Do common vaccines, such as the Tetanus vaccine, contain polyethylene glycol (PEG), polysorbate, or tromethamine?

No, these vaccines typically do not contain any components found in the COVID-19 vaccine.

? Common questions about allergies and the COVID-19 vaccine for kids and teens

Allergists routinely review Canadian and USA surveillance data for real time and current adverse events that may be reported.

How often do allergies to COVID-19 vaccine primary series occur in kids and teens?

Age group	Vaccine Product	Clinical Trial	Allergy Incidence
6 months to 4 years	Pfizer-BioNTech Original (monovalent)	Ongoing phase 2-3 (findings reported by Health Canada)	No cases of vaccine-related anaphylaxis.
6 months to 5 years	Moderna Original (monovalent)	Ongoing phase 2-3	With over 4500 children receiving two doses, one participant developed a maculopapular rash a few days after having a fever and febrile seizure that were considered unrelated to vaccination.
5-11 years	Pfizer-BioNTech Original (monovalent)	Ongoing phase 2-3	No reports of hypersensitivity or anaphylaxis. With over 1500 kids receiving 2 doses in the trial, there were four cases of mild, self-limiting rashes on the arm, torso, face or body reported 7 days or more after vaccination.
6-11 years	Moderna Original (monovalent)	Ongoing phase 2-3	No cases of anaphylaxis.
12-17 years	Pfizer-BioNTech Original (monovalent)	Phase 3	No cases of hypersensitivity or vaccine-related anaphylaxis.
	Moderna Original (monovalent)	Ongoing phase 2-3	No cases of anaphylaxis considered related to vaccination.

How often do allergies to COVID-19 boosters occur in kids and teens?

Age group	Vaccine Product	Allergy Incidence
5-11 years	Pfizer Bivalent	As reported by Health Canada , safety is inferred from bivalent boosters in adults and the original (monovalent) vaccine in this age group.
12-17 years	Pfizer Bivalent	As reported by Health Canada , safety is inferred from bivalent booster doses (BA.1) in adults and booster doses of the original (monovalent) vaccine in this age group.
12-17 years immunocompromised (off-label)	Moderna Bivalent	Safety is inferred from an ongoing phase 2-3 clinical trial involving adults 18+ . With over 400 adults receiving the Moderna bivalent booster in the trial, one participant experienced dermatitis after vaccination.

? Common questions about allergies and the COVID-19 vaccine for kids and teens (continued)

Can kids with severe food, venom, antibiotic or latex allergies get a COVID-19 vaccine?

Yes, children with severe food, venom, antibiotic or latex allergies can safely receive the COVID-19 vaccine without consulting an Allergist.

Is myocarditis and/or pericarditis after getting the COVID-19 vaccine a contraindication to getting further mRNA COVID-19 vaccine doses?

No, myocarditis and/or pericarditis after getting a COVID-19 vaccine are not considered contraindications to further COVID-19 vaccine doses.

Myocarditis and pericarditis following COVID-19 vaccination are rare adverse events that generally occur within about a week of receiving a mRNA COVID-19 vaccine. These adverse events occur more

commonly among males, in teens and young adults ages 12-29 years, after the second dose of a primary series, and with the Moderna vaccine compared to the Pfizer vaccine due to its higher dose.

Although not considered a contraindication, kids diagnosed with myocarditis (with or without pericarditis) or who had abnormal cardiac investigations within 6 weeks of receiving a mRNA vaccine should defer further COVID-19 vaccine doses as a precautionary measure until more is known. If there is uncertainty around the myocarditis diagnosis, vaccination options should be discussed on a case-by-case basis with the patient. If there is a history of pericarditis with no or normal cardiac workups after receiving a mRNA vaccine, kids can receive their next dose when they are symptom free or it has been ≥ 90 days since their last dose.

Refer to [OMA COVID-19 vaccine reference tool](#) for a summary of provincial recommendations on when kids can get vaccinated following myocarditis and/or pericarditis.

Can kids who had reactions to their routine immunizations get vaccinated?

Yes, children who reacted to their routine immunizations like MMR or Tetanus can safely receive the COVID-19 vaccine without consulting with an Allergist or getting allergy tested. These routine vaccines do not contain the same components as the COVID vaccines.

i Connecting with an Allergist

What should I include in a referral to an Allergist?

Please include the following information with your referral:

- Details of the reaction of concern the patient had, including timing
- What COVID-19 vaccine they received (if applicable) or what known component allergy the patient has
- Full past medical history and medication list

How can I find an allergist to refer to?

The Canadian Society of Allergy and Clinical Immunology (CSACI) provides a geographic look-up service: <https://csaci.ca/find-an-allergist/>

Can I get advice about COVID-19 vaccine reactions from an Allergist without referring my patient?

Yes, you can get advice from an Allergist through:

- [Ontario eConsult](#)
- [Ontario Telemedicine Network \(OTN\)](#)

Physicians must provide all relevant information, including their patient's allergy or condition, medical history and any drugs they are taking.

You can use these services when a referral is not necessary for your patient (see page 1 for more details).



References and more reading

General information on COVID-19 vaccine allergies:

- [Canadian Society of Allergy and Clinical Immunology \(CSACI\): COVID-19 vaccine FAQ](#). Jun 2021.
- [CSACI: COVID-19 Testing & Administration Guidance for Allergists/Immunologists](#). Nov 2021.
- [CSACI: SARS-CoV-2 Vaccines & Tromethamine: Guidance for Allergists/Immunologists](#). Jan 2023.
- [Immediate reactions after mRNA SARS-CoV-2 vaccination](#). (Can Med Assoc J. 2021 Dec 21)
- [Ministry of Health: COVID-19 vaccine guidance](#). Dec 2022.
- [COVID-19 vaccine: Canadian Immunization Guide](#). Dec 2022.
- [The risk of allergic reaction to SARS-CoV-2 vaccines and recommended evaluation and management: A systemic review, meta-analysis, GRADE assessment, and international consensus approach](#) (J Allergy Clin Immunol Pract. 2021 Jun)
- [Vaccine allergy](#). (Can Med Assoc J. 2019 Apr 8)

Rashes following COVID-19 vaccination:

- [Delayed large local reactions to mRNA-1273 vaccine against SARS-CoV-2](#). (N Engl J Med. 2021 Apr)
- [Cutaneous reactions reported after Moderna and Pfizer COVID-19 vaccination: a registry-based study of 414 cases](#). (J Am Acad Dermatol. 2021 Apr 7)
- [Incidence of cutaneous reactions after messenger RNA COVID-19 vaccines](#). (JAMA Dermatol. 2021 Jun 23)