COVID – 19 VACCINE CONTRAINDICATIONS & PRECAUTIONS BACKGROUND DOCUMENT 2022-01-21

NOTE: This document is to be used by Healthcare Professionals to assess clients with the following conditions who live or work in high-risk environments. Please note there are two tables. Table one includes recommendations for 12+ years vaccination and Table 2 includes recommendations for pediatric 5-11 vaccine
This table does not address all Contraindications and Precautions.

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Table 1: Recommendations for 12+ Years Vaccination

Condition	Recommendations	Script
Severe Immediate Allergic Reactions	• In individuals with a history of a severe, immediate (≤4h 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 or other appropriate physician should be sought prior to revaccination. ○ If re-vaccinated, vaccine administration should be done in a controlled setting with expertise and equipment to manage anaphylaxis. 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., VITT, capillary leak syndrome and Guillain-Barré Syndrome). • In individuals with a history of a severe, immediate (≤4h following vaccination) allergic reaction (e.g., anaphylaxis) after previous administration of a viral vector COVID-19 vaccine, revaccination 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 revaccinated, individuals should be observed for at least 30 minutes after re-vaccination. • In individuals with a confirmed severe, immediate (≤4h following exposure) allergy (e.g., anaphylaxis) to a component of a specific COVID-19 vaccine or its container (e.g., PEG), consultation with an allergist is recommended before receiving the specific COVID-19 vaccine. • Individuals who are allergic to tromethamine should be offered a vaccine that does not contain this excipient. • Individuals who are allergic to polysorbates (found in viral vector vaccines), should be offered an mRNA vaccine. NACI October 22, 2021 https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-covid-19-vaccines.html?hq_e=el&hq_m=2188311&hq_l=1&hq_v=91d220e044).	• Individuals who report having had a previous severe immediate allergic reaction such as anaphylaxis should be referred to an allergist for further investigation and assessment with recommendation provided to allow for re-immunization as per the specification shown in the recommendation column,
SARS-CoV-2 (COVID-19) Infection Current or Previous	NACI recommends that a complete series with a COVID-19 vaccine may be offered to individuals in the authorized age group without contraindications to the vaccine who have had previously PCR-confirmed SARS-CoV-2 infection (NACI October July 22, 2021). NACI October 22, 2021 https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-covid-19-vaccines.html?hq_e=el&hq_m=2188311&hq_l=1&hq_v=91d220e044).	• Individuals should wait to receive a vaccine until they no longer have acute symptoms of COVID-19 and are no longer infectious to others.

Condition	Recommendations	Script
Completion of a mRNA COVID-19 Vaccine Series	• If easily available at the time of vaccination without delay or vaccine wastage, the same mRNA COVID-19 vaccine product should be offered for the subsequent dose in a primary vaccine series started with an mRNA COVID-19 vaccine. • If not easily available at the time of vaccination without delay or vaccine wastage or is unknown, another mRNA COVID-19 vaccine product recommended for use in that age group can be considered interchangeable and should be offered to complete the primary vaccine series.	• Either mRNA COVID-19 vaccine can be used to complete a 2-dose primary vaccine series when the brand administered for the first dose is not available at the time for the second dose.
Intervals between COVID-19 and other vaccines	**For those 12 years and older**, Health Canada approved COVID-19 vaccines can be given concomitantly with other vaccines; no intervals are required before or after COVID-19 vaccine administration. NACI October 22, 2021 https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-covid-19-vaccines.html?hq_e=el&hq_m=2188311&hq_l=1&hq_v=91d220e044	• **For those 12 years and older**, COVID-19 vaccines may be given at the same time as other non-COVID-19 vaccines.
Optimal interval between 1st and 2nd doses	• NACI recommends that an 8 week interval is optimal between first and second doses but the minimum interval of 28 days (recommended in SK) will still be provided if people choose the shorter interval. NACI October 22, 2021 https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-covid-19-vaccines.html?hq_e=el&hq_m=2188311&hq_l=1&hq_v=91d220e044)	• A longer interval between first and second doses results in a stronger more robust and durable immune response in adult studies.
Second Dose for 12 Year Olds if First Dose Pediatric Formulation	• Give vaccine appropriate for age at time of second dose, regardless of initial dose received: ○ For individuals who received a pediatric vaccine as a first dose when they were 11, complete second dose with the 12+ formulation. NACI November 19, 2021 https://www.canada.ca/content/dam/phac-aspc/documents/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-covid-19-vaccines/pfizer-biontech-10-mcg-children-5-11-years-age/pfizer-biontech-10-mcg-children-5-11-years-age.pdf	• Children who received the Pediatric vaccine for their first dose and who have turned 12 years old by the time the second dose is due may received the 30mcg Pfizer-BioNTech COVID-19 vaccine that is authorized for individuals aged 12 years and older to complete their primary series.
Booster dosages	For AstraZeneca's Vaxzevria and Pfizer's Comirnaty, all booster dose recipients are to receive a full dose booster (0.5 ml for AZ or 0.3 ml for Pfizer 12+). For Moderna's Spikevax, the booster dosage depends on the risk factor: • 0.5 ml for those 70 years and older. • 0.5 ml for Long Term Care (Special Care Homes), Personal Care Homes and Seniors' Assisted Living residents, regardless of age. • 0.25 ml for all others prioritized for booster doses **(immunocompromised always to receive full 0.5 ml dose**). NACI October 29, 2021: https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-covid-19-vaccines/statement-guidance-booster-doses.html.	• Age and residency status are factors in determining who is eligible to receive a full dose or half dose of Moderna. • Full doses of Moderna are recommended for those with a higher risk of getting COVID-19. • Half doses of Moderna are very effective in the general population.

Condition	Recommendations		Script
Additional / Third / Booster Dose Intervals	LTC or PCH residents- eligible for a fourth dose five months following their third dose.	Min. 3 months from their second dose Min. 5 months between third and fourth dose	
	Persons 18 years and older living in the community	Min. 3 months from their second dose	
	Immunocompromised persons – **to receive a 3-dose primary mRNA series given a minimum of 28 days apart and booster doses given 3 months after the third dose. Each dose is a full dose.**	Min. 28 days between second and third dose Min. 3 months between third and fourth dose	• Eligibility letters will no longer be provided to clients, thus are not required as proof of eligibility for immunization.
	Those living in: ○ homeless and other emergency shelters ○ group homes ○ mental health residential care ○ correctional institutions ○ seniors' assisted living	Min. 3 months from their second dose	
	All healthcare workers	Min. 3 months from their second dose	• HCWs need to present a copy of their licence from your professional licensing body, a workplace pay stub or their Saskatchewan Health Authority staff identification at the point of immunization.
	Individuals born in 2009 or earlier with underlying health conditions that are clinically extremely vulnerable including: 1. People with severe respiratory conditions, including all cystic fibrosis, severe asthma and severe chronic obstructive pulmonary disease (COPD) 2. People with rare diseases that significantly increase the risk of infections (such as homozygous sickle cell disease) 3. People who had their spleen removed 4. People with very significant developmental disabilities that increase risk (such as Down's syndrome) 5. People on dialysis or with chronic kidney disease (stage 5) 6. People with significant neuromuscular conditions requiring respiratory support 7. People with diabetes (any)	Min. 3 months from their second dose	• Except for diabetics, others will receive a notification letter from their physician or Ministry of Health.
Additional / Third / Booster Dose Directives for Viral	• For those who received COVISHIELD® or AstraZeneca Vaxzevria® as their first dose and a mRNA vaccine for their second dose, consider that they receive the same mRNA vaccine brand for their additional/booster doses when possible to avoid potentially needing a fourth dose for travel purposes.		• Some countries or events /organizations in other countries are requiring 2 doses of the same mRNA vaccine as proof of

Condition	Recommendations	Script

Vector Vaccine recipients	• **General Statements on Booster Vaccines.**
	  ○ Booster doses should be mRNA vaccine unless contraindication.
	  ○ Either mRNA may be used as a booster dose regardless of the mRNA vaccine used in the primary series.
	
	Booster Doses for those who received two doses of AstraZeneca (AZ) as their primary series.
	• It is recommended that people who received two doses of AZ as primary series receive an mRNA booster vaccine at least 3 months after completion of their primary series. A viral vector vaccine could be given to those for whom there is a contraindication to an mRNA vaccine.
	
	Booster Doses for those who received the Janssen Vaccine.
	• It is recommended that an mRNA booster vaccine be given at least 2 months after the primary dose of Janssen was received, for those aged 18 years and over, if only a single dose has been received.
	
	NACI October 29, 2021: https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-covid-19-vaccines/statement-guidance-booster-doses.html.
		vaccination. Although receiving two different mRNA vaccines is safe and effective, to avoid potentially needing additional COVID-19 vaccine doses in the future, we will provide the same vaccine product that you received for your second dose.
		• mRNA vaccines are recommended as booster doses following viral vector vaccines because the mRNA vaccine provides a better booster immune response.

Treatment with COVID-19 Monoclonal Antibodies or Convalescent Plasma	• If client received anti-SARS-CoV-2 monoclonal antibodies or convalescent plasma for treatment of infection, delay vaccination with COVID-19 vaccine for at least 90 days. Delaying vaccination due to treatment is applicable to the first dose and second dose, depending on when treatment was received (e.g. if treatment is received after the first dose is administered, delay the second dose for at least 90 days). • For persons receiving antibody therapies not specific to COVID-19 treatment (e.g., intravenous immunoglobulin, RhoGAM), they are recommended to receive and/or complete a full COVID-19 vaccine series either simultaneously with or at any interval before or after treatment. **NACI Recommendation:** **NACI recommends that COVID-19 vaccines should not be given simultaneously with monoclonal antibodies or convalescent plasma.** NACI October 22, 2021 https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-covid-19-vaccines.html?hq_e=el&hq_m=2188311&hq_l=1&hq_v=91d220e044). **Centre for Disease Control (US):** **People who previously received passive antibody therapy** Currently, there are no data on the safety and efficacy of COVID-19 vaccines in people who received monoclonal antibodies or convalescent plasma as part of COVID-19 treatment. Based on the estimated half-life of such therapies and evidence suggesting that reinfection is uncommon in the 90 days after initial infection, vaccination should be deferred for at least 90 days. This is a precautionary measure until additional information becomes available, to avoid potential interference of the antibody therapy with vaccine-induced immune responses.	• Currently, there is insufficient evidence on the receipt of both a COVID-19 vaccine and anti-SARS-CoV-2 monoclonal antibodies or convalescent plasma. • Administering these products close together may result in less effectiveness of the COVID-19 vaccine and/ or the SARS-CoV-2 monoclonal antibodies. • **Based on your treatment the recommendation is to wait at least 90 days to receive the COVID-19 vaccine.** • **(If recommendation in second column supports immunization)** Do you have any additional questions or concerns about getting immunized with the COVID-19 vaccine?

Condition	Recommendations	Script
	For more information, see CDC clinical considerations: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html	
Pregnancy or Planning Pregnancy	**Only mRNA COVID-19 vaccines should be offered during pregnancy unless there are contraindications. Viral vector COVID-19 vaccines should only be offered if there are allergies to mRNA vaccine ingredients or mRNA vaccine is not readily available.** **NOTE:** Pregnancy is not a contraindication for any of the currently approved COVID-19 Vaccines, including AstraZeneca/COVISHIELD. **NACI Recommendation** **NACI preferentially recommends that a complete vaccine series with an mRNA COVID19 vaccine should be offered to individuals in the authorized age group who are pregnant. If an mRNA vaccine is contraindicated, another authorized COVID-19 vaccine should be offered. Informed consent should include discussion about emerging evidence on the safety of mRNA COVID-19 vaccines in this population. (Strong NACI Recommendation)** • An mRNA vaccine is preferred due to published safety data. Recently published preliminary analyses of 35,691 pregnant women in the United States who received an mRNA COVID-19 vaccine did not reveal any obvious safety signals. If VITT were to occur after receipt of a viral vector vaccine in a pregnant person, there might be complexity in the medical care. The US safety data suggests mRNA vaccine administration within 30 days of conception is safe. Those who are trying to become pregnant do not need to avoid pregnancy after vaccination with an mRNA vaccine. • To date, no safety signals have been detected in Development and Reproductive Toxicity (DART) animal studies for Pfizer, Moderna, Janssen, and AstraZeneca vaccines. NACI October 22, 2021 https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-covid-19-vaccines.html?hq_e=el&hq_m=2188311&hq_l=1&hq_v=91d220e044).	• Studies from around the world show COVID-19 vaccines are safe during pregnancy. • Do you have any additional questions or concerns about getting immunized with the COVID-19 vaccine? • Do you consent to being immunized with the (Brand) of COVID-19 vaccine?
Breastfeeding	Those who are breastfeeding should be offered COVID-19 immunization in the same manner as the general adult population. **NACI Recommendation:** **NACI recommends that a complete vaccine series with an mRNA COVID-19 vaccine should be offered to individuals in the authorized age group who are breastfeeding. If an mRNA vaccine is contraindicated, another authorized COVID-19 vaccine should be offered. Informed consent should include discussion about the emerging evidence on the safety of mRNA COVID-19 vaccines in this population. (Strong NACI Recommendation)** NACI October 22, 2021 https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-covid-19-vaccines.html?hq_e=el&hq_m=2188311&hq_l=1&hq_v=91d220e044).	• Studies from around the world show COVID-19 vaccines are safe while breastfeeding. • Getting the COVID-19 vaccine is not a reason to stop breastfeeding. • Do you have any additional questions or concerns about getting immunized with the COVID-19 vaccine? • Do you consent to being immunized with the (Brand) of COVID-19 vaccine?
Immunocompromised	**It is preferred that clients on immunosuppressive therapy discuss the timing between their therapy and receiving vaccine doses (including additional/booster doses) with their health care provider.**	• Studies from around the world show COVID-19 vaccines are safe

Condition	Recommendations	Script
Also see sections below for Cancer/ Oncology patients **And** **Patients with Auto-Immune Disease**	**(HSCT) Blood and Bone Marrow Stem Cell Transplant (autologous or allogeneic):** ○ Patients **MUST** talk with their oncology team prior to vaccine administration. ▪ If feasible vaccine should be administered 2 weeks prior to starting conditioning regimen for their transplant. ▪ Post-transplant - if transmission in the community is high, vaccination can be initiated 3 months after HSCT. If the transmission in the community is controlled, vaccination can wait until 6 months after HSCT. ▪ Postpone vaccination in severe, uncontrolled acute GVHD, Grade 3-4. **Medically stable SOLID ORGAN TRANSPLANT PATIENTS** followed up by the Saskatchewan Transplant Program **DO NOT NEED to consult their specialist prior to immunization with COVID-19 vaccines.** **However:** ○ **If the client had a recent transplant (less than month ago) or was recently (less than 1 month ago) treated for rejection or if the immunizer is unsure of the client's eligibility, please ask the client to contact the Saskatchewan Transplant Program to determine if and when they should receive the vaccine.** • It is preferred that all other clients with immune suppression discuss the vaccine with their healthcare provider prior to presenting. **However:** ○ If they have not discussed vaccination with their healthcare provider **AND** their **condition is UNSTABLE consult** with the area MHO. ○ If they have not discussed vaccination with their healthcare provider **AND** their **condition is stable** proceed as below. **NACI Recommendation** **NACI preferentially recommends that a complete COVID-19 vaccine series with an mRNA COVID-19 vaccine should be offered to individuals in the authorized age group who are immunosuppressed due to disease or treatment. If an mRNA vaccine is contraindicated, another authorized COVID-19 vaccine should be offered. Informed consent should include discussion about the possibility that individuals who are immunosuppressed may have a diminished immune response to any of the authorized COVID-19 vaccines. (Strong NACI Recommendation)** NACI October 22, 2021 https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-covid-19-vaccines.html?hq_e=el&hq_m=2188311&hq_l=1&hq_v=91d220e044).	for people with immune system conditions. • The vaccine antibody response in immune comprised individuals may not be a strong as the immune response in individuals who are not immune suppressed. **Immunized individuals still need to take precautions against COVID–19 disease**. • Do you have any additional questions or concerns about getting immunized with the COVID-19 vaccine? • **(If the treatment plan in second column supports immunization)** Do you consent to being immunized with the (Brand) of COVID-19 vaccine?
Immuno-compromised **Oncology Patients**	**Cancer survivors** should be vaccinated against COVID-19 if there are no contraindications to receiving vaccine. Vaccinate as any other client who does not have a precaution or contraindication. **(HSCT) Blood and Bone Marrow Stem Cell Transplant (autologous or allogeneic):** ○ Patients **MUST** talk with their oncology team prior to vaccine administration. ▪ If feasible vaccine should be administered 2 weeks prior to starting conditioning regimen for their transplant.	• Studies from around the world show COVID-19 vaccines are safe for people with immune system conditions. • The vaccine antibody response in immune comprised individuals may not be a strong as the immune response in individuals who are not immune suppressed.

Condition	Recommendations	Script
	▪ Post-transplant - if transmission in the community is high, vaccination can be initiated 3 months after HSCT. If the transmission in the community is controlled, vaccination can wait until 6 months after HSCT. ▪ Postpone vaccination in severe, uncontrolled acute GVHD, Grade 3-4. • It is preferred that **all other clients with cancer** discuss the vaccine with their healthcare provider prior to presenting. **However:** o If they have not discussed vaccination with their healthcare provider **AND** their **condition is UNSTABLE, consult** with the area MHO. o If they have not discussed vaccination with their healthcare provider **AND** their **condition is STABLE** proceed as below. The following guidelines on the **timing of COVID-19 vaccine in terms of cancer treatment** has been adapted from the information from inactivated influenza and other vaccines in immunocompromised patients. If client's therapy is: • **Targeted Hormonal and single agent immune therapy treatments:** Vaccine can be administered at any time during treatment. • **Radiation therapy:** Vaccine can be administered at any time during radiation therapy. • **Cytotoxic chemotherapy:** o **New treatment starts**: ▪ If possible, vaccination should be completed at least two weeks prior to starting systemic therapy or immunosuppressive therapy. If both of the doses cannot be given prior to starting treatment, at least the first dose of vaccine should be given two weeks before starting treatment. The second dose should be administered 4-5 days prior to the next cycle. o **Patients already on chemotherapy treatment**: ▪ Ideally a vaccine dose would be administered 4- 5 days prior to a dose of cytotoxic chemotherapy so that vaccine side effects and chemotherapy side effects don't overlap. • **B-Cell directed therapy** ((Anti CD 20 (rituximab, obinotuzimab), CD 19 – (blinatumomab), CD 22 antibodies (inotuzumab) and BTK inhibitors (ibrutinib)): o If therapy is of short duration (limited number of cycles), Vaccination should be postponed until 1-3 months after B- cell directed treatment due to decreased ability to develop immunity to COVID-19 by vaccination. o If therapy is part of a maintenance treatment, Vaccination should be given 4 weeks after the last dose of therapy. o Patients on BTK inhibitors (ibrutinib) can receive vaccination at any time.	**Immunized individuals still need to take precautions against COVID–19 disease.** • **Based on your therapy the recommendation is as follows: refer to treatments in second column.** • Do you have any additional questions or concerns about getting immunized with the COVID-19 vaccine? • **(If the treatment plan in second column supports immunization)** Do you consent to being immunized with the (Brand) of COVID-19 vaccine?

Condition	Recommendations	Script
	• **T-Cell directed therapy** (Calcineurin inhibitors (e.g. oral and injection: cyclosporine and tacrolimus) (e.g. topical: pimecrolimus, tacrolimus), ATG (e.g. antithymocyte globulin – rabbit and equine) or Alemtuzumab) ○ Vaccination should be postponed until 3 months after of T- cell directed treatment due to decreased ability to develop immunity to COVID-19 by vaccination. **NACI Recommendation** **NACI preferentially recommends that a complete COVID-19 vaccine series with an mRNA COVID-19 vaccine should be offered to individuals in the authorized age group who are immunosuppressed due to disease or treatment. If an mRNA vaccine is contraindicated, another authorized COVID-19 vaccine should be offered. Informed consent should include discussion about the possibility that individuals who are immunosuppressed may have a diminished immune response to any of the authorized COVID-19 vaccines. (Strong NACI Recommendation)** NACI October22, 2021 https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-covid-19-vaccines.html?hq_e=el&hq_m=2188311&hq_l=1&hq_v=91d220e044).	

Autoimmune conditions
 	
See MS section below
	For any autoimmune condition that involves the **neurological system, it is preferred** the client discuss vaccination with their primary physician / specialist before immunization is provided. If the client has not discussed vaccination with their primary physician or specialist, immunization can proceed with their informed consent.
	
	Clients receiving ongoing treatment with **Rituximab** should delay vaccination **until a minimum of 4 weeks** after last dose of Rituximab, unless directed differently by their health care provider/prescriber.
	• See table below for a list of common autoimmune conditions.
	• It is preferred that clients with immune suppression discuss the vaccine with their healthcare provider prior to presenting. **However:**
	  ○ If they have not discussed vaccination with their healthcare provider **AND** their **condition is UNSTABLE consult** with the area MHO.
	  ○ If they have not discussed vaccination with their healthcare provider **AND** their **condition is STABLE** proceed as below.
	
	NACI Recommendation:
	NACI preferentially recommends that a complete vaccine series with an mRNA COVID19 vaccine should be offered to individuals in the authorized age group with an autoimmune condition. If an mRNA vaccine is contraindicated, another authorized COVID-19 vaccine should be offered. Informed consent should include discussion about the emerging evidence on the safety of mRNA COVID-19 vaccines in these populations. (Strong NACI Recommendation)
	
	NACI July 22, 2021 https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-covid-19-vaccines.html?hq_e=el&hq_m=2188311&hq_l=1&hq_v=91d220e044).
		• Studies from around the world show COVID-19 vaccines are safe for people with an autoimmune disease.
		• The vaccine antibody response in individuals with autoimmune conditions may not be as strong as the immune response in individuals who do not have an autoimmune condition. The immune response may vary according to condition severity and current medical treatment. **Immunized individuals still need to take precautions against COVID–19 disease.**
		• Do you have any additional questions or concerns about getting immunized with the COVID-19 vaccine?
		• **(If the treatment plan in second column supports immunization)** Do you consent to being immunized with the (Brand) of COVID-19 vaccine?

<table>
<tr><th>Condition</th><th>Recommendations</th><th>Script</th></tr>
<tr>
<td>Autoimmune disorders

MULTIPLE SCLEROSIS</td>
<td>

It is preferred that clients with Multiple Sclerosis (MS) discuss the vaccine with their healthcare provider prior to presenting. However:

If they have not discussed vaccination with their healthcare provider AND their condition is UNSTABLE consult with the area MHO.
If they have not discussed vaccination with their healthcare provider AND their condition is stable proceed as below, taking into consideration the timing of vaccines based on Disease Modifying Therapies (See Table below).

For <u>MULTIPLE SCLEROSIS (MS)</u> patients the following recommendations <u>should</u> be followed:
<table>
<tr><th>Medication(s)</th><th>Effect on vaccination</th><th>Delay of vaccination after treatment*</th><th>Delay of treatment after vaccination**</th></tr>
<tr><td>Glatiramer acetate (any type)

Interferon-beta (any type)
Teriflunomide

Dimethyl fumarate (or any type of fumaric acid ester)

Natalizumab</td><td>Little to no effect</td><td>None required</td><td>None required</td></tr>
<tr><td>Fingolimod
Ozanimod
Siponimod</td><td>May have a modest decrease in vaccine effectiveness</td><td>None required</td><td>4 weeks for treatment initiation; no delay for treatment continuation</td></tr>
<tr><td>Ocrelizumab
Rituximab</td><td>May have a more pronounced decrease in vaccine effectiveness</td><td>4 weeks</td><td>4 weeks</td></tr>
<tr><td>Ofatumumab</td><td>May have a more pronounced decrease in vaccine effectiveness</td><td>4 weeks</td><td>4 weeks</td></tr>
<tr><td>Cladribine
Alemtuzumab</td><td>Unlikely to affect vaccine response after immune reconstitution has taken place</td><td></td><td>4 weeks</td></tr>
</table>
*: The time period after a treatment dose during which vaccine should not be administered.
**: The time period after a vaccination series (i.e. all doses) during which treatment should not be (re)started.
</td>
<td>

Studies from around the world show COVID-19 vaccines are safe for people with an autoimmune disease.
The vaccine antibody response in MS patients may not be as strong as the immune response in individuals who do not have MS. This will depend on the disease process and the client’s MS treatment. Immunized individuals still need to take precautions against COVID–19 disease.
Based on your therapy the recommendation is as follows: [refer to treatments in Table].
Do you have any additional questions or concerns about getting immunized with the COVID-19 vaccine?
(If the treatment plan in Table supports immunization) Do you consent to being immunized with the (Brand) of COVID-19 vaccine?

</td>
</tr>
</table>

Condition	Recommendations	Script
	<u>NACI Recommendation:</u> **NACI preferentially recommends that a complete vaccine series with an mRNA COVID19 vaccine should be offered to individuals in the authorized age group with an autoimmune condition. If an mRNA vaccine is contraindicated, another authorized COVID-19 vaccine should be offered. Informed consent should include discussion about the emerging evidence on the safety of mRNA COVID-19 vaccines in these populations. (Strong NACI Recommendation)** NACI July 22, 2021 https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-covid-19-vaccines.html?hq_e=el&hq_m=2188311&hq_l=1&hq_v=91d220e044).	
Tuberculin (TB) Skin Test or TB Blood Work (IGRA)	• If TB skin testing or TB blood work is required, it should be administered and read before immunization or delayed for at least 4 weeks after vaccination with COVID-19 vaccine. • Vaccination with COVID-19 vaccines may take place at any time after all steps of tuberculin skin testing have been completed. NACI October 22, 2021 https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-covid-19-vaccines.html?hq_e=el&hq_m=2188311&hq_l=1&hq_v=91d220e044).	• Have you had a tuberculin (TB) skin test or need TB blood work (IGRA) done? If testing has been done but not read/completed: • Receiving the COVID-19 vaccine prior to having all steps of the TB test completed may cause the test to show a false-negative result which means the test negative result but it should be a positive result. • **The recommendation is to wait until your test result is read before receiving the COVID-19 vaccine.** • **(If recommendation in second column supports immunization)** Do you have any additional questions or concerns about getting immunized with the COVID-19 vaccine?

Condition	Recommendations	Script
Venous Thromboembolism (VTE)	• Very rare cases of VTE have been reported following immunization with Janssen vaccine. • The European Medical Agency states the risk of VTE should be considered for individuals with increased risk for thromboembolism. This may include deep vein thrombosis (DVT) or pulmonary embolism (PE).	• Rarely, blood clots have occurred after the Janssen vaccine and some people are more prone to developing blood clots. If you choose to get the Janssen vaccine, you should be aware of the risk and seek medical attention if you notice any symptoms listed on after care sheet. If you are not sure about your medical conditions, you can consult your health care provider.

Condition	Recommendations	Script

Thrombosis, Thrombocytopenia or history of immune thrombocytopenia	**AstraZeneca/COVISHIELD & Janssen COVID-19 Vaccines:**
	CONTRAINDICATIONS:
	• Clients with a history of the following conditions should **not** receive this vaccine:
	  ○ Heparin Induced Thrombocytopenia (HIT)
	  ▪ HIT antibody lingering might interfere with lab assay to detect the VIPIT/VITT antibody and may complicate management
	  ○ Thrombotic Antiphospholipid Antibody Syndrome (APS)
	  ○ Major venous or arterial thrombosis with thrombocytopenia following a viral vector COVID-19 vaccine
	PRECAUTIONS:
	• Cerebral Sinus Venous Thrombosis (CVST) with thrombocytopenia
	  ○ Should only receive a viral vector COVID-19 vaccine if the potential benefits outweigh the potential risks. An alternate COVID-19 vaccine should be offered.
	• Platelet monitoring may be recommended for individuals with a history of immune thrombocytopenia following immunization with a viral vector vaccine.
	
	Data on Vaccine-induced Immune Thrombotic Thrombocytopenia (VITT) cases outlined by NACI:
	• Cases of VITT usually occur between 4 and 28 days after receipt of a viral vector COVID-19 vaccine, and patients should be monitored for symptoms up to 42 days.
	• The rate of VITT is estimated to be between 1 per 26,000 and 1 per 100,000 persons vaccinated with a first dose of AstraZeneca/COVISHIELD COVID-19 vaccine. As of June 1, 2021, PHAC has estimated the rate of VITT in Canada to be 1 in 73,000 doses administered, however, as investigations continue, this rate could be as high as 1 in 50,000.
	• The frequency of VITT following a second dose of AstraZeneca vaccine is currently reported between 1 per 600,000 and 1 per 750,000 individuals vaccinated with a second dose but continues to evolve, based on vaccine safety surveillance data from the United Kingdom.
	• The case fatality rate of VITT also varies between countries, and ranges between 20 and 50%.
	
	NACI October 22, 2021 https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-covid-19-vaccines.html?hq_e=el&hq_m=2188311&hq_l=1&hq_v=91d220e044).
		• Due to very rare reports of a combination of blood clots and low levels of blood platelets following immunization with a viral vector vaccine, it is not recommended that people with a history of this condition receive a viral vector vaccine.
		• Those with a history of immune thrombocytopenia may be recommended by their healthcare professional to have their platelet levels monitored closely following immunization with viral vector vaccines.

Capillary Leak Syndrome	**AstraZeneca/COVISHIELD and Janssen COVID-19 Vaccines:** • These vaccines are contraindicated for clients with a history of capillary leak syndrome. NACI October 22, 2021 https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-covid-19-vaccines.html?hq_e=el&hq_m=2188311&hq_l=1&hq_v=91d220e044).	• Due to rare reports of capillary leak syndrome after vaccination, people with a history of this CLS should not be vaccinated with a viral vector COVID-19 vaccine.
Myocarditis and/or Pericarditis	• **mRNA COVID-19 Vaccines Only:** For individuals aged 30 and younger who are receiving their primary COVID-19 vaccine series and both Moderna and Pfizer are readily available, Pfizer is the preferred vaccine as there is a lower risk of myocarditis compared to immunization with Moderna. Individuals opting to receive Moderna shall be informed of the increased risk of myocarditis/pericarditis compared to receiving Pfizer.	• Due to very rare reports of myocarditis (inflammation of the heart) and/or pericarditis (inflammation of the outer lining of the heart), people with a history of

Condition	Recommendations	Script
	• It is unclear if people who developed myocarditis or pericarditis after a first dose of an mRNA COVID-19 vaccine are at increased risk of further adverse cardiac events following a second dose of the vaccine. **NACI continues to recommends that further doses of mRNA COVID-19 vaccines should be deferred among people who experienced myocarditis and/or pericarditis within 6 weeks of receiving a previous dose of an mRNA COVID-19 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.** • **NACI recommends that those with a history compatible with pericarditis and who either had no cardiac workup or had normal cardiac investigations can be revaccinated once they are symptom free and at least 90 days has passed since previous vaccination.** NACI will continue to monitor the evidence and update recommendations as needed. • If an individual is at high risk of COVID-19 acquisition or severe outcome due to community transmission or underlying condition, then a decision to get the second dose should be made in consultation with the individual's physician (cardiologist if possible) with the patient's informed consent. • Decisions about proceeding with the second dose should include a conversation between the patient, their parent/guardian/caregiver (when relevant), and their clinical team. These individuals should be informed of the risks of myocarditis and pericarditis following a second mRNA COVID-19 vaccine dose and advised to seek medical attention if they develop symptoms People with a history of myocarditis or pericarditis following a first dose of an mRNA COVID-19 vaccine, who choose or are recommended by their specialist to receive the second dose of an mRNA COVID-19 vaccine, should wait at least until their episode of myocarditis or pericarditis has completely resolved. This includes resolution of symptoms attributed to myocarditis or pericarditis, as well as no evidence of ongoing heart inflammation or sequelae as determined by the person's clinical team, which may include a cardiologist, and special testing to assess cardiac recovery. **Data on myocarditis and pericarditis as outlined by NACI:** Based on cases reported internationally, available information indicates that cases of myocarditis and pericarditis after vaccination with an mRNA COVID-19 vaccine occur: • More often after the second dose in a homologous series • Preliminary analyses suggest a higher unadjusted rate of myocarditis/pericarditis cases reported after vaccination with Moderna compared to Pfizer-BioNTech, however the analysis is ongoing. • Usually within a week after vaccination • More often in adolescents and young adults (12 – 30 years of age) • More often in males than females.	these conditions discuss immunization with an mRNA vaccine prior to receiving.

Table 2: Recommendation for Pediatric 5-11 years Vaccination

Condition	Recommendations	Script
Severe Immediate Allergic Reactions	See recommendation in Table 1: Recommendations for 12+ Vaccination.	• See script in Table 1: Recommendations for 12+ Vaccination
SARS-CoV-2 (COVID-19) Infection Current or Previous	• Children aged 5-11 years with a history of previous SARS-CoV-2 infection (confirmed by PCR or antigen testing from a respiratory specimen) should no longer be considered infectious based on current criteria, and symptoms of an acute illness should be completely resolved prior to vaccination. • Consistent with current recommendations for adolescents and adults with previous infection, two doses of a COVID-19 vaccine may be offered to children with a previous history of SARS-CoV-2 infection. NACI November 19, 2021 https://www.canada.ca/content/dam/phac-aspc/documents/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-covid-19-vaccines/pfizer-biontech-10-mcg-children-5-11-years-age/pfizer-biontech-10-mcg-children-5-11-years-age.pdf	• Individuals should wait to receive a vaccine until they no longer have acute symptoms of COVID-19 and are no longer infectious to others.
Intervals between COVID-19 and other vaccines	**In Saskatchewan, for those 5 to 11 years old**, Health Canada approved COVID-19 vaccines can be given concomitantly with other vaccines; no intervals are required before or after COVID-19 vaccine administration.	• **For those 5 to 11 years**, COVID-19 vaccines may be given at the same time as other non-COVID-19 vaccines.
Optimal interval between first and second doses	• For those 5 years and older, NACI recommends that an 8 week interval is optimal between first and second doses but the minimum interval of 21 days will still be provided if people choose the shorter interval. NACI November 19, 2021 https://www.canada.ca/content/dam/phac-aspc/documents/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-covid-19-vaccines/pfizer-biontech-10-mcg-children-5-11-years-age/pfizer-biontech-10-mcg-children-5-11-years-age.pdf	• A longer interval between first and second doses results in a stronger, more robust and durable immune response in adult studies and may reduce the risk of myocarditis/pericarditis following the second dose.
Second Dose for 11 Year Old if Started with 12+ Formulation	• Give vaccine appropriate for age at time of second dose, regardless of initial dose received: ○ For individuals who received the 12+ vaccine as a first dose and are still 11 when they present for their second dose, complete the series with the pediatric vaccine formulation.	• It is recommended to complete the series with the authorized vaccine for the age group at time of presentation.
Myocarditis and/or Pericarditis	• As a precautionary measure, and consistent with current recommendations for adolescents and adults, the second dose in the mRNA COVID-19 vaccination series should be deferred in children who experience myocarditis or pericarditis following the first dose of the Pfizer-BioNTech COVID-19 vaccine until more information is available. • Children who have a history of myocarditis unrelated to mRNA COVID-19 vaccination should consult their clinical team for individual considerations and recommendations. If they are no longer being followed clinically for cardiac issues, they may receive the vaccine. • Rare cases of myocarditis and/or pericarditis have been reported following administration of the Pfizer-BioNTech vaccine (30 mcg dose) in adolescents and young adults 12 years of age and older, most commonly after dose 2 and in males.	• As a precautionary measure, due to very rare reports of myocarditis (inflammation of the heart) and/or pericarditis (inflammation of the outer lining of the heart), children who experience these conditions after the first dose should wait to receive the second dose until more information is available. • Children with a history of myocarditis/pericarditis unrelated to vaccine should discuss

Condition	Recommendations	Script
	• It is unknown whether myocarditis/pericarditis will occur after the lower doses of mRNA present within pediatric COVID-19 vaccines for children 5-11 years of age. The Pfizer pediatric clinical trials did not have cases of myocarditis and/or pericarditis. NACI November 19, 2021 https://www.canada.ca/content/dam/phac-aspc/documents/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-covid-19-vaccines/pfizer-biontech-10-mcg-children-5-11-years-age/pfizer-biontech-10-mcg-children-5-11-years-age.pdf	immunization with their clinical team prior to receiving the vaccine. However, if they are no longer receiving active care, they may receive the vaccine.
Multisystem Inflammatory Syndrome in Children (MIS-C)	• For children with a previous history of MIS-C, vaccination with COVID-19 vaccine should be postponed until clinical recovery has been achieved or until it has been ≥ 90 days since diagnosis, whichever is longer. NACI November 19, 2021 https://www.canada.ca/content/dam/phac-aspc/documents/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-covid-19-vaccines/pfizer-biontech-10-mcg-children-5-11-years-age/pfizer-biontech-10-mcg-children-5-11-years-age.pdf	• For children with a previous history of MIS-C, COVID-19 vaccination should be postponed until clinical recovery has been achieved or until it has been ≥ 90 days since diagnosis, whichever is longer.
Treatment with COVID19 Monoclonal Antibodies or Convalescent Plasma	See recommendation in Table 1: Recommendations for 12+ Vaccination.	See script in Table 1: Recommendations for 12+ Vaccination
Immunocompromised (excluding cancer/oncology patients)	See recommendation in Table 1: Recommendations for 12+ Vaccination.	See script in Table 1: Recommendations for 12+ Vaccination
Immunocompromised-Cancer/Oncology Patients	See recommendation in Table 1: Recommendations for 12+ Vaccination.	See script in Table 1: Recommendations for 12+ Vaccination
Autoimmune Conditions (excluding Multiple Sclerosis patients)	See recommendation in Table 1: Recommendations for 12+ Vaccination.	See script in Table 1: Recommendations for 12+ Vaccination
Tuberculin (TB) Skin Test or TB Blood Work (IGRA)	See recommendation in Table 1: Recommendations for 12+ Vaccination.	See script in Table 1: Recommendations for 12+ Vaccination

References

1. Cohn A, Mbaeyi S. What clinicians need to know about the Pfizer-BioNTech COVID-19 vaccine. Centers for Disease Control and Prevention (CDC). 2020.
2. NACI October 22, 2021 https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-covid-19-vaccines.html
3. American Autoimmune Related Disease Ltd. https://www.aarda.org/diseaselist/
4. Centers for Disease Control: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html

Common Auto Immune Conditions*[1]

*This is not an exhaustive list

Addison's	Guillain-Barre syndrome	Optic Neuritis
Alopecia areata	Hashimoto's thyroiditis	Psoriasis
Amyloidosis	Hemolytic anemia	Psoriatic arthritis
Ankylosing spondylitis	Henoch-Schonlein purpura	Raynaud's syndrome
Celiac disease	Juvenile arthritis	Restless legs syndrome
Crohn's disease	Kawasaki disease	Rheumatoid arthritis
Diabetes (type 1)	Lupus	Sarcoidosis
Endometriosis	Meniere's disease	Scleroderma
Erythema nodosum	Multiple Sclerosis	Thrombocytopenic purpura
Fibromyalgia	Myasthenia gravis	Ulcerative Colitis
Graves' disease	Neutropenia	

[1]list obtained American Autoimmune Related Disease Ltd. https://www.aarda.org/diseaselist/