NOTE: Refer to the Saskatchewan Immunization Manual (SIM) Chapter 10 Biological Products for additional COVID-19 vaccine information. Refer to the Canadian Immunization Guide for additional information on contraindications and precautions.

Table 1: Recommendations for Individuals 6 Months and Older

- History of Severe Immediate Allergic Reactions to a Previous COVID-19 Vaccine Dose
- Recent COVID-19 Infection
- Multisystem Inflammatory Syndrome in Adults (MIS-A) and Children (MIS-C)
- History of Myocarditis and/or Pericarditis Following COVID-19 Vaccination

Appendix A- List of moderately to severely immunocompromising conditions and autoimmune conditions

Appendix B- Summary of immunocompromising and autoimmune conditions and timing of vaccination

Table 1: Recommendations for Individuals 6 Months and Older

Condition	Recommendations
History of Severe Immediate Allergic Reactions to a Previous COVID-19 Vaccine Dose	• **History of an anaphylactic reaction to a dose of mRNA COVID-19 vaccine is generally a contraindication to receipt of further doses of mRNA-type COVID-19 vaccines.** • Consultation with an allergist-immunologist is recommended to provide expert evaluation of the original allergic reaction as studies have shown that individuals with a severe immediate allergic reaction after a previous dose of mRNA vaccine can be re-vaccinated with the same vaccine or another mRNA COVID-19 vaccine following an appropriate medical assessment. In these studies, re-vaccination was safe and well tolerated with predominantly no, or mild, reactions after re-vaccination when provided in a controlled environment. Available evidence also suggests that most of the reported severe immediate allergic reactions following mRNA COVID-19 vaccines are likely not immunoglobulin E (IgE)-mediated and therefore have a low risk of recurrence following future vaccine doses. • 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 an mRNA platform if a risk assessment deems that the benefits outweigh the potential risks for the individual and informed consent is obtained. • In individuals with a history of a severe, immediate (≤4h following vaccination) allergic reaction (e.g., anaphylaxis) after previous administration of a **non-mRNA** 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 informed consent is obtained. • 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.
Recent COVID-19 Infection	• Previously immunized individuals with any immune competency status **may consider** delaying immunization by 3 months from recent symptom onset or positive test. T**hey may be immunized sooner (i.e., feeling better) if they choose.** • Individuals receiving a primary series should delay immunization following illness for: o at least 8 weeks for non-immunocompromised individuals. o at least 4 to 8 weeks for moderately to severely immunocompromised individuals.
Multisystem Inflammatory Syndrome	Individuals with a history of multisystem inflammatory syndrome in adults (MIS-A) or children (MIS-C) should wait to be vaccinated until: 1. Clinical recovery has been achieved, including return to baseline cardiac function; and 2. It has been at least 90 days after the diagnosis of MIS-C or MIS-A
History of Myocarditis and/or Pericarditis Following Immunization	For individuals who experienced myocarditis (with or without pericarditis) within 6 weeks of receiving a previous dose: • Further doses of mRNA COVID-19 vaccines should be deferred in most circumstances as a precautionary measure until further recommendations are available. 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. • 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 another dose should be made in consultation with the individual's physician (cardiologist if possible) with the patient's informed consent.

Condition	Recommendations

	• For individuals who experienced pericarditis following immunization and who either had no cardiac workup or had normal cardiac investigations:
	  ○ Can receive the next dose(s) once they are symptom free and at least 90 days have passed since previous vaccination.
	  ○ For individuals with history of myocarditis or pericarditis following mRNA COVID-19 vaccine who choose or are recommended by their specialist to receive another dose of an mRNA COVID-19 vaccine:
	  ▪ Should discuss the risks and benefits of receiving an additional dose with their health care provider.
	  ▪ Should wait at least until their episode of myocarditis or pericarditis has completely resolved. This includes resolution of symptoms 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.
	• Informed consent should include:
	  ○ discussion about the unknown risk of recurrence of myocarditis and/or pericarditis following receipt of additional doses of COVID-19 vaccine in individuals with a history of confirmed myocarditis and/or pericarditis after a previous dose of mRNA COVID-19 vaccine.
	  ○ the need to seek immediate medical assessment and care should symptoms develop.

Appendix A

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the vaccine. Moderately to severely immunocompromised includes individuals with the following conditions:

- Immunocompromised due to solid tumour or hematologic malignancies or treatments for these conditions
- Solid-organ transplant and taking immunosuppressive therapy
- Hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy)
- Immunocompromised due to chimeric antigen receptor (CAR) T cell therapy targeting lymphocytes
- Moderate to severe primary immunodeficiency with associated humoral and/or cell-mediated immunodeficiency or immune dysregulation
- HIV with AIDS-defining illness or TB diagnosis in last 12 months before starting vaccine series, or severe immune compromise with CD4<200 cells/µL or CD4%<15%, or without HIV viral suppression
- Recent treatment with the following categories of immunosuppressive therapies: anti-B cell therapies (monoclonal antibodies targeting CD19, CD20 and CD22), high-dose systemic corticosteroids, alkylating agents, antimetabolites, or tumor-necrosis factor (TNF) inhibitors and other biologic agents that are significantly immunosuppressive
- Chronic kidney disease on dialysis
- Source: https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-4-active-vaccines/page-26-covid-19-vaccine.html#a6.4.considerations

Common Autoimmune Conditions*[1]

*This is not an exhaustive list

Addison's disease	Guillain-Barre syndrome	Optic neuritis
Alopecia areata	Hashimoto's thyroiditis	Psoriasis
Amyloidosis	Hemolytic anemia	Psoriatic arthritis
Ankylosing spondylitis	Henoch-Schonlein purpura	Raynaud's phenomenon
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]Source: Autoimmune Association https://autoimmune.org/disease-information/

Appendix B - Health Condition Precautions and Recommendations

Health Condition	Recommendations

Immunocompromised See list of conditions in **Appendix A**	• It is preferred that clients on immunosuppressive therapy discuss the timing between their therapy and receiving recommended vaccine doses with their health care provider. Refer to SIM Chapter 10 2024-25 COVID-19 Immunization Schedules for intervals.
	• **For clients who have not discussed vaccination with their healthcare provider:**
	  ○ If their condition is unstable, consult with the area MHO.
	  ○ If their condition is stable, proceed with their informed consent.

(HSCT) Blood and Bone Marrow Stem Cell Transplant (autologous or allogeneic)	• **Patients MUST talk with their oncology team prior to vaccine administration.**
	• **Refer to SIM Chapter 7 Appendix 7.6**
	• **Pre-transplant**
	  ○ If feasible, a vaccine series should be administered at least 4 weeks prior to starting conditioning regimen for their transplant.
	• **Post- transplant**
	  ○ Postpone vaccination in severe, uncontrolled acute GVHD, Grade 3-4.
	  ○ For previously immunized or unimmunized HSCT recipients, immunization can begin at 4 months post transplant (3 months post autologous transplant for patients who will be started on maintenance therapy post transplant).
	  ○ Vaccinated HSCT recipients should receive a booster dose 3 months after their previous vaccine dose.
	  ○ HSCT recipients with previous COVID-19 infection should defer vaccination for 3 months post-infection.
	• The HSCT transplant program will provide a letter for recipients to take into their immunizer when they are eligible to start their COVID vaccination series with schedule to return in 4 weeks, 8 weeks, then 3 months for booster.

Solid Organ Transplant NOTE: Medically stable adult SOT recipients followed by the Saskatchewan Transplant Program DO NOT NEED to consult their specialist prior to immunization with COVID-19 vaccines and have provided these recommendations:	• **Pre-transplant – Refer to SIM Chapter 7 Appendix 7.9**
	  ○ **Unvaccinated SOT candidates** should receive 3 doses (using min. 4-week intervals) of mRNA vaccine as a primary series, with the final dose given 1-2 weeks prior to transplantation whenever possible.
	  ○ If indicated, an additional dose given 3 months after their last vaccine dose may be recommended by the Transplant Program.
	• **Post-transplant – Refer to SIM Chapter 7 Appendix 7.10**
	  ○ **Unvaccinated SOT recipients** should receive 3 doses (using min. 4-week intervals) of mRNA vaccine as a primary series. If indicated, an additional dose given 3 months after their last vaccine dose may be recommended by the Transplant Program.
	  ○ **Vaccinated SOT recipients** should receive an additional dose given 3 months after their previous vaccine dose as recommended by the Transplant Program.
	  ○ All SOT recipients should wait at least 1-month post-transplant to continue vaccine series, regardless of induction therapy.
	  ○ SOT recipients undergoing active treatment for acute rejection should defer vaccination for 1 month.
	  ○ SOT recipients who have received rituximab should defer vaccination for at least 3 months.
	  ○ SOT recipients with previous COVID-19 infection should defer vaccination for 3 months post-infection.
	• The SK Transplant Program will provide a letter for recipients to take into their immunizer when they are eligible for their first dose, and it will specify that the recipient return for a second dose 3 months later.

<table>
<tr><td>T-cell Directed Therapy Agents</td><td>
<table>
<tr><td>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)
• Alemtuzumab</td><td>• Vaccination should be postponed until 3 months after T- cell directed treatment due to decreased ability to develop immunity to COVID-19 vaccination.</td></tr>
</table>
</td></tr>
<tr><td>All clients with current cancer diagnosis</td><td>
• It is preferred that all other clients with cancer discuss the vaccine with their healthcare provider prior to presenting.
• For clients who have not discussed vaccination with their healthcare provider:
○ If their condition is unstable, consult with the area MHO
○ If their condition is stable, proceed based on client's therapy (see below) with their informed consent.
<table>
<tr><th>Type of cancer therapy</th><th>Timing of Vaccination</th></tr>
<tr><td>Targeted hormonal and single agent immune therapy treatments</td><td>Vaccine can be administered at any time during treatment.</td></tr>
<tr><td>Radiation therapy</td><td>Vaccine can be administered at any time during radiation therapy.</td></tr>
<tr><td>Cytotoxic chemotherapy</td><td>New treatment:
• If possible, vaccination should be completed at least two weeks prior to starting systemic therapy or immunosuppressive therapy.
• If two doses are needed, both doses cannot be given prior to starting treatment, 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</td></tr>
<tr><td>B-cell directed therapy
• Anti-CD20 (rituximab, obinutuzimab)
• Anti-CD19 (blinatumomab)
• Anti-CD22 (inotuzumab)
• BTK inhibitors (ibrutinib)</td><td>• If therapy is of short duration (limited number of cycles), vaccination should be postponed until 1-3 months after anti-CD20, anti-CD19, and anti-CD22 directed treatment due to decreased immune response.
• If therapy is part of a maintenance treatment, vaccination should be given 4 weeks after the last dose of therapy.
• Patients on BTK inhibitors (ibrutinib) can receive vaccination at any time.</td></tr>
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</td></tr>
<tr><td>Autoimmune conditions
See list of conditions in Appendix A</td><td>
• 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.
• For clients with immune suppression it is preferred they discuss the vaccine with their healthcare provider prior to presenting. However, for clients who have not discussed vaccination with their healthcare provider:
○ If their condition is unstable, consult with the area MHO.
○ If their condition is stable, proceed with their informed consent.
</td></tr>
</table>

Multiple Sclerosis (MS)

- It is preferred that clients with Multiple Sclerosis (MS) discuss the vaccine with their healthcare provider prior to presenting.
- **For clients who have not discussed vaccination with their healthcare provider:**
  - If their condition is unstable, consult with the area MHO.
  - If their condition is stable, proceed based on type of therapy (see below) with their informed consent.

Disease Modifying Therapy	Effect on Vaccination	Delay of vaccination after treatment*	Delay of treatment after vaccination*
• Glatiramer acetate (any type) • Interferon-beta (any type) • Teriflunomide • Dimethyl fumarate (or any type of fumaric acid ester) • Natalizumab	Little to no effect	None required	None required
• Fingolimod • Ozanimod • Ponesimod • Siponimod	May have a modest decrease in vaccine effectiveness	None required	2 weeks for treatment initiation. No delay for treatment continuation
• Rituximab and • Ocrelizumab • Ofatumumab	May have a more pronounced decrease in vaccine effectiveness	None required	2 weeks
• Cladribine	Unlikely to affect vaccine response after immune reconstitution has taken place	None required	2-4 weeks
• Alemtuzumab	May have a modest decrease in vaccine effectiveness	24 weeks	2-4 weeks

***Recommended timing.**

Canadian source: CNMSC US source: National MS Society