COVID–19 VACCINE CONTRAINDICATIONS & PRECAUTIONS BACKGROUND DOCUMENT 2024-04-04

NOTE: This document is for Healthcare Professionals to assess clients with the following conditions. **Table 1** has recommendations for ages 12+. **Table 2** has recommendations for pediatric 5-11 years. **Table 3** has recommendations for young pediatric 6 months to 4 years. Also refer to the Canadian Immunization Guide for additional information on contraindications and precautions.

Refer to the Saskatchewan Immunization Manual (SIM) Chapter 10 Biological Products for additional COVID-19 vaccine information.

Table 1: Recommendations for Age 12+ Years (Moderna Spikevax™ XBB.1.5 Royal Blue Cap/Coral Blue Label 50 mcg/0.5 ml; Pfizer Comirnaty® XBB.1.5 Grey Cap/Border Label 30 mcg/0.3 ml; and Novavax Nuvaxovid™ XBB.1.5 5 mcg/0.5 ml)

- Severe Immediate Allergic Reactions
- Concurrent Illness
- SARS-CoV-2 (COVID-19) Infection Current or Previous
- Additional XBB.1.5 Dose Eligibility
- Treatment with COVID-19 Monoclonal Antibodies or Convalescent Plasma
- Thrombocytopenia and bleeding disorders
- Immunocompromised Individuals & Autoimmune Conditions
- History of Myocarditis and/or Pericarditis following COVID-19 vaccination

Table 2: Recommendations for Age 5 to 11 Years (Moderna Spikevax™ XBB.1.5 Royal Blue Cap/Coral Blue Label 25 mcg/0.25 mL; Pfizer Comirnaty® XBB.1.5 Blue Cap/Border Label 10 mcg/0.3 ml)

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Table 3: Recommendations for 6 months to 4 Years (Moderna Spikevax™ XBB.1.5 Royal Blue Cap/Coral Blue Label 25 mcg/0.25 mL; Pfizer Comirnaty® XBB.1.5 Maroon Cap/Border Label 3 mcg/0.2 ml)

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- History of Myocarditis and/or Pericarditis

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 Age 12+ Years (Moderna Spikevax™ XBB.1.5 Royal Blue Cap/Coral Blue Label 50 mcg/0.5 ml; Pfizer Comirnaty® XBB.1.5 Grey Cap/Border Label 30 mcg/0.3 ml; and Novavax Nuvaxovid™ XBB.1.5 5 mcg/0.5 ml)

Condition	Recommendations

History of Severe Immediate Allergic Reactions to previous COVID-19 vaccine dose	• 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 using 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 re-vaccination.
	  ○ 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 where consultation with an allergist or other appropriate physician precludes further vaccination with an mRNA vaccine, vaccination with Novavax Nuvaxovid should be offered if the individual is in the authorized age group and does not have contraindications to the vaccine. They should also be observed for an extended period of at least 30 minutes after re-vaccination.
	• 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 if informed consent is provided. If re-vaccinated, 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 or polyethylene glycol (PEG) should be offered a vaccine that does not contain these excipients.

Concurrent Illness	• Administration should be postponed in individuals suffering from acute severe febrile illness.
SARS-CoV-2 (COVID-19) Infection Current or Previous	• A 6-month interval (minimum 3 months) is recommended between infection and an XBB.1.5 dose. More time between infection and vaccination ensures a strong immune response. • **For the purposes of vaccinating long term care facility, personal care home and other senior congregate living facility (i.e. assisted living residents),** XBB.1.5 vaccine can be administered **less than 3** months after the last non-XBB.1.5 vaccine dose. • Table 5 of the CIG COVID-19 chapter provides other interval guidelines: (https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-4-active-vaccines/page-26-covid-19-vaccine.html#a6.2). • Individuals presenting for immunization do not need to be tested for previous COVID-19 infection. • Immunization of individuals who may be currently infected with SARS-CoV-2 is not known to have a detrimental effect on the illness.
Additional XBB.1.5 Dose Eligibility	• Refer to Additional XBB.1.5 COVID-19 Vaccine Dose Eligibility in SIM Chapter 10
Thrombocytopenia and bleeding disorders	• Individuals receiving anticoagulant therapy or those with a bleeding disorder that would contraindicate intramuscular injection should not be given the vaccine unless the potential benefit clearly outweighs the risk of administration.
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, COVID-19 vaccination does not need to be delayed. COVID-19 vaccine can be given at any time before, during or after treatment.
Immunocompromised & Autoimmune conditions (includes cancer and MS)	• Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the vaccine. • COVID-19 vaccine should be offered to individuals in the eligible group who are immunosuppressed due to disease or treatment and those with an auto-immune condition. • Refer to list of conditions in **Appendix A**. • See **Appendix B** for recommendations, including timing of vaccination, based on health condition.

Condition	Recommendations
History of myocarditis and/or pericarditis following immunization	• See **Appendix B** for recommendations.

Table 2: Recommendations for Age 5 to 11 Years (Moderna Spikevax™ XBB.1.5 Royal Blue Cap/Coral Blue Label 25 mcg/0.25 mL; Pfizer Comirnaty® XBB.1.5 Blue Cap/Border Label 10 mcg/0.3 ml)

Condition	Recommendations
Severe Immediate Allergic Reactions	See recommendation in Table 1: Recommendations for 12+ Years
Concurrent Illness	See recommendation in Table 1: Recommendations for 12+ Years
SARS-CoV-2 (COVID-19) Infection Current or Previous	See recommendation in Table 1: Recommendations for 12+ Years
Additional XBB.1.5 Dose Eligibility	Refer to Additional XBB.1.5 COVID-19 Vaccine Dose Eligibility in SIM Chapter 10
Thrombocytopenia and bleeding disorders	See recommendation in Table 1: Recommendations for 12+ Years
Treatment with COVID-19 Monoclonal Antibodies or Convalescent Plasma	See recommendation in Table 1: Recommendations for 12+ Years
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.
Immunocompromised & Autoimmune conditions (includes cancer and MS)	• Refer to list of conditions in **Appendix A**. • See **Appendix B** for recommendations, including timing of vaccination, based on health condition.
History of 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 a mRNA 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.

Table 3: Recommendations for 6 months to 4 Years (Moderna Spikevax™ XBB.1.5 Royal Blue Cap/Coral Blue Label 25 mcg/0.25 mL; Pfizer Comirnaty® XBB.1.5 Maroon Cap/Border Label 3 mcg/0.2 ml)

Condition	Recommendations
Severe Immediate Allergic Reactions	See recommendation in Table 1: Recommendations for 12+ Years
Concurrent Illness	See recommendation in Table 1: Recommendations for 12+ Years
SARS-CoV-2 (COVID-19) Infection Current or Previous	See recommendation in Table 1: Recommendations for 12+ Years
Additional XBB.1.5 Dose Eligibility	Refer to Additional XBB.1.5 COVID-19 Vaccine Dose Eligibility in SIM Chapter 10
Thrombocytopenia and bleeding disorders	See recommendation in Table 1: Recommendations for 12+ Years
Treatment with COVID-19 Monoclonal Antibodies or Convalescent Plasma	See recommendation in Table 1: Recommendations for 12+ Years
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.
Immunocompromised & Autoimmune conditions (includes cancer and MS)	• Refer to list of conditions in **Appendix A**. • See **Appendix B** for recommendations, including timing of vaccination, based on health condition.
History of 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 a mRNA 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.

Appendix A

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/uL 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 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/

Appendix B - Health Condition Precautions and Recommendations

Health Condition	Recommendations
Immunocompromised (also see Oncology section)	

Immunocompromised
• See list of conditions in **Appendix A**
• See below for specific conditions
	• Either an mRNA or protein subunit COVID-19 XBB.1.5 vaccine can be used in unvaccinated or previously vaccinated individuals who do not have contraindications to the vaccine.
	  ○ From NACI (2024-03-08:) "*Due to lower overall usage to date, there is less data available about the protein subunit platform compared to the mRNA platform for COVID-19 vaccines, particularly for people who are pregnant or who are immunocompromised. Additional evidence on the use of protein subunit COVID-19 vaccines is expected to accumulate over time*".
	• 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.
	• **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.**
	• **Pre-transplant**
	  ○ If feasible, an XBB 1.5 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, vaccination with XBB 1.5 vaccine 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	• 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:**
	  ○ **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**:
	  ○ **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.

Oncology	

<table>
<tr><td>Cancer survivors</td><td>• 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</td></tr>
<tr><td>(HSCT) Blood and Bone Marrow Stem Cell Transplant (autologous or allogeneic)</td><td>• Refer to the Immunocompromised section above.</td></tr>
<tr><td>All clients with current cancer diagnosis</td><td>• It is preferred that <u>all other clients with cancer</u> discuss the vaccine with their healthcare provider prior to presenting.
• For clients who have not discussed vaccination with their healthcare provider:
o If their condition is unstable, consult with the area MHO
o 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><u>Targeted Hormonal and single agent immune therapy treatments</u></td><td>Vaccine can be administered at any time during treatment.</td></tr>
<tr><td><u>Radiation therapy</u></td><td>Vaccine can be administered at any time during radiation therapy</td></tr>
<tr><td><u>Cytotoxic chemotherapy</u></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><u>B-Cell directed therapy</u>
• Anti CD 20 (rituximab, obinotuzimab)
• CD 19 – (blinatumomab)
• CD 22 antibodies (inotuzumab)
• BTK inhibitors (ibrutinib)</td><td>• Patients on BTK inhibitors (ibrutinib) can receive vaccination at any time.
• 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.
• 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>
<tr><td><u>T-Cell directed therapy</u>
• 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 colspan="2">Autoimmune conditions</td></tr>
<tr><td>Autoimmune conditions
- List of conditions in Appendix A</td><td>• For any autoimmune condition that involves the neurological system:
o 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.</td></tr>
</table>

<table>
<tr><td>- Also see MS section below</td><td>

Clients receiving ongoing treatment with <u>Rituximab</u> 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>
<tr><td>Multiple Sclerosis (MS)</td><td>

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.

<table>
<tr><th>Disease Modifying Therapy</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 <u>initiation</u>; 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 period after a treatment dose during which vaccine should not be administered.
**The period after a vaccination series (i.e. all doses) during which treatment should not be (re)started.
</td></tr>
<tr><td>Age 12+ years: History of myocarditis and/or pericarditis after COVID-19 immunization</td><td>

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 (NACI). 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.

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

	• For individuals who experienced **pericarditis** following immunization and who either had no cardiac workup or had normal cardiac investigations:
	  o Can receive the next dose(s) once they are symptom free **and** least 90 days has 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:**
	  o Should discuss the risks and benefits of receiving an additional dose with their health care provider.
	  o 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.
	  o 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.