

COVID-19 Vaccine – Novavax XBB.1.5 (NUVAXOVID)

Recombinant protein, adjuvanted

12 years of age and older

Implementation Date: April 15, 2024

Rationale for Update:

- Includes indications for an additional COVID-19 XBB.1.5 vaccine dose for eligible individuals.
- Decrease from two-dose series to single dose for unimmunized individuals who are not moderately to severely immunocompromised.
- Three-dose series for unimmunized post-hematopoietic stem cell transplant (HSCT) and/or chimeric antigen receptor (CAR) T-cell therapy recipients.

This policy is evergreen and will be updated as new information becomes available.

Please consult the Product Monograph ⁽¹⁾ for further information about the vaccines.	
Novavax COVID-19 Vaccine (Nuvaxovid)	
Manufacturer	Novavax
Licensed use	<ul style="list-style-type: none">• Single dose for individuals 12 years of age and older who have previously completed a COVID-19 vaccine series.⁽¹⁾• Two-dose series for unimmunized individuals 12 years of age and older.⁽¹⁾
Off-license use	<ul style="list-style-type: none">• An interval of less than 6 months from a previous dose for individuals 12 years of age and older who previously received a COVID-19 vaccine series.• Second or third doses for individuals who are moderately to severely immunocompromised.• Three-dose series for unimmunized post-hematopoietic stem cell transplant (HSCT) and/or chimeric antigen receptor (CAR) T-cell therapy recipients.• Single dose for unimmunized individuals who are not moderately to severely immunocompromised.• Additional XBB.1.5 COVID-19 vaccine dose for eligible individuals.
Indications for use	<ul style="list-style-type: none">• Individuals 12 years of age and older.
Dose	0.5mL (5 mcg) ⁽¹⁾
Route	Intramuscular injection ⁽¹⁾

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<p>Schedule See below schedule for individuals with certain immunocompromising conditions</p>	<p>Individuals 12 years of age and older</p> <p><u>Previously Unimmunized:</u></p> <ul style="list-style-type: none"> ❖ One dose⁽²⁾ <p><u>Previously received 1 or more doses of non-XBB.1.5 COVID-19 vaccine:</u></p> <ul style="list-style-type: none"> ❖ One dose, at least 3 months from previous non-XBB.1.5 vaccine dose, regardless of the number of doses received in this past. <p>Note:</p> <ul style="list-style-type: none"> • As of April 15, 2024, unimmunized individuals only require a single dose of Novavax XBB.1.5 COVID-19 vaccine to have a complete COVID-19 vaccine series.⁽²⁾ <ul style="list-style-type: none"> ○ This takes into account high levels of seroprevalence in the population due to COVID-19 infection.⁽³⁾
<p>Additional XBB.1.5 COVID-19 vaccine dose</p>	<ul style="list-style-type: none"> • Starting April 15, 2024, the following individuals who are at increased risk of severe illness from COVID-19 may receive an additional dose of Novavax XBB.1.5 COVID-19 vaccine: <ul style="list-style-type: none"> ○ Individuals 65 years of age and older⁽⁴⁾ ○ Adults 18 years of age and older who reside in seniors congregate care living settings.⁽⁴⁾ ○ Individuals 12 years of age and older who have certain moderate to severe immunocompromising conditions⁽⁴⁾ ○ First Nations, Métis, and Inuit individuals who are 12 years of age and older, including First Nations on and off reserve⁽⁵⁾ ❖ One dose, at least 6 months from previous XBB.1.5 COVID-19 vaccine dose.⁽⁴⁾ However, a shorter interval of 3 months may be used in senior congregate care settings.⁽⁵⁾
<p>Schedule for individuals with certain moderate to severe immunocompromising conditions</p>	<p>Individuals 12 years of age and older:</p> <ul style="list-style-type: none"> • It is recommended that all immunocompromised individuals receive mRNA XBB.1.5 COVID-19 vaccine as there is less data available about the Novavax XBB.1.5 COVID-19 vaccine compared to mRNA COVID-19 vaccines in this population. However, Novavax XBB.1.5 COVID-19 vaccine can be offered to individuals if requested. <p><u>Previously Unimmunized:</u> (see section below for post-HSCT and/or CAR T-cell therapy recipients)</p> <ul style="list-style-type: none"> ❖ Dose 1: day 0 ❖ Dose 2: at least 8 weeks after dose 1; however, a minimum interval of 4 weeks may be considered. <p><u>Unimmunized post-HSCT and/or CAR T-cell therapy recipients:</u>⁽³⁾</p> <ul style="list-style-type: none"> ❖ Dose 1: day 0 ❖ Dose 2: 28 days after dose 1 ❖ Dose 3: 8 weeks after dose 2; however, a minimum interval of 4 weeks may be considered.

Previously received one or two doses of non-XBB.1.5 COVID-19 vaccine dose(s):^(2,6)

- If an individual has received one or two non-XBB.1.5 COVID-19 vaccine doses, the previous dose(s) should be counted, and the series should not be restarted.
 - ❖ Dose 1: day 0
 - ❖ Dose 2: 28 days after dose 1
 - ❖ Dose 3: 8 weeks after dose 2; however, a minimum interval of 4 weeks may be considered.

This information is also outlined in [Table 2](#).

Previously received 3 or more doses of non-XBB.1.5 COVID-19 vaccine:

- ❖ 1 dose, at least 3 months from previous dose.

Note:

- There are no data available on the interchangeability of Novavax XBB.1.5 with other COVID-19 vaccines to complete a series.⁽¹⁾
 - Evidence from original COVID-19 vaccines indicates that a mixed schedule that included original Novavax demonstrated acceptable safety profiles.⁽²⁾ It is not unreasonable to expect a similar safety profile for a mixed schedule which includes Novavax XBB.1.5 COVID-19 vaccine.
 - Based on evidence from original COVID-19 vaccines, a mixed schedule including Novavax may not be as immunogenic as continuing with an mRNA vaccine.⁽²⁾
- With non-XBB.1.5 COVID-19 vaccine formulations, the immune response was somewhat better with longer intervals between vaccine doses.⁽²⁾ It is reasonable to assume that this would also apply to Novavax XBB.1.5 COVID-19 vaccine.
- Specific immunocompromising conditions that make an individual eligible for a COVID-19 vaccine series:⁽²⁾
 - Solid organ transplant recipients – pre-transplant and post-transplant
 - Hematopoietic stem cell transplant recipients – pre-transplant and post-transplant while in immunosuppressed state and individuals receiving Chimeric Antigen Receptor T-Cell therapy (CAR T-cell therapy). See:
 - [Principles of Immunization in Hematopoietic Stem Cell Transplant and Solid Organ Transplant Recipients](#)
 - [Child HSCT](#)
 - [Adult HSCT](#)
 - Individuals with malignant hematologic disorders and non-hematologic malignant solid tumors prior to receiving or while receiving active treatment which includes chemotherapy, targeted therapies, and immunotherapy or having received previous COVID-19 vaccines while on active treatment (does not include individuals receiving solely hormonal therapy, radiation therapy or a surgical intervention).
 - Individuals with chronic kidney disease on peritoneal dialysis or hemodialysis.

	<ul style="list-style-type: none"> ○ Individuals on: <ul style="list-style-type: none"> ▪ long term high-dose systemic steroid treatment (prednisone equivalent of ≥ 2 mg/kg/day or 20 mg/day if weight > 10 kg, for ≥ 14 days), or ▪ alkylating agents, or ▪ Individuals on anti-B-cell therapies – including anti-CD19, anti-CD20, anti-CD22 and anti-CD52 monoclonal antibodies (such as rituximab, ocrelizumab, and ofatumumab), or ▪ antimetabolites (e.g., methotrexate, azathioprine, mycophenolate), or ▪ tumor-necrosis factor (TNF) inhibitors (e.g., adalimumab, certolizumab, etanercept, golimumab, infliximab), or ▪ other agents that are significantly immunosuppressive at clinicians' discretion ○ HIV-infected individuals without viral suppression or those with acquired immunodeficiency syndrome (AIDS). ○ Individuals with moderate to severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome). ● Documentation of immunocompromising conditions is not required. Individuals who identify themselves as meeting at least one of the criteria above should be offered the appropriate number of COVID-19 vaccine doses that an individual is eligible for. <p>Immunization of immunocompromised individuals should occur at a time when the individual is most likely to mount an immune response. Physician consultation is recommended regarding the timing of immunization (initiation and interval) based on the individual's treatment and unique circumstances.</p>
<p>Additional XBB.1.5 COVID-19 vaccine dose</p>	<ul style="list-style-type: none"> ● Starting April 15, 2024, moderately to severely immunocompromised individuals 12 years of age and older who are at an increased risk of severe illness from COVID-19 may receive an additional dose of XBB.1.5 COVID-19 vaccine: <ul style="list-style-type: none"> ❖ One dose, at least 6 months from previous XBB.1.5 COVID-19 vaccine dose.⁽⁴⁾ However, a shorter interval of 3 months may be used in senior congregate care settings.⁽⁵⁾
<p>Interval between previous COVID-19 infection and COVID-19 immunization</p>	<p>For individuals with a history of COVID-19 infection the following guidance is provided on suggested intervals between infection and COVID-19 immunization.⁽²⁾</p> <p>Note:</p> <ul style="list-style-type: none"> ● These suggested intervals are based on immunological principles and expert opinion, and may change as evidence on COVID-19, variants of concern (VOCs), and COVID-19 vaccines emerge. When considering whether or not to administer vaccine doses following the suggested intervals outlined in this table, biological and social risk factors for exposure (e.g., local epidemiology, circulation of VOCs, living settings) and risk of severe disease should also be taken into account. These intervals are a guide and clinical discretion is advised. Individuals can be immunized at less than the recommended intervals from infection upon request. ● For individuals who have not had any previous doses, they may receive their first dose after acute symptoms of COVID-19 have resolved and they are no longer infectious, or they may follow these suggested intervals (with the exception of those with MIS-C who should wait at least 90 days).

	Infection prior to initiation or completion of a COVID-19 immunization series	Individuals without certain immunocompromising conditions AND no history of multisystem inflammatory syndrome in children (MIS-C)	8 weeks after a positive test.
		Individuals with certain immunocompromising conditions (as listed above) AND no history of MIS-C	4 to 8 weeks after a positive test.
		History of MIS-C (regardless of immunocompromised status)	Receive the vaccine when clinical recovery has been achieved or at least 90 days since the onset of MIS-C, whichever is longer.
	Infection after COVID-19 vaccine series	All individuals	3 months after a positive test.
Contraindications	<ul style="list-style-type: none"> • Known severe hypersensitivity to any component of the vaccine.⁽¹⁾ <ul style="list-style-type: none"> ○ One non-medicinal ingredient in the vaccine that has the potential to cause type 1 hypersensitivity reactions is polysorbate 80. Polysorbate 80 may be found in medication preparations (e.g., vitamin oils, tablets, anticancer agents) and cosmetics. • Anaphylaxis to a previous dose of Novavax COVID-19 vaccine. See COVID-19 Immunization for Individuals with Allergies and Other Health Conditions for recommendations.⁽¹⁾ 		
Precautions	<ul style="list-style-type: none"> • The safety of Novavax XBB.1.5 is inferred from safety data of the original strain administered as a series and as an additional dose.⁽¹⁾ • At the time of authorization, there are no known serious warnings or precautions associated with this product.⁽¹⁾ • Very rare cases of myocarditis and/or pericarditis following immunization with Novavax vaccines have been reported, and available data cannot determine a causal association with Novavax XBB.1.5.⁽¹⁾ • Anyone receiving a Novavax XBB.1.5 COVID-19 vaccine should be informed of the potential risk of myocarditis and pericarditis and advised to seek medical attention if they develop related symptoms including shortness of breath, chest pain, or the feeling of a rapid or abnormal heart rhythm.^(1,2) • Healthcare professionals are advised to consider the possibility of myocarditis and/or pericarditis in their differential diagnosis if individuals present with chest pain, shortness of breath, palpitations or other signs and symptoms of myocarditis and/or pericarditis following immunization with Novavax XBB.1.5 COVID-19 vaccine.^(1,2) • Generally, deferral of COVID-19 immunization is not required for those with a prior history of myocarditis or pericarditis that is unrelated to COVID-19 mRNA or Novavax vaccines. 		

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	<ul style="list-style-type: none"> ○ If these individuals have questions or concerns about their prior history of myocarditis or pericarditis and immunization, it is recommended that individuals consult with their clinician. However, consultation with a clinician is not required to receive COVID-19 vaccines. ● Individuals with a history compatible with pericarditis within 6 weeks of receiving a dose of a Novavax COVID-19 vaccine, who either had no cardiac workup or who had normal cardiac investigations, can be re-immunized when they are symptom free and at least 90 days have passed since previous immunization.⁽²⁾ ● In most circumstances, further doses of Novavax COVID-19 vaccines should be deferred among people who experienced myocarditis (with or without pericarditis) within 6 weeks of receiving a previous dose of a Novavax COVID-19 vaccine.⁽²⁾ <ul style="list-style-type: none"> ○ However, further doses may be offered if individuals with confirmed myocarditis or pericarditis with abnormal cardiac investigation choose to receive another dose of vaccine after discussing the risks and benefits with their clinician. ○ Informed consent should discuss the unknown risk of recurrence of myocarditis and/or pericarditis following additional doses of COVID-19 vaccine in individuals with a history of confirmed myocarditis and/or pericarditis after a previous dose of Novavax COVID-19 vaccine. ○ Individuals who have had a serious allergic reaction to another vaccine, drug or food should talk to their health care provider before receiving the vaccine.⁽²⁾ ● 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.^(1,2) ● Administration should be postponed in individuals suffering from acute severe febrile illness.⁽¹⁾
Pregnancy	<ul style="list-style-type: none"> ● It is recommended that individuals who are pregnant receive mRNA XBB.1.5 COVID-19 vaccine as there is less data available about the Novavax XBB.1.5 COVID-19 vaccine compared to mRNA COVID-19 vaccines in this population. However, Novavax XBB.1.5 COVID-19 vaccine can be offered to individuals if requested. ● The safety and efficacy of Novavax COVID-19 vaccines in pregnant women has not yet been established in clinical trials.⁽¹⁾ However, there is evidence on the safety profile and effectiveness of mRNA COVID-19 vaccines in this population based on real world use with large numbers of individuals. ● Novavax vaccine may be offered to individuals in the eligible group who are pregnant if a risk assessment with their primary health care provider or obstetrician determines that the benefits outweigh the potential risks for the woman and fetus. <ul style="list-style-type: none"> ○ However, the individual may also be immunized without consulting their primary health care provider or obstetrician following their acknowledgment of the absence of evidence on the use of a Novavax COVID-19 vaccine in this population and the preference for an mRNA vaccine due to published effectiveness and safety data.⁽⁷⁾ <p><u>Additional resources:</u></p> <ul style="list-style-type: none"> ● Society of Obstetricians and Gynecologists of Canada Statement on COVID-19 Immunization in Pregnancy

<p>Lactation</p>	<ul style="list-style-type: none"> • It is unknown whether this vaccine is excreted in human milk. A risk to the newborns/infants cannot be excluded.^(1,2) • COVID-19 vaccine is recommended for individuals who are breastfeeding.⁽²⁾ <ul style="list-style-type: none"> ○ It is recommended that individuals consult their primary health care provider or medical specialist for any vaccine related questions or concerns. ○ However, consultation with a primary health care provider or medical specialist is not required to receive COVID-19 vaccine.
<p>Administration with other products</p>	<ul style="list-style-type: none"> • The Novavax XBB.1.5 COVID-19 vaccine may be co-administered with, or at any time before or after other vaccines (including, live, inactivated, adjuvanted, or unadjuvanted vaccines), tuberculin skin tests or IGRA (QFT) tests to individuals 12 years of age and older.⁽²⁾ <ul style="list-style-type: none"> ○ There is a theoretical risk that COVID-19 vaccines may temporarily affect cell-mediated immunity, resulting in false-negative tuberculin skin testing or IGRA (QFT) test results.⁽²⁾ ○ In the absence of data and acknowledging the importance of both timely tuberculosis testing and immunization, immunization with COVID-19 vaccines can take place at any time before, after or at the same visit as the TST or IGRA test.⁽²⁾ ○ However, repeat tuberculin skin testing or IGRA (at least 4 weeks post COVID-19 immunization) of individuals with negative TST or IGRA results for whom there is high suspicion of latent tuberculosis may be considered to avoid missing persons with TB infection.⁽²⁾ • Deferral of COVID-19 immunization is not recommended for individuals who have received anti-SARS-CoV-2 monoclonal antibodies or convalescent plasma provided for treatment or prophylaxis of COVID-19 just because they received these pharmacological interventions. This applies to people who received these before receiving any COVID-19 vaccine dose or between doses. <ul style="list-style-type: none"> ○ A study among nursing home residents and staff demonstrated that recipients of a SARS-CoV-2 monoclonal antibody (bamlanivimab), mounted a robust immune response to mRNA immunization, regardless of age, risk category or vaccine type.⁽⁸⁾ ○ Although antibody response was numerically lower in people who received monoclonal antibodies, they were still considered to be high and the clinical significance of the reduction is unknown.⁽⁸⁾ ○ There was no correlation between interval to COVID-19 immunization and neutralizing titres in recent monoclonal antibody recipients.⁽⁸⁾ ○ Intervals between previous COVID-19 infection and COVID-19 immunization outlined in this document would still apply to individuals who got the monoclonal antibodies or convalescent plasma for their infection. • Individuals who are to receive Evusheld (tixagevimab and cilgavimab) as pre-exposure prophylaxis should wait at least 2 weeks following COVID-19 immunization to minimize interference. <p>Note:</p> <ul style="list-style-type: none"> • Timing of administration and potential interference between COVID-19 vaccine and monoclonal products not used for treatment or prophylaxis of COVID-19 infection are currently unknown and the primary health care provider or medical specialist should be consulted on a case-by-case basis.

	<ul style="list-style-type: none"> • COVID-19 vaccines may be given at any time before or after an immunoglobulin preparation (including Rhlg) or blood product has been administered. There is no recommended minimum interval between these products and COVID-19 vaccine.
<p>Program notes</p>	<ul style="list-style-type: none"> • December 05, 2023 – Licensed for use in Canada. • January 05, 2024 – Implemented in Alberta. • January 29, 2024 – Updated to include CAR T-cell therapy. • April 15, 2024 - Updated to include indications for an additional COVID-19 XBB.1.5 vaccine dose for eligible individuals. Decrease from two-dose series to single dose for unimmunized individuals who are not moderately to severely immunocompromised. Three-dose series for unimmunized post-HSCT and/or CAR T-cell therapy recipients.

References

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