

## COVID-19 Vaccine – Novavax (Nuvaxovid) XBB.1.5 Recombinant protein, Adjuvanted Vaccine

# **Biological Page**

Section 7:	Biological Product Information		Standard #: 07.245	
Created by:	Provincial Immunization Program Standards and Quality			
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	Novavax (Nuvaxovid) XBB.1.5 COVID-19 Vaccine
Manufacturer	Novavax, Inc.
<b>Biological Classification</b>	SARS-CoV-2 recombinant spike protein (Omicron XBB.1.5 strain) adjuvanted with Matrix-M
Indications for Provincially Funded Vaccine	Individuals 12 years of age and older
Preferred Use	N/A
Dose	0.5 mL (5mcg)
Route	IM in the deltoid or vastus lateralis muscle
Schedule for healthy immunocompetent	Individuals 12 years of age and older: <u>Previously unimmunized:</u>
(See below Schedule for	One Dose
individuals with certain	Previously received 1 or more doses of non-XBB.1.5 COVID-19 vaccine:
immunocompromising conditions)	<ul> <li>1 dose, at least 3 months from previous non-XBB.1.5 COVID-19 vaccine dose, regardless of the number of doses received in the past.</li> </ul>
	<ul> <li>Notes:</li> <li>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.         <ul> <li>This takes into account high levels of seroprevalence in the population due to COVID-19 infection.</li> </ul> </li> </ul>
Additional XBB.1.5 COVID- 19 vaccine dose	<ul> <li>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> <li>Individuals 65 years of age and older</li> <li>Adults 18 years of age and older who reside in seniors congregate care living settings.</li> <li>Individuals 12 years of age and older who have certain moderate to severe immunocompromising conditions.</li> <li>First Nations, Métis, and Inuit individuals who are 12 years of age and older, including First Nations on and off reserve.</li> </ul> </li> <li>One dose, at least 6 months from previous XBB.1.5 COVID-19 vaccine dose. However, a shorter interval of 3 months may be used in senior congregate care settings.</li> </ul>
Schedule for individuals with certain moderate to severe immunocompromising conditions	Individuals 12 years of age and older: 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.

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Previously Unimmunized:
Dose 1: day 0
• Dose 2: at least 8 weeks after dose 1; however, a minimum interval of 4 weeks may be considered.
Unimmunized post-HSCT and/or CAR T-cell therapy recipients:
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 1 or 2 doses of non-XBB.1.5 COVID-19 vaccine dose(s): 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.
Previously received 3 or more doses of non-XBB.1.5. COVID-19 vaccine:
1 dose, at least 3 months from previous dose.
Notes:
There are no data available on the interchangeability of Novavax Nuvaxovid XBB.1.5 with other COVID-19 vaccines to complete a series.
<ul> <li>Evidence from the original COVID-19 vaccines indicates that a mixed schedule that included original Novavax (Nuvaxovid) demonstrated acceptable safety profiles. It is not unreasonable to expect a similar safety profile for a mixed schedule which includes Novavax (Nuvaxovid) XBB.1.5 COVID-19 vaccine.</li> </ul>
<ul> <li>Based on evidence from the original COVID-19 vaccines, a mixed schedule including Novavax (Nuvaxovid) may not be as immunogenic as continuing with an mRNA vaccine.</li> </ul>
• With non-XBB COVID-19 vaccine formulations, the immune response was somewhat better with longer intervals between vaccine doses. It is reasonable to assume that this would also apply to Novavax (Nuvaxovid) XBB.1.5 COVID-19 vaccine.
Specific immunocompromising conditions that make an individual eligible for a COVID-19 vaccine series:
Solid organ transplant recipients-pre-transplant and post-transplant.
transplant while in immunosuppressed state and individuals receiving Chimeric Antigen Receptor (CAR) T-Cell therapy. See:
<ul> <li>Standard for Immunization of Transplant Candidates and Recipients</li> </ul>
Child HSCT
<ul> <li>Adult HSCI</li> <li>Individuals with malignant bematologic disorders and non-bematologic</li> </ul>
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).

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	<ul> <li>Individuals with chronic kidney disease on peritoneal dialysis or hemodialysis.</li> </ul>		
	<ul> <li>Individuals on:</li> <li>long term high-dose systemic steroid treatment (prednisone equivalent of ≥ 2 mg/kg/day or 20 mg/day if weight &gt; 10 kg, for ≥ 14 days), or</li> <li>alkylating agents, or</li> </ul>		
	<ul> <li>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</li> </ul>		
	<ul> <li>antimetabolites (e.g., methotrexate, azathioprine, mycophenolate), or</li> <li>tumor-necrosis factor (TNF) inhibitors (e.g., adalimumab, certolizumab, etanercept, golimumab, infliximab), or</li> </ul>		
	<ul> <li>other agents that are significantly immunosuppressive at clinicians discretion</li> <li>HIV-infected individuals without viral suppression or those with acquired</li> </ul>		
	<ul> <li>immunodeficiency syndrome (AIDS).</li> <li>Individuals with moderate to severe primary immunodeficiency (e.g., DiGeorge</li> </ul>		
	syndrome, Wiskott-Aldrich syndrome).		
	<ul> <li>Documentation of immunocomptomising conditions is not required, individuals who identify themselves as meeting at least one of the criteria above should be offered the appropriate number of eligible COVID-19 vaccine doses.</li> </ul>		
	• Immunization for 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.		
Additional XBB.1.5 COVID- 19 vaccine dose	<ul> <li>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 10 may receive an additional data of XBB 1.5 COVID 10 years increased</li> </ul>		
	<ul> <li>One dose, at least 6 months from previous XBB.1.5 COVID-19 vaccine dose.</li> </ul>		
	However, a shorter interval of 3 months may be used in senior congregate care settings.		
Interval between previous COVID-19 infection and	For individuals with a history of COVID-19 infection the following guidance is provided on suggested intervals between infection and COVID-19 immunization.		
COVID-19 immunization	Notes:		
	• These suggested intervals are based on immunological principles and expert		
	and COVID-19 vaccines emerge. When considering whether 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		
	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 seriesIndividuals without certain immunocompromising conditions AND no history of multisystem inflammation syndrome in children (MIS- C)8 weeks after positive test		
	Individuals <b>with</b> certain immunocompromising conditions (as listed above) AND no history of MIS-C		

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		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/	Contraindications:		
Precautions	<ul> <li>Persons under 12 years of age</li> <li>Known severe hypersensitivity to any component of the vaccine.         <ul> <li>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 medical preparations (e.g., vitamin oils, tablets, anticancer agents) and cosmetics.</li> </ul> </li> <li>Anaphylaxis to a previous dose of Novavax COVID-19 vaccine. See <u>COVID-19</u> Immunization for Individuals with Allergies and Other Health Conditions for recommendations.</li> </ul>		
	Precautions:		
	<ul> <li>The safety of Novavax (Nuv Nuvaxovid original strain va dose.</li> <li>At the time of authorization associated with this product</li> </ul>	axovid) XBB.1.5 is inferred from ccine administered as a series a , there are no known serious wa t.	n safety data of the and as an additional arnings or precautions
	<ul> <li>Individuals receiving anticoa would contraindicate intrame the potential benefit clearly</li> </ul>	agulant therapy or those with a b uscular injection should not be g outweighs the risk of administra	bleeding disorder that given the vaccine unless tion.
	Individuals who have had a food should talk to their hea	serious allergic reaction to anot Ith care provider before receivin	her vaccine, drug or g the vaccine.
	<ul> <li>Administration should be po febrile illness.</li> </ul>	stponed in individuals experience	cing an acute severe
Myocarditis/Pericarditis	Very rare cases of myocard Novavax Nuvaxovid vaccine determine a causal associat	itis and/or pericarditis following i es have been reported, and avai ion with Novavax XBB.1.5.	mmunization with lable data cannot
	<ul> <li>Anyone receiving Novavax ( informed of the potential risk medical attention if they dev chest pain, or the feeling of</li> </ul>	(Nuvaxovid) XBB.1.5 COVID-19 c of myocarditis and pericarditis relop related symptoms including a rapid or abnormal heart rhythr	vaccine should be and advised to seek g shortness of breath, m.
	<ul> <li>Healthcare professionals are and/or pericarditis in their di pain, shortness of breath, pa and/or pericarditis following COVID-19 vaccine.</li> </ul>	e advised to consider the possib fferential diagnosis if individuals alpitations or other signs and sy immunization with Novavax (Nu	bility of myocarditis present with chest mptoms of myocarditis waxovid) XBB.1.5
	Generally, deferral of COVII history of myocarditis or per Novavax vaccines.	D-19 immunization is not require icarditis that is unrelated to CO	ed for those with a prior /ID-19 mRNA or
	<ul> <li>If these individuals have myocarditis or pericarditi consult with their clinician to receive COVID-19 vac</li> </ul>	questions or concerns about the s and immunization, it is recommen. However, consultation with a scines.	eir prior history of nended that they clinician is not required
	<ul> <li>Individuals with a history con dose of Novavax COVID-19</li> </ul>	mpatible with pericarditis within vaccine, who either had no car	6 weeks of receiving a diac workup or who had

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	<ul> <li>normal cardiac investigations, can be re-immunized when they are symptom free and at least 90 days have passed since previous immunization.</li> <li>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.</li> <li>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.</li> <li>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.</li> </ul>
Possible Reactions	<ul> <li>Common:</li> <li>Pain, tenderness, redness, and swelling at the injection site</li> <li>Headache, fatigue, and malaise</li> <li>Fever</li> <li>Myalgia and arthralgia</li> <li>Pain in arm, hand, leg or foot</li> <li>Nausea, vomiting</li> <li>Rare:</li> <li>Allergic reaction</li> <li>Anaphylaxis</li> <li>As with any immunization, unexpected or unusual side effects can occur</li> <li>Refer to product monograph for more detailed information.</li> </ul>
Pregnancy	<ul> <li>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.</li> <li>The safety and efficacy of Novavax COVID-19 vaccines in pregnant women has not yet been established in clinical trials, 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.</li> <li>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.</li> <li>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.</li> <li><u>Additional resources</u>:         <ul> <li>Society of Obstetricians and Gynecologists of Canada Statement on COVID-19 Immunization in Pregnancy.</li> </ul> </li> </ul>
Lactation	<ul> <li>It is unknown whether Novavax COVID-19 Vaccine is excreted in human milk as breastfeeding individuals were excluded from the initial trials. A risk to newborns/infants cannot be excluded.</li> <li>COVID-19 vaccine is recommended for individuals who are breastfeeding.</li> <li>It is recommended that individuals consult with their primary health care provider or medical specialist for any vaccine related questions or concerns.</li> <li>However, consultation with a primary health care provider or medical specialist is not required to receive COVID-19 vaccine.</li> </ul>

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Composition	Each 0.5 mL dose contains:	
	<ul> <li>SARS-CoV-2 recombinant spike protein (Omicron, XBB.1.5 strain) – 5 mcg</li> </ul>	
	Non-medicinal ingredients:	
	<ul> <li>Disodium hydrogen phosphate heptahydrate</li> <li>Hydrochloric acid (for adjustment of pH)</li> </ul>	
	<ul> <li>Polysorbate 80</li> </ul>	
	Sodium chloride	
	Sodium dihydrogen phosphate monohydrate	
	<ul> <li>Sodium hydroxide (for adjustment of pH)</li> <li>Water for injection</li> </ul>	
	<ul> <li>Matrix-M adjuvant (Quillaja saponaria saponins fraction-A and fraction-C) – 50 mcg</li> </ul>	
	Non-medicinal ingredients:	
	Cholesterol	
	Disodium hydrogen phosphate dihydrate	
	Phosphatidylcholine     Detassium chloride	
	<ul> <li>Potassium chloride</li> <li>Potassium dihvdrogen phosphate</li> </ul>	
	Sodium chloride	
	No preservatives	
Blood/Blood Products	Contains no human blood/blood products.	
Bovine/Porcine Products	Contains no bovine/porcine products.	
Latex	Does not contain latex.	
Interchangeability	There are no data available on the interchangeability of Nuvaxovid XBB.1.5 with other COVID-19 vaccines to complete an immunization series.	
Administration with Other Products	• Novavax (Nuvaxovid) 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.	
	<ul> <li>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.</li> </ul>	
	<ul> <li>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.</li> </ul>	
	<ul> <li>However, repeat tuberculin skin testing or IGRA (at least 4 weeks post COVID- 19 vaccine) of individuals with negative TST or IGRA results for whom there is high suspicion of latent tuberculosis may be considered to avoid missing cases of TB infection.</li> </ul>	
	• 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 doses or between doses.	
	<ul> <li>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.</li> </ul>	
	<ul> <li>Although antibody response was numerically lower in people who received monoclonal antibodies, the response was still considered to be high and the clinical significance of the reduction is unknown.</li> </ul>	

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	<ul> <li>There was no correlation between interval to COVID-19 immunization and neutralizing titres in recent monoclonal antibody recipients.</li> <li>Intervals between previous COVID-19 infection and COVID-19 immunization outlined in this document would still apply to individuals who received the monoclonal antibodies or convalescent plasma for their infection.</li> <li>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.</li> </ul>
	Nata
	<ul> <li>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.</li> </ul>
	<ul> <li>COVID-19 vaccines may be given at any time before or after an immunoglobulin preparation (including RhIg) or blood product has been administered. There is no recommended minimum interval between these products and COVID-19 vaccine.</li> </ul>
Appearance	<ul> <li>The solution is colourless to slightly yellow, clear to mildly opalescent, free of particles.</li> </ul>
Storage	<ul> <li>Unopened vaccine vials can be stored between +2°C to +8°C for up to 12 months.</li> <li>Punctured vials (first dose is withdrawn) can be stored between +2°C to +8°C for up to 12 hours or between &gt;+8°C to +25°C for up to 6 hours.</li> <li>Post-puncture vaccine that has been stored between +2°C to +8°C for more than 12 hours or between &gt;+8°C to +25°C for more than 6 hours must be discarded.</li> <li>Store in the original carton to protect from light.</li> <li>Do not freeze.</li> </ul>
Packaging	<ul> <li>5 doses per vial.</li> <li>2.5 mL of suspension in a 5-dose vial (clear glass) with a bromobutyl rubber stopper and a blue plastic flip-off cap.</li> <li>2 multidose vials per carton.</li> </ul>
Preparation/ Reconstitution	<ul> <li>No reconstitution is required.</li> <li>Gently swirl the multidose vial before and in between each dose withdrawal.</li> <li>Do not shake.</li> </ul>
Vaccine Code	COVNVASubXBB
Antigen Code	COVID-19
Licensed Use	<ul> <li>Single dose for individuals 12 years of age and older who have previously completed a COVID-19 vaccine series.</li> <li>Two-dose series for individuals 12 years of age and older who have not previously completed a COVID-19 vaccine series.</li> </ul>
Off-License Use	<ul> <li>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.</li> <li>Second or third dose for individuals who are moderately to severely immunocompromised</li> <li>Three-dose series for unimmunized post-hematopoietic stem cell transplant (HSCT) and/or chimeric antigen receptor (CAR) T-cell therapy recipients.</li> <li>Single dose for unimmunized individuals who are not moderately to severely immunocompromised.</li> <li>Additional XBB.1.5 COVID-19 vaccine dose for eligible individuals.</li> </ul>

## Novavax (Nuvaxovid) XBB.1.5 COVID-19 Vaccine

## **Program Notes:**

- December 5, 2023: Licensed for use in Canada.
- January 5, 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.

## **Related Resources:**

• Alberta Health Services Website (2024). COVID-19 vaccines – protein-based vaccine information sheet.

#### **References:**

- Alberta Health. Public Health Division. Alberta Immunization Policy. (2024 April 15) COVID-19 Vaccine Novavax XBB.1.5 (Nuvaxovid), recombinant protein, adjuvanted.
- <sup>2</sup> Alberta Health. Public Health Division. Alberta Immunization Policy. (2023 December 14). Alberta Vaccine Storage and Handling for COVID-19 Vaccine.
- <sup>3.</sup> Benschop, et al. (2021). The effect of anti-SARS-CoV-2 monoclonal antibody, bamlanivimab, on endogenous immune response to COVID-19 vaccination. medRxiv. Preprint. <u>https://doi.org/10.1101/2021.12.15.21267605</u>.
- <sup>4.</sup> Centers for Disease Control and Prevention. (2021, September). Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States. <u>https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#CoV-19-vaccination</u>
- <sup>5.</sup> Expert opinion of Alberta Advisory Committee on Immunization. (September 20, 2023: January 18, 2024).
- <sup>6</sup> National Advisory Committee on Immunization. Guidance on an additional dose of COVID-19 vaccines in the spring of 2024 for individuals at high risk of severe illness due to COVID-19 [Internet]. 2024. Available from: <u>https://www.canada.ca/content/dam/phac-aspc/documents/services/publications/vaccines-immunization/national-advisorycommittee-immunization-guidance-additional-dose-covid-19-vaccines-spring-2024-individuals-high-risk-severe-illness-duecovid-19/naci-statement-2024-01-12.pdf</u>
- <sup>7.</sup> National Advisory Committee on Immunization. (2023 December 05). Canadian Immunization Guide (Evergreen ed.). Ottawa, ON: Public Health Agency of Canada <u>https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-4-active-vaccines/page-26-covid-19-vaccine.html</u>
- 8. National Advisory Committee on Immunization. (2023 October 27). Updated guidance on the use of COVID-19 vaccines in individuals who have not previously been vaccinated against COVID-19. https://www.canada.ca/content/dam/phacaspc/documents/services/publications/vaccines-immunization/national-advisory-committee-immunization-updated-guidancecovid-19-vaccines-individuals-not-previously-vaccinated/naci-statement-2023-10-27.pdf
- <sup>9.</sup> National Advisory Committee on Immunization. (2022 February 4) NACI rapid response: Updated guidance on COVID-19 vaccination timing for individuals previously infected with SARS-CoV-2. <u>https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/rapid-response-guidance-covid-19-vaccination-timing-individuals-previously-infected-sars-cov-2.html</u>
- <sup>10.</sup> National Advisory Committee on Immunization. (2022). Recommendations on the use of Novavax Nuvaxovid COVID-19 Vaccine. <u>https://www.canada.ca/content/dam/phac-aspc/documents/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-novavax-nuvaxovid-covid-19-vaccine.pdf</u>
- <sup>11.</sup> National Advisory Committee on Immunization. (2022 April 5). Initial guidance on a second booster dose of COVID-19 vaccines in Canada. <u>https://www.canada.ca/content/dam/phac-aspc/documents/services/immunization/national-advisory-committee-onimmunization-naci/naci-guidance-second-booster-dose-covid-19-vaccines.pdf</u>
- National Advisory Committee on Immunization. (2022 October 7). Updated guidance on COVID-19 vaccine booster doses in Canada. https://www.canada.ca/content/dam/phac-aspc/documents/services/immunization/national-advisory-committee-onimmunization-naci/guidance-covid-19-vaccine-booster-doses.pdf
- <sup>13.</sup> Novavax. (2023 December 5). Nuvaxovid XBB.1.5 COVID-19 Vaccine (recombinant, adjuvanted) *Product Monograph* <u>https://covid-vaccine.canada.ca/info/pdf/nuvaxovid-xbb-1-5-pm-en.pdf</u>
- Shimabukuro, T., Kim, S., et al. Preliminary Findings of mRNA Covid-19 Vaccine Safety in Pregnant Persons. American Journal of Medicine. (2021 April 21) <u>https://www.nejm.org/doi/full/10.1056/NEJMoa2104983</u>