COVID-19 Vaccine (Recombinant protein, Adjuvanted)
NUVAXOVID™ XBB.1.5 Supplier: Novavax Inc.

INDICATIONS: [A]

- Individuals 12 years of age and older. See COVID-19 Vaccine Eligibility.

The vaccine is not approved for use in those less than 12 years of age.

DOSES AND SCHEDULE: [B]

- Individuals 12 years of age and older: [C] 1 dose given as 0.5 mL **IM** at least 6 months [D] after last dose of COVID-19 vaccine.

- Individuals 12 years of age and older who are moderately to severely immunosuppressed: Individuals who are moderately to severely immunosuppressed (see COVID-19 Vaccine Eligibility), should receive at least 2 doses of COVID-19 vaccine. However, if any dose in the series is a non-XBB.1.5 COVID-19 vaccine, a total of at least 3 doses of COVID-19 vaccine is recommended with at least one of these doses provided as COVID-19 XBB.1.5 formulation. New recipients of HSCT or CART should receive 3 doses, regardless of formulation. Refer to intervals table below.

Recommendations for Moderately to Severely Immunosuppressed Clients		
Previous COVID-19 Vaccination History	**Number of Dose(s) of COVID-19 XBB.1.5 Vaccine**	**Recommended Interval Between Doses**
3 or more doses, no XBB.1.5 vaccine	1 dose	6 months after last dose [D]
2 doses, 1 or no XBB.1.5 vaccine(s)	1 dose	8 weeks after last dose [E]
1 dose, no XBB.1.5 vaccine	2 doses	8 weeks after last dose *and* 8 weeks between doses [E]
1 dose, XBB.1.5 vaccine	1 dose	8 weeks after last dose [E]
0 doses	2 doses	8 weeks between doses [E]

- Spring 2024 Booster Dose: [F]
  - Individuals 12 years of age and older: 1 dose given as 0.5 mL **IM** at least 6 months [E] after last dose of COVID-19 vaccine. See BOOSTER DOSES.

[A] Novavax COVID-19 vaccine is interchangeable with mRNA COVID-19 vaccines. Moderna COVID-19 XBB.1.5 mRNA vaccine is the preferred product for individuals who are moderately to severely immunosuppressed due to a potentially greater immune response induced by this vaccine in these populations; however, if unavailable, or upon client request, an age-appropriate Novavax XBB.1.5 vaccine can be given.

[B] Previously vaccinated includes any product type or formulation of World Health Organization Emergency Use Authorization Qualified COVID-19 Vaccine, unless otherwise specified.

[C] No prior receipt of COVID-19 XBB.1.5 formulation.

[D] A 3 month minimum interval may be considered for operational considerations or other exceptional circumstances.

[E] A 28 day minimum interval may be considered. For optimal response, the recommended interval should be observed.

[F] Those who have not received previous COVID-19 XBB.1.5 dose(s) per recommended schedule above should be offered the recommended dose(s) now. An additional Spring 2024 Booster Dose is not recommended, however those that wish to receive an additional dose may receive a Spring 2024 Booster Dose at the recommended interval.

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ADMINISTRATION:[A]

- No reconstitution required.

Storage and Handling:

- Unopened multidose vial:
  - +2°C to +8°C up to the end of its expiry date, kept in the original packaging and protected from light. Do not freeze.

- Opened multidose vial:
  - Gently swirl the multidose vial before and in between each dose withdrawal. Do not shake.
  - After first vial puncture, the vaccine is stable at +2°C to +8°C for 12 hours or at room temperature (up to +25°C) for 6 hours. Once punctured, the vial can be re-refrigerated, but the cumulative storage time at room temperature must not exceed 6 hours, and the total cumulative storage time must not exceed 12 hours. After these times, the vial must be discarded.
  - The vaccine can be pre-loaded into a syringe provided the preceding storage temperatures and times following first vial puncture are adhered to.
  - Ensure that the vial/syringe is clearly labeled with the date and time of first vial entry.

BOOSTER DOSES:

At least one COVID-19 XBB.1.5 vaccine is recommended for everyone 6 months of age and older. An additional dose of COVID-19 XBB.1.5 vaccine in Spring 2024 is recommended for eligible populations at increased risk of severe disease as outlined on the COVID-19 Vaccine Eligibility page under Spring 2024 Booster Dose Recommendations.

SEROLOGICAL TESTING:

Serological testing is not recommended before or after immunization.

CONTRAINDICATIONS:

1. History of anaphylactic reaction to a previous dose of the vaccine or to any component of the vaccine. These individuals should be offered an mRNA COVID-19 vaccine and observed for at least 30 minutes after immunization.

PRODUCT COMPONENTS:

Potential allergens: polysorbate 80.
Other components: disodium hydrogen phosphate heptahydrate, hydrochloric acid, sodium chloride, sodium dihydrogen phosphate monohydrate, sodium hydroxide, cholesterol, disodium hydrogen phosphate dihydrate, phosphatidylcholine, potassium chloride, potassium dihydrogen phosphate, Matrix-M adjuvant (Quillaja saponaria saponins fraction-A and fraction-C).

PRECAUTIONS:

- For individuals with suspected hypersensitivity or non-anaphylactic allergy to COVID-19 vaccine components, the vaccine should be administered in a controlled setting with

[A] For a period of time, Novavax, Inc. will distribute product vials, cartons and a printed package insert labelled as 'Novavax COVID-19 Vaccine, Adjuvanted (2023-2024 Formula)' with non-Canadian, English-only labelling. All vaccine with non-Canadian labels will expire July 31, 2024. This date has been approved by Health Canada.

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PRECAUTIONS (continued):

expertise and equipment to manage anaphylaxis, with an extended period of observation post-vaccination of at least 30 minutes.

- Wait until symptoms of an acute illness are resolved before vaccinating with COVID-19 vaccine to differentiate symptoms of illness from vaccine side effects.
- Individuals diagnosed with Multisystem Inflammatory Syndrome in Children (MIS-C) or Adults (MIS-A) should delay COVID-19 vaccination until they have recovered from illness and for 90 days after the date of diagnosis of MIS-C or MIS-A.
- Additional doses of a COVID-19 vaccine should be deferred in those who experienced a physician-diagnosed myocarditis or pericarditis event following a previous dose of a COVID-19 vaccine. However, those with a history compatible with pericarditis who had no cardiac workup or had normal investigations may proceed to further vaccination once symptoms have resolved and 90 days have passed since receipt of the dose associated with the event. For those with confirmed myocarditis (with or without pericarditis), an individual risk/benefit discussion between the patient and their healthcare provider should occur so that the patient (with their parent/guardian as applicable) can make an informed decision about proceeding with a subsequent dose. Informed consent should include the unknown rates of recurrence of myocarditis and/or pericarditis following receipt of additional doses of the Novavax COVID-19 vaccine, as well as the need to seek immediate medical assessment and care should symptoms develop. Deferral is not required for those with a prior history of myocarditis or pericarditis that is unrelated to COVID-19 vaccines and are no longer being followed by a medical professional for heart issues. For more information refer to the NACI summary.

SPECIAL CONSIDERATIONS:

- COVID-19 vaccines can be administered concomitantly or at any time before or after the administration of another inactivated or live vaccine.
- Deferral of COVID-19 vaccination is no longer recommended for individuals who have received anti-SARS-CoV-2 monoclonal antibodies or convalescent plasma for treatment or prevention of COVID-19.
- COVID-19 vaccine may be offered to individuals without contraindications who have recovered from SARS-CoV-2 infection.
- COVID-19 vaccine may be deferred in those who have tested positive for COVID-19 (by PCR or rapid antigen test) until 3-6 months from symptom onset or, for asymptomatic cases, from the time of the positive test.

ADVERSE EVENTS:

Local: tenderness, pain, redness, swelling.
Systemic: fatigue, myalgia, headache, malaise, arthralgia, nausea, vomiting, fever.

Pericarditis and myocarditis in association with the original Novavax COVID-19 vaccine formulation have been reported internationally and there has been 1 report in Canada per Public Health Agency of Canada reports to January 5, 2024 meeting the Brighton Case Definition Levels 1-3. Data from Japan, Australia and Europe report approximately 0-4 cases of myocarditis and 13 cases of pericarditis per 100,000 doses administered, per the Canadian Immunization Guide. A longer interval of 8 weeks, between doses of the primary series may reduce the likelihood of pericarditis and myocarditis, particularly for males 12-39

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ADVERSE EVENTS (continued):
years of age. Most cases recover fully. The exact cause of these events is not known but is thought to be related to the immune response to the spike protein which is also important in immunity against COVID-19 virus.

REFERENCES:
1. Nuvaxovid™ XBB.1.5 product monograph
2. 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
3. National Advisory Committee on Immunization: Updated guidance on the use of protein subunit COVID-19 vaccine (Novavax Nuvaxovid)