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October 28, 2022

COVID-19 Vaccine: Approval of Pfizer/Comirnaty™ Infant Pediatric and guidance for children aged 6 months to ≤ 4 years

On September 9, 2022, Health Canada authorized the Pfizer/ComirnatyTM infant pediatric COVID-19 vaccine (3 mcg) for use as a <u>3-dose primary series</u> in children aged six months to \leq four years.

Health Canada authorized the Moderna/Spikevax[™] infant pediatric COVID-19 vaccine (25mcg) for use as a <u>2-dose primary</u> series in children six months to ≤ five years on July 14, 2022.

Please note the following differences between these products:

| Product and dose | Time between doses of primary series | Number of doses in primary series | Immunosuppressed*: Time between doses of primary series | Immunosuppressed*: Number of doses in primary series |
|-------------------------------|--|--|---|--|
| Moderna/Spikevax™ (25mcg)* | 8 weeks | 2 | 4-8 weeks | 3 |
| Pfizer/Comirnaty™ (3mcg) | 8 weeks | 3 | 4-8 weeks | 4 |

Please note the following recommendations from the National Advisory Committee on Immunization (NACI):

- Infants must be at minimum six months of age at the time of immunization.
- If readily available, the same mRNA COVID-19 vaccine should be offered for all doses in a primary series.
- If the same mRNA COVID-19 vaccine is not available, the number of doses required to be considered fully immunized should align with the Pfizer/Comirnaty[™] schedule. For example, if their first dose was Moderna/Spikevax[™] (25mcg) but they received Pfizer/Comirnaty[™] (3mcg) as their second dose, they should receive an age-appropriate dose(s) of either mRNA vaccine to complete a 3-dose primary series if immunocompetent or a 4-dose primary series if immunocompromised.
- Children who received one or two doses of Pfizer/Comirnaty™ (3mcg) and turn five years of age before series completion are recommended to receive the age-appropriate

dose(s) of Pfizer/Comirnaty™ (10mcg) to complete a 3-dose primary series if immunocompetent or a 4-dose primary series if immunocompromised.

- For infants 6 month to 4 years who are moderately to severely immunocompromised, NACI strongly recommends a 3-dose primary series of the Moderna/Spikevax (25 mcg). If the Moderna/Spikevax (25 mcg) vaccine is not readily available, a 4-dose primary series with the Pfizer/Comirnaty (3mcg) vaccine may be offered, with an interval of 4 to 8 weeks between each dose.
- As a precautionary measure for children 6 months to 4 years, try not to administer a
 COVID-19 vaccine less than 14 days before or after the administration of another
 vaccine. This is recommended in order to prevent an erroneous attribution of an adverse
 event to one particular vaccine over another. Concomitant administration or waiting less
 than 14 days is acceptable if needed (e.g., when other childhood vaccines are already
 scheduled).

More information on the NACI guidance/recommendations is available at:

- https://www.canada.ca/content/dam/phac-aspc/documents/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-pfizer-biontech-comirnaty-3-mcg-covid-19-vaccine-children-6-months-4-years.pdf
- www.canada.ca/content/dam/phac-aspc/documents/services/immunization/nationaladvisory-committee-on-immunization-naci/recommendations-use-moderna-spikevaxcovid-19-vaccine-children-6-months-5-years.pdf.

More information on Manitoba's eligibility criteria will be available at: www.gov.mb.ca/covid19/vaccine/eligibility-criteria.html.

Detailed product information is available in the product monograph, including the storage and stability at https://manitoba.ca/asset library/en/covid/mrna vaccine children 6mos-4 factsheet.pdf

Access: These vaccines will be offered through vaccine clinics, doctors' offices, and in First Nation communities.

Communications: An updated provincial factsheet will be available in the coming days at: www.gov.mb.ca/covid19/vaccine/resources.html.

Reporting doses administered: All immunizations administered are to be recorded and reported with the correct product and strength to ensure accurate electronic immunization records.

 Physicians are to use tariff 8263 for Pfizer/Comirnaty™ infant pediatric (3 mcg) when billing for doses administered. Physicians are to use tariff 8261 for Moderna/Spikevax™ infant pediatric (25 mcg) when billing for doses administered.

Distribution and allocation: Participating health care providers can order infant pediatric vaccine doses using the same method (via a weekly survey) as is done for all other COVID-19 vaccine products.

- If not yet registered as a COVID-19 vaccine immunizer, go to <u>www.manitoba.ca/covid19/vaccine/partners/index.html</u> to register.
- If already registered, Manitoba will be including requests for infant pediatric vaccine in the weekly surveys and the requests will be reviewed and filled accordingly.

Please share this information with all relevant colleagues in your facility/clinic.

Sincerely,

Richard Baydack, PhD

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Director

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