

Saskatchewan Immunization Manual Amendments July 2023

Instructions: Please remove and discard the corresponding pages in each chapter section as applicable and insert the amended pages as noted below in each corresponding chapter section.

Chapter 10 Biological Products

- TOC first page
 - **New!** Recommended bivalent Omicron-containing mRNA vaccines, dosages and schedules for primary series)
 - **Age 6 years removed from MODERNA** Spikevax™ 0/O Original/Omicron BA.4/5 **Bivalent** formulation (0.1mg/ml; **Royal blue cap/grey label**)
 - All mRNA monovalent vaccines removed from TOC
- **New!** Recommended bivalent Omicron-containing mRNA vaccines, dosages and schedules for primary series
 - Recommendations are based on age at presentation, vaccination history, and immune status of client.
- COVID-19 Booster Dose Parameters and Recommendations
 - Added statement: If the client started or completed their primary series with an Omicron-containing bivalent vaccine, no bivalent booster dose is required at this time unless eligible for a second bivalent booster - refer to COVID-19 Booster Dose Parameters and Recommendations.
 - mRNA monovalents removed as booster options for 5-11 years and 12+ years.
 - JCOVDEN removed as booster option for 18+ years.
- COVID-19 Vaccine Q & A for Immunizers
 - Added to #1: Individuals 6 months to 4 years old are ineligible for a booster dose.
 - #6b context revised: Refers to Moderna COVID-19 bivalent vaccine doses to start or to complete a primary series?
 - #10a recommendations revised: ... provide 1 mRNA bivalent dose 4 weeks after their first dose. Refer to COVID-19 Booster Dose Parameters and Recommendations for current recommendations.
 - #11:
 - Question revised to: If a client 5+ receives bivalent vaccine off-label to start or to complete their primary series, are they eligible to receive a booster in 6 months?
 - #12 deleted, as only Moderna bivalent to be used in children 6 months to 4 years old.
- Moderna Spikevax® 0/O Bivalent Original/Omicron BA.4/5
 - Indications updated:
 - Off-label: primary series to those age 6 months and older.
 - Booster immunization of those age 6+ years who completed a monovalent primary series.
 - Dosage of 25 mcg applies to children 6 months to 11 years old.
 - Schedule information updated: Refer to the *Recommended bivalent Omicron-containing mRNA vaccines, dosages and schedules for primary series, Booster Dose Parameters and Recommendations* and *COVID-19 Q&A for Immunizers* documents in SIM chapter 10.
 - Other Considerations revised:
 - **Ages 6 months to 4 years**
 - A primary series dose should be given at least 8 weeks after the start of symptoms or a positive test (if child had no symptoms). This may be shortened to 4 weeks for children considered moderately to severely immunocompromised.

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Age 5 years and older

- Immunization with a COVID-19 vaccine dose in a primary series should be given at least 3 months after infection.
- Immunization with a COVID-19 vaccine as a booster dose should be given at least 6 months after infection.
- NACI *Interim guidance on the use of bivalent Omicron-containing COVID-19 vaccines for primary series* added to references.
- Pfizer BioNTech Comirnaty® Bivalent Original & Omicron BA.4/5 12+ years
 - Indications updated:
 - Primary series and booster for 12+ years.
 - Schedule information updated: Refer to the *Recommended bivalent Omicron-containing mRNA vaccines, dosages and schedules for primary series, Booster Dose Parameters and Recommendations* and *COVID-19 Q&A for Immunizers* documents in SIM chapter 10.
 - Other Considerations revised:
 - Immunization with a COVID-19 vaccine dose in a primary series should be given at least 3 months after infection.
 - Immunization with a COVID-19 vaccine as a booster dose should be given at least 6 months after infection.
 - NACI *Interim guidance on the use of bivalent Omicron-containing COVID-19 vaccines for primary series* added to references.
 - Product monograph date updated.
- Pfizer BioNTech Comirnaty® Bivalent Original & Omicron BA.4/BA.5 5-11 years
 - Indications updated:
 - Primary series and booster for 5-11 years.
 - Schedule information updated: Refer to the *Recommended bivalent Omicron-containing mRNA vaccines, dosages and schedules for primary series, Booster Dose Parameters and Recommendations* and *COVID-19 Q&A for Immunizers* documents in SIM chapter 10.
 - Other Considerations revised:
 - Immunization with a COVID-19 vaccine dose in a primary series should be given at least 3 months after infection.
 - Immunization with a COVID-19 vaccine as a booster dose should be given at least 6 months after infection.
 - NACI *Interim guidance on the use of bivalent Omicron-containing COVID-19 vaccines for primary series* added to references
 - Product monograph date updated.