

Saskatchewan Immunization Manual Amendments January 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 updates
 - Age revised: MODERNA Spikevax® 6 months to 5 years **Monovalent** formulation (Blue Cap/purple label)
 - Novavax Novaxovid **Monovalent** formulation - age revised to 12+ years.

- COVID-19 Booster Dose Parameters and Recommendations
 - Third bullet age updated from 12+ to 5+; Pfizer-BioNTech Comirnaty® 10 mcg (0.2 mL) BA.4/5 Bivalent (age 5-11 years) added to this bullet.
 - **New bullet!** NACI is currently only recommending one booster dose after the primary series for children 5-11 years of age. However, a bivalent booster dose should be offered to all children 5-11 years old after 4 months if a monovalent booster has already been received.
 - Table reformatted with:
 - Ages removed from yellow row, as 1 bivalent booster dose is recommended for all SK children 5-11 years, including those who have received their monovalent booster.
 - 12+ replacing separate 12-17 and 18+ recommendation, as are the same.
 - Bivalent parameter added to 5-11 years.

- COVID-19 Vaccine Q &A for Immunizers
 - Section 2 revised to: COVID-19 vaccine off-label administration.
 - Question 6 and response revised: **Is written consent required prior to the off label administration of specific COVID-19 vaccines in the following scenarios?**
 - a. Prior to the immunization of a client 12 to 17 years of age who has an immunocompromising medical condition with Moderna BA.4/5 bivalent (18+ formulation)?
 - b. Prior to the immunization of a client 12 to 17 years of age with Novavax Nuvaxovid monovalent vaccine as a booster dose?
 - c. Prior to providing COVID-19 bivalent vaccine doses for a primary series to an individual 12+ years old?

Response: As noted in the *Saskatchewan Immunization Manual* chapter 3 *Informed Consent* (<https://www.ehealthsask.ca/services/Manuals/Documents/sim-chapter3.pdf>), verbal informed consent must be obtained prior to the administration of a COVID-19 vaccine for off-label use. SHA employees should abide by recommendations from their legal advisory experts and continue to receive written consent using their current process. Other agency employees should follow their own off label use consent process if different from the SIM recommendation.
 - **New!** Question 11
 - **An 8 year old received a Pfizer monovalent booster dose in October 2022. Are they recommended to get a bivalent booster dose?**

Response: Yes, as long as 4 months (minimum 3 months) has elapsed since their last dose. Booster recommendations are subject to change in the future.
 - Question 12 (renumbered from #11):
 - Response A interval corrected from months to weeks: **If they have received 1 dose of a non-HC approved dose** and now in Canada, provide 1 monovalent dose 4 weeks after ...
 - **New!** Question 14
 - **If a client 12+ chooses 2 doses of bivalent off label for primary series, are they eligible to receive a bivalent as a booster if nothing has changed in 4 months' time? What about if they receive 1**

Saskatchewan Immunization Manual Amendments January 2023

monovalent and choose bivalent off label for their second dose? Can they receive a bivalent booster in 4 months?

Response: When a client completes their primary series with bivalent vaccine (off label with informed consent, either one or both doses), they develop immunity against Omicron (and original strain). New COVID-19 immunization programming and recommendations will be determined based on future epidemiology, data on waning immunity, new emerging variants, and new vaccines.

- Janssen JCOVDEN
 - Facial paralysis including Bell's Palsy added under possible reactions.
 - Interchangeability now states: mRNA vaccine is preferred for further doses for those who received viral vector vaccine doses.
 - Product monograph date updated.

- Moderna Spikevax® Monovalent 6+ years (Red cap/light blue label) 0.2 mg/ml
 - Added to Indications for use:
 - Pfizer-BioNTech's Comirnaty monovalent is the preferred vaccine to start or complete a primary series in those 5-29 years old because the risk of myocarditis / pericarditis is higher in this age group after immunization with Moderna's Spikevax monovalent vaccine.
 - Under Precautions: Age changed from 30 and younger to 5 to 29 years old.
 - Added to Immunocompromised and Auto-Immune Conditions:
 - While Pfizer-BioNTech original is generally preferred for the primary series in those 5 to 29 years of age due to the lower risk of myocarditis/pericarditis, given the potential benefit in the immune response, for some moderately to severely immunocompromised individuals 5 to 29 years of age administration of Moderna Spikevax original as a primary series may be considered (based on clinical judgement).
 - Bullet added in Preparation section:
 - Swirl the vial gently after thawing and in between each withdrawal. **Do not shake.**

- Moderna Spikevax® Monovalent 6 months to 5 years (Blue cap/Purple label)
 - Added to Indications for use:
 - Pfizer-BioNTech's Comirnaty monovalent is the preferred vaccine to start or complete a primary series in those 5-29 years old because the risk of myocarditis / pericarditis is higher in this age group after immunization with Moderna's Spikevax monovalent vaccine.
 - Added under Precautions - Myocarditis:
 - For individuals aged 5 to 29 years old who are receiving their primary COVID-19 vaccine series and both Moderna and Pfizer are readily available, Pfizer monovalent is the preferred vaccine as there is a lower risk of myocarditis compared to immunization with Moderna monovalent . Individuals opting to receive Moderna shall be informed of the increased risk of myocarditis/pericarditis compared to receiving Pfizer.
 - Added to Immunocompromised and Auto-Immune Conditions:
 - While Pfizer-BioNTech original is generally preferred for the primary series in those 5 to 29 years of age due to the lower risk of myocarditis/pericarditis, given the potential benefit in the immune response, for some moderately to severely immunocompromised individuals 5 to 29 years of age administration of Moderna Spikevax original as a primary series may be considered (based on clinical judgement).
 - For those 6 months to 4 years of age who are moderately to severely immunocompromised, a primary series of Moderna Spikevax vaccine (25 mcg) is preferred because it only requires 3 doses.

Saskatchewan Immunization Manual Amendments January 2023

- Novavax Novaxovid
 - Licensed for use in 12+ years.
 - Indications for use revised:
 - Primary series and booster dose for 18+.
 - Primary series and approved off-label booster dose for 12+.
 - Product monograph date updated.
- Pfizer BioNTech Comirnaty® Bivalent Original & Omicron BA.4/5 12+ years (Gray cap/gray label)
 - Under Storage, Handling and Administration:
 - **Invert** the vial... changed from swirl the vial to align with product monograph direction.
- Pfizer BioNTech Comirnaty® **Bivalent** Original & Omicron BA.4/BA.5 **5-11 years** (**Orange cap/orange label**)
 - Added under Preparation/Reconstitution
 - **Vials After Dilution:** If stored in the fridge, let each vial stand at room temp for 15 minutes before administering.
- Pfizer BioNTech Comirnaty® Monovalent 12+ years (Gray cap and label border)
 - Added to Indications for use:
 - Pfizer-BioNTech's Comirnaty monovalent is the preferred vaccine to start or complete a primary series in those 5-29 years old because the risk of myocarditis / pericarditis is higher in this age group after immunization with Moderna's Spikevax monovalent vaccine.
 - Under Precautions: Age changed from 30 and younger to 5 to 29 years old.
 - Added to Immunocompromised and Auto-Immune Conditions:
 - While Pfizer-BioNTech original is generally preferred for the primary series in those 5 to 29 years of age due to the lower risk of myocarditis/pericarditis, given the potential benefit in the immune response, for some moderately to severely immunocompromised individuals 5 to 29 years of age administration of Moderna Spikevax original as a primary series may be considered (based on clinical judgement).
- Pfizer BioNTech Comirnaty® Monovalent **PEDIATRIC 5-11 years** (**Orange cap and label border**)
 - Added to Indications for use:
 - Pfizer-BioNTech's Comirnaty monovalent is the preferred vaccine to start or complete a primary series in those 5-29 years old because the risk of myocarditis / pericarditis is higher in this age group after immunization with Moderna's Spikevax monovalent vaccine.
 - Added under Precautions - Myocarditis:
 - For individuals aged 5 to 29 years old who are receiving their primary COVID-19 vaccine series and both Moderna and Pfizer are readily available, Pfizer monovalent is the preferred vaccine as there is a lower risk of myocarditis compared to immunization with Moderna monovalent. Individuals opting to receive Moderna shall be informed of the increased risk of myocarditis/pericarditis compared to receiving Pfizer.
 - Added under Preparation/Reconstitution
 - **Vials After Dilution:** If stored in the fridge, let each vial stand at room temp for 15 minutes before administering.

Saskatchewan Immunization Manual Amendments January 2023

- Pfizer BioNTech Comirnaty® Monovalent **PEDIATRIC 6 mo-4 yrs (Maroon cap and label border)**
 - Added under Schedule – series for Immunocompromised children
 - For those 6 months to 4 years of age who are moderately to severely immunocompromised, a primary series of Moderna Spikevax vaccine (25 mcg) is preferred because it only requires 3 doses.
 - Added to Immunocompromised and Auto-Immune Conditions:
 - For those 6 months to 4 years of age who are moderately to severely immunocompromised, a primary series of Moderna Spikevax vaccine (25 mcg) is preferred because it only requires 3 doses.
 - Added under Preparation/Reconstitution
 - Vials After Dilution: If stored in the fridge, let each vial stand at room temp for 15 minutes before administering.