

## Saskatchewan Immunization Manual Amendments April 24, 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
  - Moderna 6+ monovalent red cap removed as stock has expired.
- COVID-19 Booster Dose Parameters and Recommendations
  - Modern removed as a monovalent booster dose option for 12+.
  - Added under All adults 65-79 years of age:
    - Those who have not had a COVID-19 infection are strongly encouraged to receive their second bivalent vaccine as they may be at higher risk of severe illness due to lack of hybrid immunity.
    - Those who have a history of previous COVID-19 infection and request their second bivalent booster can receive it as long as six months has passed since infection or last booster dose (whichever is longer).
- COVID-19 Vaccine Q & A for Immunizers - Amendments
  4. Is there a preferred bivalent vaccine brand to be offered to individuals?  
Response: No, there is no bivalent vaccine brand preference for immunocompromised or non-immunocompromised individuals.
  12. Is there a preferred vaccine brand to be offered as a primary series to immunocompromised children age 6 months to 4 years old?  
Response: For those 6 months to 4 years of age who are moderately to severely immunocompromised, a primary series of Moderna vaccine (25 mcg) is preferred **only** because it requires 3 doses. 4 doses of the Pfizer (3 mcg) vaccine may be offered if Moderna is not readily available.
- Janssen JCOVDEN 18+ Monovalent vaccine
  - Under Other Consideration, booster dose added to 6-month interval post-infection bullet.
  - Added under Preparation
    - Thaw vaccine prior to administration.
    - Inspect vaccine for particulate matter and discolouration prior to administration.
  - Added under Storage and Handling:
    - Refer to the Vaccine Storage and Handling and Cold Chain Break Procedure for COVID-19 Vaccines work standard and Appendix C in the COVID-19 Immunization Manual for additional storage and handling details.
- Moderna Spikevax® 0/O Bivalent Original/Omicron BA.4/5 18+ years 0.1 mcg/mL
  - Added under Storage and Handling:
    - Refer to the Vaccine Storage and Handling and Cold Chain Break Procedure for COVID-19 Vaccines work standard and Appendix C in the COVID-19 Immunization Manual for additional storage and handling details.
- Moderna Spikevax® Monovalent 6 months to 5 years 0.1 mcg/ml
  - Added under Indication for use:
    - This vaccine has not been authorized as booster dose for those age 6 to 11 years of age.
  - Removed from Precautions:
    - 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 vaccine. Individuals opting to receive Moderna shall be informed of the increased risk of myocarditis/pericarditis compared to receiving Pfizer.

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- Removed from Immunocompromised and Autoimmune Conditions:
  - While Pfizer-BioNTech original Comirnaty® 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 1129 years of age administration of Moderna Spikevax original as a primary series may be considered (based on clinical judgement).
- Removed under Interchangeability:
  - For individuals aged 5 years who are receiving their primary COVID-19 vaccine series and both Moderna and Pfizer are readily available, Pfizer is the preferred vaccine.
- Added under Storage and Handling:
  - Refer to the Vaccine Storage and Handling and Cold Chain Break Procedure for COVID-19 Vaccines work standard and Appendix A in the COVID-19 Immunization Manual for additional storage and handling details.
- Novavax Nuvaxovid 12+ Monovalent vaccine
  - Added under Storage and Handling:
    - Refer to the Vaccine Storage and Handling and Cold Chain Break Procedure for COVID-19 Vaccines work standard and Appendix C in the COVID-19 Immunization Manual for additional storage and handling details.
- Pfizer BioNTech Comirnaty® Bivalent Original & Omicron BA.4/5 12+ years
  - Detailed Preparation row added.
  - Added to Storage and Handling:
    - Refer to the Vaccine Storage and Handling and Cold Chain Break Procedure for COVID-19 Vaccines work standard and Appendix B in the COVID-19 Immunization Manual for additional storage and handling details.
- Pfizer BioNTech Comirnaty® Bivalent Original & Omicron BA.4/5 5-11 years
  - Added to Storage and Handling:
    - Refer to the Vaccine Storage and Handling and Cold Chain Break Procedure for COVID-19 Vaccines work standard and Appendix B in the COVID-19 Immunization Manual for additional storage and handling details.
- Pfizer BioNTech Comirnaty® Monovalent 12+ years
  - Added under Indications:
    - May be used as a booster dose for those age 12 years and older who choose a monovalent instead of a bivalent vaccine.
  - Removed from Precautions:
    - 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 vaccine. Individuals opting to receive Moderna shall be informed of the increased risk of myocarditis/pericarditis compared to receiving Pfizer.
  - Removed under immunocompromised and autoimmune 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).
  - Clarified under Other Considerations
    - In SK, a 3-month interval is recommended post-infection before a primary series COVID-19 vaccine is administered to client to ensure a strong immune response is developed.

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- Revisions under Interchangeability
  - **Removed:** If easily available at the time of vaccination without delay or vaccine wastage, the same mRNA COVID-19 vaccine product should be offered for the subsequent dose in a vaccine series started with an mRNA COVID-19 vaccine.
  - **Bullet now states:** When the original vaccine is not available to complete a primary series, any age-appropriate monovalent COVID-19 vaccine is considered interchangeable and should be offered to complete the vaccine series.
- Deleted under Preparation:
  - Vials should be discarded 12 hours after first puncture. Vial labels and cartons may state that a vial should be discarded 6 hours after the first puncture. The information in the Product Monograph supersedes the number of hours printed on vial labels and cartons.
- Added under Storage and Handling:
  - Refer to the Vaccine Storage and Handling and Cold Chain Break Procedure for COVID-19 Vaccines work standard and Appendix A in the COVID-19 Immunization Manual for additional storage and handling details.
- Pfizer BioNTech Comirnaty® Monovalent PEDIATRIC 5-11 years
  - Under Indications:
    - **Removed:** Pfizer-BioNTech's Comirnaty is the preferred vaccine to start or complete a primary monovalent series in those 5-11 years old because the risk of myocarditis / pericarditis is higher in this age group after immunization with Moderna's Spikevax monovalent vaccine.
    - **Added:** May be used as a booster dose for those age 5-11 years old who choose a monovalent instead of a bivalent vaccine.
  - Removed under Schedule:
    - For those who are moderately to severely immunocompromised in the authorized age group who have not yet been immunized, a primary series of three doses of an authorized mRNA vaccine should be offered. For those who are moderately to severely immunocompromised in the authorized age group who have previously received a 1- or 2-dose COVID-19 vaccine series (with a homologous or heterologous schedule using mRNA or viral vector vaccines), an additional dose of an authorized mRNA COVID-19 vaccine should be offered (NACI, 2021).
  - Under Precautions:
    - **Removed:** 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 vaccine. Individuals opting to receive Moderna shall be informed of the increased risk of myocarditis/pericarditis compared to receiving Pfizer.
    - Pfizer dose revised to 10 mcg in last bullet under Myocarditis/Pericarditis section.
  - Clarified under Other Considerations
    - In SK, a 3-month interval is recommended post-infection before a primary series COVID-19 vaccine is administered to client to ensure a strong immune response is developed.
  - Preparation and Reconstitution row: All details revised to align with the current product monograph.
  - Added under Storage and Handling:
    - Refer to the Vaccine Storage and Handling and Cold Chain Break Procedure for COVID-19 Vaccines work standard and Appendix A in the COVID-19 Immunization Manual for additional storage and handling details.

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- Pfizer BioNTech Comirnaty® Monovalent PEDIATRIC 6 mo-4 yrs
  - Preparation and Reconstitution row: **All details revised to align with the current product monograph.**
  - Added under Storage and Handling:
    - Refer to the Vaccine Storage and Handling and Cold Chain Break Procedure for COVID-19 Vaccines work standard and Appendix A in the COVID-19 Immunization Manual for additional storage and handling details.