Saskatchewan Immunization Manual Amendments January 2023
Revised January 17, 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

- COVID-19 Booster Dose Parameters and Recommendations
  - Eligibility dates for age groups removed from fourth bullet, as new column added to table titled Fall Booster Campaign Start date.
  - New footnote #3 added at bottom of table: *Those who consented to receive a monovalent booster dose in the fall campaign are ineligible to receive a bivalent booster dose*.

Saskatchewan Immunization Manual Amendments February 2023

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Chapter 5 Immunization Schedules

- Section 3.7 Tetanus Prophylaxis in Wound Management
  - Footnote #5 revised, now states: TIg should be given as soon as possible, ideally within 24 hours after a tetanus prone wound has occurred. In rare circumstances where TIg is not available or there is a delay in the client reporting or presenting for follow up, it can be given up to 21 days after sustaining injury, based on the incubation period of 3-21 days. If more than 21 days or if a tetanus-containing vaccine was given prior to TIg, consult with MOH/MOH designate.

Chapter 7 Immunization of Special Populations

- Appendix 7.8: Publicly Funded Immigrant and Refugee Immunization and Serology Recommendations
  - HB serology no longer required for those 18+ prior to immunization, so original footnote #1 deleted.
  - HC map link updated.

Chapter 8 Administration of Biological Products

- Certolizumab pegol (CIMZIA) added to list in Appendix 8.2 Monoclonal Antibody Medications

Chapter 10 Biological Products

- TOC page 1 revised:
  - MODERNA Spikevax® 0/O Original/Omicron BA.1 **Bivalent** formulation (Blue cap/green label) now licensed for 6+ years.
- COVID-19 Booster Dose Parameters and Recommendations
  - Fourth bullet revised and new row added, as Modern Spikevax BA.1 Bivalent authorized as booster for 6-11 years (25 mcg) and 12-17 (50 mcg).
- COVID-19 Vaccine Q &A for Immunizers
  - Previous intervals for booster doses revised to state 6 months.
  - #5 – Age 18 changed to 12 years for myocarditis risk.
  - #6 – Previous scenario of off-label Modern bivalent for 12-17 years removed.
  - New #12: **Is there a preferred vaccine brand to be offered to immunocompromised individuals?**
    Response: Yes, Moderna is the preferred vaccine brand for those who are moderately to severely immunocompromised.
- Modern Spikevax Bivalent BA.1 6+ years
  - Age indication revised to 6 years.
  - Dosages revised for 6-11 years (25 mcg) and 12+ years (50 mcg).
  - Product monograph date updated.
- Moderna Spikevax® Monovalent 6+ years (Red cap/light blue label) page 6 of 6
  - Product monograph date updated
- Novavax Nuvaxovid
  - Product monograph updated to 2023-02-09.
  - New bullet added under Contraindications: The product monograph states, "*A second dose of the vaccine should not be given to those who have experienced anaphylaxis to the first dose of NUVAXOVID*".
  - Revised bullets added to Precautions:

        - Myocarditis and pericarditis have been reported following NUVAXOVID administration.
        - Available data suggest that the course of myocarditis and pericarditis following vaccination is not different from myocarditis and pericarditis in general.
        - Available data cannot determine a causal association with NUVAXOVID.
        - Vaccinated individuals (including parents or caregivers) should be instructed to seek immediate medical attention if they develop symptoms indicative of myocarditis or pericarditis such as (acute and persisting) chest pain, shortness of breath, or palpitations following vaccination.
    - New bullet added under Pregnancy
        - There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to NUVAXOVID during pregnancy. Women who are vaccinated with NUVAXOVID during pregnancy are encouraged to enroll in the registry by visiting https://c-viper.pregistry.com/.
    - New bullet added under Possible Reactions section: Hypoesthesia and paresthesia have been reported as post-market adverse reactions.
- Pfizer Comirnaty BA. 4/5 12+ and 5-11 years bivalent vaccines product monograph date updated to 2023-02-09, as shelf extended from 12-18 months as noted in storage and handling sections.
- Publicly Funded Hepatitis A (HA) Vaccine Indications
    - 6 months added to select publicly funded indications.
    - New footnote #3 added: CIG Hepatitis A chapter https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-4-active-vaccines.html.
    - Pharmacists added to footnote #2.
- AVAXIM HA vaccine
    - New note added to child dose/series:
        - In SK, AVAXIM Pediatric may be provided off-label to those 6-11 months.
- Havrix HA vaccine
    - New note added to Adult and child dose/series:
        - In SK, AVAXIM Pediatric may be provided off-label to those 6-11 months.
        - In SK, HAVRIX 1440 may be provided off-label to those 18 years old if another adult HA vaccine brand is unavailable.
- VAQTA HA vaccine
    - New note added to child dose/series:
        - In SK, VAQTA Pediatric may be provided off-label to those 6-11 months.
- Publicly Funded Hepatitis B (HB) Vaccine Indications
    - Pharmacists added to footnote #8.
- SHINGRIX product monograph date updated.
- MMRV (ProQuad and Priorix-Tetra)
    - Indication revised to: Healthy children 1 year up to and including 12 years of age who require protection against MMR and varicella diseases.
    - ProQuad product monograph date and link updated.
- NIMENRIX
    - Product monograph date and link updated.
    - Infant schedule updated to align with product monograph.

Chapter 14 – Appendices

- APPENDIX 14.2: Former REGIONAL HEALTH AUTHORITIES AND FIRST NATIONS JURISDICTIONS
    - Indigenous Services Canada and former Five Hills Health Region information updated.

Saskatchewan Immunization Manual Amendments March 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 7 Immunization of Special Populations

- Appendix 7.7: Tdap Immunization Decision Chart for Pregnant Women
  - First bullet under **NO** now states: Recommend and offer her one Tdap dose, ideally between 27 to 32 weeks gestation.
- Appendix 7.8: Publicly Funded Immigrant and Refugee Immunization and Serology Recommendations
  - Specific HB serology tests recommended; and
  - New footnote #2: HB vaccination can occur prior to specified serology being completed. There should be a minimum of 1 month between a HB vaccine and HBsAg test to avoid false positive result. Complete the HB immunization series if serology results are received during the series unless the HBsAg or Anti HBc total come back positive. Once the HB vaccine series is completed, HBsAb can be drawn 1 month after the last dose.

Chapter 10 Biological Products

- TOC page 1 revised:
  - New! MODERNA Spikevax® 18+ 0/O Original/Omicron BA.4/5 **Bivalent** formulation (Royal blue cap/grey label)
- COVID-19 Booster Dose Parameters and Recommendations
  - Previous bullets referring to fall program deleted.
  - Last bullet addressing monovalent vaccine error deleted as covered in COVED-19 Vaccine Q & A for Immunizaers.
  - New vaccine option added: Moderna Spikevax™ BA.4/5 Bivalent (50 mcg (0.5 mL) ≥ 18 years and 12-17 years **&** 25 mcg (0.25 mL) 6-11 years
- COVID-19 Vaccine Q &A for Immunizers
  - Minimum 3 month interval pertaining to booster doses removed throughout document.
  - #2 – during a primary series added to question.
  - #4 – reference to immunocompromised adults changed to individuals. a
  - #6 –permitted off-label Moderna BA.4/5 bivalent for 6-17 years added.
  - #7 – last response sentence amended to A 6 months interval (min. interval 3 months) is recommended before administering a bivalent dose, however consult a Medical Health Officer if a shorter interval is requested.
  - #11 – Question now reads: If a client 12+ chooses bivalent vaccine off-label for or to complete their primary series, are they eligible to receive a booster in 6 months?
  - #12: *Primary series* added to questions and responses.
    - 6 months to 4 years bullet now reads as 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 because it only requires 3 doses. However, 4 doses of the Pfizer (3mcg) vaccine may be offered if Moderna is not readily available.
- Janssen (Johnson & Johnson) 18+ JCOVDEN™ Monovalent
  - Product monograph date updated to Feb. 16, 2023
  - Pregnancy
    - First bullet revised: There is limited experience with the use of JCOVDEN in pregnant women. Animal studies with JCOVDEN did not indicate harmful effects with respect to reproductive toxicity.
    - Added to second bullet: Administration of JCOVDEN in pregnancy should only be considered when the potential benefits outweigh any potential risks to the mother and fetus.

- Lactation
  - Vaccine name added within second bullet: It is not known whether the components of JCOVDEN or antibodies induced by JCOVDEN are excreted in human milk. Human data are not available to assess the impact of JCOVDEN on milk production or its effects on the breastfed child.

- Moderna Spikevax® 0/O Bivalent Original/Omicron BA.1 (Blue cap/green label) 6+ years
  - 6 month interval recommended between COVID-19 infection and bivalent immunization.
  - Product monograph date updated.
  - Possible reactions now includes systemic reactions.
- New! MODERNA Spikevax® 0/O Original/Omicron BA.4/5 **Bivalent** formulation (Blue cap/grey label) for 18+ years
  - NOTE: As this vaccine is currently licensed for age 18+, and will replace the Modern BA.1 bivalent vaccine that is licensed for 6+ years, the Ministry of Health permits the **off-label** use of Moderna's BA.4/5 bivalent vaccine as a booster dose for 6-17 years.
- Pfizer Comirnaty Bivalent Original & Omicron BA.4/5 vaccines for 5-11 years and 12+ years
  - 6 month interval recommended between COVID-19 infection and bivalent immunization.
- GARDASIL HPV-t
  - Product monograph date and link updated
  - Indication for males clarified:
    - Males born since January 1, 2006, who are either currently in Grade 6 or who did not receive or complete a series when in Grade 6, up to and including 26 years old.
    - Buller re males born in 2005 removed as ineligible for publicly funded HPV-9 vaccine.
  - Pregnancy no longer noted under Contraindications as per product monograph. Footnote 1 deleted.
  - Vaccine components: Latex, antibiotic and preservative free.
  - Expected reactions:
    - Local: Mild to moderate pain, swelling, erythema and pruritus at injection site.
    - **Reported post-market**: vomiting, swollen glands (neck, armpit, or groin), Guillain-Barré syndrome, joint pain, aching muscles, unusual tiredness, weakness, or confusion, chills, stomach ache, muscle weakness, leg pain, shortness of breath, generally feeling unwell, bleeding or bruising more easily than normal, and skin infection.
  - Effectiveness: Please refer to the product monograph for data for females and males in specific age categories.
  - Other Considerations:
    - Immunization with HPV vaccine does not remove the need for screening for cervical, vulvar, vaginal, anal, and certain head and neck cancers, such as throat and back of mouth cancers as recommended by a health care professional; women should still get routine cervical cancer screening.
    - It is not known whether GARDASIL®9 is excreted in human milk.
    - There are no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, pregnancy should be avoided during the vaccination regimen for GARDASIL®9. Women who become pregnant before completion of the vaccine series should complete their vaccination schedule after childbirth. Pregnant women exposed to GARDASIL® are encouraged to report their exposure or suspected adverse reactions by contacting Merck Canada Inc., at 1-800-567-2594.

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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

- COVID-19 Booster Dose Parameters and Recommendations
  - Off-license use noted for Modern BA.4/5 in ages 6-17 years.
  - New first and second bullets:
    - People 5 years of age and older are eligible to receive **one** bivalent booster dose **6** months (absolute minimum of 5 months if operationally required) from their previous dose (i.e., after a primary series or a previous monovalent booster dose (regardless of the number of booster doses previously received)) **or** COVID-19 infection (whichever interval is longer as applicable).
    - The following populations are recommended to receive a **second** COVID-19 bivalent vaccine booster dose **6** or more months (absolute minimum of 5 months if operationally required) from their last COVID-19 booster dose **or** COVID-19 infection (whichever interval is longer as applicable):
      - Adults 80 years of age and older
      - Adult residents 18 years of age and older in long-term care facilities, personal care homes, and congregate living settings providing care for seniors (i.e. assisted living settings).
      - Adults 18 years of age and older who are moderately to severely immunocompromised with medical conditions described at https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-4-active-vaccines/page-26-covid-19-vaccine.html#a6.4.considerations
      - Adults 65-79 years of age, ***particularly*** if they do not have a known prior history of COVID-19 infection (verbal confirmation is acceptable from the client or their caregiver).
- COVID-19 Vaccine Q &A for Immunizers
  - New! #3
    - **A. Are there any exceptions regarding the 6-month interval for booster doses?**
    - B. Response: The 6-month interval is recommended after SARS-CoV-2 infection and the administration of a booster dose, as more time between infection and vaccination may result in a better immune response. The absolute minimum interval is 5 months, only to be applied if operationally required.
  - #9 responses:
    - A. If they have received 1 dose of a non-HC approved vaccine and now are in Canada, provide 1 monovalent dose 4 weeks after their first dose (preferably mRNA vaccine), and 1 bivalent booster dose (as age eligible; refer to COVID-19 Booster Dose Parameters and Recommendations) 6 months later to be considered up to date for current recommendations.
    - B. Select populations are recommended to receive a second bivalent booster dose. Refer to COVID-19 Booster Dose Parameters and Recommendations.
  - #10 responses:
    - A. If they have received 2 non-HC approved doses and are now in Canada, provide 1 bivalent dose (as age eligible; refer to COVID-19 Booster Dose Parameters and Recommendations) 6 months after their second dose, as their additional dose. They will be considered up to date based on current recommendations.

B. If they have received 3 non-HC approved doses and are now in Canada, provide 1 bivalent dose (if age eligible; refer to COVID-19 Booster Dose Parameters and Recommendations) 6 months after their third dose as their booster.

- Added to #12: 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).

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Chapter 7 Immunization of Special Populations

- Appendix 7.6: Publicly Funded Immunization Schedule for Adult Post-Hematopoietic Stem Cell Transplant
  - COVID-19 booster dose changed to 6 months interval to align with provincial recommendations.
- Recipients Appendix 7.8: Publicly Funded Immigrant and Refugee Immunization and Serology Recommendations
  - Added as footnote #2A: Screen adults and children from countries where the seroprevalence of chronic HB infection is ≥2% for all 3 markers (Pottie et al., 2011).

Chapter 8 Administration of Biological Products

- TOC Appendix 8.2 renamed Potentially Immunosuppressive Biologic Agents
- P. 33 Appendix 8.2 renamed Potentially Immunosuppressive Biologic Agents

Chapter 10 Biological Products

- TOC addition
  - New vaccine added! PREHEVBRIO™ 3-antigen Hepatitis B Vaccine (recombinant)
- Novavax Nuvaxovid 12+ **Monovalent** formulation
  - Product monograph date updated.
  - Storage and Handling:
    - Time for use after first vial puncture increased to 12 hours from 6 hours
    - Time out of Refrigeration (ToR) in syringe increased to 12 h from 6 hours
- Pfizer Comirnaty monovalent vaccines (6 mo-4 yrs, 5-11 years and 12+)
  - Product monograph dates updated.
  - Possible Reactions
    - Deleted:
      - ~~Bell's Palsy has been reported post-immunization in adults but is considered a rare event.~~
      - ~~Paresthesia, hypothesia and erythema multiforme are noted in the product monograph.~~
    - Added:
      - Facial paralysis / Bell's Palsy, hypoesthesia, paresthesia, dizziness, skin rash, pruritus, urticaria, angioedema, erythema multiforme and pain in extremity (arm) reported as post-market adverse events.
  - Added under Precautions:
    - Very rare cases of myocarditis and/or pericarditis following vaccination with COMIRNATY have been reported during post-authorization use. These cases occurred more commonly after the second dose and in adolescents and young adults. Typically, the onset of symptoms has been within a few days following receipt of COMIRNATY. Based on accumulating data, the reporting rates of myocarditis and pericarditis after COMIRNATY primary series in children ages 5 through <12 years are lower than in ages 12 through 17 years. Available short-term follow-up data suggest that the symptoms resolve in most individuals, but information on long-term sequelae is lacking. The decision to administer COMIRNATY to an individual with a history of myocarditis or pericarditis should take into account the individual's clinical circumstances.

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- New! PREHEVBRIO™ 3-antigen Hepatitis B Vaccine (recombinant)
    - This HB vaccine is only available on private market at this time.

Saskatchewan Immunization Manual Amendments April 24, 2023

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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.

- 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.

- 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 5-1129 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.

Saskatchewan Immunization Manual Amendments

May 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 5 Immunization Schedules

- P. 28 Appendix 5.2: Publicly Funded MMR Vaccine Eligibility
    - Eligibilities in #2 refined, now note that all post-secondary students born before 1970 who are studying in SK or out of province/country are eligible for publicly funded MMR vaccine.

Chapter 7 Immunization of Special Populations

- TOC page 2
    - New heading!: section 6.2.1 Students of Health Care Professions – Eligible for Publicly Funded Vaccines
- P. 19 Section 3.7 Medical Treatment
    - Last statement under live vaccines now states: Refer to SIM Appendix 8.2 Potentially Immunosuppressive Biologic Agents for live vaccine contraindications for infants whose mothers took monoclonal antibody medications during pregnancy.
- P. 26 New section added! 6.2.1 Students of Health Care Professions – Eligible for Publicly Funded Vaccines
    - Post-secondary students of health care professions are eligible to receive the same vaccines as noted in section 6.2, so refer to section *6.3 Health Care Worker – Eligible for Publicly Funded Vaccines* and to *Publicly Funded Hepatitis B Vaccine Eligibility for Students of Health Care Professions i*n Chapter 10.
- P. 41 Appendix 7.6: Publicly Funded Immunization Schedule for Adult Post-Hematopoietic Stem Cell Transplant Recipients
    - Additional non-publicly vaccines added to footnote 15.
    - New bullet #17! May be administered off label to HSCT recipients (whose age is beyond the vaccine's licensed age range) to reduce the number of injections they require to meet the antigen requirements as noted in this schedule.
- P. 42 Appendix 7.7 Tdap Decision Chart for Pregnant Women
    - New addition! Note: Tdap-IPV may be provided if the client requires a dose of IPV vaccine.
- P. 44 Appendix 7.9: Publicly Funded Immunization Schedule for Adult Solid Organ Pre-Transplant Candidates
    - Zostavax removed from bullet #14 as discontinued by manufacturer.
- P. 45 Appendix 7.10: Publicly Funded Immunization Schedule for Adult Solid Organ Post-Transplant Recipients
    - New bullet #12! May be administered off label to solid organ transplant recipients (whose age is beyond the vaccine's licensed age range) to reduce the number of injections they require to meet the antigen requirements as noted in this schedule.

Chapter 10 Biological Products

- TOC – first page
    - First 3 bullets at top of TOC page 1 reformatted with hyperlinks.
    - VIVAXIM removed, as discontinued by manufacturer.
    - New chapter section title added: Publicly Funded Hepatitis B Vaccine Eligibility for Students of Health Care Professions
- TOC – second page
    - ZOSTAVAX removed, as discontinued by manufacturer.

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- TOC – third page
  - SMV abbreviation added beside Smallpox and Mpox Vaccine
  - TYPHERIX removed, as discontinued by manufacturer.
  - IMOGAM Rabies removed, as discontinued by the manufacturer.
- DTaP-IPV-Hib vaccines (INFANRIX-IPV/Hib and PEDIACEL)
  - New footnote #5 added: May be administered off label to HSCT and solid organ transplant recipients (whose age is beyond the vaccine's licensed age range) to reduce the number of injections they require.
- DTaP-HB-IPV-Hib (INFANRIX hexa®)
  - New bullet added! Refer to Appendix 5.1: DTaP-IPV-Hib and HB Vaccine Schedule for Children who have previously Received DTaP-HB-IPV-Hib (INFANRIX hexa®) Vaccine Doses for immunization directives.
- Publicly Funded Hepatitis B (HB) Vaccine Indications
  - New addition! Select students of health care professions
- New content added! Publicly Funded Hepatitis B Vaccine Eligibility for Students of Health Care Professions
  - Specified students must meet all eligibility parameters to qualify for publicly funded HB vaccine series.
  - Review the NOTES for specific situations.
- **GARDASIL®9** (page 1 of 2)
  - Publicly funded indications now state:
    - Grade 6 students
    - Females born since January 1, 1996 and males born since January 1, 2006 up to and including 26 years old.
    - Immunocompromised females and males aged 9 up to and including 26 years old.
- RotaTeq
  - Appendices 8.2 and 8.4 now hyperlinked in the vaccine pages.
- IMVAMUNE
  - Dosage by route: dose sparing clarified for ID route.
  - PrEP series and eligibility revisions to first 2 bullets:
    - Those working in research laboratory settings with replicating orthopoxviruses
    - In the context of an active mpox outbreak, NACI recommends that immunization using the Imvamune vaccine should be offered to individuals with highest risk of mpox. During the outbreak in 2022, eligibility was as follows:
- Tdap-IPV (ADACEL-POLIO & BOOSTRIX-POLIO) (each vaccine now 2 pages)
  - New indication #4! Pregnant women: one dose in every pregnancy, ideally between 27-32 weeks gestation, only if IPV also required.
  - New footnote added #6: Refer to Chapter 7 Appendix 7.7: Tdap Immunization Decision Chart for Pregnant Women.
- PM dates and/or link updates – These are posted on the online SIM Chapter 10 and not included in the All Pages document.

DUKORAL PEDIACEL INFANRIX hexa Act-HIB VAQTA NeisVac-C VAXNEUVANCE PREVNAR 20 ROTARIX RotaTeq Td Adsorbed ADACEL BOOSTRIX ADACEL POLIO BOOSTRIX-POLIO Vivotif VARIVAX III TUBERSOL HepaGam B HyperRAB VariZIG

Saskatchewan Immunization Manual Amendments

May 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 7 Immunization of Special Populations

- DTaP-IPV-Hib now specified in Appendix 7.6 footnote # 17 and Appendix 7.10 footnote # 12.

Chapter 10 Biological Products

- TOC page 1 updated
  - MODERNA Spikevax® **6+** 0/O Original/Omicron BA.4/5 Bivalent formulation (Royal blue cap/grey label)
- COVID-19 Booster Dose Parameters and Recommendations
  - Moderna Spikevax BA.4/5 licensed by Health Canada as booster dose for ages 6 years to 17 years, so reference for off-label use removed.
- COVID-19 Vaccine Q & A for Immunizers
  - Moderna Spikevax BA.4/5 off-label use removed from question #6.
  - #11 response has been revised: "Individuals 12+ who completed a primary series with bivalent vaccine may receive one bivalent booster after 6 months. Additionally, individuals who are eligible for a second bivalent booster may receive another one 6 months later. Future COVID-19 vaccine booster doses the client becomes eligible for will be determined based on future epidemiology, data on waning immunity, new emerging variants, and/or new vaccines.
- IMVAMUNE
  - PM link and date updated
  - Storage and handling information updated, with 2 table added for frozen and refrigerated storage.
  - New resource added! Imvamune: Storage temperatures, shelf life, shipment and supportive temperature excursion information

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 page 1
  - Hiberix removed as no longer available in Canada.
- TOC page 2
  - New! Pneu-P-23 recommendations for adults 18+ immunized with only Pneu-C-15 or Pneu-C-20
- Hiberix removed as no longer available in Canada.
- New! Pneu-P-23 recommendations for adults 18+ immunized with only Pneu-C-15 or Pneu-C-20
- Pneu-C-15 and Pneu-C-20 pages include addition to refer to Pneu-P-23 recommendations for adults 18+ immunized with only Pneu-C-15 or Pneu-C-20.

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.

Saskatchewan Immunization Manual Amendments

September 2023

Notice: As of September 1, 2023, an 'all pages' amendments document is no longer produced. Immunizers can print vaccine amendment pages from the online SIM at their convenience.

Chapter 9 Management of Biological Products

- Pp. 27-28 Section 5.2 Cold Chain Break Report form and separate link updated
- P. 29 Section 5.2A How to complete a CCB report form – Instructions updated.
- P. 30 – Section 5.3 Product Wastage report form and separate link updated for Moderna XBB.1.5. **However, continue to report BA.4/5 wastages as 10 doses per vial.**
- P. 32 Section 5.4 Vaccine Returns form and separate link updated
- Pp. 35-36 Section 5.6 Vaccine Supply Problem Report form – Most current version Dec. 2021 added.

Chapter 10 Biological Products

- TOC third page
  - New! AREXVY RSV vaccine for 60+ years added as a non-publicly funded vaccine.
- Infanrix-IPV/Hib and Pediacel (DTaP-IPV-Hib)
  - Both vaccines are now 2 pages.
  - Additions to Contraindications as noted on fact sheets and product monographs:
    - Individuals who have experienced transient thrombocytopenia or other neurological complications following an earlier immunization against diphtheria and/or tetanus.
    - Pertussis-containing vaccine should not be administered to persons with uncontrolled neurologic disorders (such as epilepsy) or to those who had a neurological event within 7 days of a getting a previous dose of a pertussis-containing vaccine that is not attributable to another identifiable cause.
- Novavax NUVAXOVID
  - Update product monographd
  - Added under Precautions: Myocarditis was identified in two teenage men shortly after receiving a second dose of vaccine resulting in a mild clinical course with complete resolution and no sequelae. Currently available information is insufficient to determine a causal relationship with NUVAXOVID.
  - Under Storage and Handling – After first puncture, vaccine is stable for 6 hours at room temperature (up to +25C).
- Gardasil 9 (HPV-9)
  - Gender at birth added to indications.
  - 2- dose schedule policy revision: Persons who received their first HPV dose before their 15th birthday **must** complete the 3-dose schedule if they present for their second dose after their 15th birthday.
- Non-public funded influenza vaccines – general manufacturer links updated.
- Publicly Funded Influenza vaccine pages -
  - Afluria Tetra updated as per 2023-24 product monograph
  - FluLaval Tetra - general manufacturer link updated.
  - FluZone Quadrivalent - general manufacturer link updated.
  - FluZone High-Dose Quadrivalent - general manufacturer link updated.
- IMVAMUNE
  - Updated under Other Considerations: IMVAMUNE is a non-replicating live vaccine and it can be co-administered with or given any time before or after another live vaccine, an immune globulin product or tuberculin skin testing.

Saskatchewan Immunization Manual Amendments
September 2023

- ProQuad and Priorix-Tetra
    - Expected reactions aligned with 2023 MMRV fact sheet.

Local: Pain, redness and swelling.
Systemic:

- A fever lasting up to 3 days may occur 7 to 10 days after getting this vaccine. Monitor your child and treat their fever (at least 6 to 8 hours after immunization) **if** they are uncomfortable, refusing fluids and not sleeping.
- Less than 1 in 3,000 children with high fevers after getting their first dose of MMRV **may** have a febrile seizure. **Febrile seizures are temporary and not harmful to the child. If you are concerned, please talk to a public health nurse.**
- Swelling of the jawline (salivary glands), cheeks and neck 7 to 12 days later.
- Joint or muscle aches and pain.
- Nausea, vomiting, diarrhea or decreased appetite.
- Headache, dizziness, fussiness, tiredness.
- Lymph nodes swelling near the immunized limb.
- A blotchy red rash 4 to 12 days later.
- A varicella-like (blister) rash 5 to 26 days after getting immunized. People who have this rash rarely spread the vaccine virus to others. To prevent possible viral spreading, the rash should be covered until the blisters have dried and crusted over**.**

Extremely rare reactions may include:

- A temporary drop of the number of blood cells (platelets) that prevent bleeding (thrombocytopenia) within 6 weeks of being immunized. In most people, this resolves within 3 months without serious complications.
- Encephalitis (less than one in one million). The risk of encephalitis from measles disease is about one in 1,000, which is much higher than from this vaccine.

- Adacel and Boostrix (Tdap)
    - Each vaccine is now 2 pages.
    - Additional contraindications added as noted in CIG and the product monographs to align with the updated fact sheets.
        - People who developed encephalopathy (e.g., coma, decreased level of consciousness, prolonged seizures) within 7 days of a previous dose of a pertussis-containing vaccine that is not attributable to another identifiable cause.
        - People with a progressive neurologic disorder, including infantile spasms, uncontrolled epilepsy or progressive encephalopathy. Pertussis-containing vaccine should not be administered to persons with such conditions until a treatment regimen has been established and the condition has stabilized.
        - Individuals who have experienced transient thrombocytopenia or other neurological complications following an earlier immunization against diphtheria and/or tetanus.
- Adacel-Polio and Boostrix-Polio (Tdap-IPV)
    - Additions to Contraindications as noted on fact sheets and product monographs:
        - Individuals who have experienced transient thrombocytopenia or other neurological complications following an earlier immunization against diphtheria and/or tetanus.
        - Pertussis-containing vaccine should not be administered to persons with uncontrolled neurologic disorders (such as epilepsy) or to those who had a neurological event within 7 days of a getting a previous dose of a pertussis-containing vaccine that is not attributable to another identifiable cause.
- Other product monograph or link updates:
  DUKORAL RECOMBIVAX HB MMRII PRIORIX PRIORIX-TETRA (link only) MENJUGATE Liquid (link only) NeisVac-C (link only) Menactra (link only) Menveo (link only) Bexsero (link only) Trumenba (link only) SYNFLORIX (link only) Prevnar 13 (link only) VAXNEUVANCE (link only) Prevnar 20 (link only) Pneumovax 23 (link only) IMOVAX Polio (link only) AREXVY (New!) BOOSTRIX (link only) VARILRIX (link only) HperHEP B (new link) GamaSTAN (link only) BAT

Saskatchewan Immunization Manual Amendments

September 2023

Chapter 14 Appendices

p. 21 – English fact sheet dates updated as applicable.

Saskatchewan Immunization Manual Amendments

2023-09-25

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 7 Immunization of Special Populations

- Page 21 section 5.1 MSM
  - Mpox vaccine added.
- Page 35 Appendix 7.1
  - Mpox added to MSM
- Page 41 Appendix 7.6 HSCT Recipients
  - New footnote! ¥ - ALL previously immunized or unimmunized patients – First XBB.1.5 dose 4 month post-transplant and second XBB.1.5 dose 3 months later (or 6 months later after COVID-19 infection).
  - Footnote 1 addition: High dose flu vaccine is publicly funded only for those 65 years and older.
  - Footnote updated to refer to Ch. 7 referral forms (Appendices 7.2 & 7.3).
  - Footnote 11 updated to: Refer to SIM Appendix 7.4 High Dose Hepatitis B Immunization Algorithm - Renal, HIV, Congenital Immunodeficiency Client. Repeat series if response is less than 10 IU/mL after series completion.
- Page 44 Appendix 7.9 SOT Candidates
  - New addition to table and new footnote for COVID-19 XBB.1.5 vaccine! ¥ Unvaccinated pre-transplant SOT candidates should receive 3 doses (0-4 weeks-8 weeks) of mRNA vaccine as a primary series, with the final dose given 1-2 weeks prior to transplantation whenever possible. Subsequent boosters should be given 3 months later.
- Page 45 Appendix 7.10 SOT recipients
  - New addition to table and new footnote for COVID-19 XBB.1.5 vaccine! ¥ Unvaccinated pre-transplant SOT recipients should receive 3 doses (0-4 weeks-8 weeks) of mRNA vaccine as a primary series. Subsequent boosters should be given 3 months later. Vaccinated SOT recipients should receive booster doses 3 months after their previous vaccine dose. All SOT recipients should wait at least 1-month post-transplant to continue vaccine series, regardless of induction therapy. SOT recipients undergoing active treatment for acute rejection should defer vaccination for 1 month. SOT recipients with previous COVID-19 infection should defer vaccination for 3 months post-infection. SOT recipients who have received monoclonal antibodies for COVID-19 disease should defer vaccination for at least 90 days after therapy.

Chapter 10 Biological Products

- TOC first page
  - New! XBB.1.5 COVID-19 Vaccine Schedules
  - New! MODERNA Spikevax™ **XBB.1.5** formulation 6+ months (0.1mg/ml; **Royal Blue Cap/Coral Blue Label**)
- COVID-19 Vaccine Q &A for Immunizers
  - Totally revised to address scenarios and questions related to XBB.1.5 vaccines. Ensure immunizers are familiar with the new content.
  - This section will be enhanced as other XBB.1.5 vaccines are licensed by Health Canada.
- New! XBB.1.5 COVID-19 Vaccine Schedules
  - Ensure immunizers are familiar with the new content.
  - Contains tables to address 5-11 and 12+ immune competent and immunocompromised individuals; children transitioning from 4 years to 5 years of age; and children presenting at 6 mo-4 years who are immune competent or immune compromised.

Saskatchewan Immunization Manual Amendments

2023-09-25

- This section will be enhanced as other XBB.1.5 vaccines are licensed by Health Canada.

- New! MODERNA Spikevax™ **XBB.1.5** formulation 6+ months (0.1mg/ml; **Royal Blue Cap/Coral Blue Label**)
  - Scheduling and dosages for this vaccine are noted in XBB.1.5 COVID-19 Vaccine Schedules.

Saskatchewan Immunization Manual Amendments
October 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 9 Management of Biological Products

- P. 30 section 5.3 PRODUCT WASTAGE REPORT FORM
  - Modern XBB.1.5 vial doses corrected to 5 doses, from 10 doses.

Chapter 10 Biological Products

- TOC first page
  - Removed:
    - Recommended bivalent Omicron-Containing mRNA vaccines. Dosages and schedules for primary series
    - COVID-19 Booster dose parameters and recommendations
  - New! Pfizer BioNTech Comirnaty® 12 + **XBB.1.5** formulation 6+ months formulation (Gray cap/label border)
  - New! Pfizer BioNTech Comirnaty® 5-11 years **XBB.1.5** formulation 6+ months formulation (Blue cap/label border)
  - New! Pfizer BioNTech Comirnaty® 6 month – 4 years **XBB.1.5** formulation 6+ months formulation (Maroon cap/label border)
- COVID-19 Vaccine Q &A for Immunizers
  - New addition to **#2C for** age transition 4 to 5 years with Pfizer vaccine. "Children who transition from age 4 years to age 5 years during the Pfizer XBB.1.5 vaccination series should complete the series as per the 6 month to 4 years schedule **using 0.2 ml (3 mcg) dose from the maroon cap/label border vial.**
- XBB.1.5 COVID-19 Vaccine Schedules
  - Schedules now included for Pfizer XBB.1.5 vaccines and recommendations for mixed schedules for young children.
- All bivalent vaccine pages removed.
- New! Pfizer BioNTech Comirnaty® 12 + **XBB.1.5** formulation 6+ months formulation (Gray cap/label border)
  - Scheduling and dosages for this vaccine are noted in XBB.1.5 COVID-19 Vaccine Schedules.
- New! Pfizer BioNTech Comirnaty® 5-11 years **XBB.1.5** formulation 6+ months formulation (Blue cap/label border)
  - Scheduling and dosages for this vaccine are noted in XBB.1.5 COVID-19 Vaccine Schedules.
- New! Pfizer BioNTech Comirnaty® 6 month – 4 years **XBB.1.5** formulation 6+ months formulation (Maroon cap/label border)
  - Scheduling and dosages for this vaccine are noted in XBB.1.5 COVID-19 Vaccine Schedules.

Saskatchewan Immunization Manual Amendments

2023-10-12

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 7 Immunization of Special Populations

- P. 41 Appendix 7.6 HSCT Recipients
  - COVID-19 XBB schedule in the table updated.
  - Footnote ¥ revised: - All previously immunized or unimmunized patients should receive 3 doses (0, 4 weeks, 8 weeks) of XBB.1.5 as a primary series starting at 4 months post transplant (3 months post autologous transplant who are going onto maintenance therapy). If indicated, an additional dose should be given 3 months later. HSCT recipients with previous COVID-19 disease should defer vaccination 3 months post-infection.
  - Arexvy added to footnote #15.

- P. 44 Appendix 7.9 Adult Solid Organs Pre-Transplant Candidates
  - Arexvy added to footnote #14.

- P. 45 Appendix 7.10 Adult Solid Organ Transplant Recipients
  - Revision to footnote ¥ - the 90-day interval from receipt of monoclonal antibodies for COVID-19 has been removed.
  - Arexvy added to footnote #13.

Saskatchewan Immunization Manual Amendments
November 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

Page 1 of COVID-19 Vaccine Q &A for Immunizers

- #2 question and response revised:

  2) Are any individuals able to get additional XBB.1.5 vaccine doses?

  Response: Consult the XBB.1.5 COVID-19 Vaccination Schedules for current recommendations.

XBB.1.5 COVID-19 Vaccination Schedules (all 4 pages)

- All tables align with the *Canadian Immunization Guide's COVID-19 vaccine* chapter, and the National Advisory Committee on Immunization's (NACI) *Updated guidance on the use of COVID-19 vaccines in individuals who have not previously been vaccinated against COVID-19* (Oct. 2023) and *Addendum to the guidance on the use of COVID-19 vaccines in the fall of 2023* (Sept. 2023). The amendments include additional dose requirements for moderately to severely immunocompromised persons, vaccine dosage directives for children based on age at presentation, as well as amended foot notes.