Saskatchewan Immunization Manual Amendments January 2022

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

- VAXNUEVANCE® (Merck's new Pneu-C-15 vaccine) added to TOR second page and as a new page in this chapter.
- Moderna 12+ vaccine Precautions section
    - For individuals aged 30 and younger who are receiving their primary COVID-19 vaccine series and both Moderna and Pfizer are readily available, Pfizer is the preferred vaccine as there is a lower risk of myocarditis compared to immunization with Moderna. Individuals opting to receive Moderna shall be informed of the increased risk of myocarditis/pericarditis compared to receiving Pfizer.
    - It is unclear if people who developed myocarditis or pericarditis after a first dose of an mRNA COVID-19 vaccine are at increased risk of further adverse cardiac events following a second dose of the vaccine. **NACI continues to recommends that further doses of mRNA COVID-19 vaccines should be deferred among people who experienced myocarditis and/or pericarditis within 6 weeks of receiving a previous dose of an mRNA COVID-19 vaccine. This includes any person who had an abnormal cardiac investigation including electrocardiogram (ECG), elevated troponins, echocardiogram or cardiac MRI after a dose of an mRNA vaccine.**
    - **NACI now also recommends that those with a history compatible with pericarditis and who either had no cardiac workup or had normal cardiac investigations, can be revaccinated once they are symptom free and at least 90 days has passed since previous vaccination.** NACI will continue to monitor the evidence and update recommendations as needed.

- Pfizer +12 years vaccine Precautions section
    - For individuals aged 30 and younger who are receiving their primary COVID-19 vaccine series and both Moderna and Pfizer are readily available, Pfizer is the preferred vaccine as there is a lower risk of myocarditis compared to immunization with Moderna. Individuals opting to receive Moderna shall be informed of the increased risk of myocarditis/pericarditis compared to receiving Pfizer.
    - It is unclear if people who developed myocarditis or pericarditis after a first dose of an mRNA COVID-19 vaccine are at increased risk of further adverse cardiac events following a second dose of the vaccine. **NACI continues to recommends that further doses of mRNA COVID-19 vaccines should be deferred among people who experienced myocarditis and/or pericarditis within 6 weeks of receiving a previous dose of an mRNA COVID-19 vaccine. This includes any person who had an abnormal cardiac investigation including electrocardiogram (ECG), elevated troponins, echocardiogram or cardiac MRI after a dose of an mRNA vaccine.**
    - **NACI now also recommends that those with a history compatible with pericarditis and who either had no cardiac workup or had normal cardiac investigations, can be revaccinated once they are symptom free and at least 90 days has passed since previous vaccination.** NACI will continue to monitor the evidence and update recommendations as needed.

- Pfizer 5-11 years vaccine Preparation/Reconstitution section
    - Pre-loading Pfizer's 5-11 years vaccine into syringes for the purpose of transporting COVID-19 vaccine in exceptional circumstances has NOT been approved.

Saskatchewan Immunization Manual Amendments February 2022

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. 11 section 2.1 min. intervals for specific vaccine series
  - 4CMenB 3-dose series: 6 weeks corrected to 6 months.

Chapter 7 – Immunization of Special Populations

- P. 35 Appendix 7.1
  - Under Treatment, Tetanus row and TIg column deleted as the correct risk factor is under post-exposure prophylaxis section of the appendix.

Chapter 8 Administration of Biological Products

- P. 10 Table 2 Ig Preparation Injection site, Needles Length and Daily Total Site Volume per Age Group.
  - New ▲ symbol added to Site column title.
  - New footnote: ▲ Different immune globulin preparations must be separated by minimum 2.5 cm if given in the same limb (e.g., TIg and RabIg in adult deltoid). It is recommended to administer in different sites if possible. This aligns with the information in SIM chapter 10.

Chapter 10 Biological Products

- TOC third page - Immune Globulin Preparation Injection Site, Needle Length and Daily Total Site Volume per Age Group
  - Daily added to title and third page TOC revised with same.
- INFANRIX-IPV-HIB
  - Under contraindications, children ages 5 years and older removed as product may be used off-label in SK.
  - Footnote 5 removed.
- PEDIACEL
  - Under contraindications, children ages 7 years and older removed as product may be used off-label in SK.
  - Footnote 5 removed.
- Bexsero MenB Page 1/2
  - Under dose/Series, second row corrected to read Infants 6 months through 11 months.
- ALL COVID-19 VACCINES
  - COVID-19 vaccination should not be delayed because of testing for tuberculosis (TB) infection. Testing for TB infection with one of the immune-based methods, either the tuberculin skin test (TST) or an interferon-gamma release assay (IGRA), can be done before, after, or during the same encounter as COVID-19 vaccination. (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#laboratory-testing)
- Moderna 12+ vaccine
  - Under Preparation/Reconstitution: Removal of reference to transporting in PFS and work standard.
  - Precautions – Individuals who developed myocarditis or pericarditis following mRNA vaccine – Revised NACI guidance:
    - It is unclear if people who developed myocarditis or pericarditis after a first dose of an mRNA COVID-19 vaccine are at increased risk of further adverse cardiac events following a second dose of the vaccine. **NACI continues to recommends that in most circumstances, and as a precautionary measure until more information is available, further doses of mRNA COVID-19 vaccines should be deferred among people who experienced myocarditis**

(with or without pericarditis) within 6 weeks of receiving a previous dose of an mRNA COVID-19 vaccine. This includes any person who had an abnormal cardiac investigation including electrocardiogram (ECG), elevated troponins, echocardiogram or cardiac MRI after a dose of an mRNA vaccine.

- **NACI now recommends that those with a history compatible with pericarditis and who either had no cardiac workup or had normal cardiac investigations, can receive the next doses once they are symptom free and at least 90 days has passed since previous vaccination.**
- **Some people with confirmed myocarditis (with or without pericarditis) after a dose of an mRNA COVID-19 vaccine may choose to receive another dose of vaccine after discussing the risks and benefits with their healthcare provider. If another dose of vaccine is offered, they should be offered the Pfizer-BioNTech 30 mcg vaccine due to the lower reported rate of myocarditis and/or pericarditis following the Pfizer-BioNTech 30 mcg vaccine compared to the Moderna 100 mcg vaccine. Informed consent should include discussion about the unknown risk of recurrence of myocarditis and/or pericarditis following receipt of additional doses of Pfizer-BioNTech COVID-19 vaccine in individuals with a history of confirmed myocarditis and/or pericarditis after a previous dose of mRNA COVID-19 vaccine, as well as the need to seek immediate medical assessment and care should symptoms develop.**

- Pfizer +12 years vaccine
  - Under Preparation/Reconstitution: Removal of reference to transporting in PFS and work standard.
  - Product monograph updated
  - Precautions – Individuals who developed myocarditis or pericarditis following mRNA vaccine – Revised NACI guidance:
    - It is unclear if people who developed myocarditis or pericarditis after a first dose of an mRNA COVID-19 vaccine are at increased risk of further adverse cardiac events following a second dose of the vaccine. **NACI continues to recommends that in most circumstances, and as a precautionary measure until more information is available, further doses of mRNA COVID-19 vaccines should be deferred among people who experienced myocarditis (with or without pericarditis) within 6 weeks of receiving a previous dose of an mRNA COVID-19 vaccine. This includes any person who had an abnormal cardiac investigation including electrocardiogram (ECG), elevated troponins, echocardiogram or cardiac MRI after a dose of an mRNA vaccine.**
    - **NACI now recommends that those with a history compatible with pericarditis and who either had no cardiac workup or had normal cardiac investigations, can receive the next doses once they are symptom free and at least 90 days has passed since previous vaccination.**
    - **Some people with confirmed myocarditis (with or without pericarditis) after a dose of an mRNA COVID-19 vaccine may choose to receive another dose of vaccine after discussing the risks and benefits with their healthcare provider. If another dose of vaccine is offered, they should be offered the Pfizer-BioNTech 30 mcg vaccine due to the lower reported rate of myocarditis and/or pericarditis following the Pfizer-BioNTech 30 mcg vaccine compared to the Moderna 100 mcg vaccine. Informed consent should include discussion about the unknown risk of recurrence of myocarditis and/or pericarditis following receipt of additional doses of Pfizer-BioNTech COVID-19 vaccine in individuals with a history of confirmed myocarditis and/or pericarditis after a previous dose of mRNA COVID-19 vaccine, as well as the need to seek immediate medical assessment and care should symptoms develop.**
- Pfizer 5-11 years vaccine
  - Product monograph updated.
  - 3-dose series schedule for immune compromised children added:

Primary series for immune compromised individuals

- 3 doses of 0.2 ml
  - Dose 1: day 0

- Dose 2: min. 28 days later
- Dose 3: min. 28 days later
- 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).

- Precautions – Individuals who developed myocarditis or pericarditis following mRNA vaccine – Revised NACI guidance:
  - It is unclear if people who developed myocarditis or pericarditis after a first dose of an mRNA COVID-19 vaccine are at increased risk of further adverse cardiac events following a second dose of the vaccine. **NACI continues to recommends that in most circumstances, and as a precautionary measure until more information is available, further doses of mRNA COVID-19 vaccines should be deferred among people who experienced myocarditis (with or without pericarditis) within 6 weeks of receiving a previous dose of an mRNA COVID-19 vaccine. This includes any person who had an abnormal cardiac investigation including electrocardiogram (ECG), elevated troponins, echocardiogram or cardiac MRI after a dose of an mRNA vaccine.**
  - **NACI now recommends that those with a history compatible with pericarditis and who either had no cardiac workup or had normal cardiac investigations, can receive the next doses once they are symptom free and at least 90 days has passed since previous vaccination.**
  - **Some people with confirmed myocarditis (with or without pericarditis) after a dose of an mRNA COVID-19 vaccine may choose to receive another dose of vaccine after discussing the risks and benefits with their healthcare provider. If another dose of vaccine is offered, they should be offered the Pfizer-BioNTech 30 mcg vaccine due to the lower reported rate of myocarditis and/or pericarditis following the Pfizer-BioNTech 30 mcg vaccine compared to the Moderna 100 mcg vaccine. Informed consent should include discussion about the unknown risk of recurrence of myocarditis and/or pericarditis following receipt of additional doses of Pfizer-BioNTech COVID-19 vaccine in individuals with a history of confirmed myocarditis and/or pericarditis after a previous dose of mRNA COVID-19 vaccine, as well as the need to seek immediate medical assessment and care should symptoms develop.**

- Immune Globulin Preparation Injection Site, Needle Length and Daily Total Site Volume per Age Group
  - Daily added to title.

Chapter 11 AEFIs

- P. 7 Section 3.1.3 Important Guidelines
  - Second last original bullet regarding "PH will complete AEFI forms" removed.

Chapter 12 Anaphylaxis Management

- This complete chapter has been revised including a new sample anaphylaxis worksheet and policy regarding the uploading of this document into the client's Panorama record. Please ensure that staff review this chapter. The full chapter will be released instead of incorparoting the chapter in the SIM all pages for Feb. 2022.

Saskatchewan Immunization Manual Amendments March 2022

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. 15 Section 3.5.1 Immune Globulin Preparations or Blood: Timing Intervals for Vaccines Containing Live Measles, Mumps, Rubella, or Varicella Viruses
    - All intervals for Standard Ig changed to 5-6 months.

Chapter 7 Immunization of Special Populations

- P. 41 Appendix 7.6: Publicly Funded Immunization Schedule for Adult Post-Hematopoietic Stem Cell Transplant Recipients (autologous and allogeneic)
    - Footnote 10: NOT PUBLICY FUNDED added to beginning of footnote.

Chapter 10 Biological Products

- TOC - Novavax NUVAXOVID added.
- New! Novavax NUVAXOVID™
    - Recombinant protein subunit, adjuvanted COVID-19 vaccine
    - Please ensure that staff read the full content.
- AstraZeneca/COVISHIELD
    - Under Contraindication re Anaphylaxis: Section now states:
        - Anaphylaxis to previous dose of viral vector or other COVID-19 vaccine. However, NACI notes: In individuals with a history of a severe, immediate (≤4h following vaccination) allergic reaction (e.g., anaphylaxis) after previous administration of COVID-19 vaccine, re-vaccination (i.e. administration of a subsequent dose in the series when indicated) may be offered with the same vaccine or an mRNA vaccine if a risk assessment deems that the benefits outweigh the potential risks for the individual and if informed consent is provided.
        - If re-vaccinated, vaccine administration should be done in a controlled setting with expertise and equipment to manage anaphylaxis. Individuals should be observed for at least 30 minutes after re-vaccination.
    - Under Precautions – Treatment with Monoclonal Antibodies
        - Previous text removed.
        - New text: Vaccination with a dose of COVID-19 vaccine should be delayed for at least 90 days after treatment.
    - Under Other Considerations, new bullet re immunization post-illness: Individuals who are eligible for immunization (either first, second or subsequent doses) may be offered immunization as soon as their symptoms have improved.

- Janssen
    - Under Contraindication re Anaphylaxis: Section now states:
        - Anaphylaxis to previous dose of viral vector or other COVID-19 vaccine. However, NACI notes: In individuals with a history of a severe, immediate (≤4h following vaccination) allergic reaction (e.g., anaphylaxis) after previous administration of COVID-19 vaccine, re-vaccination (i.e. administration of a subsequent dose in the series when indicated) may be offered with the same vaccine or an mRNA vaccine if a risk assessment deems that the benefits outweigh the potential risks for the individual and if informed consent is provided.

        - If re-vaccinated, vaccine administration should be done in a controlled setting with expertise and equipment to manage anaphylaxis. Individuals should be observed for at least 30 minutes after re-vaccination.
    - Under Precautions – Treatment with Monoclonal Antibodies
        - Previous text removed.
        - New text: Vaccination with a dose of COVID-19 vaccine should be delayed for at least 90 days after treatment.
    - Under Other Considerations, new bullet re immunization post-illness: Individuals who are eligible for immunization (either first, second or subsequent doses) may be offered immunization as soon as their symptoms have improved.

- Moderna Spikevax – Now approved for use in ages 6+ years
    - Product monograph updated 2022-03-17
    - New NACI recommendation 2022-03-17 - *Recommendations on the use of Moderna Spikevax COVID-19 vaccine in children 6 to 11 years of age.* *https://www.canada.ca/content/dam/phac-aspc/documents/services/immunization/national-advisory-committee-on-immunization-naci/statement-recommendations-use-moderna-spikevax-covid-19-vaccine.pdf*
    - Indications for use - those 6 years and older
    - Dosage – Children 6-11 years = 0.25 ml (50 mcg); Those 12+ years = 0.50 ml (100 mcg)
    - Number of dose and scheduling – Dosages removed.
    - New bullet under Primary series for moderately to severe immune compromised individuals
        - Indirect data from adult populations (≥18 years of age) suggest Moderna's Spikevax may result in higher vaccine effectiveness after a 2-dose primary series compared to Pfizer's Comirnaty and is associated with a higher seroconversion rate among adult immunocompromised patients. Given this potential benefit, administration of Moderna's Spikevax vaccine as a 3-dose primary series may be considered for some immunocompromised individuals 6 to 11 years of age (NACI, 2022)
    - Under Contraindication re Anaphylaxis: Section now states:
        - Anaphylaxis to previous dose of viral vector or other COVID-19 vaccine. However, NACI notes: In individuals with a history of a severe, immediate (≤4h following vaccination) allergic reaction (e.g., anaphylaxis) after previous administration of COVID-19 vaccine, re-vaccination (i.e. administration of a subsequent dose in the series when indicated) may be offered with the same vaccine or an mRNA vaccine if a risk assessment deems that the benefits outweigh the potential risks for the individual and if informed consent is provided.
        - If re-vaccinated, vaccine administration should be done in a controlled setting with expertise and equipment to manage anaphylaxis. Individuals should be observed for at least 30 minutes after re-vaccination.
    - Under Precautions – Individuals who developed myocarditis or pericarditis following mRNA vaccine
        - Added: Current analyses show the number of reports of myocarditis/pericarditis following the Moderna Spikevax COVID-19 vaccine is higher than what would be expected in the general population, particularly among males and females less than 40 years old and following the second dose.
    - Under Precautions – Treatment with Monoclonal Antibodies
        - Previous text removed.
        - New text: Vaccination with a dose of COVID-19 vaccine should be delayed for at least 90 days after treatment.

- Under Other Considerations, new bullet re immunization post-illness: Individuals who are eligible for immunization (either first, second or subsequent doses) may be offered immunization as soon as their symptoms have improved.
- Under Possible Reaction – New second last sentence added to first bullet: No cases of myocarditis or pericarditis were reported in the 6-11 years old studies.
- Under Storage and handling – New bullet: **DO NOT DILUTE THIS VACCINE!**

Pfizer 12+ vaccine

- Under Contraindication re Anaphylaxis: Section now states:
  - Anaphylaxis to previous dose of viral vector or other COVID-19 vaccine. However, NACI notes: In individuals with a history of a severe, immediate (≤4h following vaccination) allergic reaction (e.g., anaphylaxis) after previous administration of COVID-19 vaccine, re-vaccination (i.e. administration of a subsequent dose in the series when indicated) may be offered with the same vaccine or an mRNA vaccine if a risk assessment deems that the benefits outweigh the potential risks for the individual and if informed consent is provided.
  - If re-vaccinated, vaccine administration should be done in a controlled setting with expertise and equipment to manage anaphylaxis. Individuals should be observed for at least 30 minutes after re-vaccination.
- Under Precautions – Individuals who developed myocarditis or pericarditis following mRNA vaccine
  - Added: Current analyses show the number of reports of myocarditis/pericarditis following the Pfizer-BioNTech Comirnaty COVID-19 vaccine is higher than what would be expected in the general population of males and females less than 30 years old and primarily following the second dose.
- Under Precautions – Treatment with Monoclonal Antibodies
  - Previous text removed.
  - New text: Vaccination with a dose of COVID-19 vaccine should be delayed for at least 90 days after treatment.
- Under Other Considerations, new bullet re immunization post-illness: Individuals who are eligible for immunization (either first, second or subsequent doses) may be offered immunization as soon as their symptoms have improved.
- Under Possible reactions: Paresthesia, hypothesia and erythema multiforme are noted in the product monograph has been added.

- Pfizer Pediatric 5-11
  - Under Contraindication re Anaphylaxis: Section now states:
    - Anaphylaxis to previous dose of viral vector or other COVID-19 vaccine. However, NACI notes: In individuals with a history of a severe, immediate (≤4h following vaccination) allergic reaction (e.g., anaphylaxis) after previous administration of COVID-19 vaccine, re-vaccination (i.e. administration of a subsequent dose in the series when indicated) may be offered with the same vaccine or an mRNA vaccine if a risk assessment deems that the benefits outweigh the potential risks for the individual and if informed consent is provided.
    - If re-vaccinated, vaccine administration should be done in a controlled setting with expertise and equipment to manage anaphylaxis. Individuals should be observed for at least 30 minutes after re-vaccination.

- Under Other Considerations, new bullet re immunization post-illness: Individuals who are eligible for immunization (either first, second or subsequent doses) may be offered immunization as soon as their symptoms have improved.
- Under Precautions – Treatment with Monoclonal Antibodies
  - Previous text removed.
  - New text: Vaccination with a dose of COVID-19 vaccine should be delayed for at least 90 days after treatment.

- Prevnar 13
  - Original foot note 3 removed as a duplicate of footnote 2, and Table A3 and A4 adjusted accordingly.
  - Original footnotes 4, 5 and 6 are now footnotes 3, 4 and 5.

Saskatchewan Immunization Manual Amendments April 2022

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Chapter 9 – Management of Biological Products

- Revised TOC second page as Appendix 9.2 has been added.
- Page 10 Section 2.5.3 Temperature Indicator Cards
  - States to refer to Appendix 9.2
- New! Appendix 9.2 Temperature Indicator Information Sheet
  - Added for staff reference.
  - It is suggested to have a printed version in each area where vaccine shipments are unpacked.

Chapter 10 Biological Products

- Janssen
  - Updated product monograph March 24/22
  - Under Contraindications: TTS
    - New bullets:
      - Individuals who have experienced thrombosis with thrombocytopenia syndrome (TTS) following vaccination with adenovirus-vectored COVID-19 vaccine should not receive Janssen COVID-19 vaccine. A combination of thrombosis and thrombocytopenia, including TTS, in some cases accompanied by bleeding, has been observed very rarely following vaccination with Janssen COVID-19 Vaccine during post-authorization use. This includes severe cases at unusual sites such as cerebral venous sinus thrombosis (CVST) and splanchnic vein thrombosis, as well as arterial thrombosis, concomitant with thrombocytopenia. The majority of cases occurred within three weeks following vaccination.
      - Cases of TTS following administration of the Janssen COVID-19 Vaccine have been reported in individuals, in a wide age range of individuals 18 years and older, with the highest reporting rate (approximately 1 case per 100,000 doses administered) in females ages 30-49 years; overall, approximately 15% of TTS cases have been fatal. The clinical course of these events shares features with autoimmune heparin-induced thrombocytopenia (HIT). Currently available evidence supports a causal relationship between TTS and the Janssen COVID-19 Vaccine.
  - Under Possible Reactions, new additions:
    - Malaise, asthenia, muscular weakness, pain in extremities, paresthesia, hypothesia, dizziness, diarrhea and vomiting; tinnitus; transverse myelitis.

Saskatchewan Immunization Manual Amendments May 2022

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Chapter 7 – Immunization of Special Populations

- TOC (second page)
  - Full algorithm title added to Appendix 7.4: High Dose Hepatitis B Immunization Algorithm - Renal, HIV, Congenital Immunodeficiency Deficiency Clients.
- Appendix 7.1 page 36
  - Foot note 2C now states: 1 dose for Pneu-C-13 naïve persons 5 years and older.

Chapter 10 Biological Products

- Gardasil 9: updated product monograph as new indication for prevention of oropharyngeal cancers.
- Bexsero: updated product monograph with additional post-market AEFIs reported including: Hypotonic-hyporesponsive episode, syncope or vasovagal responses to injection, lymphadenopathy, injection site reactions like extensive swelling of the vaccinated limb, blisters at or around the injection site and/or a hard lump at the injection site (which may persist for more than one month) and allergic reactions (including anaphylactic reactions) have been reported as post-market events.

COVID-19 vaccines

- References to vaccine efficacy removed for most vaccines as this varies according to number of doses received.
- AstraZeneca Vaxzevria vaccine removed as no longer available in Canada.
- Janssen
  - Under Schedule: Last bullet now states: For booster dose details, refer to the Ministry of Health's COVID – 19 Vaccine Contraindications and Precautions Background Document found in the COVID-19 Immunization Manual.
  - Under Other Considerations: revised to the following:
    - In SK, individuals who are eligible for immunization (either first, second or subsequent doses) may be offered immunization as soon as their symptoms have improved.
    - However, Table 5 of the CIG COVID-19 chapter provides other interval guidelines: (https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-4-active-vaccines/page-26-covid-19-vaccine.html#a6.2)
    - Individuals presenting for immunization do not need to be tested for previous COVID-19 infection.
    - Immunization of individuals who may be currently infected with SARS-CoV-2 is not known to have a detrimental effect on the illness.
  - New reference: *Canadian Immunization Guide*: COVID-19 Vaccines: https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-4-active-vaccines/page-26-covid-19-vaccine.html
- Moderna Spikevax 6+ years (Red cap)
  - Under Schedule: Last bullet now states: For booster dose details, refer to the Ministry of Health's COVID – 19 Vaccine Contraindications and Precautions Background Document found in the COVID-19 Immunization Manual.
  - Under Other Considerations: revised to the following:
    - In SK, individuals who are eligible for immunization (either first, second or subsequent doses) may be offered immunization as soon as their symptoms have improved.

        - However, Table 5 of the CIG COVID-19 chapter provides other interval guidelines: (https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-4-active-vaccines/page-26-covid-19-vaccine.html#a6.2)
        - Individuals presenting for immunization do not need to be tested for previous COVID-19 infection.
        - Immunization of individuals who may be currently infected with SARS-CoV-2 is not known to have a detrimental effect on the illness.
    - Under Storage and Handling, new bullet added to thawed unpunctured and thawed punctured to align with current work standard: **The duration of time an unpunctured vial is stored at room temperature is counted against the 24 hour stability period after puncture**.
    - New reference: *Canadian Immunization Guide*: COVID-19 Vaccines: https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-4-active-vaccines/page-26-covid-19-vaccine.html
- Novavax Nuvaxovid
    - Under Schedule: Last bullet now states: For booster dose details, refer to the Ministry of Health's COVID – 19 Vaccine Contraindications and Precautions Background Document found in the COVID-19 Immunization Manual.
    - Under Other Considerations: revised to the following:
        - In SK, individuals who are eligible for immunization (either first, second or subsequent doses) may be offered immunization as soon as their symptoms have improved.
        - However, Table 5 of the CIG COVID-19 chapter provides other interval guidelines: (https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-4-active-vaccines/page-26-covid-19-vaccine.html#a6.2)
        - Individuals presenting for immunization do not need to be tested for previous COVID-19 infection.
        - Immunization of individuals who may be currently infected with SARS-CoV-2 is not known to have a detrimental effect on the illness.
    - New reference: *Canadian Immunization Guide*: COVID-19 Vaccines: https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-4-active-vaccines/page-26-covid-19-vaccine.html
- Pfizer Comirnaty 12+ vaccine (purple cap and label):
    - Updated product monograph
    - Under Schedule: Last bullet now states: For booster dose details, refer to the Ministry of Health's COVID – 19 Vaccine Contraindications and Precautions Background Document found in the COVID-19 Immunization Manual.
    - Under Other Considerations: revised to the following:
        - In SK, individuals who are eligible for immunization (either first, second or subsequent doses) may be offered immunization as soon as their symptoms have improved.
        - However, Table 5 of the CIG COVID-19 chapter provides other interval guidelines: (https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-4-active-vaccines/page-26-covid-19-vaccine.html#a6.2)
        - Individuals presenting for immunization do not need to be tested for previous COVID-19 infection.

        - Immunization of individuals who may be currently infected with SARS-CoV-2 is not known to have a detrimental effect on the illness.
    - Under Interchangeability: **Pfizer's 12+ Grey cap formulation (not yet available) is interchangeable with the 12+ years purple cap formulation.**
    - New reference: *Canadian Immunization Guide*: COVID-19 Vaccines: https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-4-active-vaccines/page-26-covid-19-vaccine.html
- Pfizer Comirnaty 5-11 years vaccine (orange cap and label):
    - Updated product monograph
    - Under Other Considerations: revised to the following:
        - In SK, individuals who are eligible for immunization (either first, second or subsequent doses) may be offered immunization as soon as their symptoms have improved.
        - However, Table 5 of the CIG COVID-19 chapter provides other interval guidelines: (https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-4-active-vaccines/page-26-covid-19-vaccine.html#a6.2)
        - Individuals presenting for immunization do not need to be tested for previous COVID-19 infection.
        - Immunization of individuals who may be currently infected with SARS-CoV-2 is not known to have a detrimental effect on the illness.
    - Under Storage and Handling second bullet: Upon moving the vaccine to a fridge between +2C to +8C, the updated expiry date must be written on the box and the vaccine should be used or discarded by the new expiry date (within 10 weeks, not exceeding the original expiry date [after 12 months from the date of manufacture printed on the vial and cartons]).

Saskatchewan Immunization Manual Amendments June 2022

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Chapter 4 Documentation

- P. 3 Section 2.1 Immunization Record Confidentiality and Security
  - Bullet #5 now states: Agency policies must be followed for requests regarding the receipt of emailed immunization records.

Chapter 10 Biological Products

- TOC page 3 updated.
- Janssen COVID-19 vaccine
  - Updated product monograph
  - Under Storage and Handling, reference to 6 month for unopened vials revised to 11 months.
- Modena 6+
  - Under Schedule: (minimum interval of 28 days recommended in SK for healthy individuals.
- Pfizer 12+
  - Under Schedule: (minimum interval of 28 days recommended in SK, but 21 days is acceptable) has been added to criteria.
  - Updated product monograph
- Pfizer 5-11 years
  - Updated product monograph
- Prevnar 13
  - Section B now titled: Medically High-Risk Children Aged 60 Months - 17 Years and Adults 18+ Who Are at Risk of Invasive Pneumococcal Disease
  - Added to text inn this section: "… age) and medically high risk adults who are Pneu-C-13 naive are eligible…"
- RotaTeq
  - G-tube administration comment on first page removed, is only on second page now.
  - New bullet: Refer to SIM chapter 8 Appendix 8.4 *Oral Vaccine Administration via Enteral Tube*.
- NEW! IMVAMUNE Smallpox and Monkeypox Vaccine (SMV) added
  - There has been an update to the schedule section, now as per NACI June 2022:
    - NACI recommends that PEP using a single dose of the Imvamune® vaccine may be offered to individuals with high risk exposures to a probable or confirmed case of monkeypox, or within a setting where transmission is happening. PEP should be offered as soon as possible and within 4 days of last exposure and can be considered up to 14 days since last exposure. PEP should not be offered to individuals who are symptomatic and who meet the definition of suspect, probable or confirmed case.
    - After 28 days, if an individual is assessed as having a predictable ongoing risk of exposure, a second dose may be offered. A second dose should not be offered to individuals who are symptomatic and therefore after medical evaluation meet suspect, probable or confirmed monkeypox case definitions.
- Updated Product Monograph
  - Vivotif
- Varilrix varicella vaccine page 1 of 2
  - Varilrix is only available for severely immunocompromised individuals 1 year and older and specialist approval is required.
  - Appendix 7.2: *Varicella Immunization Referral Form* must be completed to order this vaccine as individual doses from RRPL.
  - Not for general population use.

- HepaGam B
  - Updated PM.
  - Contraindications and expected reactions updated.
- HYPER HepB
  - Updated PM
  - Updated contraindications.
- HYPERTET
  - Updated PM.
  - Contraindications and components updated.
- VariZIG
  - Updated PM
  - Contraindications and components updated.

Chapter 11 AEFIS

- TOC updated appendix 11.4
- P. 1 Section 1 Introduction
  - First paragraph now states:
    - Publicly funded active immunizing agents
  - Second paragraph now states:
    - Non-publicly funded active immunizing agents, passive immunizing agents and diagnostic agents
      Health Canada (HC) maintains a surveillance system called the Canada Vigilance Program, which monitors adverse reactions…
- P. 12 Appendix 11.4
  - Now states:

Appendix 11.4: Canada Vigilance Program (for non-publicly funded vaccines, Tubersol and passive immunizing agents)

Contact the Canada Vigilance Program by one of the following 3 ways:

1. Report online at www.healthcanada.gc.ca/medeffect
2. Call toll-free at 1-866-234-2345
3. Complete a Canada Vigilance Reporting Form and:
   Fax toll-free to 1-866-678-6789, **or**
   Mail to: Canada Vigilance Program
   Health Canada
   Postal Locator 0701D
   Ottawa, Ontario
   K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

- P. 15 Appendix 11.5
  - Smallpox vaccine (historical entry) Sma and Smallpox/monkeypox vaccine (SMV) added to table.

Chapter 12 Anaphylaxis Management

- P. 2 Section 1.2 Presentation
  - First sentence now states, *Changes develop over several minutes and involve two or more body systems (e.g., affecting the skin, respiration, circulation, GI system*).

Saskatchewan Immunization Manual Amendments June 2022

Chapter 14 Appendices

- Appendix 14.3: Immunization fact sheets for June
- Updates include product monographs, side effects and the removal of the statement, ***Individuals who have a mild illness, with or without a fever, may be asked to defer their routine immunization based on current COVID-19 screening criteria*.**

Saskatchewan Immunization Manual Amendments June 2022 Supplement

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

- Modena 6+
  - Under Storage and handling: Store frozen between -50°C to -15°C up to expiry date.
- Pfizer 12+
  - Under Schedule: (minimum interval of 28 days recommended in SK, but 21 days is acceptable for 12+) has been added to criteria.
- Pfizer 5-11 years
  - Min. 28 days interval between doses 2 and 3 for 5-11 year olds who have select medical conditions or who are immunocompromised.
- HYPERTET
  - Components updated and latex-free added.

Saskatchewan Immunization Manual Amendments July 2022

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 now 4 pages to allow for new vaccines to be listed.
- Pediacel
  - Removed under footnote 1: This vaccine is indicated for ages 6 weeks up to and including 5 years of age.
- Hepatitis B Series Completion Recommendations for Children 11-15 Years Old
  - Now for children who have an incomplete HAHB or HB series.
- NEW! Prevnar 20™ added with product monograph link; not publicly funded.
- IMVAMUNE
  - Added under Contraindications: Egg-allergic individuals may be immunized except if there is a known previous anaphylactic reaction to egg. Egg-allergic vaccine recipients should be kept under observation for 30 minutes following the administration of this vaccine.

Chapter 11 AEFIs

- Pp. 13-14 Appendix 11.5 Canadian Biological Product Abbreviations
  - Pneu-C-15 and Pneu-C-20 added to table on p. 14.

Saskatchewan Immunization Manual Amendments September 2022

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

- Section 4.1 Unknown or Uncertain Immunization Status
  Adults ≥ 18 years who were born or spent their childhood in Canada section has been revised to reflect a verbal history of immunization is not considered proof of immunity, especially for post-exposure tetanus prophylaxis. Please ensure that staff have reviewed this revision.

Chapter 10 Biological Products

- TOC updated
  - Janssen JCOVDEN - trade name added
  - Supemtak added
  - INFLUVAC TETRA removed

COVID-19 vaccines

- Janssen COVID-19 vaccine
  - Trade name is JCOVDEN
  - Product monograph updated Aug. 5, 2022
- Pfizer 12+ Purple and Gray cap/label vaccines
  - New statement added to DOSE section –
    - Each 0.3 mL dose of COMIRNATY contains 30 mcg of a nucleoside modified messenger RNA (modRNA) encoding the viral spike (S) glycoprotein of SARS-CoV-2 (original strain).
  - Product monograph updated for Aug. 19. 2022
- Pfizer 5-11 years Orange cap/label vaccine
  - New statement added to DOSE section –
    - Each 0.2 mL dose of COMIRNATY contains 10 mcg of a nucleoside modified messenger RNA (modRNA) encoding the viral spike (S) glycoprotein of SARS-CoV-2 (original strain).
  - Product monograph updated for Aug. 19. 2022
  - NACI statement re Pfizer boosters for 5-11 years added.

Influenza vaccines

- Non-Publicly funded vaccines:
  - Supemtak™ added.
  - INFLUVAC® TETRA and AFLURIA® Tetra removed.
- NEW! AFLURIA® TETRA for ages 5 years and older
  - AFLURIA® TETRA multidose vials will be provided to pharmacists for the 2022-23 season.
  - Contains neomycin sulfate and polymyxin B sulfate.
- Product monographs updated for FLULAVAL TETRA, FLUZONE Quadrivalent, and FLUZONE High Dose Quadrivalent.

Saskatchewan Immunization Manual Amendments October 2022

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

- TOC page new
  - New Appendices!
    - Appendix 7.9: Publicly Funded Immunization Schedule for Adult Solid Organ Pre-Transplant Candidates
    - Appendix 7.10: Publicly Funded Immunization Schedule for Adult Solid Organ Post-Transplant Recipients
- P. 17 Section 3.4 Transplant Candidate or Recipient – Islet Cell and 3.5 Transplant Candidate or Recipient – Solid Organ/Tissue
  - Revised bullets for both sections
    - Refer to Appendix 7.9: Publicly Funded Immunization Schedule for Adult Solid Organ Pre-Transplant Candidates and Appendix 7.10: Publicly Funded Immunization Schedule for Adult Solid Organ Post-Transplant Recipients.
    - For patients who receive their transplant outside of SK, consult with the jurisdictional transplant program coordinating things for the patient and to follow whatever schedule is requested even if their recommendations differ from Saskatchewan guidelines. The type of transplant, medical history, current medical condition, and immunosuppressive drugs are important factors when determining immunization regimens for post-transplant patients.
- P. 28 section 7.1 Premature Birth
  - Link to RSV program updated.
- p. 28 section 7.2 Individuals Recently New to Canada
  - Link in last bullet updated for WHO Immunization Data website.
- P. 37 Appendix 7.2: Varicella Immunization Referral Form
  - Following statement removed from second bullet, right column as directed by SCA: No need to test for VZV IgG prior to immunization.
- P. 38 Appendix 7.3: MMR Immunization Referral Form
  - First bullet interval changed from 6-12 months to 2 months as directed by SCA.
- P. 41 Appendix 7.6: Publicly Funded Immunization Schedule for Adult Post-Hematopoietic Stem Cell Transplant Recipients (autologous and allogeneic)
  - Complete immunization schedule has been updated with vaccine recommendations and related footnotes. This was prepared by the SCA.
- New! P. 44 Appendix 7.9: Publicly Funded Immunization Schedule for Adult Solid Organ Pre-Transplant Candidates
  - Please ensure staff review this new section.
- New! P. 45 Appendix 7.10: Publicly Funded Immunization Schedule for Adult Solid Organ Post-Transplant Recipients
  - Please ensure staff review this new section.

Chapter 10 Biological Products

- TOC updated with additions:
  - Label colours added to monovalent Modern Spikevax vaccines.
  - FLUAD Pediatric and FLUAD

COVID-19 vaccines

- Janssen JCOVDEN COVID-19 vaccine
  - Removed - Third and Fourth COVID-19 Dose Recommendations for Travellers
  - Removed - Provision of COVID-19 Vaccine Booster Doses

  - Other considerations revised: In SK, a 3-month interval is recommended post-infection before a COVID-19 vaccine is administered to client to ensure a strong immune response is developed. However, a client can be immunized once their symptoms have resolved at their request.
  - TB skin test/IGRA bullet removed from Administration with Other Products row.
- Modern Spikevax 0/O bivalent 18+ blue cap/green label
  - Other considerations revised: In SK, a 3-month interval is recommended post-infection before a COVID-19 vaccine is administered to client to ensure a strong immune response is developed. However, a client can be immunized once their symptoms have resolved at their request.
- Moderna Spikevax 6+ red cap/light blue label
  - Light blue label added to description.
  - Removed - Third and Fourth COVID-19 Dose Recommendations for Travellers
  - Removed - Provision of COVID-19 Vaccine Booster Doses
  - Other considerations revised: In SK, a 3-month interval is recommended post-infection before a COVID-19 vaccine is administered to client to ensure a strong immune response is developed. However, a client can be immunized once their symptoms have resolved at their (or their parent's/guardian's) request.
  - Under Contraindications
    - Non-medicinal ingredient in the vaccine known to cause type 1 hypersensitivity reactions are tromethamine, tromethamine hydrochloride and polyethylene glycol (PEG).
  - Under Administration with Other Products row
    - TB skin test/IGRA bullet removed.
    - Can be given concomitantly with most non-COVID-19 vaccines; no intervals are required before or after COVID-19 vaccine administration.
    - However, NACI recommends that Imvamune® smallpox/monkeypox vaccine be given at least 4 weeks after or before an mRNA vaccine for COVID-19 as a precaution in order to prevent erroneous attribution of myocarditis or pericarditis to one particular vaccine or the other. Protection from monkeypox exposure should be prioritized and recent mRNA vaccine receipt should not delay Imvamune® PEP or PrEP if protection is urgent.
  - Product monograph date updated.
- Moderna Spikevax 6 month-5 years blue cap/purple label
  - Purple label added to description.
  - Other considerations revised:
    - **For children 5+ years**: In SK, a 3-month interval is recommended post-infection before a COVID-19 vaccine is administered to client to ensure a strong immune response is developed. However, a client can be immunized once their symptoms have resolved at their parent's / guardian's request.
    - **For children 6 months to 4 years** of age previously infected with SARS-CoV-2, NACI suggests an 8-week interval between infection and initiation or completion of a COVID-19 primary series (i.e., 8 weeks after symptom onset or positive test if asymptomatic). This interval may be shortened for children considered moderately to severely immunocompromised (e.g., 4 to 8 weeks after symptom onset or positive test if asymptomatic).
  - Under Contraindications
    - Non-medicinal ingredient in the vaccine known to cause type 1 hypersensitivity reactions are tromethamine, tromethamine hydrochloride and polyethylene glycol (PEG).
  - Product monograph date updated.
- Novavax Nuvaxovid
  - Removed - Third and Fourth COVID-19 Dose Recommendations for Travellers
  - Removed - Provision of COVID-19 Vaccine Booster Doses
  - Other considerations revised: In SK, a 3-month interval is recommended post-infection before a COVID-19 vaccine is administered to client to ensure a strong immune response is developed. However, a client can be immunized once their symptoms have resolved at their request.

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- Pfizer 12+ Purple cap/label vaccine
  - Under Contraindications
    - Non-medicinal ingredient in the vaccine known to cause type 1 hypersensitivity reactions is polyethylene glycol (PEG).
  - Removed - Third and Fourth COVID-19 Dose Recommendations for Travellers
  - Removed - Provision of COVID-19 Vaccine Booster Doses
  - Other considerations revised: In SK, a 3-month interval is recommended post-infection before a COVID-19 vaccine is administered to client to ensure a strong immune response is developed. However, a client can be immunized once their symptoms have resolved at their request.
  - Under Administration with Other Products row
    - TB skin test/IGRA bullet removed.
    - Can be given concomitantly with most non-COVID-19 vaccines; no intervals are required before or after COVID-19 vaccine administration.
    - However, NACI recommends that Imvamune® smallpox/monkeypox vaccine be given at least 4 weeks after or before an mRNA vaccine for COVID-19 as a precaution in order to prevent erroneous attribution of myocarditis or pericarditis. To one particular vaccine or the other. Protection from monkeypox exposure should be prioritized and recent mRNA vaccine receipt should not delay Imvamune® PEP or PrEP if protection is urgent.
  - Product monograph date updated.
- Pfizer 12+ Gray cap/label vaccine
  - Under Contraindications
    - Non-medicinal ingredient in the vaccine known to cause type 1 hypersensitivity reactions are tromethamine, tromethamine hydrochloride and polyethylene glycol (PEG).
  - Removed - Third and Fourth COVID-19 Dose Recommendations for Travellers
  - Removed - Provision of COVID-19 Vaccine Booster Doses
  - Other considerations revised: In SK, a 3-month interval is recommended post-infection before a COVID-19 vaccine is administered to client to ensure a strong immune response is developed. However, a client can be immunized once their symptoms have resolved at their (or their parent's/guardian's) request.
  - Under Administration with Other Products row
    - TB skin test/IGRA bullet removed.
    - Can be given concomitantly with most non-COVID-19 vaccines; no intervals are required before or after COVID-19 vaccine administration.
    - However, NACI recommends that Imvamune® smallpox/monkeypox vaccine be given at least 4 weeks after or before an mRNA vaccine for COVID-19 as a precaution in order to prevent erroneous attribution of myocarditis or pericarditis to one particular vaccine or the other. Protection from monkeypox exposure should be prioritized and recent mRNA vaccine receipt should not delay Imvamune® PEP or PrEP if protection is urgent.
  - Product monograph date updated.
- Pfizer 5-11 years Orange cap/label vaccine
  - Under Contraindications
    - Non-medicinal ingredient in the vaccine known to cause type 1 hypersensitivity reactions are tromethamine, tromethamine hydrochloride and polyethylene glycol (PEG).
  - Other considerations revised: In SK, a 3-month interval is recommended post-infection before a COVID-19 vaccine is administered to client 5-11 years to ensure a strong immune response is developed. However, a client can be immunized once their symptoms have resolved at their parent's / guardian's request.
  - Under Administration with Other Products row
    - TB skin test/IGRA bullet removed.
  - Product monograph date updated.

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Influenza vaccines

- Non-Publicly funded vaccines additions
  - FLUAD Pediatric and FLUAD with updated PM.
  - Flucelvax Quad PM updated.
- FluLaval Tetra PM updated.
- Afluria Tetra PM updated.

- Imvamune revisions

Dosage by Route	0.5 ml Subcutaneous (SC) injection or 0.1 ml Intradermal (ID) injection
Route Administration notes	• Off-label intradermal administration can be used **only for immunocompetent adults** when given as a second dose following a first dose given subcutaneously. • Those <18 years of age, at risk of keloid scars, or moderately to severely immunocompromised should be immunized using the subcutaneous route of administration only.
Series and eligibility	**Post-exposure Prophylaxis (PEP)** (1 dose; see second bullet re second dose) • For individuals with high risk exposures to a probable or confirmed case of monkeypox, or within a setting where transmission is happening, PEP should be offered as soon as possible and within 4 days of last exposure and can be considered up to 14 days since last exposure. PEP should not be offered to individuals who are symptomatic and who meet the definition of suspect, probable or confirmed case. • After 28 days, if an individual is assessed as having a predictable ongoing risk of exposure, a second dose may be offered in consultation with a Medical Health Officer. A second dose should not be offered to individuals who are symptomatic and therefore after medical evaluation meet suspect, probable or confirmed monkeypox case definitions. • For individuals who had received a live replicating 1st or 2nd generation smallpox vaccine in the past and who sustain a high risk exposure to a probable or confirmed case of monkeypox, a single dose may be offered (i.e. as a booster dose) at least 28 days after the latest live replicating smallpox vaccine dose. **Pre-exposure Prophylaxis (PrEP)** (2 doses four weeks apart) • Individuals who self-identify as sex workers, regardless of their self-identified gender. • Men who have sex with men (MSM), and individuals who have sex with MSM, and who meet at least one of the following criteria: ➢ Having had a confirmed sexually transmitted infection acquired in the last year. ; ➢ Engage in sexual contact in sex-on –premises venues ➢ Individuals who self-identify as sex workers regardless of self-identified sex/gender. ➢ Have had or plan to have sexual contact with an anonymous partner (at an event or via a hook-up app); ➢ Are planning to travel in the next three months to an area in Canada or internationally currently reporting monkeypox cases (https://www.who.int/emergencies/disease-outbreak-news/item/2022-DON396); ➢ Individuals who work or volunteer at in sex-on-premises venues (sauna, bath house, club) where workers may have contact with fomites potentially contaminated with monkeypox, without the use of personal protective

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	equipment. Imvamune® may be offered to the following individuals: • Those who are pregnant or breastfeeding and who are at risk. • Those who are immunocompromised due to disease or treatment and are at risk. • Those younger than 18 years of age where infection could have significant negative outcomes.
Possible reactions	• Local reactions may last longer/be more common if the vaccine was administered by the ID route.
Storage, stability and disposal	• If a vial is used for multiple doses, it should be discarded after 6 hours following first puncture.

- NACI rapid response document updated.

Saskatchewan Immunization Manual Amendments November 2022

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 3 Informed Consent

- P. 7 Section 3.0 STEP BY STEP PROCESS FOR OBTAINING INFORMED CONSENT
  - Revised second last bullet under Step 3: If the client does not understand English, provide translated versions or use an interpreter if available. Refer to SIM Chapter 4 Appendix 4.2 *Where do I document* for guidance.
  - New second sentence added after first bullet in Step 7: Refer to SIM Chapter 4 Appendix 4.2 *Where do I document* for guidance.

Chapter 4 Documentation

- P.8 Appendix 4.2 Where do I document? New scenarios added and subsequent renumbering of existing scenarios.
  - New #1! Translations Services Used to Obtain Consent Directives.
  - Revised #76: Incomplete child vaccine history, documentation unavailable and vaccine refusal.
  - Revised #77: Incomplete child vaccine history, documentation unavailable but accepts boosters.
  - Revised #78: Incomplete adult vaccine history, documentation unavailable and vaccine refusal.
  - Removed: Incomplete vaccine history, documentation unavailable.
  - Removed: Incomplete vaccine history, documentation unavailable, assume unimmunized.
  - New #79! Translation Services used to obtain client information.

Chapter 10 Biological Products

- Janssen JCOVDEN COVID-19 vaccine
  - Added under Possible reactions: Very rare reports of small-vessel vasculitis with cutaneous manifestation (inflammation of small blood vessels with skin rash or small red or purple, flat, round spots under the skin's surface or bruising) have been reported following immunization with this vaccine.
  - Product monograph date updated.
- Moderna Spikevax 6+ red cap/light blue label
  - Vaccine concentration of 0.2 mg/ml added to main page.
- Moderna Spikevax 6 month-5 years blue cap/purple label
  - Vaccine concentration of 0.1 mg/ml added to main page.

Chapter 14 Appendices

- APPENDIX 14.3: IMMUNIZATION FACT SHEETS
  - HB and HPV-9 dates revised to Nov. 2022.

Saskatchewan Immunization Manual Amendments December 2022

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
  - New! COVID-19 Booster Dose Parameters and Recommendations
  - New! COVID-19 Vaccine Q &A for Immunizers
  - Removed: Pfizer BioNTech Comirnaty®+12 years **Monovalent** formulation (Purple cap/label) as stock expired.
- New! COVID-19 Booster Dose Parameters and Recommendations
  - This document provides booster dose parameters and recommendations, and will be updated when new parameters and recommendations are made. This document replaces all booster recommendation sections and information that were previously noted in the COVID-19 Contraindications and Precautions Background document.
- New! COVID-19 Vaccine Q &A for Immunizers
  - This document addresses FAQ regarding immunization parameters/recommendations, Moderna bivalent off-label administration, and sample scenarios for mRNA booster doses.
- Janssen (Johnson & Johnson) JCOVDEN™
  - Added under Schedule: Refer to the Booster Dose Parameters and Recommendations and COVID-19 Q&A for Immunizers documents in SIM chapter 10.
- Moderna Spikevax® 0/O Bivalent Original/Omicron BA.1 18+ years
  - BA.1 added to vaccine name throughout pages.
  - Added under Schedule: Refer to the Booster Dose Parameters and Recommendations and COVID-19 Q&A for Immunizers documents in SIM chapter 10.
- Moderna Spikevax® Monovalent 6+ years
  - Added under Schedule: Refer to the Booster Dose Parameters and Recommendations and COVID-19 Q&A for Immunizers documents in SIM chapter 10.
  - Added under Storage and Handling:
    - Thaw in refrigerator between 2°C to 8°C for 2 hours and 30 minutes. (Let each vial stand at room temperature for 15 minutes before administering).
    - OR
    - Thaw at room temperature between
    - 15°C to 25°C for 1 hour.
- Moderna Spikevax® Monovalent 6 months to 5 years
  - Added under number of doses and scheduling: Refer to the Booster Dose Parameters and Recommendations and COVID-19 Q&A for Immunizers documents in SIM chapter 10.
  - Added under Storage and Handling:
    - Thaw in refrigerator between 2°C to 8°C for 2 hours and 30 minutes. (Let each vial stand at room temperature for 15 minutes before administering).
    - OR
    - Thaw at room temperature between
    - 15°C to 25°C for 1 hour.
- Novavax NUVAXOVID™ Monovalent 18+ years
  - Added under Schedule: Refer to the Booster Dose Parameters and Recommendations and COVID-19 Q&A for Immunizers documents in SIM chapter 10.
  - Revised under preparation: NUVAXOVID must not be diluted or mixed with other medicinal products.
  - Product monograph date updated.

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- Pfizer BioNTech Comirnaty® Bivalent Original & Omicron BA.4/5 12+ years
  - Added under Schedule: Refer to the Booster Dose Parameters and Recommendations and COVID-19 Q&A for Immunizers documents in SIM chapter 10.
  - Added under Storage, Handling and Administration: There is no requirement for COMIRNATY Original & Omicron BA.4/BA.5 vaccine to come to room temperature prior to use, although it may be done for patient comfort.
- Pfizer BioNTech Comirnaty® Monovalent 12+ years
  - Added under Schedule: Refer to the Booster Dose Parameters and Recommendations and COVID-19 Q&A for Immunizers documents in SIM chapter 10.
  - Added under Preparation: There is no requirement for COMIRNATY 12+ Gray cap and label vaccine to come to room temperature prior to use, although it may be done for patient comfort.
- Pfizer BioNTech Comirnaty®+12 years monovalent formulation (Purple cap/label) removed from Ch. 10 as all stock expired.
- Pfizer BioNTech Comirnaty® Monovalent PEDIATRIC 5-11 years
  - Added under Schedule: Refer to the Booster Dose Parameters and Recommendations and COVID-19 Q&A for Immunizers documents in SIM chapter 10.
  - Added under Storage and Handling: Let each vial stand at room temperature for 15 minutes before diluting.
  - Under Preparation/Reconstitution: 1)Thaw vaccine before use removed. 2) Added to Vials after dilution: Let diluted vial stand for 15 minutes at room temperature before administering.
- Pfizer BioNTech Comirnaty® Monovalent PEDIATRIC 6 mo-4 yrs
  - Added under Schedule: Refer to the Booster Dose Parameters and Recommendations and COVID-19 Q&A for Immunizers documents in SIM chapter 10.
  - Added under Storage and Handling: Allow the vial to sit at room temperature for about 15 minutes, before dilution. Also added: If stored in the fridge, let each vial stand at room temp for 15 minutes before administering.
  - Under Preparation/Reconstitution, Thaw vaccine before use removed. Added to Vials after dilution: If stored in the fridge, let each vial stand at room temp for 15 minutes before administering.
- Diphtheria-Tetanus-acellular Pertussis-Polio-Haemophilus influenzae type b Adsorbed Vaccine (DTaP-IPV-Hib) PEDIACEL®
  - Footnote 5 removed under Dose/Primary Series, as there is no footnote #5 on page.
- Meningococcal Conjugate ACYW-135 Vaccine (Men-C-ACYW-135) NIMENRIX®
  - Product monograph updated
  - Latex-free.
- Varicella Vaccine (Var) (live, attenuated) VARIVAX® III
  - Previous indication 4 (immunocompromised) removed, as only Varilrix is indicated for use in this population.
  - Added under Contraindications: Immunocompromised individuals – Refer to Chapter 7, Immunization of Special Populations. Appendix 7.2: Varicella Immunization Referral Form for Varilrix vaccine.
  - Previous footnote #4 removed.
  - PM link updated.

Chapter 14 Appendices

- APPENDIX 14.3: IMMUNIZATION FACT SHEETS
  - TIg date revised to Nov. 2022.
- APPENDIX 14.4: IMMIGRANT IMMUNIZATION RESOURCES
  - All resources reviewed, and titles and links updated for all except the CMAJ 2011 article.

Saskatchewan Immunization Manual Amendments Part 2: December 2022

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
  - New! Pfizer BioNTech Comirnaty® 5-11 years Original & Omicron BA.4/5 **Bivalent** formulation (Orange cap/label border) NOTE: Requires dilution prior to administration.

- COVID-19 Vaccine Q &A for Immunizers
  - New! Additional question and response added to page 3 with recommendations for a person who was immunized outside of Canada with one dose of a WHO-approved COVID-19 vaccine

- Pfizer BioNTech Comirnaty® Bivalent Original & Omicron BA.4/BA. vaccine 12+ years
  - Product monograph date updated.

- New! Pfizer BioNTech Comirnaty® **Bivalent** Original & Omicron BA4./BA.5 vaccine **5-11 years** (Orange cap/label border) START DATE is Jan. 9, 2023.
  - Has orange cap/orange label, the same as the monovalent vaccine so read label prior to administration.
  - Must be diluted prior to administration!