Scheduled Substance Treatment Protocol SSTP

Comirnaty® (Pfizer) Omicron XBB.1.5 for COVID 19 vaccination of Children aged 5 to 11 years

Areas Applicable	NT Wide
Health Professionals authorised by this SSTP	Nurses Midwives Aboriginal and Torres Strait Islander Health Practitioners
Scheduled Substance(s)	SARS-COV-2 (COVID-19) vaccine Each 0.3mL dose contains 10 micrograms Raxtozinameran (Omicron XBB.1.5 subvariant). 0.3mL (10 micrograms) single dose vial with a light blue cap. Product is presented in a carton containing ten (10) single use vials. Light blue cap.
Indication	Active immunisation to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2, in individuals 5 to 11 years of age Omicron XBB.1.5 vaccines are now preferred for use in a primary course and as further doses
Contraindications and/or Exclusions*	**Contraindications** • Anaphylaxis to the active substance or to any of the excipients including a previous dose of an mRNA COVID-19 vaccine (Spikevax® or Comirnaty®) **Exclusions** • People under 5 years old • People 12 years and older • Administration of vaccine to individuals with an acute severe febrile illness or acute infection (minor infection or low grade fever should not delay vaccination) should be deferred until they are symptom-free. **Precautions** • Individuals with a history of allergy to previous doses of a COVID-19 vaccine or any component of COVID-19 vaccines or with a history of anaphylaxis to other drugs or vaccines may need prior assessment before receiving a COVID-19 vaccine. Refer to ATAGI advice in Australian Immunisation Handbook for further information. • Individuals with a cardiac condition may require a consultation with a medical officer or cardiologist as per ATAGI advice outlined in Australian Immunisation Handbook

	• People who develop myocarditis and/or pericarditis after a COVID-19 vaccine should defer further doses and discuss options for further COVID-19 vaccination with their treating doctor. Please refer to the Product Information for list of precautions COMIRNATY® Omicron XBB.1.5 (tga.gov.au)
Dose and Route*	10 micrograms (0.3mL) given intramuscularly, preferably in the deltoid muscle of the upper arm* *preferred route is in the deltoid muscle of the upper arm. However alternate sites, such as vastus lateralis muscle of the thigh or ventrogluteal muscle of the hip, may also be used at clinician's discretion. **Note** If a child turns 12 after their first dose they should receive a 30mcg dose (0.3mL) of Comirnaty® using the formulation for people 12+ years.

Dose Frequency*	**Dose scheduling for children aged 5-11 years**
	Primary series
	• 2 dose course given 8 weeks apart.
	• An additional (3rd) primary dose is recommended 8 weeks after the second dose for severely immunocompromised children
	Booster dose
	Booster frequency should be in accordance with the Australian Technical Advisory Group on Immunisation (ATAGI) advice as in place from time to time. Refer to COVID-19 | The Australian Immunisation Handbook (health.gov.au) for current recommendations.
	• A booster dose can be considered at least 6 months after the last COVID-19 vaccine dose for children aged 5-11 years;
	  ○ who are severely immunocompromised,
	  ○ who have a disability with significant or complex health needs, or
	  ○ who have complex and/or multiple health conditions that increase the risk of severe COVID-19
	• A person may be vaccinated earlier than the recommended 6-month interval in exceptional circumstances, such as before starting immunosuppressant therapy, before overseas travel or if someone cannot reschedule vaccination easily (such as in an outreach vaccination program).

Dilution	Product does not require reconstitution or dilution.
Drug Interactions*	No interaction studies have been performed. COVID 19 vaccines and influenza or other immunisation can be administrated without consideration of timing such as on the same day. There is a potential for an increase in mild or moderate adverse event when more than one vaccine is given at the same time.
Monitoring requirements*	Ensure the vaccines are not expired and have been stored in accordance with product information.

	Ensure vials are completely thawed before use by placing in refrigerator (2-8^{0}C) for up to 6 hours ***or*** Allow the frozen vial to sit at temperature up to 30°C for 30 minutes for immediate use. Once thawed, the vaccine should not be re-frozen. **Unopened vial** Unopened vials can be stored for up to 10 weeks at 2°C to 8^{0}C or between 8°C to 30°C for up to 24 hours. Store protected from light. **Pre-drawn dose** Pre-drawn doses should be used within 1 hour if kept at room temperature (between pre-drawn doses should be used within 1 hour if kept at room temperature (15°C to 25°C), and within 6 hours if kept at 2°C to 8°C, and within 6 hours if kept at 2°C to 8°C. During storage, protect from light. **Post vaccination** Follow usual health service post vaccination monitoring and report any adverse events following immunisation to Centre for Disease Control.
Health Professional Accreditation Requirements	Health professionals using this guideline must meet the requirements outlined by the NT Chief Health Officer: ***Nurses and Midwives***: • Be registered with the Nursing and Midwifery Board of Australia with no conditions, undertakings or notations which may limit delivery of clinical services directly to patients. ***Aboriginal Health Practitioners:*** • Be registered with the Aboriginal and Torres Strait Islander Health Practice Board of Australia with no conditions or undertakings which may limit delivery of clinical services directly to patients. **All health professionals following this protocol must:** • Maintain continuing professional development related to skills and competencies required, including COVID-19 vaccines and management of anaphylaxis. • Hold a current Cardiopulmonary Resuscitation (CPR) certificate. **All health professionals administering vaccines from this protocol must have completed:** • A program of study for the administration of vaccines accredited by Health Education Services Australia (HESA) or; • A program of study approved by the Chief Health Officer or; • completed the assessment of an immuniser program of study that meets the curriculum content requirements of the National Immunisation Education Framework for Health Professionals.
Documentation *(including necessary information to the patient)*	The health professional must: • Complete all clinical documentation requirements as outlined by the Health Service. Enter the patient details and vaccine brand name, dose, site of administration and batch number in the Australian Immunisation Register (AIR) within 24 hours and no later than 10 days after administration

Related Documents	The Australian Immunisation Handbook (health.gov.au) and associated links within the COVID-19 Disease Chapter Product Information COMIRNATY® Omicron XBB.1.5 (tga.gov.au) ASCIA Guide: Allergy and COVID-19 Vaccination **ATAGI check list for administration sites** **Pre Vaccination Screening Checklist** **Immunisation: Health Professionals; NT Upskilling Courses**		
Chief Health Officer	**Signature**	**Name**	**Date**
	EDOC 2023/386213	Adjunct Professor Christine Connors	22/12/2023
Period of effect	This SSTP remains in force until 22/12/2025 unless revoked earlier.		

References:

* The drug information provided is to act as a guide to outline the limits of legal dealing with the named scheduled substances. Further information reference should be made to the full manufacturer's product info and other reliable sources of medicines information. If contraindications or interactions are present refer to medical officer before administration