Scheduled Substance Treatment Protocol

Comirnaty® (Pfizer) Omicron XBB.1.5 for COVID 19 vaccination of 12 years and over

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 30 micrograms raxtozinameran (Omicron XBB.1.5 subvariant) Comirnaty® Omicron XBB.1.5 COVID-19 vaccine is a multi-dose vial containing 6 doses in 2.25mL (6 doses of 0.3mL (30 micrograms total per dose)). Product is presented in a carton containing ten (10) multidose vials. Dark grey cap. Note that both Comirnaty formulations have a grey cap and Comirnaty Omicron XBB.1.5 ≥12 years formulation has a dark grey cap. These vaccines are approved for use in different age groups. To minimise the risk of administration errors, providers should preferably prepare and store doses of these vaccines separately. Doses withdrawn in advance of administration should be clearly labelled.
Indication	Active immunisation to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2 in individuals 12 years of age and older including in pregnancy. 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 any of excipients including a previous dose of mRNA COVID -19 vaccine (Spikevax® or Comirnaty®) **Exclusions** • People under 12 years old • 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 or any other serious event attributed to a previous dose of COVID-19 vaccine 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*	Only approved in people aged 12 years and over. A single dose of 30 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.
Administration*	Each dose must contain 0.3mL of vaccine. If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3mL discard the vial.
Dose Frequency*	**Primary series** All people aged 12 years and older without risk factors. 30 micrograms (0.3mL). • 2 doses, 8 weeks apart. People aged 12 years and older with severe immunocompromise. • An additional vaccine (3 dose primary series) is required for people who are immunocompromised, as defined in the ATAGI guidelines. The third dose can be given 2 months after the 2nd dose. **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. ATAGI recommends a minimum interval between primary course and further doses of at least 6 months in eligible people. • 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 multi dose vial** Unopened vials can be stored for up to 10 weeks at 2-8^{0}C. Store protected from light. **Open Multi-dose vial** Opened vials should be stored between 2°C to 30°C and used within 6 hours after initial puncture. **Pre-drawn doses** 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, 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 for the delivery of medicines and COVID-19 vaccines including the use of multi-dose vials and management of anaphylaxis. • Hold a current Cardiopulmonary Resuscitation (CPR) certificate.

<table>
<tr><td></td><td colspan="3">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.</td></tr>
<tr><td>Documentation</td><td colspan="3">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 within 24 hours and no later than 10 days after administration.</td></tr>
<tr><td>Related Documents</td><td colspan="3">Australian Product Information – COMIRNATY® Omicron XBB.1.5 COVID-19 VACCINE PI Template (tga.gov.au)
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</td></tr>
<tr><td rowspan="2">Chief Health Officer</td><td>Signature</td><td>Name</td><td>Date</td></tr>
<tr><td>EDOC 2023/386213</td><td>Adjunct Professor Christine Connors</td><td>22/12/2023</td></tr>
<tr><td>Period of effect</td><td colspan="3">This SSTP remains in force until 22/12/2025 unless revoked earlier.</td></tr>
<tr><td colspan="4">References:
* The drug information provided is to act as a guide only, for 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</td></tr>
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