Scheduled Substance Treatment Protocol

Comirnaty® (Pfizer) 6 months to 4 years for COVID 19 vaccination

Version 1 of *Comirnaty® Original Pfizer (MAROON) for COVID-19 vaccination of persons aged 6 months to 4 years*

Areas Applicable	NT Wide
Health Professionals authorised by this SSTP	Nurses Midwives Aboriginal and Torres Strait Health Practitioners
Scheduled Substance(s)	SARS-CoV-2 (COVID-19) vaccine Each 0.2mL dose contains 3 micrograms of tozinameran (original) COVID-19 mRNA vaccine. This is a concentrated suspension for injection multi-dose vial with a maroon cap. It must be diluted before use. One vial (0.4mL) contains 10 doses of 0.2mL after dilution.
Indication	Active immunisation to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2 in children aged 6 months to 4 years with severe immunocompromise, complex or multiple health conditions, or disability with significant or complex health needs. This includes children with the following or similar conditions: see ATAGI advice • Severe primary or secondary immunodeficiency, including those undergoing treatment for cancer, or on immunosuppressive treatments as listed in the ATAGI advice on 3rd primary doses of COVID-19 vaccine in individuals who are severely immunocompromised; • Bone marrow or stem cell transplant, or chimeric antigen T-cell (CAR-T) therapy recipients; • Complex congenital cardiac disease; • Structural airway anomalies or chronic lung disease; • Type 1 diabetes mellitus; • Chronic neurological or neuromuscular conditions; or • A disability with significant or complex health needs, such as severe cerebral palsy or Down Syndrome (Trisomy 21). This vaccine **is not recommended** as a booster vaccine.
Contraindications and/or Exclusions*	**Contraindications** • People under 6 months of age • Anaphylaxis to the active substance or any of excipients including a previous dose of mRNA COVID -19 vaccine (Spikevax® or Comirnaty®) (including Propylene Glycol)

	Exclusions • People aged 5 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 or any other serious event attributed to a previous dose of COVID-19 vaccine may need prior assessment before receiving a COVID-19 vaccine. See ATAGI advice for further information. • People with a history of any of the following conditions o recent (i.e., within the last 3 months) myocarditis or pericarditis o acute rheumatic fever or acute rheumatic heart disease (i.e., with evidence of active inflammation) o acute decompensated heart failure may need prior assessment before receiving a COVID-19 vaccine. See ATAGI advice for further information. Those with confirmed SARS-CoV-2 infection should wait a minimum of six (6) months after their diagnosis (either by PCR test or Rapid Antigen Test) before they receive any subsequent dose of COVID-19 vaccination. Vaccination can occur prior to 6 months in exceptional circumstances such as prior to starting an immunosuppressant, prior to overseas travel or if someone cannot reschedule vaccination easily (such as due to an infrequent outreach vaccinating schedule).
Dose and Route*	Only approved in people aged between 6 months and 5 years. A single dose if 3 micrograms (0.2mL) of vaccine given intramuscularly (IM). Preferred route for those 6 to <12 months of age is the anterolateral aspect of the thigh, and for those 1 to 4 years of age is in the anterolateral aspect of the thigh or the deltoid muscle. Alternate sites may also be used at clinician's discretion. Children who will turn from 4 years to 5 years of age between their doses in the vaccination series should receive their age-appropriate dose at the time of the vaccination
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*	**The primary schedule is a series of 3 doses (3 micrograms/0.2mL each).** • Dose 1 and 2 given at least 8 weeks apart • Dose 3 given 8 weeks after dose 2 Dosing interval between dose 1 and dose 2 can be shortened to 3 weeks in specific circumstances (e.g. those with medical risk factors in the context of ongoing community transmission or before international travel). Benefits of

	earlier protection should be weighed against benefits of longer dose interval (e.g. slightly lower risk of adverse events and longer duration of protection). • ATAGI does not recommend a booster dose for children aged under 5 years at this time. • Children with severe immunocompromise who receive the 3-dose primary schedule of the Pfizer Comirnaty® 6 months to 4 years vaccine do not require a fourth primary dose. • ATAGI currently recommends the administration of COVID-19 vaccines be deferred for 6 months after a confirmed SARS-CoV-2 infection. Vaccination after this interval is likely to provide a better immunological response and optimise the duration of protection.
Dilution	The thawed vaccine must be diluted in its original vial with 2.2mL of sodium chloride 9mg/mL (0.9%) solution for injection – see PI Comirnaty-Tozinameran for instructions. The total volume in the vial after dilution will be 2.6mL.
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 Comirnaty (MAROON CAP) Product Information If the multidose vial is stored frozen at -60°C to -90°C it must be completely thawed prior to use. • Transfer frozen vial(s) to an environment of 2°C to 8°C to thaw; a 10-vial pack may take up to 2 hours to thaw • Alternatively, individual frozen vials may be thawed for 30 minutes at temperatures up to 30°C • Upon moving vial(s) to 2°C to 8°C storage, update the expiry date on the packaging • Once removed from the freezer, the unopened thawed vial(s) can be stored at 2°C to 8°C for up to 10 weeks (70 days) within the manufacturer use-by date and up to 24 hours at temperatures 8°C to 30°C. • Thawed or partially thawed vials cannot be re-frozen. • Prior to dilution, verify that the vial has a maroon plastic cap. • Do not shake the vial. • ATAGI recommends that after dilution, vials must be kept at 2°C to 30°C and used within 6 hours from the time of dilution. • Confirm diluted liquid is white to off white in the vial prior to drawing up dose(s). • For doses pre-drawn into syringes, ATAGI recommends discarding unused doses after 1 hour if stored at 8°C to 30°C or after 6 hours if stored at 2°C to 8°C. **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 **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 within 24 hours and no later than 10 days after administration
Related Documents	**Australian Product Information** –Tozinameran [mRNA] Comirnaty® COVID-19 Vaccine - Pfizer **ATAGI Clinical guidance on use of COVID-19 vaccine in Australia (most recent version)** **ATAGI COVID-19 vaccination – Provider resources** COVID-19 vaccination – Provider resources | Australian Government Department of Health and Aged Care **ATAGI recommendations on Comirnaty® (Pfizer) COVID-19 vaccine I children under 5 years of age.** ATAGI recommendations on COVID-19 vaccine use in children aged 6 months to (health.gov.au)

<table>
<tr><td></td><td colspan="3">ATAGI – COVID-19 vaccination – Shared decision making guide for people with immunocompromised
COVID-19 Primary Course Vaccines in Australia (health.gov.au)
Australian Government Department of Health and Aged Care | Transporting, storing and handling COVID-19 vaccines
ATAGI check list for administration sites
ATAGI Guidance on the use of multi-dose vials for COVID-19 vaccination
Australian Immunisation Handbook
Pre Vaccination Screening Checklist
COVID-19 Vaccination Eligibility Declaration Form for People certain conditions or on therapies leading to severe immunocompromise,
Immunisation: Health Professionals; NT Upskilling Courses
Australian Immunisation Handbook: After Vaccination
Australian Government COVID 19 Vaccination Training Program
ATAGI clinical guidance on COVID-19 vaccine administration errors</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>Date for Review</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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