Scheduled Substance Treatment Protocol

Moderna Bivalent Original/ Omicron BA.4/5 for COVID 19 vaccination of 12 years and over

Version 2 of *Moderna Bivalent Original/ Omicron BA.4/5 for COVID 19 vaccination. Changes include update for use as primary and booster series*

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 0.5 mL dose contains 25 micrograms elasomeran (ancestral SARS-CoV-2) and 25 micrograms davesomeran (Omicron BA.4/5 subvariants) 0.5 mL (50 micrograms) per dose as single use pre-filled syringe (PFS). Product is presented in a carton containing ten (10) PFS.
Indication	Active immunisation to prevent COVID-19 in individuals 12 years of age and older including in pregnancy
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** 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. People aged under 12 years **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 for further information.

	• People 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 or prior to overseas travel. • 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. Refer to ATAGI advice for further information. Please refer to the Product Information for list of precautions PI Spikevax Bivalent Covid-19 Vaccine (tga.gov.au)
Dose and Route*	Only approved in people aged 12 years and over A single dose (0.5mL) 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.
Dose Frequency*	**Primary series** All people aged 12 years and older without risk factors. 30 micrograms (0.3mL) • 2 doses, 8 weeks apart • The dose interval can be shortened to 3 weeks for people at higher risk of severe infection from COVID-19 infection (such as older adults or people with underlying medical conditions), in an outbreak setting or prior to international travel. The benefits of earlier protection with a shorter interval should be weighed against the benefits of the longer dose interval, such as a slightly lower risk of adverse events and a longer duration of protection. People aged 12 years and older with severe immunocompromised 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 If a person has a confirmed SARS-CoV-2 infection any due dose can be given to the person 6 months after the infection.
Administration*	• The product does not require reconstitution or dilution • Do not shake the pre-filled syringe

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The pre-filled syringe is for single use only
Each dose must contain 0.5mL of vaccine

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<tr><td>Drug Interactions*</td><td>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</td></tr>
<tr><td>Monitoring requirements*</td><td>Moderna Bivalent (BA.4-5) pre-filled syringe needs to be thawed before use.
Pre-filled syringes may be thawed in the blister packs (each blister containing 2 pre-filled syringes) or in the carton itself, either in the refrigerator or at room temperature. See table below for instructions and duration.
<table>
<tr><th>Configuration</th><th>Thaw Temperature (in a refrigerator)</th><th>Thaw Duration</th><th></th><th>Thaw Temperature (at room temperature)</th><th>Thaw Duration</th></tr>
<tr><td>Pre-filled syringe in blister pack</td><td>+2°C to +8°C</td><td>55 minutes</td><td></td><td>+15°C to +25°C</td><td>45 minutes</td></tr>
<tr><td>Carton</td><td>+2°C to +8°C</td><td>155 minutes</td><td></td><td>+15°C to +25°C</td><td>140 minutes</td></tr>
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An unopened thawed pre-filled syringe can be stored at +2°C to +8°C for a maximum of 30 days from the thaw date.
Unopened, thawed pre-filled syringes may be stored at +8°C to +25°C for up to 24 hours immediately prior to administration.
Ensure the vaccines are not expired and have been stored in accordance with Product Information.
Confirm liquid is white to off white in the syringe.
Post vaccination
Follow usual health service post vaccination monitoring and report any adverse events following immunisation to Centre for Disease Control</td></tr>
<tr><td>Health Professional Accreditation Requirements</td><td>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

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<tr><td></td><td colspan="3">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</td></tr>
<tr><td>Documentation
(including necessary information to the patient)</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 ® (original/ Omicron BA.4-5 COVID-19 VACCINE PI Template (tga.gov.au)
ATAGI recommendations on use of the Moderna bivalent (Original/Omicron BA.4/5) COVID-19 vaccine
ATAGI 2023 booster advice
ATAGI Clinical guidance on use of COVID-19 vaccine in Australia (most recent version)
ATAGI recommendations on the use of a third primary dose of COVID-19 vaccine in individuals who are severely immunocompromised
ATAGI – COVID-19 vaccination – Shared decision making guide for people with immunocompromise
COVID-19 vaccination decision guide for women who are pregnant, breastfeeding or planning pregnancy
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</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>
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Date for Review	This SSTP remains in force until 22/12/2025 unless revoked earlier.

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