# Table of Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Legislation</td>
<td>3</td>
</tr>
<tr>
<td>Human Rights Act 2019</td>
<td>3</td>
</tr>
<tr>
<td>STAGE 1a: Assessment of the individual presenting for vaccination</td>
<td>3</td>
</tr>
<tr>
<td>Clinical condition or situation to which this Protocol applies</td>
<td>3</td>
</tr>
<tr>
<td>Criteria for inclusion</td>
<td>3</td>
</tr>
<tr>
<td>Criteria for exclusion</td>
<td>4</td>
</tr>
<tr>
<td>Criteria for medical referral</td>
<td>5</td>
</tr>
<tr>
<td>Cautions including any relevant action to be taken</td>
<td>5</td>
</tr>
<tr>
<td>Action to be taken if the patient is excluded</td>
<td>7</td>
</tr>
<tr>
<td>Action to be taken if the patient or carer declines treatment</td>
<td>8</td>
</tr>
<tr>
<td>STAGE 1b: Description of treatment</td>
<td>8</td>
</tr>
<tr>
<td>Name, strength &amp; formulation of drug</td>
<td>8</td>
</tr>
<tr>
<td>Legal category</td>
<td>8</td>
</tr>
<tr>
<td>Black triangle</td>
<td>9</td>
</tr>
<tr>
<td>Drug interactions</td>
<td>9</td>
</tr>
<tr>
<td>Identification &amp; management of adverse reactions</td>
<td>9</td>
</tr>
<tr>
<td>Reporting procedure of adverse reactions</td>
<td>10</td>
</tr>
<tr>
<td>Written information available to be given to patient or carer</td>
<td>10</td>
</tr>
<tr>
<td>Patient advice / follow up treatment</td>
<td>10</td>
</tr>
<tr>
<td>Special considerations / additional information</td>
<td>11</td>
</tr>
<tr>
<td>STAGE 2: Vaccine Preparation</td>
<td>12</td>
</tr>
<tr>
<td>Vaccine presentation</td>
<td>12</td>
</tr>
<tr>
<td>Supplies</td>
<td>12</td>
</tr>
<tr>
<td>Storage</td>
<td>13</td>
</tr>
<tr>
<td>Vaccine preparation</td>
<td>14</td>
</tr>
<tr>
<td>STAGE 3: Vaccine Administration</td>
<td>16</td>
</tr>
<tr>
<td>Consent</td>
<td>16</td>
</tr>
<tr>
<td>Vaccine to be administered</td>
<td>16</td>
</tr>
<tr>
<td>Dose and frequency of administration</td>
<td>16</td>
</tr>
<tr>
<td>Route / method of administration</td>
<td>16</td>
</tr>
<tr>
<td>Disposal</td>
<td>17</td>
</tr>
<tr>
<td>Post-vaccination monitoring and advice</td>
<td>18</td>
</tr>
<tr>
<td>STAGE 4: Recording vaccine administration</td>
<td>18</td>
</tr>
<tr>
<td>Section</td>
<td>Page</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>------</td>
</tr>
<tr>
<td>Records</td>
<td>18</td>
</tr>
<tr>
<td>Cold Chain Breaches or Wastage</td>
<td>18</td>
</tr>
<tr>
<td>Clinical incidents</td>
<td>18</td>
</tr>
<tr>
<td>Acknowledgements</td>
<td>19</td>
</tr>
<tr>
<td>Appendix</td>
<td>20</td>
</tr>
<tr>
<td>Appendix 1 – Storage of COVID-19 Comirnaty™ Vaccine.</td>
<td>20</td>
</tr>
<tr>
<td>Appendix 2 – COVID-19 Comirnaty™ Vaccine Preparation</td>
<td>21</td>
</tr>
<tr>
<td>References</td>
<td>24</td>
</tr>
</tbody>
</table>
Scope

This protocol is applicable to those authorised to handle, prepare and/or administer the COVID-19 Comirnaty™ vaccine (Pfizer®/BioNTech®).

Legislation

- Health (Drugs and Poisons) Regulation 1996
- Health (Drugs and Poisons) Regulation 1996 - Drug Therapy Protocol – Communicable Diseases Program
- COVID-19 Vaccination Code

Human Rights Act 2019

To the extent an act or decision under this document may engage human rights under the Human Rights Act 2019, regard will be had to that Act in undertaking the act or making the decision. For further information on the Human Rights Act 2019 see: https://www.forgov.qld.gov.au/humanrights

STAGE 1a: Assessment of the individual presenting for vaccination

<table>
<thead>
<tr>
<th>ACTIVITY STAGE 1a:</th>
<th>Assess the individual presenting for vaccination against the inclusion and exclusion criteria below. If they are not eligible for vaccination or need to return at a later date, advise them accordingly.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical condition or situation to which this Protocol applies</td>
<td>COVID-19 Comirnaty™ vaccine is indicated for the active immunisation of individuals for the prevention of coronavirus (SARS-CoV-2) infection and subsequent COVID-19, in accordance with the National COVID-19 vaccination rollout.</td>
</tr>
<tr>
<td>Criteria for inclusion</td>
<td>COVID-19 Comirnaty™ vaccine should be offered to individuals in accordance with the Commonwealth’s national rollout strategy in the following order of priority, (unless directed by the Queensland Health Director General):</td>
</tr>
<tr>
<td>Priority</td>
<td>Risk group</td>
</tr>
<tr>
<td>---------</td>
<td>------------</td>
</tr>
</tbody>
</table>
| 1a | Quarantine and border workers  
Frontline health care worker sub-groups for prioritization  
Aged care and disability care staff  
Aged care and disability care residents |
| 1b | Elderly adults aged 80 years and over  
Elderly adults aged 70-79 years  
Other health care workers  
Aboriginal and Torres Strait Islander people > 55  
Younger adults with an underlying medical condition, including those with a disability |
<table>
<thead>
<tr>
<th>1b (cont’d)</th>
<th>Critical and high-risk workers including defence, police, fire, emergency services and meat processing</th>
</tr>
</thead>
<tbody>
<tr>
<td>2a</td>
<td>Adults aged 60-69 years&lt;br&gt;Adults aged 50-59 years&lt;br&gt;Aboriginal and Torres Strait Islander people 18-54&lt;br&gt;Other critical and high-risk workers</td>
</tr>
<tr>
<td>2b</td>
<td>Balance of adult population&lt;br&gt;Catch up any unvaccinated Australians from previous phases</td>
</tr>
<tr>
<td>3</td>
<td>&lt; 18 if recommended</td>
</tr>
</tbody>
</table>

Only individuals included in one or more of the priority groups tabled above may be vaccinated in accordance with this protocol.

Implementation of the COVID-19 vaccination program should aim to achieve high vaccine uptake whilst prioritising those most at risk. Implementation should also involve flexibility in vaccine deployment at a local level. Operational considerations, such as minimising wastage, may require a flexible approach to prioritisation, where decisions are taken in consultation with national or local public health experts. However, the priority order in the table above should be followed if it is reasonably practicable to do so.

### Criteria for exclusion

<table>
<thead>
<tr>
<th>Individuals who:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Have not consented</td>
<td></td>
</tr>
<tr>
<td>• Are less than 16 years of age</td>
<td></td>
</tr>
<tr>
<td>• Anaphylaxis to a previous dose of COVID-19 Comirnaty™ vaccine or to any component of the vaccine or residues from the manufacturing process.</td>
<td></td>
</tr>
<tr>
<td>• Have received a dose of COVID-19 vaccine in the preceding 21 days</td>
<td></td>
</tr>
<tr>
<td>• Have completed a course of COVID-19 vaccination</td>
<td></td>
</tr>
<tr>
<td>• Have a confirmed medical history of cerebral venous sinus thrombosis (CVST)</td>
<td></td>
</tr>
<tr>
<td>• Have a confirmed medical history of heparin induced thrombocytopenia</td>
<td></td>
</tr>
</tbody>
</table>

For anyone who is unable to receive the vaccination, document the reason for exclusion and any action taken.

See also Action to be taken if the patient is excluded and Drug Interactions.
### Criteria for medical referral

- Individuals for whom valid consent has not been obtained
- Individuals with immediate (within 4 hours) and generalised symptoms of a possible allergic reaction (e.g. urticaria/hives) to a previous dose of a COVID-19 vaccine
- Individuals with a generalised allergic reaction (without anaphylaxis) to any component of the COVID-19 vaccine to be administered (e.g. PEG in Comirnaty or polysorbate 80 in COVID-19 Vaccine AstraZeneca)
- Individuals with a prior history of severe allergy and/or anaphylaxis to previous vaccines and/or multiple drugs (injectable and/or oral)
- Individuals with a known systemic mast cell activation disorder with raised mast cell tryptase that requires treatment.
- Individuals with a prior history of severe allergy and/or anaphylaxis to previous vaccines and/or multiple drugs (injectable and/or oral)
- Individuals with a known systemic mast cell activation disorder with raised mast cell tryptase that requires treatment.
- Have had any vaccination within the previous 14 days. Sites are responsible for determining this via Australian Immunisation Record, medical record and/or asking the patient. Note: shortening of this interval may be justified if adhering to the interval may result in non-adherence to the vaccination or if there is an imminent need to administer either of these vaccines because of the prevailing local epidemiological situation. If same day or reduced-interval vaccination is proposed, patients should be counselled about the possible adverse events from each vaccine and advised to report adverse events.
- Have had allergen immunotherapy (AIT) or venom immunotherapy (VIT) injections in the previous 48 hours of the COVID-19 vaccine injection.
- Immunocompromised individuals
- Are pregnant or breastfeeding
- Elderly > 85 years of age

### Specific allergies

The individuals with specific allergies listed above should be assessed for suitability for vaccination before being given a vaccine dose, if necessary, in consultation with an allergist/immunologist or specialist immunisation clinic. If people in these categories are vaccinated, they may require vaccination in a facility with medical staff in attendance, and to be observed for 30 minutes following administration of a COVID-19 vaccine dose.

All other vaccine recipients, including those with a history asthma, atopic dermatitis (eczema) or allergic rhinitis (hay fever), should be observed for at least 15 minutes following administration of the vaccine at the clinic site.

### Cautions including any relevant action to be taken

- **Have had any vaccination within the previous 14 days.**
  Shortening of this interval may be justified if adhering to the interval may result in non-adherence to the vaccination or if there is an imminent need to administer either of these vaccines because of the prevailing local epidemiological situation. If same day or reduced-interval vaccination is proposed, patients should be counselled about the possible adverse events from each vaccine and advised to report adverse events.

- **Individuals with a bleeding disorder**
  This patient cohort may develop a haematoma at the injection site. Individuals with bleeding disorders may be vaccinated intramuscularly if, in the opinion of a doctor familiar with the individual’s bleeding risk, vaccines or similar small volume intramuscular injections can be administered with reasonable safety by this route.

  - If the individual receives medication/treatment to reduce bleeding, for example treatment for haemophilia, intramuscular vaccination can be scheduled shortly after such medication/treatment is administered.
• Individuals on stable anticoagulation therapy, including individuals on warfarin who are up to date with their scheduled INR testing and whose latest INR was below the upper threshold of their therapeutic range, can receive intramuscular vaccination. A fine needle (equal to 23 gauge or finer calibre such as 25 gauge) should be used for the vaccination, followed by firm pressure applied to the site (without rubbing) for at least 2 minutes. If in any doubt, consult with the clinician responsible for prescribing or monitoring the individual’s anticoagulant therapy.

If the registered professional clinically assessing the individual is not the vaccinator, they must ensure the vaccinator is aware of the individuals increased risk of haematoma and the need to apply firm pressure to the injection site for at least 2 minutes. The individual/carer should be informed about the risk of haematoma from the injection.

**Pregnant or breastfeeding**

Women who are pregnant should not routinely be offered COVID-19 Comirnaty™ vaccine during pregnancy and should postpone vaccination until completion of pregnancy. However, Comirnaty™ is not contraindicated.

The Comirnaty™ vaccine is Australian category for prescribing medicines in pregnancy Category B1. There is limited experience with use of Comirnaty™ in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryo/fetal development, parturition or post-natal development. Administration of Comirnaty™ in pregnancy should only be considered when the potential benefits outweigh any potential risks for the mother and fetus.

Some pregnant women may choose to be vaccinated after considering the benefits and risks of vaccination. In particular, COVID-19 vaccination may be considered in pregnant women who are in a high-risk priority group for vaccination, have a higher risk of exposure to SARS-CoV-2 infection, or where the woman has underlying medical conditions that put her at high risk of serious complications from COVID-19.

Pregnant women with COVID-19 have a higher rate of hospitalisation, intensive care unit admission and mechanical ventilation, but not death, than age-matched non-pregnant women. The risk of preterm delivery is also increased. There is no evidence to suggest that SARS-CoV-2 infection in pregnancy increases the risk for congenital anomalies.

Women who are breastfeeding or who are planning pregnancy can receive COVID-19 vaccine. There are no theoretical concerns regarding the safety of Comirnaty™ in these groups.

**Immunocompromised**

The efficacy of Comirnaty™ may be lower in immunosuppressed individuals. However, Comirnaty™ is not live-attenuated vaccine and is safe for people with immune system disorders such as allergy, primary or secondary immunodeficiency or autoimmune conditions, who are not considered to be at greater risk of vaccine allergy compared to the general population. It is important that regular treatments for immunodeficiencies and autoimmune conditions are continued, because stopping these treatments can place people with these conditions at greater risk from COVID-19. For people taking immunosuppressive therapies, the timing of vaccination should be discussed with their
treating specialist, taking into account disease severity, characteristics of the immunosuppressive therapy, and patient preferences.

Vaccination should occur on a different day (if possible) from regular infusion treatments, such as immunoglobulin (Ig) or immunosuppressant infusions. For example, people on monthly intravenous immunoglobulin (IVIg) may be advised by their specialist to be vaccinated two weeks after an IVIg infusion. This avoids confusion about the cause of side effects or allergic reactions, if they occur in response to the COVID-19 vaccine or the infusion treatment. See also ATAGI – Provider guide to COVID-19 vaccination of people with immunocompromise and ATAGI – COVID-19 vaccination decision guide for people with immunocompromise.

Have had allergen immunotherapy (AIT) or venom immunotherapy (VIT) injections in the previous should 48 hours of the COVID-19 vaccine injection.

It is important that regular hay fever (allergic rhinitis), eczema (atopic dermatitis) and asthma treatments are continued when having the COVID-19 vaccine. However, it is recommended that allergen immunotherapy (AIT) or venom immunotherapy (VIT) injections should not be given within 48 hours of the COVID-19 vaccine injection. This avoids confusion about the cause of side effects or allergic reactions, if they occur in response to the COVID-19 vaccine or immunotherapy.

Past history of COVID-19 infection

It is possible for people who have already had COVID-19 to have the vaccine. The vaccine can offer more protection or boost any antibodies (immunoglobulins) that the body has already made in response to COVID-19. Vaccination is therefore recommended even if a person has already had COVID-19. There is no evidence of any safety concerns from vaccinating individuals with a history of COVID-19 infection, or with detectable COVID-19 antibodies.

Vaccination of individuals who may be infected but asymptomatic or incubating COVID-19 infection is unlikely to have a detrimental effect on the illness. Vaccination should be deferred in those with confirmed infection to avoid onward transmission and confusing the differential diagnosis. As clinical deterioration can occur up to two weeks after infection, ideally vaccination should be deferred until clinical recovery to around four weeks after onset of symptoms or four weeks from the first confirmed positive specimen in those who are asymptomatic.

Having prolonged COVID-19 symptoms is not a contraindication to receiving a COVID-19 vaccine but if the individual is seriously debilitated, still under active investigation, or has evidence of recent deterioration, deferral of vaccination may be considered to avoid incorrect attribution of any change in the person’s underlying condition to the vaccine.

| Action to be taken if the patient is excluded | The risk to the individual of not being immunised must be considered. The indications for risk groups are not exhaustive, and the healthcare practitioner should consider the risk of coronavirus exacerbating any underlying disease that an individual may have, as well as the risk of serious illness from coronavirus itself. Where appropriate, such individuals should be referred for assessment of clinical risk. |

**Allergic reactions**
Individuals who have had previous anaphylaxis to a previous dose of Comirnaty™ or any component of the vaccine should not receive further Comirnaty™.

There will be at least two different types of vaccines available. This means that if someone is allergic to one type of vaccine, they may be able to have another type of vaccine, without having an allergic reaction. For these individuals, consultation with a clinical immunology/allergy specialist for assessment is recommended.

**Pregnancy**

If the benefits of vaccination do not outweigh the potential risks for the pregnant woman, the vaccination should be postponed. See also, COVID-19 vaccination decision guide for women who are pregnant, breastfeeding or planning pregnancy.

**Acute Severe Febrile Illness**

In case of postponement due to acute illness, advise when the individual can be vaccinated and, if possible, ensure another appointment is arranged.

**Have received a dose of COVID-19 vaccine in the preceding 21 days**

The Comirnaty™ vaccine requires at least 21 days between administration. If a patient presents earlier, they should be re-booked to ensure at least a 21-day lapse between doses.

**Have completed a course of COVID-19 vaccination**

Individuals who have completed a COVID-19 vaccination course i.e. 2 doses of the vaccine, do not require a second course.

For anyone who is unable to receive the vaccination, document the reason for exclusion and any action taken.

<table>
<thead>
<tr>
<th>Action to be taken if the patient or carer declines treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Informed consent, from the individual or a person legally able to act on the person’s behalf, must be obtained for each administration and recorded appropriately.</td>
</tr>
<tr>
<td>Advise the individual/carer about the protective effects of the vaccine, the risks of infection and potential complications if not immunised. Document advice given and the decision reached.</td>
</tr>
</tbody>
</table>

### STAGE 1b: Description of treatment

**ACTIVITY STAGE 1b:** Consider any relevant cautions, interactions or adverse drug reactions. Provide advice to the individual and obtain informed consent. Record patient consent and ensure vaccinator, if another person, is informed of the vaccine product to be administered.

**Name, strength & formulation of drug**

Comirnaty™ vaccine (BNT162b2[mRNA]) concentrate for solution for injection, presented as a multidose vial. Pack size: 195 vials.

2 mL clear multidose vial (Type I glass) with a stopper (synthetic bromobutyl rubber) and a flip-off plastic cap with aluminium seal. Each vial contains at least 5 doses.

**Legal category**

The COVID-19 Comirnaty™ vaccine is a Schedule 4 – Prescription Only Medicine. It has been provisionally approved by the TGA for therapeutic use. This decision was made.
Based on short-term efficacy and safety data. Continued approval depends on the evidence of longer-term efficacy and safety from ongoing clinical trials and post-market assessment.

**Black triangle ▼**

This vaccine is subject to additional monitoring in Australia. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected Adverse Events Following Immunisation (AEFI) via the Queensland COVID-19 Vaccine Management System (QCVMS), when it is available for use.

**Drug interactions**

Immunological response may be diminished in those receiving immunosuppressive treatment, but it is important to still immunise this group.

Although no data for co-administration of COVID-19 vaccine with other vaccines exists, in the absence of such data first principles would suggest that interference between inactivated vaccines with different antigenic content is likely to be limited. Based on experience with other vaccines, any potential interference is most likely to result in a slightly attenuated immune response to one of the vaccines. There is no evidence of any safety concerns, although it may make the attribution of any adverse events more difficult.

It should not be routine to offer appointments to give this vaccine at the same time as other vaccines. **Scheduling should ideally be separated by an interval of at least 14 days to avoid incorrect attribution of potential adverse events.**

Where individuals in an eligible cohort present having received another inactivated or live vaccine, COVID-19 vaccination should still be considered. The same applies for other live and inactivated vaccines where COVID-19 vaccination has been received first or where an individual presents requiring two vaccines. In most cases, vaccination should proceed, and may be provided, to avoid any further delay in protection and to avoid the risk of the individual not returning for a later appointment. In such circumstances, individuals should be informed about the likely timing of potential adverse events relating to each vaccine.

**Identification & management of adverse reactions**

The most frequent adverse reactions in participants 16 years of age and older were pain at the injection site (> 80%), fatigue (> 60%), headache (> 50%), myalgia (> 30%), chills (> 30%), arthralgia (> 20%) and pyrexia (> 10%) and were usually mild or moderate in intensity and resolved within a few days after vaccination. Redness at the injection site, injection site swelling, and nausea are reported as common. Lymphadenopathy was reported in less than 1%.

Individuals should be provided with the advice on adverse reactions and their management, such as with analgesic and/or antipyretic medication.

Testing for SARS-CoV-2 infection or implementing (non-medically recommended) isolation of someone who develops symptoms of fever, headache, fatigue or other systemic symptoms within and lasting for <48 hours after receipt of a COVID-19 vaccine is not necessarily required. If a vaccine recipient develops typical vaccine-related adverse events (refer to Adverse events section) and there is complete absence of respiratory symptoms (including loss of smell), it is more likely that they have an expected vaccine response. However, vaccine-induced protection is not immediate, and it is possible that
SARS-CoV-2 could be contracted within several days before or after vaccination (this would not constitute vaccine failure).

A detailed list of adverse reactions is available in the Australian Product Information – Comirnaty™ (BNT162b2 [MRNA]) Covid-19 Vaccine. A tabulated comparison of adverse reactions vs. age can be found in Clinical guidance on use of COVID-19 vaccine in Australia in 2021 (v2.0).

See also Clinical Incidents.

Reporting procedure of adverse reactions

The TGA will maintain surveillance post deployment of COVID-19 vaccines in Australia. In response to any safety signals, the TGA may provide temporary advice or make substantive amendments to the authorised conditions of the vaccine product’s supply in the Australia.

Healthcare professionals should report any AEFIs via the QCVMS (once available) within 12 hours of presentation. Escalation of all severe AEFIs to the Queensland Health Vaccine Command Centre (QH VCC) are critical for state-wide coordination with the TGA and the Commonwealth Vaccine Operations Center.

Severe AEFIs are defined as:

- Death
- Anaphylaxis or anaphylactic shock
- Facial Drooping
- Rash
- Other AEFIs not defined in Australian Product Information – Comirnaty™ (BNT162b2 [MRNA]) Covid-19 Vaccine.
- All other symptoms persisting longer than 24 hours

Local AEFI reporting processes are to be used in the interim until the QCVMS is available. Individuals/carers with a suspected AEFI should contact their primary care health professional.

Any AEFIs to a vaccine should also be documented in the individual’s medical record and the individual’s GP should be informed.

Additional requirements, as dictated by local procedures for AEFIs should also be followed e.g. submitting a RiskMan report.

Written information available to be given to patient or carer

Ensure the individual can be provided with appropriate written information if requested:

- COVID-19 Vaccine 2021 - Vaccination Information
- COVID-19 Vaccine Record Card

Patient advice / follow up treatment

- As with all vaccines, immunisation may not result in protection in all individuals. Immunosuppressed individuals should be advised that they may not make a full immune response to the vaccine. Nationally recommended protective measures should still be followed. Individuals may not be fully protected until 7 days after their second dose of the Comirnaty™ vaccine.
- Inform the individual/carer of possible side effects and their management.
- The individual/carer should be advised to seek appropriate advice from a healthcare professional in the event of an AEFI.
- Advise the individual/carer that they can report side effects directly to their
primary care health professionals. Inform the patient an AEFI survey will be sent via text on days 3 and 8 after each dose and 30 days after the second dose (once the QCVMS is available).

- Vaccine recipients should be monitored for 15 mins after vaccination, with a longer observation period (30 minutes) when indicated after clinical assessment (see Cautions including any relevant action to be taken).
- When applicable, advise the individual/carer when to return for vaccination or when a subsequent vaccine dose is due.

**Special considerations / additional information**

**Emergency kits**

In existing Queensland Health clinical facilities, access to a facilities normal Medical Emergency Response Team (MERT), if available, is sufficient and appropriate to respond to serious AEFI as required. A medical officer (at least PGY2) should be utilised for any other attendances in the clinic, including less serious AEFI. There is no specific requirement for a medical officer to be physically present in the clinic for the duration of operations providing they are readily accessible and can attend.

In vaccine locations where medical officers are not already working onsite or in close vicinity, other health professionals on site must be trained and capable recognise an anaphylactic reaction and be familiar with techniques for resuscitation of an individual with anaphylaxis including providing Advanced Life Support (ALS). Local systems must be in place to transport patients with serious AEFI to appropriate health facilities as required.

Ensure there is immediate access to adrenaline (epinephrine) 1 in 1,000 injection and access to a telephone at the time of vaccination.

Before each vaccination session, check that you have the protocols, equipment and medicines to manage anaphylaxis. Always keep an anaphylaxis response kit on hand. This kit should contain:

- adrenaline 1:1000 (at least 3 ampoules — check expiry dates)
- at least three drawing-up needles
- at least three 1 mL syringes and 25 mm needles (22 or 23 gauge) for intramuscular injection
- cottonwool swabs
- pen and paper to record the time the adrenaline was administered
- laminated copy of Table. Doses of intramuscular 1:1000 adrenaline for anaphylaxis and Table. Recognising and treating anaphylaxis

A protocol for the management of anaphylaxis and an anaphylaxis pack must be readily available in case of an anaphylactic event. See Managing anaphylaxis. Sites must also have in place processes for checking the appropriate emergency equipment is in place.

In the event of anaphylaxis:

1. Call a CODE BLUE (hospital sites) or the Queensland Ambulance Service (QAS) emergency call (000) for community centres.
2. If any respiratory and/or cardiovascular symptoms or signs of anaphylaxis, give adrenaline 500microg* via the adrenaline (epinephrine) 1:1,000 ampoule by intramuscular injection into anterolateral thigh (not into the buttocks).
Adrenaline (epinephrine) is NOT required for non-anaphylactic reactions (e.g. skin rash in isolation).

3. Lay the patient flat, with feet elevated, do not allow the patient to stand or walk. If breathing is difficult, allow the patient to sit, administer high flow oxygen by face mask (if available). If unconscious, use the recovery position.


5. If there is no improvement in condition 5 minutes post adrenaline (epinephrine) 1:1,000 ampoule administration, administer a second adrenaline (epinephrine) 500microg* dose with a 1:1,000 ampoule and document time of administration in an emergency response record.

6. Stay with the patient until the Medical Emergency Team – MET / Rapid Response Team – RRT or QAS arrives.

7. Record the incident, including doses of adrenaline given. In an acute facility, complete the relevant Code Blue documentation. Other sites see – Queensland Health Anaphylaxis Emergency Treatment Response Record Form.

*For a patient >50kg. For patient less than 50kg see dose advice below.
<50kg: 10 micrograms/kg = (0.01mL/kg).

**Previous incomplete vaccination**

Other COVID-19 vaccines may become available after this protocol has been written. There is no evidence on the interchangeability of the COVID-19 vaccines although studies are underway. Therefore, every effort should be made to determine which vaccine the individual received and to complete the course with the same vaccine. This option is preferred if the individual is likely to be at immediate high risk or is considered unlikely to attend again.

---

**STAGE 2: Vaccine Preparation**

<table>
<thead>
<tr>
<th>ACTIVITY STAGE 2:</th>
<th>Vaccine preparation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaccine presentation</td>
<td>Comirnaty™ vaccine (BNT162b2[mRNA]) concentrate for solution for injection, presented as a multidose vial. Pack size: 195 vials. It is a white to off-white frozen suspension. 2 mL clear multidose vial (Type I glass) with a stopper (synthetic bromobutyl rubber) and a flip-off plastic cap with aluminum seal. Each vial contains 6 doses.*</td>
</tr>
<tr>
<td></td>
<td>*The 6th dose may be dependent on the use of low dead space syringe / needle.</td>
</tr>
<tr>
<td></td>
<td>To enable timely distribution of COVID-19 vaccines, international labels will be used during the initial global rollout, including in Australia. The TGA has issued a labelling exemption for this product. Some information typically present on the Australian label (e.g. ‘Keep Out of Reach of Children’) may be absent and/or modified on the international label, as well as additional information present that is not relevant to the Australian context.</td>
</tr>
<tr>
<td>Supplies</td>
<td>The Comirnaty™ vaccine is in short supply globally. Hubs will be allocated Comirnaty™ vaccine by the QH VCC. There will not be an option to order additional vaccines to those that are supplied.</td>
</tr>
</tbody>
</table>
**Storage**

The Comirnaty™ vaccine is a Schedule 4 medicine and must be stored in an area inaccessible by the public. Sites should consider implementing additional security measures as well. These measures need to minimize the chance the product could be stolen, diverted or tampered with as well as ensuring staff safety for those involved in the vaccine administration.

Notify the QH VCC (who will notify the Australian Government) immediately if any doses are stolen, diverted, tampered with, substituted, or otherwise subjected to abuse or misuse.

The Comirnaty™ vaccine is supplied from the manufacturer as a multiple-dose vial of frozen, preservative-free concentrate, which requires storage in an ultra-low temperature freezer at -80°C to -60°C or a thermal container at -90°C to -60°C. Freezers and refrigerators utilised for vaccine management must have continuous temperature monitoring – see also Cold Chain Breaches or Wastage.

The Comirnaty™ vaccine must be protected from light. Appropriate opaque containers should be utilised when removing vials from the original Pfizer tray.

**Unopened vial**

Unopened vials may be stored and transported at -25°C to -15°C for a total of 2 weeks and can be returned to -90°C to -60°C. Once removed from the freezer, the unopened vial can be stored for up to 5 days (120 hours) at 2°C to 8°C. Within the 5 days shelf-life at 2°C to 8°C, up to 12 hours may be used for transportation. Prior to use, the unopened vial can be stored for up to 2 hours at temperatures up to 30°C.

*If stored/defrosted in a refrigerator, they must be brought to room temperature before dilution.*

*Once thawed, the Comirnaty™ vaccine should not be re-frozen.*

Thawed vials and syringes can be handled in room light conditions.

**Moving frozen vials**

**Transfers of frozen vials stored at ultra-low temperature (<-60°C)**

Closed-lid vial trays containing 195 vials removed from frozen storage (< -60 °C) may be at room temperature (< 25 °C) for up to 5 minutes for transfer between ultra-low-temperature environments. After vial trays are returned to frozen storage following room temperature exposure, they must remain in frozen storage for at least 2 hours before they can be removed again.

Open lid and/or less than 195 vial trays removed from frozen storage (<-60°C) may be at room temperature for up to 3 minutes for transfer between ultra-low-temperature environments or to remove vials for use. After vial trays are returned to frozen storage following room temperature exposure, they must remain in frozen storage for at least 2 hours before they can be removed again.

**Transfers of frozen vials stored at -25°C to -15°C**

Closed-lid vial trays containing 195 vials removed from frozen storage (-25°C to -15°C) may be at temperatures up to 25°C for up to 3 minutes.
Open-lid vial trays, or vial trays containing less than 195 vials, removed from frozen storage (-25°C to -15°C) may be at temperatures up to 25°C for up to 1 minute.

**Diluted medicinal product**

Chemical and physical in-use stability, including during transportation, has been demonstrated for 6 hours at 2°C to 30°C after dilution (in the vial or syringe) in sodium chloride 9 mg/mL (0.9%) solution for injection. From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user. See Appendix 2 - Storage of COVID-19 Comirnaty™ vaccine

**Transportation**

If local redistribution of unopened vials is needed, and full trays containing vials cannot be transported at -90°C to -60°C, available data support physical and chemical stability during transportation of 1 or more thawed vials at 2°C to 8°C for up to 12 hours. Any hours used for transport of unopened vials at 2°C to 8°C count against the 120-hour limit for storage at 2°C to 8°C.

If local redistribution of diluted medicinal product in vials or syringes is needed, available data support physical and chemical stability during transportation at 2°C to 30°C for up to 6 hours. Any hours used for transport of diluted medicinal product in vials or syringes at 2°C to 30°C count against the 6-hour limit for storage at 2°C to 30°C. Microbiological risks and package integrity, particularly for prepared dosing syringes, are the responsibility of the preparer during transportation of diluted medicinal product.

**Each time a vaccine is moved, there is a risk of damage and/or a cold chain breach. Sites should limit vaccine movement as much as possible.**

**Vaccine preparation**

COVID-19 vaccine resources are scarce. Organisation and timing is critical to minimise wastage. Clear grouping of vaccinations, labelling and timers will be essential.

Sites must have a workflow that shows the **clear separation of the vaccine preparation workflow, processes and governance to the area where administration of the vaccine will be conducted**. There needs to be a clearly delineated handover of prepared doses (including governance and accountability) from the preparation area staff to the administration area staff. Whilst discouraged, this does not preclude both areas co-habiting the same physical space.

There must be a clear list of roles and responsibilities of staff in the vaccine preparation area, which includes cold chain management, dose preparation, tracking and record keeping, information entry into the QCVMS Vaccine stock management.

A clear list of roles and responsibilities of staff in the vaccine administration area is also required.

**Thawing vials for use**

- The multidose vial is stored frozen and must be thawed prior to dilution. Frozen vials should be transferred to an environment of 2 °C to 8 °C to thaw; a 195-vial pack may take 3 hours to thaw. Note: Vials do not need to be thawed a full tray at a time. Individual vials can be removed to be thawed.
• Alternatively, frozen vials may also be thawed for 30 minutes at temperatures up to 30°C for immediate use.
• Vaccine should be prepared in accordance with the product information and the standard operating procedures for the service using low dead-volume syringes and/or needles. The low dead-volume syringe and needle combination should have a dead volume of no more than 35 microlitres.
• Using aseptic technique, thawed COVID-19 Comirnaty™ vaccine requires dilution in its original vial with 1.8mL of unpreserved sodium chloride 0.9% solution for injection, prior to withdrawing a 0.3mL dose for administration (Note - do not use bacteriostatic 0.9% sodium chloride). The top of the vial should be swabbed with an alcohol swab before inserting the needle.
• Gently invert the diluted solution 10 times. Do not shake the vaccine.
• The vaccine dose should be drawn up from the diluted vial immediately prior to administration. See Appendix 3 – COVID-19 Comirnaty™ vaccine preparation.
• It is essential the syringes be labelled with the batch number, date, time of reconstitution, expiry and the initials of the person who prepared the dose. Once diluted the syringe must be utilized within 6 hours.

Each vial contains at least 5 doses (usually 6). It is normal for a small amount of liquid to remain in the vial after withdrawing the final dose. When low dead volume syringes and/or needles are used, the amount remaining in the vial after 5 doses have been extracted may be sufficient for an additional dose. If low dead volume syringes are not available, sites should utilise a 23G needle and a 1mL syringe. Note: the sixth dose may not be able to be extracted.

Care should be taken to ensure a full 0.3mL will be administered. Where a full 0.3mL dose cannot be extracted the contents should be discarded. Discarded vaccine should be recorded in the QCVMS. The reason for discarding must be included.

**Do NOT pool excess vaccine from multiple vials.**

The vaccine should be diluted and drawn up by a different person to the person administering the dose. This is for infection control, to minimize distraction and the risk of inadvertent disposal of the vaccine after one dose (which is common with most vaccines) and streamlining the workflow for mass vaccination.

Pre-drawn syringes should be taken into the administration area in, ideally an opaque container protected from light* with a timer. There should be clear local procedures for transferring the vaccine to the vaccinator in a safe way, allowing for appropriate checks of vaccine particulars e.g. batch number and expiry by both parties. The vial used to prepare the doses should be kept with the pre-drawn syringes to enable appropriate documentation into the QCVMS.

It is the responsibility of the lead in the preparation area to determine the number of vials that should be opened. This decision must be made after considering the number of scheduled booking, number of pre-drawn syringes already in the administration area and the time left for the clinic. Sites should be gradually slowing dilution of vials as the end of the clinic approaches to minimise waste.
STAGE 3: Vaccine Administration

**ACTIVITY STAGE 3:** Before administering the vaccine, ensure:

1. the individual has been assessed in accordance with stage one of this protocol
2. the vaccine to be administered has been identified, by the registered practitioner consenting the individual, as Comirnaty™ vaccine
3. consent for vaccination has been provided and documented

Administer the Comirnaty™ vaccine and provide post-vaccination written advice if requested.

<table>
<thead>
<tr>
<th>Consent</th>
<th>Informed consent is required before administering a COVID-19 vaccine.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaccine to be administered</td>
<td>Comirnaty™ vaccine, COVID-19 mRNA vaccine BNT162b2 30micrograms in 0.3mL dose (embedded in lipid nanoparticles)</td>
</tr>
</tbody>
</table>
| Dose and frequency of administration | A two-dose course should be administered consisting of 30micrograms in 0.3mL followed by a second dose of 30micrograms in 0.3mL after an interval of at least 21 days. For operational purposes the second dose may be given between 19 and 42 days following the first dose.

Booster doses of COVID-19 vaccines are not yet recommended because the need for, and timing of, boosters has not yet been determined.

If an interval longer than the recommended interval is left between doses, the second dose should still be given (using the same vaccine as was given for the first dose if possible). The course does not need to be restarted. |
| Route / method of administration | Comirnaty™ vaccine is for administration (after dilution) by intramuscular injection only, preferably into deltoid region of the upper arm.

If you are not familiar with intramuscular injections at this site for adults, please review the in-depth information sheets and information available within the Australian Immunisation Handbook (AIH).

Anatomical markers used to identify the deltoid injection site

Below are some summary points on intramuscular (IM) administration:

- The person’s arm should be clean. If visibly dirty, ideally soap and water should be used to clean. There is no need to use an alcohol wipe as part of normal practice if the skin is visibly clean. If an alcohol wipe needs to be used for cleanliness, ensure the skin is fully dry before administering a vaccination as otherwise this may lead to increased injection site reactions.
- In most cases, a 25mm length needle is recommended as per the AIH, however if the individual is obese then a 38mm length needle is recommended*.
- The person should be sitting on a chair with their arm relaxed.
- The vaccine should be inserted at a 90° angle. |
- There is no need to withdraw to check your position during IM vaccinations. However, if a flash of blood is seen in the needle hub before injection, withdraw the needle and select a new site for injection.
- The vaccine should be injected slowly over a count of 5 seconds.

*If 38mm-length needles are absolutely unavailable, 32mm needles may be used for vaccine recipients who are of very large size or obese. However, 32mm-length needles are too short for morbidly obese recipients and a 38mm needle is the only suitable needle length for this group.*

Do NOT inject Comirnaty™ vaccine intravascularly, subcutaneously or intradermally.

The dose should be administered after being prepared in accordance with **Stage 2** above. There must be a safe process in place for the person vaccinating to receive, check, and use the vaccine immediately after preparation (within the 6-hour time frame).

Do not shake the vaccine.

1. Confirm patient identification (e.g. Photo ID / work ID badge, date of birth, first line of address).
2. Clean hands
3. Check product vial name and expiry and syringe date and time of vaccine expiry (6 hours after reconstitution)
4. Ensure a secure connection between the needle and syringe as is standard practice.
5. Inspect visually prior to administration and ensure appearance is an off-white solution with no particulates visible. Discard the vaccine if particulates or discoloration are present.
6. If the skin is visibly clean, there is no need to wipe it with an antiseptic (such as an alcohol wipe). If you use alcohol or other disinfecting agents to clean skin that is visibly dirty, the skin must be allowed to dry before injecting the vaccine. This reduces the likelihood of irritation at the injection site.
7. Administer vaccine into deltoid muscle (intramuscular).
8. Apply cotton wool to site and ask patient to hold for 1-2 mins*.
9. Dispose of the needle / syringe into the sharps bin.
10. Ensure patient is comfortable and no immediate signs of side effects.
11. Discuss the importance of monitoring for 15 minutes and give the patient their completed record card (if one was requested).
12. Record administration details in the QCVMS.
13. Clean workspace
14. Clean hands with hand sanitiser or if soiled wash hands with soap and water.

*Where the individual has been identified as being at increased risk of bleeding, a fine needle (equal to 23 gauge or finer calibre such as 25 gauge) should be used for the vaccination, followed by firm pressure applied to the site (without rubbing) for at least 2 minutes. The individual/carer should be informed about the risk of haematoma from the injection.*

### Disposal

The COVID-19 vaccine is categorised as a Schedule 4 drug under the Health (Drugs and Poisons) Regulations 1996 and is considered clinical waste under the Queensland Environmental Protection Regulation 2019. Therefore, all COVID-19 vaccines must be disposed of in accordance with the Queensland Department of Environment and Science.
**Guideline: Clinical and related waste.** The QCVMS must be used to account for the disposal of COVID-19 vaccines. All sharps must be discarded in a sharps bin.

**Post-vaccination monitoring and advice**

Vaccine recipients should be monitored for 15 mins (30 mins if high risk) after vaccination.

Ensure the individual has been provided with the appropriate written information if requested, such as the:

- COVID-19 Vaccination Record Card specifying which brand of vaccine they have received.
- COVID-19 Vaccine 2021 - Vaccination Information

**STAGE 4: Recording vaccine administration**

<table>
<thead>
<tr>
<th>ACTIVITY STAGE 4</th>
<th>Complete a record of vaccination for the individual</th>
</tr>
</thead>
<tbody>
<tr>
<td>Records</td>
<td>All details of the vaccination are to be kept in the state digital solution. There is no additional requirement for clinicians to upload information into the Australian Immunisation Register (AIR). This will be done at a state level. Below is the minimum information to be entered into the state digital solution:</td>
</tr>
<tr>
<td></td>
<td>• that valid informed consent was given</td>
</tr>
<tr>
<td></td>
<td>• name of individual, address, date of birth and GP (or record where an individual does not have a GP and that appropriate advice has been given)</td>
</tr>
<tr>
<td></td>
<td>• name of immuniser and, where different from the immuniser, ensure the professional assessing the individual, person preparing the vaccine, and person completing the vaccine record are identified</td>
</tr>
<tr>
<td></td>
<td>• name and brand of vaccine</td>
</tr>
<tr>
<td></td>
<td>• date of administration</td>
</tr>
<tr>
<td></td>
<td>• dose, form and route of administration of vaccine</td>
</tr>
<tr>
<td></td>
<td>• quantity administered</td>
</tr>
<tr>
<td></td>
<td>• batch number and expiry date</td>
</tr>
<tr>
<td></td>
<td>• anatomical site of vaccination</td>
</tr>
<tr>
<td></td>
<td>• advice given, including advice given if excluded or declines immunisation</td>
</tr>
<tr>
<td></td>
<td>• details of any adverse drug reactions and actions taken</td>
</tr>
<tr>
<td></td>
<td>It is important that vaccinations are recorded in a timely manner on appropriate health care records for the individual. The vaccination record will be accessible by the individual and other primary care health professionals via My Health Record or My Gov.</td>
</tr>
</tbody>
</table>

**Cold Chain Breaches or Wastage**

In the event of a potential or actual wastage incident (e.g. damaged vials, breach of cold chain requirements) for AstraZeneca, that exceeds the threshold (*5 or more vials at a time*), each Administration Site or other location which receives deliveries of Vaccines must notify the QH VCC immediately by calling 07 3608 5960. Sites must also submit this data by using the state provided Excel template. The Excel template has two sheets for data entry. These sheets align with the two forms previously supplied to Citizen Link and the fields are the same.

**Clinical incidents**
Any clinical incident must be reported via local processes. Any clinical incident involving the vaccine, dosage and/or administration must also be reported to the QH VCC: 07 3608 5960 (Mon-Fri: 8am-6pm) or QH.VCC@health.qld.gov.au.

Acknowledgements

The Queensland Health Vaccine Taskforce greatly acknowledges Public Health England for their content utilized in this protocol.
Appendix 1 – Storage of COVID-19 Comirnaty™ Vaccine.

For information on frozen storage (-25°C to -15°C) and further information on transportation see the ‘Storage’ section above.

## Appendix 2 – COVID-19 Comirnaty™ Vaccine Preparation

### THAWING PRIOR TO DILUTION

- The multidose vial is stored frozen and must be thawed prior to dilution. Frozen vials should be transferred to an environment of 2 °C to 8 °C to thaw; a 195 vial pack may take 3 hours to thaw. Alternatively, frozen vials may also be thawed for 30 minutes at temperatures up to 30 °C for immediate use.
- Allow the thawed vial to come to room temperature and gently invert it 10 times prior to dilution. **Do not shake.**
- Prior to dilution, the thawed suspension may contain white to off-white opaque amorphous particles.

### DILUTION

- The thawed vaccine must be diluted in its original vial with 1.8 mL sodium chloride 9 mg/mL (0.9%) solution for injection, using a 21 gauge or narrower needle and aseptic techniques. Do not use any other diluent.

| 1.8 mL of 0.9% sodium chloride injection |  |
Equalise vial pressure before removing the needle from the vial stopper by withdrawing 1.8 mL air into the empty diluent syringe.

Gently invert the diluted suspension 10 times. Do not shake.

The diluted vaccine should present as an off-white suspension with no particulates visible. Discard the diluted vaccine if particulates or discolouration are present.

The diluted vials should be marked with the date and time of dilution. Do not freeze or shake the diluted suspension. If refrigerated, allow the diluted suspension to come to room temperature prior to use.

Gently x 10
**PREPARATION OF INDIVIDUAL 0.3 mL DOSES OF COMIRNATY**

- After dilution, the vial contains 2.25 mL from which 6 doses of 0.3 mL can be extracted.
- Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab.
- Withdraw 0.3 mL of COMIRNATY.
  Low dead-volume syringes and/or needles should be used in order to extract 6 doses from a single vial.
  The low dead-volume syringe and needle combination should have a dead volume of no more than 35 microlitres.
  If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial.
- Each dose must contain 0.3 mL of vaccine.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume.
- Verify a final injection volume of 0.3 mL prior to administration.
- Discard syringe and needle after administration to a single patient.
- Use a new, sterile needle and syringe to draw up each new dose.
- Discard any unused vaccine 6 hours after dilution.

References


Version Control

<table>
<thead>
<tr>
<th>Version</th>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>21/2/2021</td>
<td>New document</td>
</tr>
<tr>
<td>2</td>
<td>3/3/2021</td>
<td>Update to allergy information, pregnancy and lactation information, medical officer requirements and wastage reporting requirements.</td>
</tr>
<tr>
<td>3</td>
<td>22/3/2021</td>
<td>Update to allergy &amp; storage information</td>
</tr>
<tr>
<td>4</td>
<td>30/3/2021</td>
<td>Update to contraindications, link to ATAGI pregnancy and lactation advice, update to immunosuppression information</td>
</tr>
<tr>
<td>5</td>
<td>13/4/2021</td>
<td>Inclusion on advice for deltoid administration and preparation images.</td>
</tr>
</tbody>
</table>