Document Version Control

Revision history

<table>
<thead>
<tr>
<th>Version</th>
<th>Date</th>
<th>Section/Appendix</th>
</tr>
</thead>
<tbody>
<tr>
<td>V1.0</td>
<td>October 2022</td>
<td>The National Immunisation Programme (Te Whatu Ora) has prepared this document as a comprehensive COVID-19 Immunisation Policy Statement outlining the operational minimum requirements for the safe use of COVID-19 vaccines. This policy document replaces all other covid policy documents and combines all relevant COVID-19 Immunisation policies.</td>
</tr>
</tbody>
</table>
## Contents

Document Version Control....................................................................................................................................................... 2  
Contents........................................................................................................................................................................................... 3  
Definitions ....................................................................................................................................................................................... 4  
Introduction .................................................................................................................................................................................... 6  
Background and context ........................................................................................................................................................... 6  
Purpose............................................................................................................................................................................................. 6  
Te Tiri o Waitangi ......................................................................................................................................................................... 6  
  Tino rangatiratanga................................................................................................................................................................ 7  
  Equity ........................................................................................................................................................................................... 7  
  Active protection..................................................................................................................................................................... 7  
  Partnership................................................................................................................................................................................. 7  
  Options........................................................................................................................................................................................ 7  
  Equity................................................................................................................................................................................................. 8  
Policy Statement........................................................................................................................................................................... 8  
  Prescription and Informed Consent............................................................................................................................................ 8  
Policy Statement Objectives..................................................................................................................................................... 9  
Planning and delivery............................................................................................................................................................ 9  
Comirnaty (Pfizer) COVID-19 Vaccines.............................................................................................................................. 13  
Nuvaxovid (Novavax) COVID-19 Vaccine ................................................................................................................................. 17  
COVID-19 Trial Vaccines.......................................................................................................................................................... 21  
References..................................................................................................................................................................................... 22  
Appendix One Consent and Prescription for COVID-19 Vaccines...................................................................................... 23  
  About written consent forms............................................................................................................................................ 24  
Appendix Two Informed consent for people aged 12-15 years .......................................................................................... 25  
Appendix Three Informed consent process.......................................................................................................................... 27  
  Consumers aged 5-11 years ............................................................................................................................................. 27  
  Whanaungatanga (informed consent) ................................................................................................................................. 27  
  **Consumers aged 12-15 years** ........................................................................................................................................ 28  
Appendix Four Vaccine Waste.............................................................................................................................................. 29  
Performance.................................................................................................................................................................................... 29  
Categories.................................................................................................................................................................................... 29
## Definitions

The following definitions and abbreviations apply to this document, unless otherwise stated.

<table>
<thead>
<tr>
<th>Word or phrase</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consumer</td>
<td>A consumer can also be a client, patient, or resident. It is the person who uses or receives health and disability services, or their representative.</td>
</tr>
<tr>
<td>Concomitant vaccination</td>
<td>Concomitant vaccination refers to administration of more than one vaccination at the same time. Concomitant vaccination aims to provide optimal protection against disease as quickly as possible by completing a person’s recommended vaccination schedule in the shortest but most effective time frame. Most routine vaccines can be safely and effectively administered at the same visit. When a person is delayed in their immunisation schedule, administration of multiple vaccines at the same visit ensures catch-up immunisation.</td>
</tr>
<tr>
<td>Contraindication</td>
<td>Anything (including a symptom or medical condition) that is a reason for a person to not receive a particular treatment because it may be harmful. For the purposes of this document, contraindications refer to those documented by Medsafe on the relevant Aotearoa New Zealand data sheet.</td>
</tr>
<tr>
<td>Comirnaty</td>
<td>Comirnaty (Pfizer-BioNTech) refers to the paediatric and adult formulations of the COVID-19 vaccine for 5-11 years and 12 years and older respectively.</td>
</tr>
<tr>
<td>Medsafe</td>
<td>Medsafe is the Aotearoa New Zealand Medicines and Medical Devices Safety Authority. It is a business unit of the Ministry of Health and is the authority responsible for the regulation of therapeutic products in Aotearoa New Zealand.</td>
</tr>
<tr>
<td>Medsafe Approval of a Clinical Trial under section 30 of the Medicines Act 1981</td>
<td>Medsafe administers the application and approval process for clinical trials under an authority delegated from the Director-General of Health. Medsafe receives and processes applications, liaises</td>
</tr>
<tr>
<td>Word or phrase</td>
<td>Definition</td>
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<td>with the relevant Health Research Council committee and the applicant, and issues approval letters.</td>
<td></td>
</tr>
<tr>
<td><strong>Medsafe Vaccine Evaluation and Approval Process</strong></td>
<td>Medsafe evaluates applications for all new medicines, including vaccines, to ensure they comply with international standards and local requirements for quality, safety, and efficacy. Once Medsafe have completed the evaluation process and international agreed criteria for safety and efficacy are met, consent can be granted either full consent under section 20, or provisional consent under section 23 of the Medicines Act 1981.</td>
</tr>
<tr>
<td><strong>National Immunisation Schedule</strong></td>
<td>The National Immunisation Schedule is the series of publicly funded vaccines available in Aotearoa New Zealand. Some vaccines are also offered as part of an extended immunisation programme for targeted special groups in response to a recognised need. For further information refer to the <a href="#">Immunisation Handbook 2020</a>.</td>
</tr>
<tr>
<td><strong>Nuvaxovid</strong></td>
<td>Nuvaxovid (Novavax) refers to the adult formulation of the COVID-19 vaccine for 12 years and older.</td>
</tr>
<tr>
<td><strong>Qualified healthcare professional</strong></td>
<td>For the purposes of this document, a qualified healthcare professional is a registered healthcare professional who is acting within their scope of practice and has completed the required COVID-19 vaccine training to be able to discuss the benefits, risks, and alternatives with the consumer.</td>
</tr>
</tbody>
</table>
Introduction

COVID-19 vaccines have been rolled out in Aotearoa New Zealand through the National Immunisation Programme (the Programme) overseen by Te Whatu Ora – Health New Zealand (Te Whatu Ora). This is the country’s largest ever immunisation programme.

The Programme offers free COVID-19 vaccinations to everyone within the approved age range. To ensure that the Programme aligns with international evidence, the COVID-19 Vaccine Technical Advisory Group (CV TAG) from the Ministry of Health continuously reviews evidence and provides advice to the Programme.

This policy statement includes advice on the Comirnaty and Nuvaxovid COVID-19 vaccines and outlines the minimum requirements in the operational setting as it relates to these vaccines and other associated matters including informed consent.

Background and context

Te Whatu Ora recommends COVID-19 vaccination for everyone of eligible age in Aotearoa New Zealand. The Comirnaty COVID-19 vaccines are the first line vaccines where the consumer has no contraindications.

Medsafe, Aotearoa New Zealand Medicines and Medical Devices Safety Authority, continues to closely monitor the safety of the COVID-19 vaccines through pharmacovigilance.

The CV TAG has advised the eligibility criteria for the COVID-19 vaccines as outlined in this policy statement.

Purpose

To provide a policy statement on the use of the COVID-19 vaccines in Aotearoa New Zealand and provide guidance on their use. The policy statement and objectives in this document align with the recommendations from the CV TAG.

This policy statement should be used alongside the Immunisation Handbook 2020, the National Immunisation Programme Operating Guidelines, the COVID-19 Vaccine Immunisation Programme Service Standards and other relevant policy statements available on the Ministry of Health’s website.

Te Tiriti o Waitangi

Te Whatu Ora has a responsibility to contribute to the Crown meeting its obligations under Te Tiriti o Waitangi (Te Tiriti). The principles of Te Tiriti o Waitangi, as articulated by the Courts and the Waitangi Tribunal provide the framework for how we will meet our obligations under Te Tiriti in the National Immunisation Programme (the Programme).
**Tino rangatiratanga**

The guarantee of tino rangatiratanga, which provides for Māori self-determination and Mana Motuhake in the design, delivery, and monitoring of health and disability services.

**Equity**

The principle of equity, which requires the Crown to commit to achieving equitable health outcomes for Māori.

**Active protection**

The principle of active protection, which requires the Crown to act, to the fullest extent practicable, to achieve equitable health outcomes for Māori. This includes ensuring that it, its agents, and its Treaty partner are well informed on the extent, and nature, of both Māori health outcomes and efforts to achieve Māori health equity.

**Partnership**

The principle of partnership, which requires the Crown and Māori to work in partnership in the governance, design, delivery, and monitoring of health and disability services. Māori must be co-designers, with the Crown, of the primary health system for Māori.

Meeting our obligations under Te Tiriti is necessary for the overall aim of Pae Ora (healthy futures for Māori) under He Korowai Oranga (the Māori Health Strategy).

**Options**

The principle of options, which requires the Crown to provide for and properly resource kaupapa Māori health and disability services. Furthermore, the Crown is obliged to ensure that all health and disability services are provided in a culturally appropriate way that recognises and supports the expression of Hauora Māori models of care.
Equity

In Aotearoa New Zealand, people have differences in health outcomes that are not only avoidable but unfair and unjust. Equity recognises that different people with various levels of advantage require different approaches and resources to get equitable health outcomes.

Overall, Māori, Pacific and whaikaha peoples are impacted more by communicable diseases as well as the social and economic consequences of serious illness. The differential impact is expected to continue or increase as these communities have lower vaccination rates, higher rates of underlying health conditions and disabilities and high-contact living conditions. These communities may face inequitable access to appropriate healthcare services, be disproportionately impacted by COVID-19 and/or be at risk of more severe illness.

Whānau-based approaches, alongside the provision of accessible vaccination services and communications, will provide an opportunity to improve delivery and uptake of the COVID-19 vaccine among Māori, Pacific and whaikaha peoples as well as uptake of the wider National Immunisation Schedule.

Note: ‘Disabled’ has been translated as ‘whaikaha’, which means to have strength, to have ability, otherly abled, enabled. This word was created with the Māori disabled community and has a deliberate emphasis on gaining strength and ability.

Policy Statement

Te Whatu Ora recommends eligible people stay up to date with their COVID-19 vaccinations. A primary course of two vaccines followed by a booster vaccine is recommended for those that are eligible. Those at risk may also be eligible for a third primary dose and/or a second booster. For further information on COVID-19 vaccinations, please refer to the Ministry of Health website.

As with any vaccine, being up to date with your vaccinations (based on age, eligibility and other factors) may not mean you’ll be fully protected from infection, however it significantly reduces your chances of becoming seriously ill or ending up in hospital. This is particularly if you have the full course (two doses for Comirnaty and Nuvaxovid) and a booster (one or two, depending on your eligibility).

Comirnaty is the preferred COVID-19 vaccine for use in Aotearoa New Zealand because of its safety and effectiveness profile, however Nuvaxovid is also available for use in Aotearoa New Zealand.

Prescription and Informed Consent

As part of the informed consent process, all consumers must be fully informed of the benefits and potential risks of the COVID-19 vaccine. This consent may be verbal unless specified in Appendix One. For a summary of consent and prescription please refer to Appendix One.

For further information on informed consent see the Immunisation Handbook section 2.1.2 and the Code of Rights Health and Disability Commissioner.

A prescription from an authorised prescriber is required when a vaccine is being administered off-label under section 25 of the Medicines Act 1981, such as when an approved medicine is being used for an un-approved indication. However, no prescription is required if the administration is authorised...
under section 34A of the Medicines Act 1981 which empowers the Director-General of Health to authorise, by notice, the use of a consented COVID-19 vaccine otherwise than in accordance with the approved vaccine data sheet.

### Policy Statement

#### Objectives

The following section outlines the Programme objectives for the different elements of the policy statement related to the COVID-19 vaccines:

1. Equity
2. Access
3. Planning and Delivery
4. Logistics
5. Correct Procedures
6. Workforce
7. Reporting and Monitoring
8. Post Vaccination Monitoring

#### 1. Equity

1.1 A provider must ensure sites administering COVID-19 vaccines provides equitable opportunity to Māori and Pacific people, other ethnic communities, and people with disabilities as per the National Immunisation Programme Operating Guidelines.

1.2 A provider must ensure sites administering COVID-19 vaccines and other vaccines on the Schedule are actively incorporating the principles and intent of Te Tiriti o Waitangi in their practice. Practical steps are available in the National Immunisation Programme Operating Guidelines.

### Planning and delivery

#### 2. Access

2.1 A provider should ensure sites administering vaccines are easily accessible and there is enough physical space as per the COVID-19 Vaccine and Immunisation Programme Operating Guidelines. This includes space to accommodate whānau groups to have their vaccines together.

2.2 The Programme recommends that a provider will administer the COVID-19 vaccines and other vaccines that can be given concomitantly at the same vaccination site where possible.
2. Access

2.3 The Programme will provide consumers with sufficient information that is easily accessible and readable to determine if they are eligible for a COVID-19 vaccination. This will be provided through a wide range of channels and languages to promote equitable outcomes.

2.4 The Programme will ensure a consumer can access bookings through bookmyvaccine.nz and Whakarongorau Aotearoa (0800 28 29 26).

2.5 Where provision of COVID-19 vaccination is proposed for rural/remote areas a provider should consider initiatives which may assist access for consumers. Such initiatives could include and are not limited to liaising with local communities to assist with publicity, arranging transport for consumers to attend a vaccination site, and hours of operation. Initiatives increasing uptake will also contribute to the minimisation of vaccine waste.

2.6 A provider may provide walk-in options for sites administering COVID-19 vaccines. Walk-in sites allow consumers to receive their vaccination without the need to book an appointment in advance.

3. Planning and Delivery

3.1 Providers will establish sites that are enabled to safely administer the COVID-19 vaccines. The location and nature of the provider will be specifically designed to promote access and achieve equity, for example wheelchair access, longer clinic hours or clinic hours outside business hours.

3.2 The Programme will plan to optimise the usage of the vaccines through all the various phases of the Programme.

3.3 The provider will forecast demand for vaccines according to the health district forecast and allocation plans.

3.4 The Programme and providers will plan to have processes and procedures in place to optimise the usage of the vaccines.

3.5 No direct contact will be made with young people under the age of 16 to promote or otherwise communicate about COVID-19 vaccination. This includes any invitation to be vaccinated or any outbound calls.

4. Logistics

4.1 The Programme will ensure an equitable distribution of the COVID-19 vaccines and will follow the Programme requirements on handling and cold chain management of the COVID-19 vaccines.
| 4.2  | The Programme will ensure there is adequate reporting and monitoring mechanisms with assigned responsibilities to ensure vaccines are transported and delivered safely and any potential cold chain breaches or exceptions are managed accordingly. |
| 4.3  | The Programme will verify conformance to relevant standards and recommended practice within the domestic logistics warehousing and distribution supply chain. |
| 4.4  | A provider will ensure that the handling and cold chain management of the COVID-19 vaccines are followed as per [Vaccine Storage and Transportation for Immunisation Providers (2017)](https://www.immunisation.org.nz) and [Annual Cold Chain Management Record (2017)](https://www.immunisation.org.nz). |
| 4.5  | A provider will ensure that vaccine is planned, ordered, receipted, and stock on hand updated (stock consumed) through the CIR (COVID Immunisation Register) Inventory system. |
| 4.6  | A provider will ensure that good inventory management practices are followed. |

### 5. Correct Procedures

| 5.1  | The Programme and providers will verify conformance to relevant standards and recommended practice is followed to increase vaccine usage and reduce the risk of vaccine waste. |
| 5.2  | The Programme will provide a reporting system embedded in CIR for providers to record vaccine use and waste. Further information on vaccine waste performance and categories refer to [Appendix Four](https). |
| 5.3  | The Programme reporting on waste will be categorised as either unopen vaccine wastage or open vaccine wastage, as per the World Health Organization Waste Definitions¹. Further information on waste is in [Appendix Four](https). |
| 5.4  | A provider will ensure they meet the [Vaccine Storage and Transportation for Immunisation Providers (2017)](https://www.immunisation.org.nz). |
| 5.5  | The Programme will make available the COVID-19 [Service Standards](https://www.immunisation.org.nz) and the [COVID-19 Vaccine Operating Guidelines](https://www.immunisation.org.nz) with updated COVID-19 vaccine resources. |
| 5.6  | A provider will ensure that the correct [COVID-19 vaccination screening and guidance form](https://www.immunisation.org.nz) from the IMAC is followed. |
| 5.7  | The provider is required to ensure meaningful and appropriate informed consent is received from the consumer as outlined in the [Code of Health and Disability Services Consumers Rights](https://www.immunisation.org.nz). This includes providing the latest post vaccination information both verbally and written to the consumer. |

¹ Human factors examine the relationship between people and the systems with which they interact by focusing on improving efficiency, creativity, productivity and job satisfaction, with the goal of minimising errors. A failure to apply human factors principles is a key aspect of most adverse events in health care.
A provider will ensure this informed consent is recorded in CIR including the person who has provided legal consent for the consumer as appropriate. Further guidance on informed consent can be found in the Immunisation Handbook section 2.1.2

5.8 A provider will ensure all COVID-19 vaccinations are correctly recorded in a timely fashion in CIR.

5.9 A provider will ensure the relevant standards, recommended practice and correct safety requirements are met for administration of the COVID-19 vaccines.

5.10 A provider will have a local standard operating procedure for the preparation and administration of COVID-19 vaccines.

6. Workforce

6.1 The IMAC provides the necessary training collateral, and updates to the clinical guidance within the Immunisation Handbook 2020 including vaccine training modules.

6.2 A provider will ensure fully authorised or provisionally authorised Vaccinators (this includes Pharmacist Vaccinators, Authorised Vaccinators, Provisional Vaccinators and COVID-19 Vaccinators working under supervision) administer vaccines within their scope of practice. Vaccinators administering Covid-19 vaccines must complete the appropriate training module prior to administering these vaccines.

7. Reporting and Monitoring

7.1 The Programme will provide the reporting and monitoring channels for the COVID-19 vaccines.

7.2 A provider will report COVID-19 vaccine usage to allow accuracy of waste reporting.

7.3 A provider will report COVID-19 vaccine supply to allow accuracy of waste reporting.

7.4 The Programme will monitor levels of COVID-19 vaccine use.

7.5 The Programme will report levels of COVID-19 vaccine waste.

Note: Further information on waste is in Appendix Four.

8. Post Vaccination Monitoring

8.1 A provider will report any Adverse Event Following Immunisation (AEFI) through CIR. If CIR is not available, the provider will report to the Centre for Adverse Reactions Monitoring (CARM) using the COVID-19 vaccine specific form as per the COVID-19 Vaccine Operating Guidelines.
8.2 The Programme will provide AEFI reporting in-line with the regulatory requirements for COVID-19 vaccines in the standard reporting channels.

8.3 A provider will report all known COVID-19 vaccine related incidents to the Programme as outlined in the COVID-19 Vaccine Operating Guidelines.

Comirnaty (Pfizer) COVID-19 Vaccines

The Comirnaty Vaccine is the first line COVID-19 vaccine for Aotearoa New Zealand.

<table>
<thead>
<tr>
<th>Comirnaty Eligibility and Timing of Doses</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary Course (first and second dose)</strong></td>
</tr>
<tr>
<td>For further information on first and second doses as well as recommended timing see the Ministry of Health's website</td>
</tr>
<tr>
<td><strong>Adult Comirnaty (12+ years)</strong></td>
</tr>
<tr>
<td>• Consumers aged 12 years and over who are unvaccinated or incompletely vaccinated for a primary course of the Comirnaty vaccine</td>
</tr>
<tr>
<td>• Eligible consumers who have received one dose of the Comirnaty vaccine should receive a second dose of the Comirnaty vaccine, at least 3 weeks (21 days) after the first dose.</td>
</tr>
<tr>
<td>• For consumers aged 12 to 18 years, the recommended dose interval is 8 weeks (56 days) between the first and second doses.</td>
</tr>
<tr>
<td>• Consumers who have received one dose of another COVID-19 vaccine (such as Nuvaxovid), should receive the Comirnaty vaccine as their second dose, at least 28 days after the most recent dose of the other COVID-19 vaccine.</td>
</tr>
</tbody>
</table>

**Paediatric Comirnaty (5-11 years)**

Consumers aged 5 to 11 years who are unvaccinated or incompletely vaccinated for a primary course, and have a parent, legal guardian or caregiver to provide consent for them to be vaccinated with the Paediatric Comirnaty vaccine. Further information on informed consent for consumers aged 5 to 11 years is in Appendix Three or in the Immunisation Handbook section 2.1.2

• Consumers aged 5 to 11 years who have received one dose of the Paediatric Comirnaty vaccine as their first dose, are recommended to receive a second dose of the Paediatric Comirnaty vaccine 8 weeks (56 days) after the first dose.

However, in the event of a community COVID-19 outbreak, international travel posing risk of COVID-19 infection or if medically indicated this interval may be shortened to a minimum of 3 weeks (21 days). The consumer's healthcare provider or IMAC should be contacted for clinical guidance if required.
# Comirnaty Eligibility and Timing of Doses

<table>
<thead>
<tr>
<th>Note: If a child receives the paediatric Comirnaty (for ages 5 to 11 years) and then turns 12 years old before their second dose, they should receive the adult Comirnaty for any subsequent doses.</th>
</tr>
</thead>
</table>
| **Third Primary Dose (Comirnaty)**  
For further information on recommendations for a third primary dose see the Ministry of Health’s website. |
| A third primary dose can be prescribed by an authorised prescriber in accordance with Section 25 of The Medicines Act 1981 for severely immunocompromised consumers, aged 5 years and over, to be given 8 weeks (56 days) after the second dose.  
Clinical judgement should be applied by the authorised prescriber to determine whether a third primary dose is required for conditions or medicines that are not listed and are associated with severe immunocompromise. |
| **First Booster (Adult Comirnaty)**  
For further information on first boosters see the Ministry of Health’s website. |
| Consumers aged 18 years and over without contraindications should be offered a booster dose of the Comirnaty vaccine 3 months after completion of their primary course.  
**Note:** This includes pregnant people and the severely immunocompromised who received a 3-dose primary course.  
OR  
Consumers aged 16 and 17 years without contraindications should be offered a booster dose of the Comirnaty vaccine 6 months after completion of their primary course of a COVID-19 vaccine.  
**Note:** This includes people who received a 3-dose primary course (i.e., immunocompromised).  
**Note:** A vaccine dose, if due, should be postponed for 3 months after a COVID-19 infection. Clinical discretion can be applied when considering vaccination prior to three months after infection. |
| **Second Booster (Adult Comirnaty)**  
For current eligibility see the details on the Ministry of Health website. |
| A second booster dose of the Comirnaty vaccine can be offered to those eligible 6 months after their first booster dose of a COVID-19 vaccine.  
**Eligibility Criteria:**  
- All people aged 65 years and older.  
- Māori and Pacific peoples aged 50 years and older.  
- Residents of aged care and disability care facilities aged 16 years and older.  
- Severely immunocompromised people (aged 16 years and older) who received a three-dose primary course and a first booster.  
  **Note:** this is an overall fifth dose for these people. |
**Comirnaty Eligibility and Timing of Doses**

- People aged 16 years and older who have a medical condition that increases the risk of severe breakthrough COVID-19 illness.\(^2\)
- People aged 16 years and older who live with disability with significant or complex health needs or multiple comorbidities.

A second booster is also available for:

- All people aged 50 years and older.
- Health, aged care, and disability workers aged 30 years and older.

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**Comirnaty Contraindications**

The *adult Comirnaty* and *paediatric Comirnaty* vaccine is contraindicated in individuals with known severe allergic reactions (such as anaphylaxis) to any component of the vaccine as outlined in the vaccine datasheets.

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**Caution to receiving the Comirnaty Vaccine**

A second or subsequent dose of the Comirnaty vaccine should not be given to those who have experienced a serious vaccine induced adverse event (such as myocarditis or pericarditis) to the first or subsequent dose of any COVID-19 vaccine without seeking advice from a medical professional.

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**Comirnaty Concomitant Vaccine usage**

*Comirnaty and other vaccines on the National Immunisation Schedule*

The Comirnaty vaccine may be concomitantly administered at any time before, after, or at the same time as influenza, MMR, HPV, Diphtheria/Tetanus/Pertussis and other vaccines in the National Immunisation Schedule.

A 7-day interval, before or after administration of the Comirnaty vaccine is advised for the live-attenuated shingles vaccine (Zostavax).
## Administration of Comirnaty vaccines

<table>
<thead>
<tr>
<th>Who can administer?</th>
<th>Consent and prescription requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary course first and second dose (Adult Comirnaty and Paediatric Comirnaty)</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Adult Comirnaty</strong></td>
<td></td>
</tr>
<tr>
<td>• Fully Authorised Vaccinators</td>
<td>• No prescription required.</td>
</tr>
<tr>
<td>• Pharmacist Vaccinators</td>
<td>• Verbal or written informed consent is required for all consumers receiving a dose of the Comirnaty vaccine.</td>
</tr>
<tr>
<td>• Provisional Vaccinators</td>
<td>• Verbal or written informed consent is required from a parent, legal guardian, caregiver, or person with an enduring power of attorney who can provide consent for consumers aged 5 to 11 years receiving a dose of the Paediatric Comirnaty vaccine.</td>
</tr>
<tr>
<td>• COVID-19 Vaccinators working under supervision and Vaccinating Health Worker.</td>
<td></td>
</tr>
<tr>
<td><strong>Paediatric Comirnaty</strong></td>
<td></td>
</tr>
<tr>
<td>• Fully Authorised Vaccinators</td>
<td>• It is required that the administration of Comirnaty as a third primary dose is prescribed by an authorised prescriber, in accordance with <a href="https://www.legislation.gov.au/Details/C1981C0084">Section 25 of The Medicines Act 1981</a> as it is considered an off-label use.</td>
</tr>
<tr>
<td>• Pharmacist Vaccinators</td>
<td>• Written informed consent is required for all consumers receiving a third primary dose of the Comirnaty vaccine.</td>
</tr>
<tr>
<td>• Provisional Vaccinators</td>
<td></td>
</tr>
<tr>
<td>• COVID-19 Vaccinators working under supervision are not authorised to vaccinate this age group.</td>
<td></td>
</tr>
<tr>
<td><strong>Third primary dose (Adult Comirnaty and Paediatric Comirnaty)</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Second primary dose (Adult Comirnaty) following a non-Comirnaty dose</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Booster dose (Adult Comirnaty)</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Second booster (Adult Comirnaty)</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• No prescription required.</td>
</tr>
<tr>
<td></td>
<td>• Verbal or written informed consent is required for all consumers receiving a dose of the Comirnaty vaccine.</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• No prescription required.</td>
</tr>
<tr>
<td></td>
<td>• Verbal or written informed consent is required for all consumers receiving a dose of the Comirnaty vaccine.</td>
</tr>
<tr>
<td></td>
<td>• <strong>Note:</strong> Further information on informed consent for consumers aged 5-11 is in Appendix Two and Three.</td>
</tr>
</tbody>
</table>
# Nuvaxovid (Novavax) COVID-19 Vaccine

The Nuvaxovid Vaccine is the second line COVID-19 vaccine for Aotearoa New Zealand.

## Nuvaxovid Eligibility and Timing of doses

<table>
<thead>
<tr>
<th><strong>Primary course (first and second dose)</strong></th>
<th>Consumers who are aged 12 years and older and unvaccinated or incompletely vaccinated who are contraindicated to receive the Comirnaty COVID-19 vaccine or people who prefer to receive Nuvaxovid.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Eligible consumers who have received a first dose of the Nuvaxovid vaccine, should receive a second dose of the Nuvaxovid vaccine <strong>at least 3 weeks (21 days)</strong> after the first dose.</td>
</tr>
<tr>
<td></td>
<td>• Consumers who have received a first dose of another COVID-19 vaccine (such as Comirnaty), should receive the Nuvaxovid vaccine <strong>28 days</strong> after the most recent dose of the other COVID-19 vaccine. A prescription from an authorised prescriber is required when using the Nuvaxovid vaccine as a second primary dose for the primary series.</td>
</tr>
</tbody>
</table>

| **Nuvaxovid as a third primary dose** | A third primary dose can be prescribed by an authorised prescriber in accordance with Section 25 of The Medicines Act 1981 for severely immunocompromised consumers, aged 18 years and over, to be given **at least 8 weeks (56 days)** after the second primary dose. See the Immunisation Handbook 2020 for details of eligibility. |

| **First Booster** | Consumers aged 18 years and over without contraindications for a booster dose **6 months** following the completion of their primary course. |
### Nuvaxovid Eligibility and Timing of doses

#### Second Booster
A second booster dose of the Nuvaxovid vaccine can be offered to consumers aged over 18 years who meet the below eligibility criteria. This can be administered from **six months** since the first booster dose of a COVID-19 vaccine.

**The eligibility criteria:**
- All people aged 65 years and older.
- Māori and Pacific peoples aged 50 years and older.
- Residents of aged care and disability care facilities from aged 18 years and older.
- Severely immunocompromised people (aged 18 years and older) who received a three-dose primary course and a first booster. **Note:** this is a fifth dose overall for these people.
- People aged 18 years or older, who have a medical condition that increases the risk of severe breakthrough COVID-19 illness.³
- People aged 18 years and older who live with disability with significant or complex health needs or multiple comorbidities.

A second booster is also available for:
- All people aged 50 years and older.
- Health, aged care, and disability workers aged 30 years and older.

### Nuvaxovid Contraindications
The Nuvaxovid vaccine is contraindicated in individuals with known severe allergic reactions (such as anaphylaxis) to any component of the vaccine as outlined in the [vaccine datasheet](#) or a previous dose of the Nuvaxovid vaccine.

### Caution to receiving the Nuvaxovid Vaccine
A second or subsequent dose of the Nuvaxovid vaccine should not be given to those who have experienced a serious vaccine induced adverse event (such as myocarditis or pericarditis) to the first or subsequent dose of any COVID-19 vaccine without seeking advice from a medical professional.
# Nuvaxovid Concomitant Vaccine usage

<p>| Nuvaxovid and other vaccines on the National Immunisation Schedule | The Nuvaxovid vaccine may be concomitantly administered at any time before, after, or at the same time as influenza, MMR, HPV, Diphtheria/Tetanus/Pertussis and other vaccines. A 7-day interval, before or after administering the Nuvaxovid vaccine is advised for the live-attenuated shingles vaccine (Zostavax), and three days before or after the adjuvanted vaccines Shingrix or Fluad Quad vaccines. |</p>
<table>
<thead>
<tr>
<th>Administration of the Nuvaxovid vaccine</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Who can administer?</strong></td>
</tr>
</tbody>
</table>
| A first primary dose and A second primary dose (following a Nuvaxovid first dose) | • Fully authorised vaccinators  
• Pharmacist vaccinators  
• Provisional vaccinators | • No prescription required.  
• Verbal or written informed consent is required for all consumers receiving a dose of the Nuvaxovid vaccine.  
• **Note:** Further information on informed consent for consumers aged 5-11 is in Appendix Two and Three. |
| Second primary dose (Nuvaxovid) following a non-Nuvaxovid dose and Third primary dose (Nuvaxovid) | • Fully authorised vaccinators  
• Pharmacist vaccinators  
• Provisional vaccinators (but not COVID-19 vaccinators working under supervision). | • It is required that the administration of the Nuvaxovid vaccine as a second primary dose following a non- Nuvaxovid COVID-19 vaccine is prescribed by an authorised prescriber, in accordance with **Section 25 of The Medicines Act 1981**, as it is considered off-label use.  
• The vaccine Programme requires written consent for all off-label use of this vaccine. |
| First or second booster dose (Nuvaxovid) | • Fully authorised vaccinators  
• Pharmacist vaccinators  
• Provisional vaccinators | • Those consumers aged 18 years and older  
• No prescription required if eligibility criteria are met (please refer to the eligibility table above).  
• Standard informed consent procedures as per the **COVID-19 Vaccine and National Immunisation Programme Operating Guidelines** apply to all ages. |
COVID-19 Trial Vaccines

According to the World Health Organisation (WHO), globally there are over 600 COVID-19 vaccine trials in progress, all proceeding at various phases. These trials help scientists understand the safety and efficacy of current, new, or experimental COVID-19 vaccines. The evidence collected from these clinical trials is then reviewed by national authorities and regulatory agencies for consideration of approval to use.

A small number of New Zealanders have consented to be participants in international clinical trials for experimental COVID-19 vaccines that are not approved by Medsafe. The Programme recognises the importance of representing the Aotearoa New Zealand population in international clinical trials and values their contribution to new COVID-19 vaccine research.

A consumer who is a participant in a COVID-19 vaccine clinical trial may receive the approved national COVID-19 vaccines if they wish.

Receiving a Medsafe-approved COVID-19 vaccine such as Comirnaty following a vaccine clinical trial would require individualised clinical advice, including the consideration of timing of the dose. This can be obtained through their usual health care provider such as a general practitioner with advice available from the Immunisation Advisory Centre (IMAC).

**Note:** Medsafe receives, processes, and evaluates both clinical trials of new medicines and applications to market new vaccines. A Medsafe-approved clinical trial does not mean it is an approved, or provisionally approved vaccine in Aotearoa New Zealand nor does it mean it is approved for use in the Programme.

Vaccine trial participants can only have their vaccine dose information recorded in CIR once the trial vaccine has been added to the WHO ‘vaccines approved by at least one country list’ or the WHO Emergency Use List (EUL). Trial participants need to contact Te Whatu Ora Help Desk to have their trial vaccine recorded in CIR.
References


## Appendix One Consent and Prescription for COVID-19 Vaccines

### Adult Comirnaty (12 years and older)

<table>
<thead>
<tr>
<th>Process Step</th>
<th>Primary Course Dose 1</th>
<th>Primary Course Dose 2</th>
<th>First Booster</th>
<th>Second Booster</th>
<th>Additional Dose**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Informed consent</td>
<td>Verbal or written</td>
<td>Verbal or written</td>
<td>Verbal or written (16 years and older)</td>
<td>Verbal or written*** (16 years and older)</td>
<td>Written consent**</td>
</tr>
<tr>
<td>Prescription</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
</tr>
</tbody>
</table>

### Paediatric Comirnaty (5 to 11 years)

<table>
<thead>
<tr>
<th>Process Step</th>
<th>Primary Course Dose 1</th>
<th>Primary Course Dose 2</th>
<th>First Booster</th>
<th>Second Booster</th>
<th>Additional Dose**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Informed consent</td>
<td>Verbal or written</td>
<td>Verbal or written</td>
<td>NA</td>
<td>NA</td>
<td>Written consent**</td>
</tr>
<tr>
<td>Prescription</td>
<td>No</td>
<td>No</td>
<td>NA</td>
<td>NA</td>
<td>Yes</td>
</tr>
</tbody>
</table>

### Nuvaxovid (12 years and older)

<table>
<thead>
<tr>
<th>Process Step</th>
<th>Primary Course Dose 1</th>
<th>Primary Course Dose 2</th>
<th>First Booster</th>
<th>Second Booster</th>
<th>Additional Dose**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Informed consent</td>
<td>Verbal or written</td>
<td>Verbal or written</td>
<td>Verbal or written (18 years and older)</td>
<td>Verbal or written (18 years and older)</td>
<td>NA</td>
</tr>
<tr>
<td>Prescription Required</td>
<td>No</td>
<td>No</td>
<td>Yes* (2nd Dose only)</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Key</td>
<td>**If first primary dose was not Nuvaxovid.</td>
<td>**Off-label additional dose eg, severely immunocompromised third-primary dose, extension, replacement.</td>
<td>*** Eligibility must be met</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**If first primary dose was not Nuvaxovid.**

**Off-label additional dose eg, severely immunocompromised third-primary dose, extension, replacement.**

*** Eligibility must be met
About written consent forms

- Written consent forms must be managed on-site or by a centralised administration team. As the information on the written form contains personal information, forms must always be held and transported securely (eg, in a locked cabinet/drawer, a tracked courier bag, or other secure containers when transported between locations). The consumer may also decide to take the written consent form with them.

- If providers choose to upload written consent forms the person uploading (eg, the administrator) must scan each form to their computer, locate the consumer’s CIR record, upload the scanned form/s to the consumer’s CIR record, delete the local copy and securely destroy the written form. When necessary, the written form may be kept in a secure place for a few days or a week to check for inaccuracies in transcribing before the written forms are destroyed.
Appendix Two
Informed consent for people aged 12-15 years

The following outlines the Programme objectives for the different elements of the policy statement related to informed consent for our younger people aged 12-15 years.

1. School-based vaccination
2. Community-based vaccination
3. Facility or residential care-based vaccination

<table>
<thead>
<tr>
<th>School Based Vaccination</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1.1</strong></td>
</tr>
<tr>
<td><strong>1.2</strong></td>
</tr>
<tr>
<td><strong>1.3</strong></td>
</tr>
<tr>
<td><strong>1.4</strong></td>
</tr>
<tr>
<td><strong>1.5</strong></td>
</tr>
<tr>
<td><strong>1.6</strong></td>
</tr>
</tbody>
</table>

**For further guidance on School-Based Vaccination refer to the Ministry of Health Professional Standards**
### Community Based Vaccination

<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.1</td>
<td>Healthcare provider will presume the young person aged 12-15 years is competent unless there is a reason to consider them not to be. The Programme will provide age-appropriate information to young people to help inform their decision. This will include after vaccination care and advice information.</td>
</tr>
<tr>
<td>2.2</td>
<td>Healthcare providers will recognise that young people aged 12-15 years have the right to give informed consent for the vaccination where competent to do so, and their decision is recorded in the CIR.</td>
</tr>
<tr>
<td>2.3</td>
<td>Healthcare providers are required to use their professional judgement to evaluate the young person's competence, understanding and maturity to form a balanced judgement to ensure they have the ability to provide informed consent.</td>
</tr>
<tr>
<td>2.4</td>
<td>Where a healthcare provider is not satisfied a young person is capable of giving informed consent then either a second opinion should be sought, or parent or guardian informed and written consent obtained.</td>
</tr>
<tr>
<td>2.5</td>
<td>When consent has been appropriately obtained on their behalf, the provider will provide the young people aged 12-15 years with information about the vaccine in an age-appropriate way and respond to and consider their views.</td>
</tr>
<tr>
<td>2.6</td>
<td>The Immunisation Advisory Centre will provide an online learning module to support healthcare providers with the consent process for younger people.</td>
</tr>
</tbody>
</table>

### Facility or Residential Care Based Vaccination

<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.1</td>
<td>Where a young person lives in a residence or supported accommodation, the informed consent will follow their usual process for other medical treatments and vaccination.</td>
</tr>
<tr>
<td>3.2</td>
<td>Healthcare providers must recognise the young person's views and wishes, and where there is disagreement, consultation with and advice from legal services, and the consumer's usual healthcare provider would be required.</td>
</tr>
<tr>
<td>3.3</td>
<td>Healthcare providers will utilise supported decision-making tools where appropriate to ensure the consumer has a good understanding of the vaccination and their decision is recorded in the CIR.</td>
</tr>
</tbody>
</table>
Appendix Three
Informed consent process

Under the [Code of Health and Disability Services Consumers’ Rights](#), every consumer has the right to the information they need to make an informed choice or to give informed consent.

For details on which vaccines require written consent please see Appendix One.

**Consumers aged 5-11 years**

A parent, legal guardian, caregiver, or person with an enduring power of attorney will need to accompany a child to their appointment(s) as the responsible adult and be able to provide consent for them to be immunised.

Accommodations must be made to enable parents, legal guardians, caregivers, or an enduring power of attorney to make informed decisions. For example, provision of interpreters, including Aotearoa New Zealand Sign Language interpreters, and information available in preferred languages or formats.

In some situations, a whanaungatanga approach may be required. If a child presents to their vaccination with whānau who cannot provide consent for the child to be immunised, written or verbal consent should be obtained from a parent, legal guardian, or person with an enduring power of attorney prior to administration of the paediatric vaccine.

Where a child is aged 5 to 11 years and lives in a residence or supported accommodation, the informed consent will follow the usual process for other medical treatments and vaccination.

The Immunisation Advisory Centre (IMAC) will provide information to support healthcare providers with the consent process for children in an online learning module.

**Whanaungatanga (informed consent)**

A responsible adult needs to accompany the child to their appointment(s). This may be a parent, adult family member, trusted family friend, legal power of attorney, or whanaungatanga carer.

Consent for vaccination needs to be given by a legal guardian of the child (under 12 years of age).

If the adult who accompanies the child to the appointment is not the child's legal guardian:

- the vaccinator will need to verbally confirm by phone with a legal guardian that they consent to the child being vaccinated, or
- the responsible adult can bring a signed copy of the COVID-19 vaccination consent form completed by a guardian.

This is standard consent process.
Consumers aged 12-15 years

The Programme recommends young people aged 12-15 years discuss the vaccination with whānau or a trusted support person. Young people can find out more information about how the vaccine protects them and answers to questions they may have on the Ministry of Health website.

Community-based vaccination

A health professional will discuss the vaccination with the young person prior to giving the vaccine and can answer any questions. If the young person has a good understanding, they can say yes or no to getting the vaccine themselves. A parent or caregiver can provide consent if preferred.

School-based vaccination

The Programme will align its policy with previous school-based vaccination Programmes and require written consent from the young person’s parent or guardian for all COVID-19 vaccines administered in schools.

Facility or residential care-based vaccination

Young people who reside in a care facility or a residence under the care of Oranga Tamariki will follow their usual process for informed consent for other medical treatments and vaccination. For further details of vaccinating consumers aged 12 to 15 years in these sites please refer to Appendix Two. See The Immunisation Handbook Appendix 4 for vaccination authorisation details including age range of consumer for specific vaccines.
Appendix Four
Vaccine Waste Performance

Vaccine Waste Performance

The Programme’s ‘line of sight’ on vaccine usage will be enabled by an efficient, Programme-wide reporting and monitoring system.

In delivering the primary objective of the Programme of administering the vaccines to as many of the population across Aotearoa New Zealand who are willing and eligible to receive the vaccine. The Programme recognises there will be vaccine waste due to warranted system and process factors including the influence of human factors

While there is no usage measure set for any vaccine, usage will be monitored and reported on to determine actions that can be implemented such that usage may be further increased, and wastage reduced.

Categories

Vaccine Waste Type/Categories

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cold Chain Excursion</td>
<td>Includes any vial that has breached the National Standards for Vaccine Storage and Transportation for Immunisation Providers.</td>
</tr>
<tr>
<td>Drop/Damage</td>
<td>Includes any vial that is damaged or dropped.</td>
</tr>
<tr>
<td>Expired Vial</td>
<td>Includes any vial that is past its expiry date.</td>
</tr>
<tr>
<td>Other Quality Issue</td>
<td>Includes any vial that does not meet quality requirements, for example, discoloured solution, presence of participate or reduced volume of vaccine, presence of foreign body or contamination</td>
</tr>
<tr>
<td>Unused</td>
<td>Includes any vial that is unopened and not administered within the required expiry timeframe.</td>
</tr>
<tr>
<td>Missing Stock</td>
<td>Includes any vial that is not able to be administered as it has been lost, misplaced or stolen.</td>
</tr>
</tbody>
</table>

4 Human factors examine the relationship between people and the systems with which they interact by focusing on improving efficiency, creativity, productivity and job satisfaction, with the goal of minimising errors. A failure to apply human factors principles is a key aspect of most adverse events in health care.