

# **Third Primary Dose of the Pfizer/BioNTech Vaccine Policy Statement and Clinical Guidance**

**New Zealand COVID-19  
Vaccine and Immunisation Programme**

Version 4

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# Definitions

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

<b>Word or phrase</b>	<b>Definition</b>
<b>Consumer</b>	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.
<b>COVID-19 vaccines</b>	The COVID-19 vaccines that have been provisionally approved for use and are available in Aotearoa New Zealand (currently the Pfizer (Comirnaty) vaccine, the Pfizer (Comirnaty) paediatric vaccine, the AstraZeneca (Vaxzevria) vaccine and the Novavax (Nuvaxovid) vaccine).
<b>Severely immunocompromised</b>	People who have a medical condition or are taking medicine used to treat a range of conditions causing severe immunodeficiency (a weakened immune system) and have a higher risk of getting serious infection if exposed to COVID-19.

# Introduction

COVID-19 vaccines are being rolled out in Aotearoa New Zealand through the National Immunisation Programme (the Programme) overseen by the Ministry of Health (the Ministry). 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) continuously reviews evidence and provides advice to the Programme.

## Background and context

CV TAG provided recommendations on the use of an additional third dose of the Pfizer/BioNTech (Pfizer) COVID-19 vaccine for those who are severely immunocompromised. It is evident that some severely immunocompromised people do not mount a sufficient immune response to provide adequate protection against COVID-19. Severely immunocompromised consumers are also at higher risk of poor health outcomes from COVID-19 compared to non-immunocompromised consumers. This group also tends to have a prolonged infection and viral shedding period, are at higher risk of developing a new variant, and are more likely to transmit the virus to any contacts compared to non-immunocompromised consumers.

Emerging evidence shows that a third dose of the Pfizer COVID-19 vaccine may increase antibody titres in immunocompromised consumers who developed low or no antibody titres to the standard two-dose regimen. Additionally, adverse reactions reported following a third dose are similar to those after a second dose for example, fatigue and pain at injection site and most were reported as mild to moderate.

People who are severely immunocompromised may have a suboptimal immune response to vaccination and should be counselled to continue to follow other public health measures, such as physical distancing, wearing a face covering, practicing hand hygiene, and isolation or quarantine as advised by public health authorities.

# Purpose

To provide a policy statement on the administration of a third Pfizer COVID-19 vaccine for severely immunocompromised consumers.

The policy statement and objectives in this document align with the recommendation from the CV TAG. This policy statement should be used alongside the [Immunisation Handbook 2020](#) and the [COVID-19 Vaccine and Immunisation Programme Operating Guidelines](#).

# 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 and Pacific 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.

Whānau-based approaches will provide an opportunity to improve delivery and uptake of the COVID-19 vaccine among Māori and Pacific peoples as well as uptake of the wider National Immunisation Schedule.

# Policy Statement

The Ministry of Health recommends that consumers with severe immunocompromise are offered a third primary dose of the Pfizer COVID-19 vaccine.

A third primary dose is part of a primary course and is distinguished from a booster dose. More information on booster doses is available in the COVID-19 [Booster Vaccination Policy Statement](#).

**Note 1:** This policy statement is specific to the **Pfizer** COVID-19 vaccine, this is the preferred vaccine in Aotearoa New Zealand for the third primary dose. AstraZeneca can be used for the third primary dose if a significant adverse reaction has occurred after a previous mRNA vaccine dose which contraindicates further doses of mRNA vaccine (eg, anaphylaxis, myocarditis). Advice is available from the Immunisation Advisory Centre (IMAC) for clinicians considering this for their consumers.

**Note 2:** The third primary dose must be prescribed by an authorised prescriber, in accordance with [Section 25 of The Medicines Act 1981](#), as it is considered off label use, and written informed consent must be obtained prior to administration.

# Eligibility Criteria

It is recommended that individuals aged 5 years and over who are severely immunocompromised are offered a third primary dose of the Pfizer COVID-19 vaccine.

Severely immunocompromised tamariki aged 5 to 11 years should be offered a third primary dose of the paediatric formulation of the Pfizer COVID-19 vaccine and individuals aged 12 years and over should be offered the adult formulation of the Pfizer COVID-19 vaccine. Clinicians caring for tamariki who turn 12 years old after their second dose should seek advice from IMAC or refer to the [Immunisation Handbook 2020](#).

The updated clinical guidance on individuals who should be offered a third primary dose of the Pfizer COVID-19 vaccine is available in the [Coronavirus Disease \(COVID-19\)](#) chapter of the [Immunisation Handbook 2020](#) and Appendix 1. Advice for clinicians on the guidance is available through IMAC.

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.

# Appendix 1

## Guidance on individuals who should be offered a third primary dose of the Pfizer COVID-19 vaccine

Guidance is available in the [Immunisation Handbook 2020](#).

Clinical judgement should be applied by the authorised prescriber to determine whether a third primary dose is required for conditions or medicines that are associated with severe immunocompromise but are not listed in the handbook. Conversely, clinicians may decide that individual patients with conditions or medicines listed in the handbook are at low risk of being severely immunocompromised and do not require a third primary vaccine dose.

**Note:** The list in the handbook is not exhaustive but provides guidance on scenarios where a consumer should receive a third primary dose. Drug dose, disease activity, and co-morbidity can affect the severity of immunocompromise. The list may expand or be modified as more evidence emerges. Advice for clinicians on the guidance is available through IMAC and this information will be updated in the handbook periodically.

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