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

## New Zealand COVID-19 Vaccine and Immunisation Programme

Version 1.0

New Zealand Government

MINISTRY OF HEALTH
MANATŪ HAUORA

# Table of Contents

Introduction ..... 3
Background and context ..... 3
Purpose ..... 4
Policy Statement ..... 4
Inclusion Criteria ..... 4
1. Consumers with primary or acquired immunodeficiency states at the time of vaccination ..... 5
2. Consumers on immunosuppressive or immunomodulating therapy at the time of vaccination ..... 6
3. Consumers with chronic immune-mediated inflammatory disease who were receiving or had received immunosuppressive therapy prior to vaccination 7
References ..... 8

# Introduction

The COVID-19 vaccine is being rolled out in New Zealand / Aotearoa through the COVID-19 Vaccine and Immunisation Programme (the Programme) run by the Ministry of Health (the Ministry). This is New Zealand's largest ever immunisation programme.

The Programme offers free COVID-19 vaccination to everyone aged 12 years and over in New Zealand / Aotearoa. In order 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 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 severe 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. Therefore, an additional dose of the Pfizer/BioNTech vaccine is likely to be beneficial and well tolerated in the severely immunocompromised, offer extra protection to this vulnerable population and reduce transmission of the virus.

Emerging evidence supports this recommendation and shows that a third dose of the Pfizer/BioNTech 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/BioNTech 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.

# Policy Statement

The Ministry of Heath recommends that consumers with severe immunocompromise, as listed in the following table, be offered a third primary dose of the Pfizer/BioNTech vaccine.

**Note:** The third primary dose must be prescribed by a medical practitioner, in accordance with Section 25 of The Medicines Act 1981, as it is considered off label use, and informed consent must be obtained prior.

# Inclusion Criteria

The following section outlines the requirements to be eligible for the third primary dose of the Pfizer/BioNTech vaccine. Conditions are grouped into three sections.

1. Consumers with primary or acquired immunodeficiency states at the time of vaccination.
2. Consumers on immunosuppressive or immunomodulating therapy at the time of vaccination.
3. Consumers with chronic immune-mediated inflammatory disease who were receiving or had received immunosuppressive therapy prior to vaccination.

**Dose Interval:** The additional dose should be administered more than eight weeks after the second dose, with special attention paid to current or planned immunosuppressive therapies. Where possible, the third dose should be delayed until two weeks after the period of immunosuppression, in addition to the time for clearance of the therapeutic agent. If not possible, consideration should be given to vaccination during a treatment 'holiday' or at a nadir of immunosuppression between doses of treatment.

# 1. Consumers with primary or acquired immunodeficiency states at the time of vaccination

| | |
|---|---|
| 1.1 | Acute and chronic leukaemias, and clinically aggressive lymphomas (including Hodgkin's lymphoma) who were under treatment or within 12 months of achieving cure. |
| 1.2 | Consumers under follow up for chronic lymphoproliferative disorders including haemotological malignancies such as indolent lymphoma, chronic lymphoid leukaemia, myeloma, Waldenstrom's macroglobulinemia and other plasma cell dyscrasias.<br><br>**Note** this list is not exhaustive but provides an indication of conditions where a consumer should receive a third primary dose. |
| 1.3 | Immunodeficiency due to HIV/AIDS with a current CD4 count of <200cells/µl. |
| 1.4 | Primary or acquired cellular and combined immune deficiencies. This includes those with lymphopaenia (<1000 lymphocytes/µl) or with a functional lymphocyte disorder. |
| 1.5 | Those who have received an allogeneic or an autologous stem cell transplant in the previous 24 months. |
| 1.6 | Those who have received a stem cell transplant more than 24 months ago but had ongoing immunosuppression or graft versus host disease. |
| 1.7 | Those with persistent agammaglobulinaemia (IgG < 3g/L) due to primary immunodeficiency. |

# 2. Consumers on immunosuppressive or immunomodulating therapy at the time of vaccination

| | |
|---|---|
| 2.1 | Those who were receiving or had received immunosuppressive therapy for a solid organ transplant in the previous six months. |
| 2.2 | Those who were receiving or had received in the previous three months targeted therapy for autoimmune disease, such as JAK inhibitors or biologic immune modulators including B-cell targeted therapies (including rituximab but in this case the recipient would be considered immunosuppressed for a six month period), T-cell co-stimulation modulators, monoclonal tumor necrosis factor inhibitors (TNFi), soluble TNF receptors, interleukin (IL)-6 receptor inhibitors, IL-17 inhibitors, IL 12/23 inhibitors, IL 23 inhibitors<br><br>**Note** this list is not exhaustive but provides a guide on the types of scenarios where a consumer should receive a third primary dose. |
| 2.3 | Those who were receiving or had received in the previous six months immunosuppressive chemotherapy or immunosuppressive radiotherapy for any indication. |

# 3. Consumers with chronic immune-mediated inflammatory disease who were receiving or had received immunosuppressive therapy prior to vaccination

| | |
|---|---|
| 3.1 | Those on, or have been on, high dose corticosteroids (equivalent to ≥20mg prednisolone per day) for more than 10 days in the previous month. |
| 3.2 | Those on long-term moderate dose corticosteroids (equivalent to ≥10mg prednisolone per day for more than four weeks) in the previous three months. |
| 3.3 | Those with non-biological oral immune modulating drugs, such as methotrexate >20mg per week (oral and subcutaneous), azathioprine >3.0mg/kg/day, 6-mercaptopurine >1.5mg/kg/day, mycophenolate >1g/day in the previous three months. |

## References

Ministry of Health. 2020. Immunisation Handbook. Wellington: Ministry of Health.

Ministry of Health. 2021. COVID-19 Vaccine Operating Guidelines. Wellington: Ministry of Health.