

A 3rd dose of the COVID-19 vaccine is now available to people in New Zealand who have a suppressed immune system.

This 3rd dose can be given 8 weeks or more after receiving the standard 2nd dose of the COVID-19 vaccine.

You are eligible for a 3rd dose of the COVID-19 vaccine because:

Reason	Criteria	Details
	2.1	You take immunosuppressive therapy for a kidney transplant
	2.2	You have received B-cell targeted therapies (including rituximab) in the previous six months
	2.3	You have received immunosuppressive chemotherapy (e.g. cyclophosphamide) for any indication in the previous six months
	3.1	You have been on high dose corticosteroids (equivalent to ≥ 20 mg prednisolone per day) for more than 10 days in the previous month
	3.2	You have been on long-term moderate dose corticosteroids (equivalent to ≥ 10 mg prednisolone per day for more than four weeks) in the previous three months
	3.3	You have been on non-biological oral immune modulating drugs, such as methotrexate > 20 mg per week (oral and subcutaneous), azathioprine > 3.0 mg/kg/day, 6-mercaptopurine > 1.5 mg/kg/day, mycophenolate > 1 g/day in the previous three months.
	3.4	You have been on combination therapies at individual doses lower than above, including ≥ 7.5 mg prednisolone per day in combination with other immunosuppressants (other than hydroxychloroquine or sulfasalazine), and those receiving methotrexate (any dose) with leflunomide in the previous three months
	4.1	You received high-dose steroids (equivalent to > 40 mg prednisolone per day for more than a week) for any reason in the month before vaccination.

Your kidney team recommend a 3rd dose of the COVID-19 vaccine for you, as this extra dose boosts immunity (improves protection) against the virus that causes COVID-19.

There are answers to frequently asked questions about a 3rd dose of the COVID-19 on the next few pages.

To get a 3rd dose of the COVID-19 vaccine, you can:

- Make an appointment to see your GP (*you will not be charged for this visit*),
- Talk about the 3rd dose of the COVID-19 vaccine with your GP
- Sign a consent form for the 3rd dose of the COVID-19 vaccine,
- Get a prescription for the 3rd dose of the COVID-19 vaccine,
- Take the consent form and the prescription to your local vaccination centre (*you may be able to get the 3rd dose of the COVID-19 vaccine at your GP practice: you can ask your GP if this option is available*),
- Get your 3rd dose of the COVID-19 vaccine.

You can ask your GP or the kidney team any questions you might have about a 3rd dose of the COVID-19 vaccine.

COVID-19 vaccination - Third primary extension dose for immunocompromised individuals

Frequently Asked Questions

The Ministry of Health has announced that a third dose of the Pfizer vaccine will be available for people who are severely immunocompromised.

Why are some people with an underlying medical condition being offered a 3rd dose of the COVID-19 vaccine?

Some people are at higher risk of severe illness from COVID-19, for example if they have a medical condition.

Underlying medical conditions that put people at higher risk include immunocompromised conditions, such as:

- organ transplantation (*such as kidney transplant, liver transplant, heart transplant and lung transplant*)
- bone marrow transplant
- some blood cancers
- having chemotherapy or radiotherapy
- immune deficiencies including HIV infection
- immunity weakening medications such as high-dose corticosteroids and disease-modifying anti-rheumatic drugs.

Getting your vaccination is an important step you can take to protect yourself and others from COVID-19.

Vaccines help prevent the spread of COVID-19 and reduce your chances of getting seriously ill or dying if you do get COVID-19.

Some people with these immunocompromised conditions:

- do not mount a strong immune response (do not create as many antibodies) from 2 doses of the vaccine
- are at higher risk of severe disease from COVID-19
- are more likely to transmit the virus to any contacts

A 3rd dose of the vaccine is expected to provide extra protection in severely immunocompromised people.

It is also expected that this additional, 3rd dose of the vaccine will reduce transmission of the virus.

The Ministry of Health therefore recommends that people with severe immunocompromise are offered a 3rd dose of the COVID-19 vaccine to get their best possible protection.

The Ministry of Health has provided a list of conditions and treatments that are classified as severe immunocompromise. The current list is provided at the end of this letter.

Why is the Ministry of Health now recommending a 3rd dose of the COVID-19 vaccine?

The COVID-19 Vaccine Technical Advisory Group (CV TAG) continuously reviews evidence and provides advice to the COVID-19 Vaccine and Immunisation Programme.

This advice ensures that the COVID-19 Vaccine and Immunisation Programme matches international evidence.

The international evidence shows that some severely immunocompromised people do not mount a sufficient immune response to 2 doses of the vaccine to get adequate protection against COVID-19.

A 3rd dose of the Pfizer/BioNTech vaccine has been shown to increase antibody titres in some immunocompromised consumers who developed low or no antibody titres to the standard two-dose regimen.

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.

The COVID-19 Vaccine Technical Advisory Group therefore provided recommendations for an additional 3rd dose of the Pfizer/BioNTech vaccine for those who are severely immunocompromised.

When can I get the 3rd dose of the COVID-19 vaccine?

The 3rd dose of the vaccine should be given at least eight weeks after the 2nd dose of the vaccine.

If there is a planned stop date for immunosuppressive treatment, then where possible the third dose should be delayed until two weeks after the immunosuppression has stopped (adding in any extra time needed for clearance of the immunosuppressive treatment from the body).

If there is no planned stop date for the immune suppression, then your doctor should consider whether the 3rd dose of the vaccine

- could be given during a treatment 'holiday',
- or between doses of immune suppression treatment when the immune system has partially recovered.

What can I expect when I get the 3rd dose of the COVID-19 vaccine?

Adverse reactions after a third dose of the vaccine are probably similar to those after a second dose (*for example, fatigue and pain at injection site, and most were reported as mild to moderate*).

The safety of the Pfizer/BioNTech Comirnaty COVID 19 vaccine in people living with organ transplants (such as kidney transplants) seems to be very similar to the safety of the vaccine in the general population.

The rate of more severe events such as myocarditis and anaphylaxis are not known for the third dose.

For the Pfizer/BioNTech Comirnaty COVID 19 vaccine the rate of anaphylaxis is between 5-11 cases per million and myocarditis is less than 1 in a million overall.

For comparison, myocarditis is about 3-times more common with COVID-19 disease than it is with the vaccine.

People who are severely immunocompromised are advised 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.

To help protect yourself, encourage your family and the people you live with to also get vaccinated.

How can I get the 3rd dose of the COVID-19 vaccine?

- Contact your GP for an appointment to discuss a 3rd dose of the COVID-19 vaccine (*note: you should not have to pay for this consultation with your GP*)
- Talk to your GP about a 3rd dose of the COVID-19 vaccine. You can ask questions and talk about the answers.
- If you choose to get a 3rd dose of the COVID-19 vaccine, you and your GP should both sign the consent form, which can currently be downloaded [here](#). You should take this consent form with you when you go for your 3rd dose.
- Your GP will need to provide a prescription for a 3rd dose of the COVID-19 vaccine – you will also need to take this prescription with you when you go for your 3rd dose.
- Your GP should record your consent for this 3rd dose of the COVID-19 vaccine in your medical records
 - You might be able to receive the 3rd dose at the same time as your consultation – check with your medical practitioner to see if they offer the Pfizer COVID-19 vaccine.
 - If your GP doesn't offer Pfizer COVID-19 vaccination, you can take the prescription and consent form to any vaccination clinic, including a vaccinating pharmacy.
- When you get to the vaccination centre, you and the vaccinator will need to sign the back of the consent form again.
- The vaccinator will administer the 3rd dose of the vaccine.
- The vaccinator will keep your consent form and your prescription, and upload your consent form and details of your 3rd dose in your vaccination records.

List of conditions and treatments that are classified as severe immunocompromise

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 haematological malignancies such as indolent lymphoma, chronic lymphoid leukaemia, myeloma, Waldenström's macroglobulinemia and other plasma cell dyscrasias.
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 for adults or children 12 years of age and over.
- 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 (for example, common variable immunodeficiency) or secondary to disease/therapy.

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
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 ≥ 20 mg prednisolone per day) for more than 10 days in the previous month.
- 3.2 Those on long-term moderate dose corticosteroids (equivalent to ≥ 10 mg 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 > 20 mg per week (oral and subcutaneous), azathioprine > 3.0 mg/kg/day, 6-mercaptopurine > 1.5 mg/kg/day, mycophenolate > 1 g/day in the previous three months.
- 3.4 Those with certain combination therapies at individual doses lower than above, including those on ≥ 7.5 mg prednisolone per day in combination with other immunosuppressants (other than hydroxychloroquine or sulfasalazine) and those receiving methotrexate (any dose) with leflunomide in the previous three months.

4. Consumers who had received high-dose steroids for any reason in the month before vaccination

- 4.1 Those who had received high-dose steroids (equivalent to > 40 mg prednisolone per day for more than a week) for any reason in the month before vaccination.

Note: Consumers who received brief immunosuppression (≤ 40 mg prednisolone per day) for an acute episode (for example, asthma / chronic obstructive pulmonary disease / COVID-19) and individuals on replacement corticosteroids for adrenal insufficiency are not considered severely immunosuppressed sufficient to have prevented response to the primary vaccination.

COVID-19 vaccination **consent form**

Patient

Surname _____ First name _____

Phone _____ Date of birth ___ / ___ / ___ NHI _____

Address _____

Medical Centre/GP _____

Please let the vaccinator know:

- If you are unwell
- If you are aged under 12 years
- If you are pregnant
- If you're on blood-thinning medications or have a bleeding disorder
- If you've had a previous severe allergic reaction to any vaccine or injection in the past
- If you have had myocarditis or pericarditis after a vaccination in the past

I have read the COVID-19 information provided, and/or have had explained to me information about the COVID-19 vaccine.

I have had a chance to ask questions and they were answered to my satisfaction.

I believe I understand the benefits and risks of COVID-19 vaccination.

I understand it is my choice to get the COVID-19 vaccination.

I understand I will need 2 doses of the Pfizer COVID-19 vaccine to have the best protection.

Signature _____ Date ___ / ___ / ___

Parent / guardian / enduring power of attorney

I am the parent, guardian or enduring power of attorney, and agree to the COVID-19 vaccination of the patient named above.

Name of parent or guardian _____ Relationship to patient _____

Signature _____ Date ___ / ___ / ___

Third primary dose

I understand I am receiving a third primary dose to provide increased protection against COVID-19.

Signature _____ Date ___ / ___ / ___

Medical practitioner

I confirm I have explained the reasons for, the risks and outcomes of a third primary vaccination to the consumer named above.

Signature _____ Date ___ / ___ / ___

PLEASE NOTE: A prescription from a medical practitioner is required for a third primary dose.

Te Kāwanatanga o Aotearoa
New Zealand Government

Unite
against
COVID-19



MANATŪ HAUORA

Information for Vaccinator

Details confirmed

Positive answer to any screening questions? Yes No

Record information and advice given:

Informed consent obtained? Yes No

Date ___/___/___ Time _____

If deferred, declined or not medical fit for vaccine record detail _____

Vaccine							Diluent		
Name of vaccine	Date	Time	Dose	Site	Batch	Expiry	Batch	Expiry	Time of reconstitution
Pfizer/BioNTech COVID-19 Vaccine			0.3ml						

Dose 1

Dose 2

Dose 3

Post vaccination information given

Signature of vaccinator _____

Name of vaccinator _____

Observation area information

Details of any AEFI or observations recorded

Signature _____

CARM Report completed

Departure time _____

Vaccination site clinical lead

If administering a third primary dose, this should be signed below by the clinical lead.

Name _____

Signature _____ Date ___/___/___

In the case of a third primary dose, the prescriber must retain this form or a copy, and hold securely as a medical record in accordance with local policy.

Access to the 3rd Primary Dose for people with severe immunocompromise



This slide outlines how an eligible consumer will access a 3rd primary dose of the Covid-19 vaccine.

THERE ARE FOUR KEY COMPONENTS TO ACCESS A 3RD PRIMARY DOSE:

1. Eligibility



1a The practice contacts the person to let them know they are eligible for a 3rd primary dose. If the person is interested, they are invited to make an appointment with their GP/Specialist for a consultation.

1b A person is aware of a 3rd primary dose for severely immunocompromised people and contacts their GP or Specialist to understand if they are eligible.

2. Consumer Consent



2 The Medical Practitioner, gathers written consent using the 3rd primary dose consent form provided by the Ministry of Health, prior to providing the person with a prescription. The medical practitioner documents the consent in their patient medical record. The consultation will be at no cost to the person.

3. Script & Consent Form



3 The medical practitioner provides the person with the prescription and the co-signed consent form.

4. Confirm Consent & Administer Vaccine



4a If the facility where the person gave their consent and received prescription is a Covid-19 vaccination site, usual vaccination processes should be followed to administer the vaccine.

4b If the consumer is to be vaccinated at a different time or place, the prescription and consent form must be taken or sent the vaccination site. The consent form must be confirmed and signed by the onsite Clinical Lead prior to vaccination. Refer to section 18.2 of the Operating Guidelines on written consent forms.

SCENARIOS

References

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