

Vaccine Temporary Medical Exemption Clinical Criteria, Clinical Guidance and Resources

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

Version 1.0 FINAL

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Principles of Temporary Medical Exemption

- There are very few situations where a vaccine is contraindicated and, as such, a medical exemption is expected to be rarely required.
- Exemptions should be limited to situations where a suitable alternative COVID-19 vaccine is not readily available for the individual.
- Exemptions should be for a specified time, reflecting, for example, recovery from clinical conditions or the availability of alternate vaccines.
- It is likely that most people who are not medically exempt can be safely vaccinated, with some requiring extra precautions.

Those not medically exempt

- People who had an otherwise negative experience that is not mentioned above, with other vaccines in the past.
- Disabled people once adequate resources are available to support safe delivery. People with disabilities are generally at higher risk from COVID-19, and therefore are a priority for vaccination.
- Pregnant people. Pregnancy is not a valid reason for exemption in the absence of any of the criteria listed in the above table. Pregnancy is associated with higher risk from COVID-19 compared to the general population and therefore this group are a priority for vaccination.
- A vaccination may reasonably be deferred for individuals with some acute major medical conditions, such as undergoing major surgery or hospital admission for a serious illness.

Medical exemption duration

The medical exemption duration is 6 months, with the ability to apply for a new exemption if required. This time period will allow individuals who can safely be vaccinated, with either the same vaccine or an alternative vaccine, as appropriate, to be protected against COVID-19 in a timely way.

			<ul style="list-style-type: none"> Has been determined following review by, and/or on the opinion of, a relevant medical specialist to be associated with a risk of recurrence of the serious adverse event if another dose of the same vaccine is given. 	<input type="checkbox"/>		1B. <input type="checkbox"/> (4 of 4 criteria required)
			<p>Examples of serious AEFIs may include but are not limited to a medically significant illness (eg, immune thrombocytopenia purpura (ITP), myocarditis, potentially life-threatening events (eg, anaphylaxis), severe ME/CFS, or persistent or significant disability (eg, Guillain-Barré Syndrome). These reactions do not include common expected local or systemic reactions known to occur within the first few days after vaccination.</p> <p>Note: If a serious adverse event to a previous dose of a COVID-19 vaccine is used as a reason for the exemption, then this will require a letter of support from the relevant medical specialist.</p>			
		1C. Unable to tolerate administration due to risk to self or others.	<ul style="list-style-type: none"> Unable to tolerate vaccine administration with resulting risk to themselves or others (eg, due to severe neurodevelopmental condition such as autistic spectrum disorder). <p>This may warrant a temporary exemption (maximum four weeks) while additional resources and support to facilitate a safe administration of a second dose are arranged.</p>		Letter of support from a medical specialist within the relevant scope practice	1C. <input type="checkbox"/>
2	Pfizer Vaccine	2A. Anaphylaxis	<ul style="list-style-type: none"> Anaphylaxis to the first dose of the vaccine or known severe allergy to the excipients of the vaccine as per the datasheet provided to Medsafe. 		CARM report	2A. <input type="checkbox"/>

			<p>This criterion will be removed as an exemption when there is an alternative vaccine available in New Zealand.</p> <p>Many of these individuals will be able to be safely vaccinated in a controlled environment, and we recommend clinical immunologist/specialist assessment.</p>	<p>Discharge summary</p> <p>Letter of support from a medical specialist within the relevant scope practice</p>	
		2B. Myocarditis / Pericarditis	Myocarditis/pericarditis following the first dose of the vaccine.		2B. <input type="checkbox"/>
		2C. Inflammatory Cardiac Illness	Inflammatory cardiac illness within the past 6 months including: acute myocarditis, pericarditis, endocarditis, acute rheumatic fever or acute rheumatic heart disease (ie, with active myocardial inflammation).		2C. <input type="checkbox"/>
		2D. Acute Decompensated Heart Failure	<ul style="list-style-type: none"> Acute decompensated heart failure. <p>Although myocarditis and/or pericarditis is very rare following vaccination, if such an event were to occur, then it may exacerbate a patient's pre-existing heart failure.</p>		2D. <input type="checkbox"/>
3	Trial Vaccine	3A. Non-Placebo participant in a vaccine trial	<ul style="list-style-type: none"> Those who are confirmed as having the vaccine (ie, non-placebo) in any COVID-19 vaccine trial in Aotearoa New Zealand (for example, the Valneva COVID-19 vaccine trial NCT04956224). 	Letter of confirmation from the Vaccine Trial Clinical Lead	3A. <input type="checkbox"/>

Other adverse events that have been reported to the Centre for Adverse Reactions Monitoring (CARM), the Immunisation Advisory Centre (IMAC), or have been observed internationally include shingles, appendicitis, lymphadenopathy with or without fever, exacerbation of myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS), regional pain syndrome, and neurological events with localised arm pain. These events **may or may not** be related to the vaccine and it is generally advised to defer the second dose until the symptoms have fully resolved.

Additional Support

If you or your patient are uncertain about the criteria, please consider contacting IMAC for clinical decision-making support on **0800 IMMUNE (466 863)**.

Ministry of Health Application

COVID-19 Vaccine Temporary Medical Exemption

Please send the completed application to temporarymedicalexemption@health.govt.nz

Consumer Details				
Full Name				
Contact Phone				
Contact Address				
Contact Email				
Address				
Vaccine Order Status	Yes <input type="checkbox"/>	or	No <input type="checkbox"/>	Date of Birth
NHI				
I [_____], consumer, certify that the information I have provided to the practitioner for the purposes of making this application is true.				
Consumer Signature			Date Signed	
Applicant Details				
Full Name				
Contact Phone				
Contact Email				
Clinic Address				
Registration number				
Health Practitioner Index Number				
Category exemption criteria (please tick those that apply)	<input type="checkbox"/> 1A <input type="checkbox"/> 1B (4 of 4 criteria required) <input type="checkbox"/> 1C	<input type="checkbox"/> 2A <input type="checkbox"/> 2B	<input type="checkbox"/> 2C <input type="checkbox"/> 2D	<input type="checkbox"/> 3A
The duration of the clinical relationship with the consumer is _____ years _____ months				
I [_____] nurse practitioner/medical practitioner [select] certify that I:				
Have reviewed the consumer's medical history and assessed the person's state of health.				Yes / No
Have clinical evidence supporting the person meets the specified COVID-19 vaccination exemption criteria.				Yes / No

The attached supporting clinical evidence is:

I certify that I provide this information believing it to be true.

Applicant Signature		Date Signed	
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COVID-19 Vaccine Temporary Medical Exemption

Ministry of Health Approval Record

Consumer Details			
Full Name			
Contact phone			
Contact email			
Contact Address			
Vaccine Order Status	Yes <input type="checkbox"/>	or	No <input type="checkbox"/>
NHI			
Exemption start date			
Exemption expiry date			
Category exemption categories	<input type="checkbox"/> 1A <input type="checkbox"/> 1B <input type="checkbox"/> 1C	<input type="checkbox"/> 2A <input type="checkbox"/> 2B	<input type="checkbox"/> 2C <input type="checkbox"/> 2D <input type="checkbox"/> 3A
Name		Role	
Signature		Date Signed	

COVID-19 Vaccine Temporary Medical Exemption Certificate

PRIVATE AND CONFIDENTIAL

DATE: *[insert date]*

Re: VACCINE TEMPORARY MEDICAL EXEMPTION

This letter certifies that *[full name of person being assessed]* application has been assessed in accordance with the Ministry of Health's Temporary Medical Exemption Process and a temporary medical exemption has been granted.

This exemption is granted pursuant to clause 9B of the COVID-19 Public Health Response (Vaccinations) Order 2021.

This exemption expires after *[insert number]* months after the date of issue being *[insert date]*.

This temporary medical exemption certificate is recorded as *[insert number]*.

[Ministry of Health]