Appendix 2.

|  |
| --- |
| Criteria for Temporary COVID-19 Vaccine Medical Exemptions |
| Step | **Vaccine** | **Category** | **Criteria Details** | **Select Criteria Present** | **Supporting Evidence** | **Select Exemption Categories** |
| 1 | **All COVID-19 Vaccines** | **1A.****COVID-19 Infection** | PCR-confirmed SARS-CoV-2 infection until complete recovery from the acute illness. **Note:** Chronic symptoms following COVID-19 ("Long COVID”) is not a contraindication to COVID-19 vaccine but does warrant a clinical discussion with the patient regarding the benefits and risks. |  | PCR resultLetter of support from their general practitioner/nurse practitioner | **1A □** |
| **1B.** **Serious Adverse Event to previous dose** | Serious adverse event attributed to a previous dose of the same COVID-19 vaccine with no other cause identified. An adverse event is considered serious for the purposes of these criteria if it:Requires in-patient hospitalisation or prolongation of existing hospitalisation OR results in persistent or significant disability/ incapacity.ANDHas been reported to CARM.ANDHas 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. | □□□□ | CARM reportDischarge summaryLetter of support from the medical specialist within the relevant scope practice | **1B. □** (4 of 4 criteria required) |
| Examples of serious AEFIs may include but are not limited to a medically significant illness (e.g., immune thrombocytopenia purpura (ITP), myocarditis, potentially life-threatening events (e.g., anaphylaxis), severe ME/CFS, or persistent or significant disability (e.g., Guillain-Barré Syndrome). These reactions do not include common expected local or systemic reactions known to occur within the first few days after vaccination.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. |
| **1C.****Unable to tolerate administration due to risk to self or others.** | Unable to tolerate vaccine administration with resulting risk to themselves or others (e.g., due to severe neurodevelopmental condition such as autistic spectrum disorder).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. | Letter of support from a medical specialist within the relevant scope practice | **1C. □** |
| 2 | **Pfizer Vaccine** | **2A.****Anaphylaxis** | 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.This criterion will be removed as an exemption when there is an alternative vaccine available in New Zealand.Many of these individuals will be able to be safely vaccinated in a controlled environment, and we recommend clinical immunologist/specialist assessment. | CARM reportDischarge summaryLetter of support from a medical specialist within the relevant scope practice | **2A. □** |
| **2B.** **Myocarditis / Pericarditis** | Myocarditis/pericarditis following the first dose of the vaccine. | **2B.□** |
| **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 (i.e., with active myocardial inflammation). | **2C.□** |
| **2D.** **Acute Decompensated Heart Failure** | Acute decompensated heart failure. 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. | **2D.□** |
| 3 | **Trial Vaccine** | **3A.** **Non-Placebo participant in a vaccine trial**  | Those who are confirmed as having the vaccine (i.e., 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. □** |