



ATAGI expanded guidance on acute major medical conditions that warrant a temporary medical exemption relevant for COVID-19 vaccines

The below guidance is prepared to support completion of the <u>Australian Immunisation Register immunisation medical exemption</u> (IM011) form, <u>Guidelines for immunisation medical exemption</u>.

This advice covers those for whom an exemption can be provided and does not cover clinical management of adverse events. For the management of adverse events refer to your local Specialist Immunisation Service.

Background

COVID-19 vaccines have been demonstrated to be safe and effective and as such are recommended for all Australians from 12 years of age. There are very few situations where a vaccine is contraindicated and as such, medical exemption is expected to be rarely required.

Temporary exemptions

Vaccinations may reasonably be temporarily deferred for individuals with some acute major medical conditions (e.g. undergoing major surgery or hospital admission for a serious illness). Typically, these are time-limited conditions (or the medical treatment for them is time limited) and therefore temporary exemptions are considered appropriate. These exemptions are only to be given where a suitable alternative COVID-19 vaccine is not readily available for the individual; all COVID-19 brands must be selected on the medical exemption (IM011) form.

- For an mRNA COVID-19 vaccines this includes: Inflammatory cardiac illness within the past 6
 months, e.g., myocarditis, pericarditis, endocarditis; acute rheumatic fever or acute rheumatic heart
 disease (i.e., with active myocardial inflammation); or acute decompensated heart failure
- For all COVID-19 vaccines: ATAGI recommends that vaccination can be deferred in those with PCR-confirmed SARS-CoV-2 infection until complete recovery from the acute illness (which may be up to 6 months), regardless of disease severity. Chronic symptoms following COVID-19 ("Long COVID") is not a contraindication to COVID-19 vaccines, but does warrant a clinical discussion with the patient.
- For all COVID-19 vaccines: Serious adverse event attributed to a previous dose of a COVID-19 vaccine and without another cause identified.

An adverse event is considered serious if it:

 requires in-patient hospitalisation or prolongation of existing hospitalisation OR results in persistent or significant disability/ incapacity

AND

has been reported to a state/territory adverse event surveillance system and/or the TGA

AND

- has been determined following review by, and/or on the opinion of, an experienced immunisation provider/medical specialist to be associated with a risk of recurrence of the serious adverse event if another dose is given
- If the vaccinee is a risk to themselves or others during the vaccination process (e.g. due to severe neurodevelopmental condition [e.g. autistic spectrum disorder]) they may warrant a temporary vaccine exemption. Specialist services may be available to facilitate the safe administration of vaccines in this population.

Pregnancy is not a valid reason for exemption in the absence of any of the criteria listed above

Assessment of serious adverse events following immunisation (AEFI)

- Assessment of an adverse event following immunisation (AEFI) requires detailed information
 on the event, a determination of the likelihood of a causal link with vaccination, as well as the
 severity of the condition.
- Examples of serious AEFI include: thrombosis with thrombocytopenia (TTS) following
 Vaxzevria [COVID-19 Vaccine AstraZeneca]); medically significant illness (e.g., immune
 thrombocytopenia purpura (ITP), myocarditis), potentially life-threatening events (e.g.,
 anaphylaxis); and/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.
- Attributing a serious adverse event to a previous dose of a COVID-19 vaccine may require discussion with the individual's GP, local immunisation service or relevant medical specialist.

Duration of temporary exemption

Temporary exemptions for longer than 6 months are NOT recommended in the first instance, as they should be reviewed as the individual recovers from their acute major medical illness. This time limitation will allow individuals who can safely be vaccinated to be protected against COVID-19 in a timely way.

- It may take a few weeks for any changes to an individual's vaccine status to be updated on the AIR with regards to a temporary medical exemption
- It should also be noted that an individual may not be optimally protected from COVID-19 until
 they have completed the recommended vaccine schedule and this temporary exemption may
 need to be reconsidered depending on the SARS CoV2 epidemiology at the time [link risk
 benefit discussion]
- Temporary medical exemptions can only be completed by those authorised to do so [AIR medical exemption criteria], utilising their Medicare provider number

More information

ATAGI Clinical Guidance on COVID-19 vaccine in Australia in 2021

The Australian Immunisation Handbook

How to report an AEFI: https://www.health.gov.au/health-topics/immunisation/health-professionals/reporting-and-managing-adverse-vaccination-events

Risk-benefit document.

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