



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

Updated: 12 January 2024

What's changed: Updates to reflect current information available in the [Australian Immunisation Handbook](#).

Purpose

The below guidance is prepared to support completion of the Australian Immunisation Register immunisation medical exemption (IM011) form. Guidelines for immunisation medical exemption are available at: www.servicesaustralia.gov.au/im011

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. A list is available on the National Centre for Immunisation Research and Surveillance website at: <https://ncirs.org.au/health-professionals/specialist-immunisation-services>.

Background

COVID-19 vaccines have been demonstrated to be safe and effective. There are very few situations where a vaccine is contraindicated and as such, medical exemption is expected to be rarely required.

To find out more about who should be vaccinated, refer to the [Australian Immunisation Handbook](#).

Temporary exemptions

An exemption should not be given when an alternative COVID-19 vaccine is available and when completing the medical exemption ([IM011](#)) form, all COVID-19 brands must be selected.

Valid reasons for a temporary exemption include:

- Inflammatory cardiac illness within the past 3 months, e.g., myocarditis or pericarditis; acute rheumatic fever or acute rheumatic heart disease (i.e., with active myocardial inflammation); or acute decompensated heart failure.
- Acute major medical condition (such as 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).
- SARS-CoV-2 infection, where vaccination can be deferred for 6 months after a confirmed infection. The next scheduled dose can be given after the 6-month period.
 - Ensure when reporting this temporary medical deferral to the AIR that you choose the category 'acute major medical illness' and that it is not for a duration longer than **6 months**.
 - For the purposes of recording a confirmed infection, it needs to be a positive SARS CoV-2 polymerase chain reaction (PCR) report, or rapid antigen test (RAT).
- Any serious adverse event attributed to a previous dose of a COVID-19 vaccine, without another cause identified, and with no acceptable alternative vaccine available. If the vaccinee is a risk to themselves or others during the vaccination process they may warrant a temporary vaccine exemption. This may include a range of individuals with underlying developmental or mental health disorders, noting that non-

pharmacological interventions can safely facilitate vaccination in many individuals with behavioural disturbances and that specialist services may be available to facilitate the safe administration of vaccines in this population.

Chronic symptoms following COVID-19 ('Long COVID') are not a contraindication to COVID-19 vaccines but do warrant a clinical discussion with the patient about the timing of subsequent doses.

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)

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 OR is potentially life-threatening.

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.

Assessment of an 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 AEFIs include: thrombosis with thrombocytopenia (TTS) following Vaxzevria (COVID-19 Vaccine AstraZeneca); medically significant illnesses (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 for acute major medical illness

Temporary exemptions for acute major medical illness 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-CoV-2 epidemiology at the time.

Temporary medical exemptions can only be completed by those authorised to do so (AIR medical exemption criteria), utilising their Medicare provider number.

More information

The Australian Immunisation Handbook: <https://immunisationhandbook.health.gov.au/contents/vaccine-preventable-diseases/covid-19>

How to report an AEFI: <https://www.tga.gov.au/resources/resource/forms/national-adverse-events-following-immunisation-aei-reporting-form>