



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

Updated: 18 February 2022

### What's changed:

Rapid antigen tests (that where possible have been reported to the relevant State or Territory reporting system) are now considered acceptable proof of infection for the purposes of a temporary medical exemption to delay vaccination.

The time frame for temporary deferral of vaccination following SARS-CoV-2 infection has been updated from 6 months to 4 months.

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

### Background

COVID-19 vaccines have been demonstrated to be safe and effective and as such are recommended for all Australians from 5 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

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:

- For an mRNA COVID-19 vaccine, 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
- For all COVID-19 vaccines:
  - Acute major medical condition (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).
  - **SARS-CoV-2 infection**, where vaccination *can* be temporarily deferred up until 4 months after the infection. Ensure when reporting this temporary medical deferral to the AIR it is not for a duration longer than 4 months.
    - Infection needs to be confirmed via polymerase chain reaction (PCR) or rapid antigen test (RAT). RAT results should only be accepted where the result has been reported to the relevant jurisdiction reporting system (where possible).

- Vaccination *should* be deferred for 90 days in people who have received anti-SARS-CoV-2 monoclonal antibody or convalescent plasma therapy.
- 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. For example, a person <60 years of age, contraindicated to receive Pfizer vaccine and in whom the risks do not outweigh the benefits for receipt of AstraZeneca vaccine, is eligible for a temporary exemption.
- 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 but 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.

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 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 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

ATAGI Clinical Guidance on COVID-19 vaccine in Australia in 2021 [www.health.gov.au/initiatives-and-programs/covid-19-vaccines/advice-for-providers/clinical-guidance](http://www.health.gov.au/initiatives-and-programs/covid-19-vaccines/advice-for-providers/clinical-guidance)

The Australian Immunisation Handbook: [immunisationhandbook.health.gov.au/](http://immunisationhandbook.health.gov.au/)

How to report an AEFI: [www.health.gov.au/health-topics/immunisation/health-professionals/reporting-and-managing-adverse-vaccination-events](http://www.health.gov.au/health-topics/immunisation/health-professionals/reporting-and-managing-adverse-vaccination-events)

Risk- benefit document: [www.health.gov.au/resources/publications/covid-19-vaccination-weighing-up-the-potential-benefits-against-risk-of-harm-from-covid-19-vaccine-astrazeneca](http://www.health.gov.au/resources/publications/covid-19-vaccination-weighing-up-the-potential-benefits-against-risk-of-harm-from-covid-19-vaccine-astrazeneca)