



Guidance for injuries caused by vaccine administration – COVID-19 Vaccine Claims Scheme

This document is intended as a guide for medical practitioners providing clinical opinion in support of COVID-19 vaccine administration injury claims following vaccination with a Therapeutic Goods Administration (TGA) approved or provisionally approved COVID-19 vaccine in accordance with the COVID-19 Vaccine Claims Scheme (the Scheme).

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Assessment Criteria for Claims

The approach to the Department of Health and Aged Care's (the Department) assessment and the type of evidence that would be expected in support of a claim for injury caused by vaccine administration is covered below.

The key threshold for assessment is whether the Claimant, in conjunction with the Reporting Practitioner, have submitted sufficient evidence to meet the claims criteria. Where missing or unclear information is provided, Services Australia may seek further information from the Claimant, Reporting Practitioner, or another Medical Practitioner.

Departmental Medical Officers will assess whether the evidence provided in support of the claim is sufficient to meet the threshold required to satisfy the criteria. The Department will not re-diagnose the claimant or perform causality assessment on behalf of the Reporting Practitioner.

Criterion 1: The patient has been diagnosed with a claimable injury(s) by a Treating Practitioner in the relevant field of practice. This diagnosis is accompanied by sufficient information to explain how that diagnosis was established including any diagnostic criteria and/or case definitions relied upon for this case

The Reporting Practitioner's statement should confirm that the patient has been diagnosed with a claimable injury and explain how that diagnosis was established. This may include the following information:

- Details of the diagnosing Medical Practitioner, including confirmation that this Practitioner is a specialist in the relevant field of practice;
- Description of relevant clinical findings, including symptoms, physical examination findings, and investigation results relied upon in establishing the diagnosis; and
- Reference to recognised clinical guidelines relevant to the diagnosis of a claimable injury. Alternatively, an explanation as to why the diagnosed claimable injury is the most likely diagnosis in the claimant's case where deviating from recognised guidelines.

Criterion 2: The Reporting Practitioner has provided opinion that the most likely cause of the diagnosed injury(s) is COVID-19 vaccination. Other causes have been considered and appear less likely to have contributed to the individual's diagnosis.

The Reporting Practitioner's statement should explain why COVID-19 vaccination is the most likely cause of the diagnosed claimable injury, including where opinion is based upon the diagnosis or view from a specialist doctor who has examined the patient. This statement may include the following:

- Provision of an opinion from the Reporting Practitioner that the COVID-19 vaccination is the most likely cause of the diagnosed claimable injury, and confirmation as to whether this opinion is based on the assessment of another Treating Practitioner.
- Reference to opinion provided by one or multiple Treating Practitioner/s regarding the most likely cause of the diagnosed claimable injury.
- Explanation regarding how other causes of the diagnosed claimable injury have been considered, and appear less likely than COVID-19 vaccination, including any relevant clinical findings or investigation results.

- Reference to recognised causality assessment guidelines relevant to the diagnosis of the claimable injury. Alternatively, an explanation as to why COVID-19 vaccination is the most likely cause of the claimable injury in the claimant's case, where deviating from recognised causality assessment guidelines.

Fatal outcomes from claimable injuries

For claims where a fatal outcome has occurred (Tier 3), a death certificate is required. The same assessment process is followed, and the same evidence requirements apply regarding the injury that resulted in death. Specifically, the Reporting Practitioner must address whether the patient was diagnosed with a claimable injury and provide an opinion that the injury was most likely caused by COVID-19 vaccination and that other causes have been considered and appear less likely to have contributed to the individual's diagnosis. Additionally, a medical practitioner must provide an opinion as to whether the injury suffered by the COVID-19 Vaccine Recipient has caused, or materially contributed to, their death (having regard to the cause(s) of death specified in the death certificate or medical cause of death certificate).

In the case of a fatal outcome, a forensic pathologist may be considered a relevant speciality for the injuries covered by the Scheme.

Role of the reporting practitioner:

- A Reporting Practitioner is an Australian registered Medical Practitioner that is qualified (by reference to their professional qualifications and expertise) to prepare a report on a patient submitting a claim under the Scheme (the claimant) outlining the claimant's injury as a result of the Harm suffered, including any treatment required.
- The Reporting Practitioner is responsible for completing the Services Australia 'COVID-19 Vaccine Claims Scheme Medical Report Form (MO063)'. The intention of this form is to ascertain the Reporting Practitioner's opinion of the circumstances, nature and severity of the Harm claimed under the Scheme.
- The Reporting Practitioner may be, but is not required to be, the Treating Practitioner. The Treating Practitioner is a Medical Practitioner who is, or has been involved in, the diagnosis, assessment and/or treatment of the Claimant's claimable injury.
- The Reporting Practitioner is not required to be a qualified specialist in the speciality relevant to the Harm suffered by the Claimant, however any opinion voiced by the Reporting Practitioner pertaining to the Harm claimed must be based on the relevant qualified specialist's assessment, i.e. a Claimant's regular General Practitioner may prepare a report to be submitted under the Scheme, with opinions expressed in that report based on separate assessment of the Claimant by a practitioner practicing in the relevant field of practice.
- Where the Reporting Practitioner completing an MO063 Medical Report Form is not the Treating Practitioner who has been involved in diagnosis or treatment of the Harm claimed under the Scheme, supporting documentation that may be provided includes, but is not limited to: correspondence from the Treating Practitioner relevant to the Harm suffered, a hospital discharge summary relevant to the Harm suffered, or investigation results relevant to the Harm suffered.
- The relevant field of practice for a qualified practitioner's diagnosis is listed in tabular form below for each clinical injury covered by the Scheme.
- There is no requirement to lodge an adverse event report through the TGA in order to lodge a claim. Adverse event reporting to the TGA is a separate and distinct process to the Scheme. However, adverse event reports form an important part of Australia's approach to monitoring vaccine safety.

Role of case definitions and causality assessment:

- A treating Medical Practitioner may choose to refer to any of the recommended national or international adverse event following immunisation (AEFI) case definition(s) to assist with expressing the level of diagnostic certainty associated with the claimant's case, for example surveillance case definitions provided by the Centers for Disease Control and Prevention, or AEFI case definitions provided by The Brighton Collaboration. However, the Department accepts that the use of such case definitions is intended primarily as a pharmacovigilance tool in the surveillance of adverse event following immunisation, and this may not always be in line with an individual's clinical diagnosis.
- A treating Medical Practitioner may also choose to refer to formal causality assessment frameworks such as the World Health Organization (WHO) causality assessment of adverse events following immunization.ⁱ However, the Department accepts that causality assessment frameworks are not always utilised by practitioners when forming a clinical opinion with regards to causation for an individual's diagnosis.
- Whilst case definition and causality assessment information, if available, may assist in the assessment of a claim, it is not a requirement. A claim under the Scheme may still undergo medical assessment in the absence of such information.
- The Department accepts that the claims approved via the Scheme will not necessarily reflect the TGA's case numbers of adverse events reported for that condition due to:
 - The difference between a surveillance case definition for pharmacovigilance purposes and a clinical diagnosis for an individual.
 - Non-mandatory adverse event reporting to the TGA.
 - No requirement for an adverse event report to be submitted to the TGA for a claim to be approved.

ⁱ Causality assessment of an adverse event following immunization (AEFI): user manual for the revised WHO classification second edition, 2019 update. Geneva: World Health Organization; 2019.

Final diagnosis

In order to assess claimants equitably, all claimants must have an established, or otherwise termed final diagnosis, and either have received or be receiving treatment at the time that the claim is lodged. Symptoms that are indicative of a condition/s but where a claimant does not have a diagnosed condition/s, are not eligible for assessment under the Scheme.

For the purposes of this document, a 'final' diagnosis is a recognised injury that:

- has been identified by an Australian registered Medical Practitioner through the evaluation of patient history, examination and review of relevant laboratory and imaging data;
- has entailed consideration and exclusion of relevant differential diagnoses; and
- lacks clinical uncertainty due to completion of standard medical processes required to establish the existence of the injury.

For the avoidance of doubt, a treating doctor discussing a symptom or sign experienced by the patient is not considered a final diagnosis. It is noted that an administrative analysis of clinical evidence may, at times, differ from what would otherwise be considered typical in clinical practice. It is also acknowledged that diagnostic opinions may change over time, and this evolution of clinical opinion will not, of itself, preclude the administrative criteria listed herein from being satisfied.

Claimable vaccines and administration injuries:

A list of TGA provisionally approved COVID-19 vaccines is available on the [TGA website](#). Please note that not all registered COVID-19 vaccines listed on this website are supplied, or part of the vaccine roll-out in Australia.

Injuries claimable under the Scheme for a COVID-19 vaccines can be found in the COVID-19 Vaccine Claims Scheme Policy 2021, Version 1.5, dated 19 December 2023.

The Scheme has been established to support people who suffer a moderate to significant injury during the physical act of administration of an approved COVID-19 vaccine.

Any clinical condition arising after the administration of a COVID-19 Vaccine that is not currently covered under the definition of 'COVID-19 Vaccine Related Harm', included in the COVID-19 Vaccine Claims Scheme Policy 2021 (Scheme Policy), is not considered to be COVID-19 Vaccine Administration Related Harm.

Claims against the following injuries are eligible for lodgement. These injuries are also referred to as 'claimable injuries'.

Injury claims included under the Scheme if thresholds are met
Shoulder injury related to vaccine administration (SIRVA)
Administration injures of a moderate to significant nature, giving rise to permanent impairment or the need for an extended period of medical treatment

Injury claims excluded from the Scheme
Injuries that do not require hospitalisation
Injuries that do not meet the \$1,000 loss threshold to access the Scheme
COVID-19 infection post COVID-19 vaccination
Psychological distress
Any clinical condition that is not recognised as a claimable clinical condition under the Scheme

Injuries with only mild impact would likely be made ineligible by virtue of the \$1,000 cost threshold as well as requirement for hospitalisation. It is anticipated that these thresholds will exclude most claims for:

- needlestick injury
- dosage error
- incorrect administration route
- incorrect vaccine administered.

The list of eligible injuries may be amended over the period of the Scheme.

Types of evidence that should be considered by the treating doctor when making a statement

I. Shoulder injury related to vaccine administration

Points to consider for claims including shoulder injury related to vaccine administration.

Evidence requirement	Types of evidence that should be considered for shoulder injury related to vaccine administration
<p>Diagnosis</p> <p>The patient has been diagnosed with a claimable injury(s) by a Reporting Practitioner in the relevant field of practice</p>	<p>The relevant field of practice is not restricted but requires a practicing medical doctor with registration in Australia.</p> <p>Examples of diagnostic criteria and/or case definitions that a treating doctor may rely upon include:</p> <ul style="list-style-type: none"> • Australian Immunisation Handbook: Avoiding shoulder injury related to vaccine administration The Australian Immunisation Handbook (health.gov.au) • RACGP: RACGP - Don't aim too high: Avoiding shoulder injury related to vaccine administration • Melbourne Vaccine Education Centre: Shoulder injury related to vaccine administration - The Melbourne Vaccine Education Centre (MVEC) (mcri.edu.au) • UpToDate Standard immunizations for children and adolescents: Overview - UpToDate <p>Clinical information that should be outlined to support the diagnosis OR appropriate justification provided for absence of information:</p> <ul style="list-style-type: none"> • Acute onset of pain in a shoulder following administration of vaccination. • Reduced range of motion in the shoulder. • Vaccination location appropriate with injury. • Imaging findings consistent with diagnosis.
<p>Link to vaccination</p>	<p>Pain onset within 48 hours of vaccination.</p> <p>Pain and reduced range of motion limited to the shoulder where the injection occurred.</p> <p>No pre-existing condition that would cause the symptoms.</p> <p>Consider exclusion of other causes as the most likely cause for the injury.</p>

II. Administration injures of a moderate to significant nature, giving rise to permanent impairment or the need for an extended period of medical treatment

Points to consider for claims including administration injures of a moderate to significant nature, giving rise to permanent impairment or the need for an extended period of medical treatment.

Evidence requirement	Types of evidence that should be considered for shoulder injury related to vaccine administration
<p>Diagnosis</p> <p>The patient has been diagnosed with a claimable injury(s) by a reporting practitioner in the relevant field of practice</p>	<p>The relevant field of practice is not restricted but requires a practicing medical doctor with registration in Australia.</p> <p>Clinical information that should be outlined to support the diagnosis OR appropriate justification provided for absence of information:</p> <ul style="list-style-type: none"> • Vaccine administration information. • Nature of injury. • Nature of ongoing impairment. • Demonstrated need for ongoing medical treatment.
<p>Link to vaccination</p>	<p>Demonstrated link between the vaccination and injury.</p> <p>No pre-existing condition that can otherwise explain the injury.</p> <p>Exclusion of other causes as the most likely cause for the injury.</p>

Version history

Version	Description of change	Author	Effective date
V1.0	Original Publication	MBD/Department of Health	13/12/2021
V1.1	Clarification of claimable injuries. Clarification of assessment process and evidence requirements in section “Fatal outcomes of claimable injuries.” Administrative change – numbering of resource documents.	MBD/Department of Health	13/05/2022
V1.2	Clarification of assessment process and requirements in sections “Role of the reporting practitioner”, “Claimable vaccines and administration injuries” and “Assessment criteria for claims.” Administrative change – insertion of table of content. Added definition of ‘final diagnosis’ and clarified wording of Criterion 1 and Criterion 2. Policy information updated to reflect policy updates.	MB&DHD/Department of Health and Aged Care	3/04/2023
V1.3	Minor amendments to definition of Reporting Practitioner. Addition of ‘Role of case definitions and causality assessment’	MB&DHD/Department of Health and Aged Care	01/08/2023
V1.4	Minor amendment to refer to update version of the Policy	MBD/Department of Health	19/11/23

