Australian Government
Department of Health and Aged Care

# Guidance for conditions – COVID-19 Vaccine Claims Scheme

This document is intended as a guide for Medical Practitioners providing clinical opinion in support of COVID-19 vaccine Harm 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).

1. Tier 1:
    a. Covers claims where the recompense claimed for the Harm is less than the amount of $20,000 AUD.
    b. Covers claims where the recompense claimed for the Harm is less than the amount of $16,000 AUD and Pain and Suffering is being claimed.
2. Tier 2:
    a. Covers claims where the recompense claimed for the Harm is greater than $20,000 AUD.
3. Tier 3:
    a. Covers claims in relation to Harm that caused, or materially contributed to, the death of a COVID-19 Vaccine Recipient.

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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 Tier 2 or Tier 3 claim is covered below for each claimable condition.

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

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 medical condition(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 that the patient has been diagnosed with a claimable condition 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 condition. Alternatively, an explanation as to why the diagnosed claimable condition 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 condition(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 condition, 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 condition, 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 condition.

- Explanation regarding how other causes of the diagnosed claimable condition 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 condition. Alternatively, an explanation as to why COVID-19 vaccination is the most likely cause of the claimable condition in the claimant's case, where deviating from recognised causality assessment guidelines.

**Fatal outcomes from claimable conditions**

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 condition that resulted in death. Specifically, the Reporting Practitioner must address whether the patient was diagnosed with a claimable medical condition and provide an opinion that the condition 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 condition 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 conditions 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 condition 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 condition.
- 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 claimable condition 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 of Health and Aged Care 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.[1] However, the Department of Health and Aged care 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 of Health and Aged Care 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.

## 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.

[1] 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.

For the purposes of this document, an established, or otherwise termed 'final', diagnosis is a recognised medical condition 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;
- lacks clinical uncertainty due to completion of standard medical processes required to establish the existence of the medical condition.

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 clinical conditions:

A list of TGA 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.

Conditions claimable under the Scheme for a COVID-19 vaccine can be found in the COVID-19 Vaccine Claims Scheme Policy 2021, Version 1.5, dated 13 December 2023.

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

| Clinical Condition | Applicable Vaccine(s) |
|---|---|
| Anaphylactic reaction | Vaxzevria (AstraZeneca)<br>Comirnaty (Pfizer)<br>Spikevax (Moderna)<br>Nuvaxovid (Novavax) |
| Thrombosis with Thrombocytopenia Syndrome | Vaxzevria (AstraZeneca) |
| Myocarditis | Comirnaty (Pfizer)<br>Spikevax (Moderna)<br>Nuvaxovid (Novavax) |
| Pericarditis | Comirnaty (Pfizer)<br>Spikevax (Moderna)<br>Nuvaxovid (Novavax) |
| Capillary Leak Syndrome | Vaxzevria (AstraZeneca) |
| Guillain Barré Syndrome (GBS) | Vaxzevria (AstraZeneca) |
| Thrombocytopenia including Immune Thrombocytopenia, where this represents a final diagnosis | Vaxzevria (AstraZeneca) |

| Clinical Condition | Applicable Vaccine(s) |
|---|---|
| CVST without thrombocytopenia | Vaxzevria (AstraZeneca) |
| Erythema Multiforme Major | Spikevax (Moderna)<br>Comirnaty (Pfizer) |
| Transverse Myelitis | Vaxzevria (AstraZeneca) |

Further clinical conditions may be added to this Table by amendment if new clinical conditions are added to the Australian Product Information document for the specific vaccine product and when verified by the Therapeutic Goods Administration as a serious clinical condition to be covered under the Scheme.

The list of eligible conditions may be amended over the two-year period of the Scheme.

## Types of evidence that should be considered by the Reporting Practitioner when making a statement

### I. Anaphylactic reaction

Points to consider for claims including anaphylaxis.

| Evidence requirement | Types of evidence that should be considered for anaphylaxis |
|---|---|
| **Diagnosis**<br>The patient has been diagnosed with a claimable medical condition(s) by a Reporting Practitioner in the relevant field of practice | The relevant field of practice is not restricted but requires a practicing medical doctor with registration in Australia.<br><br>Clinical features of anaphylactic reaction are variable, but multiple of the following symptoms and signs may be elicited,[2] and should be outlined to support the diagnosis OR appropriate justification provided for absence of information:<br><br>• Acute onset<br>• Difficult or noisy breathing<br>• Typical skin features, including urticaria, flushing, and/or angioedema<br>• Hypotension<br>• Swelling of tongue<br>• Swelling or tightness in throat<br>• Difficulty talking or hoarse voice<br>• Wheeze or persistent cough (unlike the cough in asthma, the onset of coughing during anaphylaxis is usually sudden)<br>• Persistent dizziness or collapse<br>• Pale and floppy (young children)<br>• Abdominal pain, vomiting<br>• Evidence of administration of adrenaline |

[2] Australasian society of Clinical Immunology and Allergy. Guidelines: Acute Management of Anaphylaxis. 2023.

| Evidence requirement | Types of evidence that should be considered for anaphylaxis |
|---|---|
| **Link to vaccination**<br><br>Opinion that the most likely cause of the diagnosed condition(s) is COVID-19 vaccination Vaxzevria (AstraZeneca) (COVID-19 vaccine AstraZeneca); OR Comirnaty (Pfizer), OR Spikevax (Moderna) OR Nuvaxovid (Novavax) | Reactions typically occur within minutes to hours of exposure.[3] For anaphylaxis after receipt of a COVID-19 vaccine, a range of 1 minute to 19 hours has been reported with a median time to onset of 10 minutes.[4]<br><br>Consider exclusion of causes other than the COVID-19 vaccination for the claimant's claimable condition of anaphylaxis. Common diagnostic dilemmas have been summarised by the World Allergy Organisation (see resources for anaphylaxis). |

### Resources for Anaphylaxis

A number of national and international bodies have provided guidance for healthcare practitioners on anaphylaxis. Diagnosis of the condition and assessment of the link to vaccination should occur in line with recognised guidelines, for example:

1) The Australasian Society of Clinical Immunology and Allergy provides guidance on the acute management of anaphylaxis https://www.allergy.org.au/hp/papers/acute-management-of-anaphylaxis-guidelines.
2) The Royal Children's Hospital Melbourne has published a clinical guideline on anaphylaxis https://www.rch.org.au/clinicalguide/guideline_index/Anaphylaxis/.
3) The World Allergy Organisation has published guidance on anaphylaxis www.sciencedirect.com/science/article/pii/S1939455120303756.

### Product Information

- Product Information Comirnaty (Pfizer)
- Product Information Spikevax (Moderna)
- Product Information Vaxzevria (AstraZeneca)
- Product Information Nuvaxovid (Novavax)

## II. Thrombosis with Thrombocytopenia Syndrome (TTS)

Points to consider for claims including TTS.

[3] McNeil MM, DeStefano F. Vaccine-associated hypersensitivity. *J Allergy Clin Immunol.* 2018;141(2):463-472.

[4] Shimabukuro TT, Cole M, Su JR. Reports of Anaphylaxis After Receipt of mRNA COVID-19 Vaccines in the US-December 14, 2020-Janaury 18, 2021. *JAMA.* 2021;325(11):1101-1102.

| Evidence requirement | Types of evidence that should be considered for TTS |
|---|---|
| **Diagnosis**<br>The patient has been diagnosed with a claimable medical condition(s) by a Reporting Practitioner in the relevant field of practice | The relevant fields of practice are Haematology, and, where clinically appropriate, Paediatrics (including General or subspecialty Paediatrics).<br>Clinical information that should be outlined to support the diagnosis OR appropriate justification provided for absence of information:<br>• Thrombocytopenia (platelet count <150 x$10^9$/L; or a significant fall in platelet count)<br>• D-dimer markedly above the upper limit of normal<br>• Anti-platelet factor 4 antibodies (in the absence of prior heparin)<br>  ○ e.g ELISA or functional testing<br>• Presence of thrombosis such as:<br>  ○ cerebral venous sinus thrombosis (CVST)<br>  ○ thrombosis in the splanchnic (abdominal) circulation<br>  ○ pulmonary emboli (PE)<br>  ○ deep vein thrombosis (DVT)<br>  ○ arterial thrombosis |
| **Link to vaccination**<br>Opinion that the most likely cause of the diagnosed condition(s) is COVID-19 vaccination Vaxzevria (AstraZeneca) (Covid-19 vaccine AstraZeneca) | Typical time to onset is 4-42 days.[5]<br>The WHO recommends that cases occurring up to 100 days should also be carefully monitored.[6] |

## Resources for TTS

A number of national and international bodies have provided guidance for healthcare practitioners on TTS.

1) Primary care approach to thrombosis with thrombocytopenia syndrome after COVID-19 AstraZeneca vaccine

[5] Thrombosis and Haemostasis society of Australia and New Zealand. Suspected Vaccine induced immune thrombotic thrombocytopenia (VITT): THANZ Advisory Statement for Haematologists. Updated 18 December 2021.

[6] World Health Organization. Guidance for clinical case management of thrombosis with thrombocytopenia syndrome (TTS) following vaccination to prevent coronavirus disease (COVID-19). Updated 20 April 2023. https://www.who.int/publications/i/item/9789240061989.

Vaxzevria (AstraZeneca) vaccine and thrombosis with thrombocytopenia syndrome (TTS) - Australian Government Department of Health and Aged and ATAGI clinical guidance

2) The Thrombosis and Haemostasis Society Australia New Zealand (THANZ) has published advice for haematologists and multidisciplinary guidance for doctors at https://www.thanz.org.au/resources/covid-19.
    - Advisory Statement for Haematologists on Suspected Vaccine Induced Prothrombotic Immune Thrombocytopenia (VIPIT)/Vaccine induced immune thrombocytopenia
    - Multidisciplinary VITT Guideline for Doctors
3) Guidance on TTS published by the World Health Organisation. https://www.who.int/publications/i/item/9789240061989.

**Product Information**

- Product Information Vaxzevria (AstraZeneca)

# III. Myocarditis

Points to consider for claims including myocarditis.

| Evidence requirement | Types of evidence that should be considered for Myocarditis |
|---|---|
| **Diagnosis**<br>The patient has been diagnosed with a claimable medical condition(s) by a Reporting Practitioner in the relevant field of practice | The relevant fields of practice are Cardiology, and, where clinically appropriate, Paediatrics (including General or subspecialty Paediatrics).<br>Clinical information that should be outlined to support the diagnosis OR appropriate justification provided for absence of information:<br>• Findings consistent with myocarditis are varied and may include:<br>  ○ Symptoms may include chest pain or dyspnoea,<br>  ○ Elevated troponin,<br>  ○ ECG showing ST or T-wave abnormalities, premature atrial or ventricular complexes,<br>  ○ Abnormal echocardiogram or cardiac MRI. |
| **Link to vaccination**<br>Opinion that the most likely cause of the diagnosed condition(s) is COVID-19 vaccination Comirnaty (Pfizer), OR Spikevax (Moderna), OR Nuvaxovid (Novavax) | Symptoms of vaccine-induced myocarditis typically begin within a few days of vaccination.[7,8] The median time of symptom onset has recently been published in the Journal of the American Medical Association[9] as:<br>• 3.5 days with a range of 3-10.8 days<br>As myocarditis has a range of aetiologies, it is important to consider and exclude causes unrelated to vaccination, which may include infectious or autoimmune causes. Other causes of the claimant's symptoms should also be considered and excluded. |

### Resources for Myocarditis

A number of national and international bodies have provided guidance for healthcare practitioners on myocarditis. Diagnosis of the condition and assessment of the link to vaccination should occur in line with recognised guidelines, for example:

[7] Australian Government Department of Health and Aged Care. Guidance on Myocarditis and Pericarditis after COVID-19 vaccines. Updated 9 November 2022. https://www.health.gov.au/sites/default/files/documents/2022/11/covid-19-vaccination-guidance-on-myocarditis-and-pericarditis-after-covid-19-vaccines.pdf.

[8] Heidecker B, Dagan N, Balicer R et al. Myocarditis following COVID-19 vaccine: incidence, presentation, diagnosis, pathophysiology, therapy and outcomes put into perspective. A clinical consensus document supported by the Heart Failure Association of the European Society of Cardiology (ESC) and the ESC Working Group on Myocardial and Pericardial Diseases. *Eur J Heart Fail.* 2022.

[9] Oster ME, Shay DK, Su JR et al. Myocarditis Cases Reported After mRNA-Based COVID-19 Vaccination in the US From December 2020 to August 2021. *JAMA.* 2022;327(4):331-340.

1) The Department of Health and Aged Care has published guidance jointly with the Australian Technical Advisory Group on Immunisation (ATAGI) and the Cardiac Society of Australia and New Zealand (CSANZ).
   COVID-19 vaccination – Guidance on myocarditis and pericarditis after COVID-19 vaccines | Australian Government Department of Health and Aged Care
2) The Brighton Collaboration has published a case definition for myocarditis and pericarditis https://brightoncollaboration.us/myocarditis-case-definition-update/

**Product Information**

- Product Information Comirnaty (Pfizer)
- Product Information Spikevax (Moderna)

## IV. Pericarditis

Points to consider for claims including myocarditis and pericarditis.

| Evidence requirement | Types of evidence that should be considered for Pericarditis |
|---|---|
| **Diagnosis**<br>The patient has been diagnosed with a claimable medical condition(s) by a Reporting Practitioner in the relevant field of practice | The relevant fields of practice are Cardiology, and, where clinically appropriate, Paediatrics (including General or subspecialty Paediatrics).<br>Clinical information that should be outlined to support the diagnosis OR appropriate justification provided for absence of information:<br>• Patient's clinical presentation and assessment, including more than one of the following:<br>I. Chest pain<br>II. Pericardial rub<br>III. Electrocardiogram changes<br>IV. Pericardial effusion<br>• Supporting findings are:<br>○ Increase in inflammatory markers;<br>○ Evidence of inflammation on multimodal imaging |

| Evidence requirement | Types of evidence that should be considered for Pericarditis |
|---|---|
| **Link to vaccination**<br><br>Opinion that the most likely cause of the diagnosed condition(s) is COVID-19 vaccination Comirnaty (Pfizer), OR Spikevax (Moderna) OR Nuvaxovid (Novavax) | The Journal of the American Medical Association[10] published the median time to symptom onset:<br><br>• 20 days with a range of 6-41 days.<br><br>As pericarditis has a range of aetiologies, it is important to consider and exclude causes unrelated to vaccination, which may include infectious or autoimmune causes. Other causes of the claimant's symptoms should also be considered and excluded. |

### Resources for Pericarditis

A number of national and international bodies have provided guidance for healthcare practitioners on pericarditis. Diagnosis of the condition and assessment of the link to vaccination should occur in line with recognised guidelines, for example:

1) The Department of Health and Aged Care has published guidance jointly with the Australian Technical Advisory Group on Immunisation (ATAGI) and the Cardiac Society of Australia and New Zealand (CSANZ). COVID-19 vaccination – Guidance on myocarditis and pericarditis after COVID-19 vaccines | Australian Government Department of Health and Aged Care
2) The Brighton Collaboration has published a case definition for myocarditis and pericarditis https://brightoncollaboration.us/myocarditis-case-definition-update/

### Product Information

- Product Information Comirnaty (Pfizer)
- Product Information Spikevax (Moderna)

## V. Capillary Leak Syndrome

Points to consider for claims including Capillary Leak Syndrome (CLS)

[10] Diaz GA, Parsons GT, Gering SK et al. Myocarditis and Pericarditis After Vaccination for COVID-19. *JAMA.* 2021;326(12):1210-1212.

| Evidence requirement | Types of evidence that should be considered for CLS |
|---|---|
| **Diagnosis**<br>The patient has been diagnosed with a claimable medical condition(s) by a treating doctor in the relevant field of practice | The relevant fields of practice are Intensive Care Medicine, Haematology, and, where clinically appropriate, Paediatrics (including General or subspecialty Paediatrics).<br>Capillary Leak Syndrome (CLS) is a very rare condition with indefinite pathogenesis that is usually diagnosed after exclusion of other diseases that cause systemic capillary leakage.<br>Clinical information that should be outlined to support the diagnosis OR appropriate justification provided for absence of information:<br>• Acute episode of oedema, hypotension, haemoconcentration and hypoalbuminaemia<br>• Steps taken to exclude other causes of capillary leak<br>• Intensive supportive therapy required |
| **Link to vaccination** - Opinion that the most likely cause of the diagnosed condition(s) is COVID-19 vaccination Vaxzevria (AstraZeneca) | Typical time to onset is within days following vaccination.[11]<br>Very rare events of CLS have been reported following AstraZeneca vaccine in the UK and Europe.[12] Vaxzevria (AstraZeneca) is contraindicated in people with a past history of CLS.<br>• Likely causes of CLS other than vaccination with Vaxzevria (AstraZeneca) include:<br>  ○ Sepsis and;<br>  ○ anaphylaxis |

### Resources for Capillary Leak Syndrome:

A number of national and international bodies have provided reports or guidance for healthcare practitioners on CLS. Diagnosis of the condition and assessment of the link to vaccination should occur in line with recognised guidelines, for example:

1) The Australian Technical Advisory Group on Immunisation (ATAGI) published clinical guidance on COVID-19 vaccines
   ATAGI clinical guidance for COVID-19 vaccine providers | Australian Government Department of Health and Aged Care
2) The EMA published a dear healthcare professional letter that advises of CLS cases following vaccination with Vaxzevria (AstraZeneca).
   www.ema.europa.eu/en/documents/dhpc/direct-healthcare-professional-

[11] European Medicines Agency. Vaxzevria: EMA advises against use in people with history of capillary leak syndrome. 2021. https://www.ema.europa.eu/en/news/vaxzevria-ema-advises-against-use-people-history-capillary-leak-syndrome.

[12] Ruggiero R, Balzano N, Di Napoli R et al. Capillary leak syndrome following COVID-19 vaccination: Data from the European pharmacovigilance database Eudravigilance. *Front Immunol.* 2022;13.

communication-dhpc-vaxzevria-previously-covid-19-vaccine-astrazeneca_en-1.pdf

3) The Canadian Medical Association Journal has published a case study on systemic capillary leak following the COVID-19 Vaccine AstraZeneca (ChAdOx1) https://www.cmaj.ca/content/193/34/E1341

**Product Information**

- Product Information Vaxzevria (AstraZeneca)

## VI. Guillain Barré Syndrome

Points to consider for claims including Guillain Barré Syndrome (GBS)

| Evidence requirement | Types of evidence that should be considered for GBS |
|---|---|
| **Diagnosis**<br>The patient has been diagnosed with a claimable medical condition(s) by a treating doctor in the relevant field of practice | The relevant fields of practice are Neurology, Immunology, and, where clinically appropriate, Paediatrics (including General or subspecialty Paediatrics).<br>GBS is a rare immune disorder in which the body's immune system attacks nerve cells. The causes are not fully understood, but it often follows a viral infection. It tends to affect both sides of the body. In many cases symptoms resolve within months but can sometimes take up to 2 years.<br>Clinical information that should be outlined to support the diagnosis OR appropriate justification provided for absence of information:<br>• Monophasic illness pattern AND interval between onset and nadir of weakness is 12 hours to 28 days AND subsequent clinical plateau<br>• Muscle strength – bilateral and flaccid paralysis of limbs<br>• Deep tendon reflexes – decreased or absent in weak limbs<br>• No identified alternative diagnosis for weakness<br>• If CSF obtained: White Blood Cell count (<50/µL), elevated protein<br>The following additional investigations may lend support to the diagnosis:<br>• Evidence of autonomic dysfunction<br>• Features of motor or sensory neuropathy on nerve conduction studies or electromyography. |

| | |
|---|---|
| **Link to vaccination** Opinion that the most likely cause of the diagnosed condition(s) is COVID-19 vaccination Vaxzevria (AstraZeneca) | Typical time to onset is 2-42 days following vaccination.[13]<br>As Guillain-Barré Syndrome has a range of aetiologies, it is important to consider and exclude causes unrelated to vaccination, which may include infectious. Other causes of the claimant's symptoms should also be considered and excluded.<br>Very rare events of Guillain-Barré Syndrome (GBS), have been reported following vaccination with Vaxzevria (AstraZeneca).[14] |

## Resources for GBS

Several national and international bodies have provided guidance for healthcare practitioners on GBS. Diagnosis of the condition and assessment of the link to vaccination should occur in line with recognised guidelines, for example:

1) The Australian Technical Advisory Group on Immunisation (ATAGI) published clinical guidance on COVID-19 vaccines ATAGI clinical guidance for COVID-19 vaccine providers | Australian Government Department of Health and Aged Care
2) The Brighton Collaboration published a case definition for Guillain Barré Syndrome Guillain Barré and Miller Fisher Syndromes: Case Definition Companion Guide - Brighton Collaboration

## Product Information

- Product Information Vaxzevria (AstraZeneca)

[13] Abara WE, Gee J, Marquez P et al, Reports of Guillain-Barré Syndrome After COVID-19 Vaccination in the United States. *JAMA.* 2023;6(2).

[14] Osowicki J, Morgan HJ, Harris A et al. Guillain-Barré syndrome temporally associated with COVID-19 vaccines in Victoria, Australia. *Vaccine.* 2022;40(52):7579-7585.

## VII. Thrombocytopenia including Immune Thrombocytopenia

Points to consider for claims including immune thrombocytopenia

| Evidence requirement | Types of evidence that should be considered for thrombocytopenia |
|---|---|
| **Diagnosis**<br>The patient has been diagnosed with a claimable medical condition(s) by a treating doctor in the relevant field of practice | The relevant fields of practice are Haematology, Immunology, and, where clinically appropriate, Paediatrics (including General or subspecialty Paediatrics).<br>Thrombocytopenia must be established as a final diagnosis to be eligible for a claim.<br>Immune thrombocytopenia is a diagnosis of exclusion with no unique identifying features when it occurs after vaccination.[15] Response to corticosteroids, intravenous immunoglobulin (IVIg), and other standard treatments used in ITP, such as TPO (thrombopoietin) agonists, supports the diagnosis of ITP post COVID-19 vaccination.<br>Immune thrombocytopenia has also emerged as a complication of Covid-19 infection.[16]<br>The autoimmune bleeding disorder is characterised by a decrease in the number of platelets, which can cause minor bruising in some patients and excessive bleeding and long-term illness in others.<br>Clinical information that should be outlined to support the diagnosis OR appropriate justification provided for absence of information:[17, 18]<br>• Thrombocytopenia (platelet count <150 x109/L),<br>• Clinical signs or symptoms of bleeding,<br>• Peripheral blood film examination consistent with immune thrombocytopenia,<br>• Consideration/exclusion of alternative causes of thrombocytopenia, including but not limited to: myelodysplastic syndrome, haematological malignancy, hypersplenism, liver disease,<br>• Bone marrow biopsy is not required to confirm a diagnosis of Thrombocytopenia, including Immune Thrombocytopenia, but if performed, pathologic features support the diagnosis of Thrombocytopenia, including Immune Thrombocytopenia. |

[15] Ruzicka M, Wurm S, Lindner L et al. Treatment, outcome and re-vaccination of patients with SARS-CoV-2 vaccine-associated immune thrombocytopenia. *Infection.* 2022;51:231-238.

[16] Choi PYI, Hsu D, Tran HA et al. Immune thrombocytopenia following vaccination during the COVID-19 pandemic. *Haematologica.* 2022;107(5):1193-1196.

[17] Choi PYI, Merriman E, Bennett A et al. Consensus guidelines for the management of adult immune thrombocytopenia in Australia and New Zealand. *MJA.* 2022;216(1).

[18] Provan D, Arnold DM, Bussel JB et al. Updated international consensus report on the investigation and management of primary immune thrombocytopenia. *Blood Advances.* 2019;3(22).

| Evidence requirement | Types of evidence that should be considered for thrombocytopenia |
|---|---|
| **Link to vaccination** Opinion that the most likely cause of the diagnosed condition(s) is COVID-19 vaccination Vaxzevria (AstraZeneca) | Typical time to onset within 28 days following vaccination.[19]<br>As Thrombocytopenia, including immune thrombocytopenia, has a range of aetiologies, it is important to consider and exclude causes unrelated to vaccination, which may include infectious, autoimmune causes, medications or liver disease. Other causes of the claimant's symptoms should also be considered and excluded.<br>A link to thrombocytopenia including immune thrombocytopenia has been reported following vaccination with Vaxzevria (AstraZeneca).[16] |

### Resources for thrombocytopenia

A number of national and international bodies have provided reports and guidance for healthcare practitioners on thrombocytopenia:

1) The Australian Technical Advisory Group on Immunisation (ATAGI) published clinical guidance on COVID-19 vaccines
   ATAGI clinical guidance for COVID-19 vaccine providers | Australian Government Department of Health and Aged Care
2) The Brighton Collaboration published a case definition for Thrombocytopenia https://brightoncollaboration.us/thrombocytopenia-case-definition-companion-guide/
3) Nature Medicine reports a link between Vaxzevria (AstraZeneca) and immune thrombocytopenia https://www.nature.com/articles/s41591-021-01419-1

### Product Information

- Product Information Vaxzevria (AstraZeneca)

## VIII. Cerebral venous sinus thrombosis (CVST) without thrombocytopenia

Points to consider for claims including CVST without thrombocytopenia

[19] Gordon SF, Clothier HJ, Morgan H et al. Immune thrombocytopenia following immunisation with Vaxzevria ChadOx1-S (AstraZeneca) vaccine, Victoria, Australia. *Vaccine.* 2021;39.

| Evidence requirement | Types of evidence that should be considered for CVST without thrombocytopenia |
|---|---|
| Diagnosis<br>The patient has been diagnosed with a claimable medical condition(s) by a treating doctor in the relevant field of practice | The relevant fields of practice are Haematology, Neurology, and, where clinically appropriate, Paediatrics (including General or subspecialty Paediatrics).<br>CVST is a rare condition of the neurovascular system which can be defined as thrombotic occlusion of the cerebral venous sinuses. CVST without thrombocytopenia refers to the presence of CVST without a concurrent low platelet count. CVST without thrombocytopenia is differentiated from CVST with thrombocytopenia, which may occur as a result of Thrombosis with Thrombocytopenia Syndrome (TTS). Symptoms of CVST without thrombocytopenia can include headache, visual changes, vomiting and seizures. CVST without thrombocytopenia is a serious condition, and can be fatal.[20]<br>Clinical information that should be outlined to support the diagnosis OR appropriate justification provided for absence of information:<br>• Evidence of cerebral venous sinus thrombosis on imaging such as Computer Tomography scanning or Magnetic Resonance Imaging.<br>• No documented evidence of thrombocytopenia (platelet count <150 x$10^9$/L;) nor a significant fall in platelet count.<br>• Onset 4-30 days post-vaccination.[21]<br>• Absence of other clear cause (for instance otitis media or intracranial malignancy). |

[20] Pavord S, Scully M, Hunt BJ et al. Clinical Features of Vaccine-Induced Immune Thrombocytopenia and Thrombosis. *N Engl J Med.* 2021;385(18):1680-1689.

[21] Kryzwicka K, van de Munckhof A, van Kammen MS et al. Age-Stratified Risk of Cerebral Venous Sinus Thrombosis After SARS-CoV-2 Vaccination. *Neurology.* 2022;98(7):e759-e768.

| | |
|---|---|
| Opinion that the most likely cause of the diagnosed condition(s) is COVID-19 vaccination Vaxzevria (AstraZeneca) | Typical time to onset is between 4-16 days after vaccination, and less frequently 16-30 days.<br><br>A link to CVST without thrombocytopenia following vaccination with Vaxzevria (AstraZeneca) has been established.<br><br>Causes other than the vaccination received by the claimant may include, but are not limited to: vasculitis and other autoimmune conditions, inherited or acquired thrombophilia, known risk factors for venous thromboembolism and pathology involving the central nervous system and head and neck including infection, inflammation, malignancy and trauma. These other potential causes should be addressed by the Reporting or Treating Practitioner when seeking to establish causation. |

**Resources for CVST without thrombocytopenia**

1. The Australian Technical Advisory Group on Immunisation (ATAGI) published clinical guidance on COVID-19 vaccines https://www.health.gov.au/sites/default/files/documents/2021/10/covid-19-vaccination-atagi-clinical-guidance-on-covid-19-vaccine-in-australia-in-2021.pdf

**Product Information**

- Product Information Vaxzevria (AstraZeneca)

## IX. Erythema Multiforme Major

Points to consider for claims including Erythema Multiforme Major:

| Evidence requirement | Types of evidence that should be considered for Erythema Multiforme Major |
|---|---|
| **Diagnosis**<br><br>The patient has been diagnosed with a claimable medical condition(s) by a treating doctor in the relevant field of practice | The relevant fields of practice are Dermatology, Immunology, and, where clinically appropriate, Paediatrics (including General or subspecialty Paediatrics).<br><br>Erythema multiforme is an acute disorder of the mucocutaneous system |

| Evidence requirement | Types of evidence that should be considered for Erythema Multiforme Major |
|---|---|
| | characterised by distinct, target-like lesions present on the skin. It is mediated by the immune system. It can be caused by medications and infections but has also been reported after vaccinations.[22] Erythema multiforme can be separated into erythema multiforme minor (80% of cases) and erythema multiforme major (20% of cases).<br><br>Erythema multiforme major is a more severe disease with increased involvement of the mucosa compared to erythema multiforme minor. Erythema multiforme major is the claimable condition referred to in this document.<br><br>Clinical information that should be outlined to support the diagnosis OR appropriate justification provided for absence of information:<br><br>• Characteristic lesions of either or both mucosa and skin present.<br>• It is noted that sometimes a diagnosis of Erythema Multiforme Major may be made in the absence of cutaneous involvement – this should be explicitly stated by the Treating or Reporting Practitioner.<br>• Explanation that the claimant's presentation constitutes Erythema Multiforme Major and not Erythema Multiforme Minor; and<br>• Consideration of alternative diagnoses.<br><br>Supportive findings may include skin biopsy, however this is not required. |
| **Link to vaccination**<br><br>Opinion that the most likely cause of the diagnosed condition(s) is COVID-19 vaccination Spikevax (Moderna) OR Comirnaty (Pfizer). | Typical time to onset is 1-2 days after vaccination.[23] Occasionally, onset may be up to a week or more after vaccination.<br><br>A link to Erythema Multiforme following vaccination with Comirnaty (Pfizer) and Spikevax (Moderna) vaccinations has been established. |

### Resources for Erythema Multiforme major

1. The Australian Technical Advisory Group on Immunisation (ATAGI) published clinical guidance on COVID-19 vaccines https://www.health.gov.au/sites/default/files/documents/2021/10/covid-19-vaccination-atagi-clinical-guidance-on-covid-19-vaccine-in-australia-in-2021.pdf
2. Erythema multiforme reactions after Pfizer/BioNTech (BNT162b2) and Moderna (mRNA-1273) COVID-19 vaccination: A case series - PMC (nih.gov)

### Product Information

- Product Information Comirnaty (Pfizer)
- Product Information Spikevax (Moderna)

[22] Karatas E, Nazim A, Patel P et al. Erythema multiforme reactions after Pfizer/BioNTech (BNT162b2) and Moderna (mRNA-1273) COVID-19 vaccination: A case series. *JAAD Case Rep.* 2023;32:55-58.

[23] Elyoussfi S, Coulson I. Skin reactions to COVID-19 vaccines. DermNet. Updated May 2023. COVID-19: Skin Reactions to COVID-19 Vaccines - DermNet (dermnetnz.org).

## X. Transverse Myelitis

Points to consider for claims including Transverse Myelitis

| Evidence requirement | Types of evidence that should be considered for Transverse Myelitis |
|---|---|
| Diagnosis:<br>The patient has been diagnosed with a claimable medical condition(s) by a treating doctor in the relevant field of practice | The relevant fields of practice are Neurology, Immunology, and, where clinically appropriate, Paediatrics (including General or subspecialty Paediatrics).<br>Transverse Myelitis is a rare neurological disorder which is caused by inflammation of one or more level/s of the spinal cord. There are a number of causes of Transverse Myelitis including infections and underlying demyelinating conditions – occasionally, a cause is not found (idiopathic).[24]<br>Clinical information that should be outlined to support the diagnosis[25] OR appropriate justification provided for absence of information:<br>• At least one feature of myelopathy, for example, neurological signs or symptoms,<br>• Evidence of spinal cord inflammation, for example CSF pleocytosis, or characteristic imaging findings. |
| Link to vaccination: Opinion that the most likely cause of the diagnosed condition(s) is COVID-19 vaccination Vaxzevria (AstraZeneca) | A link to Transverse Myelitis following vaccination with Vaxzevria (AstraZeneca) has been rarely reported.[26]<br>As Transverse Myelitis has a range of aetiologies, it is important to consider and exclude causes unrelated to vaccination, which may include infectious or autoimmune causes. Other causes of the claimant's symptoms should also be considered and excluded. |

[24] Beh SC, Greenberg BM, Frohman T, Frohman EM. Transverse myelitis. *Neurol Clin.* 2013;31(1):79-138.

[25] Law, B. Safety Platform for Emergency vACcines SO2-D2.5.2.1- AESI Case Definition Companion Guide for 1st Tier AESI Acute Myelitis. Brighton Collaboration. 2021.

[26] Naz Naeem F, Saba Hasan AF, Doulat Ram M, Waseem S, Hassan Ahmed S, Gul Shaikh T. The association between SARS-CoV-2 vaccines and transverse myelitis: A review. *Ann Med Surg (Lond).* 2022;79.

### Resources for Transverse Myelitis

Several national and international bodies have provided reports and guidance for healthcare practitioners on Transverse Myelitis.

1. The Australian Technical Advisory Group on Immunisation (ATAGI) published clinical guidance on COVID-19 vaccines https://www.health.gov.au/sites/default/files/documents/2021/10/covid-19-vaccination-atagi-clinical-guidance-on-covid-19-vaccine-in-australia-in-2021.pdf
2. What is Transverse Myelitis (TM)? | Johns Hopkins Transverse Myelitis Center (hopkinsmedicine.org)
3. The Brighton Collaboration published a case definition for Transverse Myelitis SPEAC_D2.5.2.1_Myelitis-Case-Definition-Companion-Guide_V3.0_13Feb2021_format12066-1.pdf (brightoncollaboration.us)
4. Product Information: Product Information Vaxzevria (AstraZeneca)

### Product Information

- Product Information Vaxzevria (AstraZeneca)

## Version history

| Version | Description of change | Author | Effective date |
|---|---|---|---|
| V1.0 | Original publication | MBD / Department of Health and Aged Care | 13/12/2021 |
| V1.1 | Addition of an applicable vaccine.<br>Clarification of assessment process and evidence requirements in section "Fatal outcomes of claimable conditions."<br>Amendment of types of evidence that should be considered for pericarditis.<br>Administrative change – numbering of resource documents. | THERAPEUTIC GOODS ADMINISTRATION and MBD/Department of Health and Aged Care | 22/4/2022 |
| V1.2 | Addition of a table of contents<br>Clarification of death certificate requirements and | Therapeutic Goods Administration and MBD/Department of Health and Aged Care | 3/4/23 |

| Version | Description of change | Author | Effective date |
|---|---|---|---|
| | having regard to cause of death in "Fatal Outcomes of Claimable Conditions"<br><br>Additional evidence required in the claimable condition of anaphylaxis, i.e administration of adrenaline<br><br>Updated wording for Tier 1, 2 and 3 claims<br><br>Rewording of "Link to Vaccination" section for clarity<br><br>Clarification of the role of the "Reporting Practitioner"<br><br>Further clarification added to "Assessment Criteria for Claims"<br><br>Very minor wording changes throughout, including addition of resources and minor edits for syntax throughout the document<br><br>Added new claimable conditions: CVST without thrombocytopenia, Transverse Myelitis and Erythema Multiforme Major. Minor updates to GBS. Added definition of 'final diagnosis' and clarified wording of Criterion 1 and Criterion 2. | | |

| Version | Description of change | Author | Effective date |
|---|---|---|---|
| V1.3 | Clarification of General Paediatrician and subspecialist Paediatrician as a relevant specialty field in the diagnosis of all claimable conditions.<br><br>Minor clarification regarding the role of the Reporting Practitioner.<br><br>Updated references, and referencing style made uniform throughout document.<br><br>Clarification regarding the role of AEFI case definitions in the Claims assessment process. | Therapeutic Goods Administration | 26/09/2023 |
| V1.4 | Minor Amendment to refer to updated Policy version | MBD/Department of Health and Aged Care | 19/12/23 |