

03 February 2022



Tēnā koe [REDACTED]

Your Official Information Act request, reference: GOV-015827

Thank you for your email of 6 December 2021, asking for the following information under the Official Information Act 1982 (the Act):

1. *How many claims have ACC received from the Pfizer vaccine?*
2. *How many have now been accepted? And declined?*
3. *What is the biggest reason most have been declined?*
4. *What are the main diagnosis's has ACC received so far? Strokes, heart attacks etc?*

Background information about treatment injury claims

ACC has provided cover for treatment injuries since 1 July 2005. The treatment injury provisions replaced the medical misadventure provisions of the Accident Compensation Act 2001, to bring it more in line with the no-fault nature of the Scheme.

A treatment injury is a personal injury caused as a result of seeking or receiving medical treatment from, or at the direction of, a registered health professional. In order to fulfil criteria for cover, the person must have suffered a personal injury and there must be a clear causal link between the treatment and the injury, and the injury must not be a necessary or ordinary consequence of the treatment.

COVID-19 vaccine data and information available online

ACC has recently published two data sets related to COVID-19 vaccines one on the data.govt.nz site which can be found here: <https://catalogue.data.govt.nz/dataset/3d063af7-b605-411b-8a08-cdcb6c305b23/resource/9e004154-c3f1-4398-944f-443970fe803b/download/gov-014568-response.pdf>

The other dataset has been published with up to date data on ACC's website here: <https://www.acc.co.nz/assets/oia-responses/IPA5361-Covid-Vaccination-Claims-Refresh-Jan22.pdf>. This dataset will be updated monthly.

Also on our website are published Official Information Act responses on this topic which can be found here: <https://www.acc.co.nz/resources/#/category/12>. Therefore, we are refusing to provide the data for your request as the information is publicly available. This decision has been made under section 18(d) of the Act.

We can only respond based on the vaccine related claims lodged with ACC, and the figures may differ to those previously reported or supplied. Up to date data on the number of adverse effects reported from the COVID-19 vaccine can be found on the MedSafe website here: <https://www.medsafe.govt.nz/COVID-19/vaccine-report-overview.asp>

How ACC assess treatment injuries

A physical injury resulting from the COVID-19 vaccine may be covered by ACC if the criteria for treatment injury are met. The following outlines how we assess applications for cover for treatment injuries:

1. Determine whether the client has suffered a personal injury.
2. Assess whether the personal injury occurred within the context of treatment by or at the direction of a registered health professional.
3. Determine if there is a direct causal link between the treatment (ie, in these circumstances, the vaccination) and the personal injury.
4. Determine whether the injury was a necessary part or ordinary consequence of treatment.

For further information about ACC cover for treatment injuries, please refer to section 32 of the Accident Compensation Act 2001 (the AC Act) which you can access through this link: <https://www.legislation.govt.nz/act/public/2001/0049/latest/DLM100934.html>.

Also attached to this response is a copy of the *Necessary Part or Ordinary Consequence of Treatment Policy*. This guidance is used when assessing a treatment injury claim to help determine whether the injury suffered by a client was a necessary part or ordinary consequence of the treatment provided.

Reasons for declining COVID-19 vaccine injury claims

The majority of treatment injury claims for COVID-19 vaccine injuries that were declined, were declined for one of the following reasons:

- There is no physical harm or damage caused
- The injury was not caused by the vaccine
- The injury was considered an ordinary consequence of the vaccination
- The client requested their claim be withdrawn

Data regarding the reasons why COVID-19 vaccine injury claims were declined is due to be made publicly available in February 2022. As such, we are refusing to provide this data as it will soon be publicly available. This decision is made under section 18(d) of the Act.

How to get in touch

If you have any questions, you can email me at GovernmentServices@acc.co.nz.

As this information may be of interest to other members of the public, ACC has decided to proactively release a copy of this response on ACC's website. All requester data, including your name and contact details, will be removed prior to release. The released response will be made available [here](#).

If you are not happy with this response, you have the right to make a complaint to the Ombudsman. Information about how to do this is available at www.ombudsman.parliament.nz or by phoning 0800 802 602.

Nāku iti noa, nā



Sasha Wood
Manager Official Information Act Services
Government Engagement & Support

Summary

Objective

Use this guidance to help you determine whether the treatment injury suffered by a client was a necessary part or ordinary consequence of the treatment. This will help you determine cover for a Treatment Injury claim.

- 1) Necessary part of the treatment
- 2) Ordinary consequence of treatment
- 3) Likelihood of injury at a population level
- 4) Client circumstances
- 5) Clinical knowledge at the time of treatment
- 6) Changes in clinical knowledge
- 7) Clinical experience of the treatment provider
- 8) Questions to consider when determining whether an injury is an ordinary consequence of treatment
- 9) Links to legislation

Background

There is no cover for a treatment injury if the personal injury suffered was a necessary part or ordinary consequence of the treatment, taking into account all the circumstances of the treatment. See the Accident Compensation Act 2001, Section 32.

Owner

Expert

Policy

1.0 Necessary part of the treatment

- a An injury that is a necessary part of the treatment is one that is an essential component of the treatment process, e.g. an incision performed as part of an operation.

2.0 Ordinary consequence of treatment

- a The Court of Appeal in ACC v Ng & others [2020] NZCA 274 interpreted 'not an ordinary consequence' as being an outcome that is outside of the normal range of outcomes, something out of the ordinary which occasions a measure of surprise.
- b This is not a precise test and requires a judgement-based approach to each case, based on the specific circumstances of the treatment and the client, such as:
 - a) the likelihood of injury at a general population level
 - b) the particular circumstances of the client's case
 - c) the clinical knowledge at the time of treatment.

NOTE Example

Many chemotherapy side effects fall within the expected treatment process and are an established consequence of treatment. However, each case needs to be assessed in light of several factors to determine whether, on balance, the nature and severity of the side effects occasion no surprise.

3.0 The likelihood of injury at a population level

- a Data on the risk of a treatment can help identify a baseline probability of injury. This information may come from medical studies, the experience of experts, or other reliable sources..
- b It is important to ensure that medical studies and statistics are both reliable and relevant to the circumstances of the client and the treatment. Some studies may lack validity because of their small sample size, for example, or the study group may not be representative of the client's circumstances.
- c Factors to consider when referring to studies include:
 - The number of cases in the study and whether they are representative of the client's circumstances. For example, a study of risks conducted at a single specialist facility overseas may be of limited relevance to a procedure in New Zealand.
 - How authoritative are the studies? Are they endorsed by other experts? Is there a general consensus within that particular field or specialty?

4.0 Client circumstances

- a The likelihood of an injury occurring must be viewed in light of the client's circumstances. Relevant factors are discussed below.
- b Duration and severity of the injury

An unusually severe outcome – either in its effect or in its duration – may not be ordinary even though a less significant injury that may commonly occur following that treatment is more likely to be ordinary. In other cases, a severe injury may still be an ordinary consequence of treatment.

NOTE Example - infections

A small localised infection at the site of an incision that clears up within a week may be considered an ordinary consequence of treatment for a person with several co-morbidities. Conversely an infected incision that leads to sepsis which has been caused by the treatment may take it beyond what would be considered ordinary.

NOTE Example - heart surgery

A person having cardiac surgery may be at a high risk of a cerebrovascular event during surgery. It is likely that if a cerebrovascular event occurred it is within the normal range of outcomes, and therefore an ordinary consequence of that treatment.

- c Underlying patient health considerations

Some people may be more susceptible to suffering adverse outcomes from treatment than others, due to their health condition. This particular criterion requires the decision maker to take into account the particular person's circumstances at the time of treatment.

While a risk of injury may be unexpected for many people undergoing the treatment, a particular person may possess certain clinical features, such as co-morbidities or a predisposition, which increases their risk to such an extent that the injury becomes an ordinary consequence for them.

Conversely, a person may have a lower risk of injury arising from a particular treatment, compared to other people. As a result, the injury may not be an ordinary consequence for that particular person.

- d Circumstances of the treatment

Ordinary consequences will also depend on the particular treatment or procedure. Each examination, treatment, or procedure will have its own profile of ordinary consequences.

The facilities available, the urgency and complexity of the treatment, as well as the experience of the attending health professional(s) may also be relevant when determining whether an outcome was an ordinary consequence.

NOTE Example - emergency surgery

An urgent procedure may not be able to implement measures that would otherwise be available and would reduce risk. An injury resulting from treatment might be ordinary even though the treatment could have been provided at another facility where better equipment would have been available that would have reduced the risk.

5.0 Clinical knowledge at the time of treatment

- a Whether an outcome is considered 'ordinary' needs to be considered in light of the clinical knowledge that existed at the time of the treatment, as recognised by the relevant profession. This includes accepted practice in New Zealand and international knowledge.
- b The focus of the assessment is also not based on whether the risk of the outcome was predicted (or could have been predicted) in advance of treatment in a particular client's case. The assessment can take into account facts discovered after treatment has commenced, including complications that were not known when the procedure started.

NOTE Example

A client underwent surgery to treat a brain aneurysm. During the procedure the aneurysm ruptured, and the arteries had to be clipped for 40 minutes to control the bleeding leading to an increased risk of cognitive deficits. Clipping times would not normally exceed 15 minutes in this sort of operation and there would only be a small risk of injury. But in this case, the client suffered cognitive deficits as a result of the prolonged clipping. The outcome could be an ordinary consequence, even though it was not predicted before the surgery how long the clipping would be required for.

6.0 Changes in clinical knowledge

- a The prevailing medical and scientific knowledge at the time that treatment is taking place is to be taken into account. Advances in clinical knowledge that are acquired after treatment has finished should not be taken into account when making a decision on whether an injury is an ordinary consequence.
- b The following table summarises how this is applied.

Clinical knowledge at the time of treatment	Clinical knowledge today	Likely outcome
The injury was considered to be a necessary part or ordinary consequence	Injury is not a necessary part or ordinary consequence of treatment today. Current clinical approaches are more effective at treating the condition. Access to improved treatment techniques or better drugs minimise the chance of the injury occurring.	Ordinary consequence
The injury was not a known occurrence from the particular treatment	Due to more contemporary research, the injury is now known to result from the treatment	Not an ordinary consequence

 Clinical knowledge summary table.jpg

- C** Cover may not be available where clinical knowledge at the time of treatment has been superseded, making an injury not a necessary part or ordinary consequence of treatment.

Cover may be available where there was no clinical knowledge at the time of treatment that an injury could occur, even though clinical knowledge today would make the injury a necessary part or ordinary consequence of treatment.


NOTE Example - radiation treatment in the 1980s to treat a tumour, causing damage to surrounding bone and tissue

Clinical knowledge at the time of treatment	Clinical knowledge today	Outcome
The injury caused by the radiation treatment was not unexpected at that time.	Today, due to new techniques in the administration of radiation, along with new cancer drugs, damage to surrounding tissue and bones would be minimised or prevented entirely. If a client suffered significant tissue damage due to recent treatment this is likely to be considered to be unexpected.	The injury was an ordinary consequence given the procedures available when the radiation treatment was provided.

 Radiation treatment example.jpg

NOTE Example - lithium drugs prescribed to treat depression, resulting in renal failure

Clinical knowledge over the time of treatment	Clinical knowledge today	Outcome
At the time lithium was first prescribed for the client in 1987, studies did not show that lithium caused significant renal impairment. Lithium treatment had only been available since the 1960s. There were no studies showing what the long-term side effects could be.	Today, lithium is accepted as a cause of chronic kidney disease. The client was diagnosed with end stage renal failure in 2007. Contemporary studies showed an association between lithium taken over a 20-year period and renal failure.	The outcome depends on when the contemporary knowledge became known over the course of treatment. If it was not known until after kidney disease was diagnosed, it is not an ordinary consequence. This is because during the course of the client's treatment, renal failure was not known to result from long term use of lithium.

 Lithium drugs example.jpg

7.0 Clinical experience of the treatment provider

- a** The clinical experience of the treatment provider may sometimes be relevant. For example, where a procedure might carry a significant risk when competently conducted by a general surgeon, even though an expert specialising in the procedure could have performed the same procedure with a lower risk of the injury occurring. It is the risk associated with procedures performed by that generalist that is relevant, not the risk associated with procedures performed by the specialist.
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8.0 Questions to consider when considering a treatment injury claim

- a** What was the treatment the client received that has given rise to the injury?

What is the nature of the injury that is being claimed for?

Are there any medical studies that provide reliable and relevant statistical analysis about the particular injury?

Are these studies relevant to the client's circumstances?

Is the injury unusually severe or long-lasting compared to the medical studies and analyses that are available?

Were there any circumstances that increased or reduced the risk of the injury occurring? That might include:


- Patient factors (which may include depending on the context such factors as age, smoking status, BMI, other health conditions);
- Circumstances of treatment (urgency, available facilities);
- What happened during treatment – what was found during surgery (eg deteriorated arteries that were not visible pre-surgery).

Have client factors increased or decreased the identified risks of the treatment? If so, by how much?

Was the risk identified before treatment and what was the scope of consent prior to treatment? This may provide evidence to help clarify how significant the risk was believed to be before treatment began, but treatment providers will obtain consent for many unlikely possibilities and things may change in the course of treatment. The question is the objective likelihood of the outcome, not whether it was identified.

Considering all the above factors, was the nature and the severity of the injury within the normal range of outcomes for the treatment provided to this patient?

9.0 Links to legislation

-  Accident Compensation Act 2001, Section 32, Treatment injury
<http://www.legislation.govt.nz/act/public/2001/0049/latest/DLM100934.html>
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