Pelvic Surgical Mesh Treatment Injury

A guide to ACC cover – Information for Health Professionals

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This guidance tool will help you to assess whether your patient is likely to be covered by ACC for a pelvic surgical mesh injury. It is based on scientific research and expert best practice in the use of surgical mesh, and provisions of the Accident Compensation Act 2001 (AC Act). This guide does NOT apply to abdominal wall hernias that have been repaired with surgical mesh.

Under the AC Act, ACC can cover pelvic surgical mesh injuries that are the result of treatment or the failure to provide clinically indicated treatment. To ensure that we work together effectively, and in our clients' best interests, it is important that you understand how to apply the principles of the AC Act to establish whether your patient is likely to be supported by ACC for a surgical mesh injury. This guidance will help you to do this.

This document is not a guideline for clinical practice. It aims to improve transparency and consistency of ACC cover decisions. ACC considers each claim on its own merit, taking into account all the circumstances of the case.

Pelvic surgical mesh injuries

Surgical mesh has been widely used in procedures to manage conditions such as pelvic organ prolapse (POP), stress urinary incontinence (SUI),[1,2] and rectopexy . However, some people have reported complications such as mesh infection, extrusion, erosion, and exposure following pelvic procedures using surgical mesh.[3,5] The complications may in turn cause issues for them like dyspareunia, voiding problems (including bladder infections), and chronic pain. The plausible association[4] between these complications and mesh surgeries has been evidenced in the literature for POP and SUI.[5]

The psychosocial impacts of surgical mesh complications for these people in New Zealand have been evidenced as outcomes and experiences that were traumatic and overwhelming.[6,7]

How this applies to ACC cover

ACC, in no way, seeks to dismiss the pain or experience people go through. However, treatment injury claims must meet the legislative criteria and be supported by clinical evidence, taking into account the relevant patient and treatment factors which can vary from case to case. A few surgical mesh-related claims are lodged for pain with no clinical evidence that a new physical injury has been sustained causing the pain.[9] For cover with ACC there needs to be evidence of a new physical injury.

There are also claims where ACC has been unable to establish a causal link between the claimed injury and the treatment provided. In other cases, given the nature of the client's underlying health condition, the claimed injury may be considered an ordinary consequence of treatment.[9]

Key questions to assess if your patient may be supported by ACC

1. Has the patient suffered physical harm or damage (injury)?

There must be *evidence of physical harm or damage* to the person. An isolated symptom, e.g. pain, may be insufficient to demonstrate a physical injury. Examples of physical harm or damage are:

1. Physical damage – Erosion /extrusion/exposure affecting tissues or organs, or as a result of infection.
2. Nerve injury shown by sensory/motor changes and the damaged nerve can be named and the mechanism is consistent with the procedure performed.

Pain, or other symptoms, may be present without clear signs of tissue, organ or nerve damage and where appropriate, expert clinical review may be obtained by ACC to identify if there is a physical injury caused by the surgery. An independent clinical examination and /or imaging may be funded by ACC where that is appropriate. Each claim is considered on the individual circumstances and treatment provided.

2. Are you able to explain what caused the injury? Is it more likely than not that the treatment caused the injury?

To receive ACC cover, your patient's personal injury must be caused by treatment. You will need to provide an explanation for how the injury/pain was caused by treatment. Include onset and duration of injury including pattern of pain and why you consider these are evidence of injury.

Use Table 1 on page 3 to work through the link between your patient's injury and the treatment provided.

3. Is the claim the result of a failure?

Failure is when the health professional could have, and should have, taken different actions. This includes:

- failure to treat, or to provide treatment in a timely manner, e.g. including inadequate consenting process
- failure to diagnose, or an unreasonable decision on treatment, scheduling or assessment, e.g. inappropriate procedure (e.g. mesh sling placed when clinical history and tests do not support sling insertion).

Evidence for the failure should be documented in the patient's records. ACC would seek external peer advice about the failure.

4. Other relevant factors to consider

The following exclusions for cover apply. These are based on all the circumstances of the treatment including the clinical knowledge and the patient's underlying health condition at the time of the treatment.

Necessary part of treatment

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.

Incisions and trocar puncture wounds are excluded but not puncture of other organs or major nerves – these are likely to be covered when the medical evidence supports there was an injury causing actual bodily harm.

Ordinary consequence of treatment

Whether an injury would be considered an *ordinary consequence of treatment* will depend on all of the circumstances of the treatment including the patient's condition at the time, what occurred during treatment and taking into account where and when any treatment is given.

Solely due to lack of resource allocation

Injuries that occur solely *due to resource allocation* are not covered.

This exclusion is unlikely to apply. See ACC Treatment Injury Claim Lodgement Guide for further details.

Patient withholds consent

This exclusion is unlikely to apply.

Treatment did not achieve the desired results

For example, the surgical mesh was inserted to suspend and support tissue and the patient continued to experience the same problem following the procedure that the treatment was provided to address, therefore the continued problem is not a new injury.

Table 1: Is personal injury caused by surgical mesh treatment?

Injury descriptions include:	Tests/Evidence	Rationale
1. Mesh has eroded / extruded through tissue or organ.	1(a) Clinician examines and confirms mesh exposure/erosion/extrusion as the physical injury. 1(b) Endoscopy showing mesh has eroded/ extruded into organs, e.g. cystoscopy mesh in urethra or bladder.	Exposure/erosion/extrusion is evidence of physical damage, it should not occur, as the mesh should not transgress through tissue planes (anatomical structures) after insertion, therefore when it does, evidence (clinically on examination – including endoscopy) will confirm the exposure/ erosion/extrusion and therefore the injury.
2(a) Nerve within surgical field was injured during the operation.	Neuropathy including neuropathic pain see flowchart – Appendix 1.	Changes in sensation or pain caused by damage to the nerves could be an indicator this has happened.
2(b) Other physical damage that is not considered to be an ordinary consequence and/or a necessary part of the procedure that has affected: – Nerves – Tissues – Organs	Description of the physical damage, including explanation of why this damage is not an ordinary consequence for this patient. Examples of some symptoms/signs may include: – Pain (if the damage causes pain this is nociceptive pain) – Bleeding (may be a sign of underlying physical damage) – A fistula.	Damage must be defined with supporting evidence, e.g. symptoms, examination, clinical findings, imaging tests that show tissue damage (e.g. 3D ultra-sound showing mesh sling is in the wall of the urethra). Examples of clinical examination findings may include mesh that is: – Tender on palpation and may suggest the presence of an underlying injury – Kinked or contracted may be palpable and cause symptoms even in the absence of erosion.
3. Bladder injury caused by excessive obstruction of urethra.	Shown by urodynamic testing. Specialist report from urologist or gynaecologist/ urogynaecologist would include determination of abnormally decreased flow with increased pressure or the effect of prolonged obstruction.	
4. Infection. Any surgery can be complicated by infection. This may be superficial or deep.	This may be evidenced by: – Pain – Fever – Purulent collection – Response to treatment e.g. antibiotics, drainage – Osteomyelitis/discitis (rare) ▪ When infection occurs with mesh fixation onto the sacrum ▪ May be an indication for MRI.	
5. Inflammation – where it may be caused by the mesh after it is implanted into the body[10].	Factors may include: – Pain in relevant distribution – Pain onset. May require further clinical assessment.	Clinical factors may include: – Imaging – MRI/ultrasound – Blood tests – inflammatory markers – Tenderness on palpation – Evidence on explantation – Biopsy where clinically appropriate
Other factors	Based on research and consensus opinion from the external advisor group from 2020, mesh cover decisions will not be affected by the client's age, menopausal status or lack of oestrogen replacement therapy.	

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This guide is to be used in conjunction with the ACC Treatment Injury Claim Lodgement Guide.

References

1. Jonsson, M et al. (2013). Trends in use of surgical mesh for pelvic organ prolapse. American Journal of Obstetric Gynecology, 208(79): e1–7.
2. Bradley S et al. (2011). Shifts in national rates of inpatient prolapse surgery emphasize current coding inadequacies. Female Pelvic Medicine & Reconstructive Surgery, 17: 204–8.
3. Diwadkar, B et al. (2009). Complication and reoperation rates after apical vaginal prolapse surgical repair: A systematic review. Obstetrics & Gynecology, 113(2): 367-373.
4. Hill, A (1965). The environment and disease: Association or causation? Proceedings of the Royal Society of Medicine, 58 (5): 295–300.
5. University of South Australia (2019). Literature Review: Surgical mesh, pain and injury. International Centre for Allied Health Evidence. Commissioned by Accident Compensation Corporation, NZ.
6. Wailling, J et al. (2019). Hearing and responding to the stories of survivors of surgical mesh: Ngā kōrero a ngā mōrehu – he urupare (A report for the Ministry of Health). Wellington, New Zealand: The Diana Unwin Chair in Restorative Justice, Victoria University of Wellington.
7. Huntington, A.D et al. (2019). The Loss of a Life Well Lived: A qualitative study exploring the impact of surgical mesh implants on the lives of a group of New Zealand women. (in press).
8. Federal Court of Australia (Dec 2019). Gill v Ethicon Sàrl & Ors (No 5) [2019] FCA 1905. Retrieved from https://www.judgments.fedcourt.gov.au/judgments/Judgments/fca/single/2019/2019fca1905/summary/2019fca1905-summary
9. ACC (2018). ACC Treatment Injury Claims - Surgical Mesh-Related Claim Data - From 1 July 2005 to 30 June 2018 (13 fiscal years), Accident Compensation Corporation.
10. Li, L et al. (2017). Pathological findings in explanted vaginal mesh. Human Pathology. 69: 46–54
11. Finnerup, N. B. et al. (2016). Neuropathic pain: an updated grading system for research and clinical practice. Pain, 157(8), 1599–1606. https://doi.org/10.1097/j.pain.0000000000000492

Appendix 1: Flowchart for Diagnosis of Neuropathic Pain[11]