Abdominal Wall Hernia Mesh Treatment Injury

A guide to ACC cover – Information for Health Professionals

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

Under the AC Act, ACC can cover abdominal wall hernia surgical synthetic 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 synthetic 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.

Abdominal wall mesh injuries

An abdominal wall hernia is the protrusion of intra-abdominal organs or tissue through a defect in the abdominal wall or groin. They can be classified into primary ventral, incisional and groin hernia. There are four main types of primary ventral hernias: umbilical, para-umbilical, epigastric, and spigelian. Incisional hernias including para-stomal hernias develop at the site of a prior surgery; depending on the technique of the original surgery – laparoscopic or open surgery [1]. Groin hernias are inguinal or femoral. Different surgical techniques are used to repair these hernias and mesh may be used to assist in closing the defect in the abdominal wall by reinforcing the tissue or bridging the defect [1]. Mesh can be made of synthetic and/or biological materials. *This cover guidance refers to mesh with synthetic material only*.

The use of mesh in general surgery to repair groin or abdominal wall hernias is well established internationally and is considered appropriate[2, 3, 4, 5, 6, 7]. Despite the clinical success and vast body of knowledge that has been gained regarding manufacturing of surgical meshes, material properties, and surgical procedures, mesh may still suffer from contraction and/or infection after implantation. Tissues may come in contact with mesh as a part of healing. Nerve injury can result in persistent neuropathic pain; bowel injury can result in obstruction, erosion or fistula formation; infection can delay wound healing and contribute to seroma; rejection and abnormal contraction can contribute to hernia recurrence [2, 5, 6, 8, 9]. The 252 adverse events for hernia surgical mesh repair reported to the FDA during 1996–2004 included infection (42%, 107 reports), mechanical failure (18%, 46), pain (9%, 23), reaction (8%, 20), intestinal complications (7%, 18), adhesions (6%, 14), seroma (4%, 9), erosion (2%, 6), and other (4%, 9) [10].

Whilst the underlying causes for these complications is still unclear [5], patients who are obese and/or have hypertension or diabetes have been identified as being at particular risk for abdominal wall hernia repair complications such as wound dehiscence or infection. The choice of mesh material and the location of the mesh insertion are other factors that may affect operation outcomes [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. Some surgical mesh-related claims are lodged for pain with no clinical evidence that a 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, and all the circumstances of the treatment, the claimed injury may be considered an ordinary consequence of treatment [11]. Cover is not available under the AC Act for injuries that are an ordinary consequence of treatment.

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 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 below to work through whether there is a 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. groin mesh placed for hernia or groin pain when clinical history and tests do not support insertion).

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

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.	Clinician examines and confirms mesh exposure/erosion/extrusion as the physical injury. Imaging confirms exposure/erosion/ extrusion.	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. e.g. ilioinguinal nerve damage on MRI and pain.	Changes in sensation or pain caused by damage to the nerves could be an indicator this has happened. Sometimes the surgeon has to cut the nerve thus numbness expected.
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, signs and imaging that show tissue injury.
3. Infection/Inflammation.	Any surgery can be complicated by infection/inflammation. This may be evidenced by: – Pain. – Fever. – Chronic seroma (>six months post-surgery). – Purulent collection. – Response to treatment e.g. antibiotics, drainage. – Osteomyelitis (rare).	Clinical factors may include: – Imaging – MRI/ultrasound. – Blood tests – inflammatory markers. – Tenderness on palpation. Evidence on explantation.

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 neurovascular structures – 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, the clinical knowledge at the time of treatment, and taking into account where and when any treatment is given.

A scarring response is expected, it is a natural part of the healing process, thus is likely to be an ordinary consequence of the surgery. Severe and excessive/unusual scarring needs to be differentiated and is considered on a case by case basis.

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 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.

The presence of a recurrent hernia does not in itself mean there has been a treatment injury. The cause of a recurrent hernia is multi-factorial thus each case will be considered on a case by case basis. If there is evidence of a defective product causing herniation, then that could potentially give rise to cover but not if this is simply an issue of fair wear and tear.

If, however the hernia repair failed within six-weeks of the surgery this may indicate a technical issue with the surgical procedure itself, causing recurrence, and may be covered. This will be assessed on a case by case basis.

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

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Appendix 1: Flowchart for Diagnosis of Neuropathic Pain[12]