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Lumbar disc replacement protocol

February 2022

ACC, together with delegated representatives from the New Zealand Orthopaedic Spine Society (NZOSS) the New Zealand Orthopaedic Association (NZOA) and the New Zealand Branch of the Neurosurgical Society of Australasia (NSA), has agreed that this protocol will be followed when ACC receives a funding request for a lumbar disc replacement (lumbar arthroplasty).

This process is in addition to the standard requirement that the surgery request is to treat a condition that has been covered by ACC.

The protocol includes patient selection, approved surgeons, approved facility, type of prosthesis and data recording.

The protocol is based on a consensus opinion of ACC, the NZOSS, and the NSA, in October 2021. This is an update of the 2009 position.

This protocol should be completed, signed and submitted alongside the Assessment Report and Treatment Plan (ARTP)

Before considering lumbar disc replacement

The patient should have the following:

- ☐ Primary disc dominant pain and have exhausted and failed a minimum of a six-month period of conservative, non-operative treatments. These include supervised and monitored activity-based or equivalent specific programmes.
- ☐ Consideration given to psychosocial factors related to persistent pain that may influence management and rehabilitation. This may include a prior Comprehensive Pain Assessment or equivalent multidisciplinary pain assessment.

Indications

All the following indications are to be satisfied:

- Age 18-60 years
- Single level symptomatic lumbar disc disease at L3/4, L4/5 or L5/S1 with objective evidence on CT or MRI.
- Clinical confirmation of disc dominant mechanical back pain at the operative level(s) (eg discogram, sodium fluoride or technetium bone scan)

If the patient falls outside any of these indications, a second opinion is required as detailed below.

Contraindications

The patient has any of the following:

- Infection/rheumatoid arthritis/osteoporosis/malignancy/spinal ossification (eg ossification of the posterior longitudinal ligament (OPLL) and diffuse idiopathic skeletal hyperostosis (DISH)/prior resection of the facet joints/clinically significant lumbar kyphosis
- Anything more than minor facet joint arthropathy at the involved level(s)

Relative contraindications:

- Spondylolisthesis at the involved level
- Sacral slope > 45-degree angle

Note: A second opinion is required when the client presents with a relative contraindication and lumbar disc replacement surgery is to be requested.

Second opinion

Any application that does not meet the above indications, and/or where a contraindication is present, will require a second opinion from an appropriately qualified spinal surgeon who meets the 'Operating surgeon' criteria below. This should be included in the Assessment Report and Treatment Plan (ARTP).

In particular, a second opinion is required for the following:

  - The L2/3 level and/or
  - More than one level – particular consideration should be given to a hybrid approach of total disc replacement (TDR) and fusion

☐ Not required

☐ Required

Pre-operative and post-operative protocol

In addition to the standard pre-operative workup routine for the operating surgeon and the standard follow-up and aftercare, the following are to be carried out:

☐ Completion of the Oswestry Disability Questionnaire (or equivalent) pre-operatively and at 12 and 24 months post-operatively

☐ Routine follow-up X-ray at six months post-procedure

☐ Registration of all cases with the National Joint Registry

Operating surgeon (qualifications)

ACC will approve surgeons to perform lumbar disc replacement surgery based on the criteria in *Appendix 1*.

An initial letter from the spinal surgeon will be required confirming they have met the criteria in *Appendix 1*. This letter will not need to accompany each surgery request.

☐ I am on the list of approved surgeons to perform lumbar disc replacements

Facility requirements

Surgery is to be carried out in a hospital performing lumbar spinal procedures, with intra-operative and post-operative radiological facilities, and on-site access to high-dependency facilities.

☐ This facility meets these requirements

Prostheses

Included prostheses:

☐ Prodisc L

☐ Baguera L (Spineart)

Any other Prosthesis

Any surgeon applying to use any other prosthesis must submit supporting information using the criteria as outlined in *Appendix 2* to their appropriate NZOSS or NSA ACC delegate.

Criteria for inclusion

Any prosthesis being considered for inclusion in the protocol must comply with relevant ACC legislation and policy.

In addition, the prosthesis must have the following:

- Endorsement from the delegated representatives of both the NZOSS and the NSA
- Consideration of the information about the prosthesis against the criteria outlined in *Appendix 2*
- United States Food and Drug Administration (FDA) approval
- If no FDA approval (ie CE mark), then a more rigorous assessment against the criteria in *Appendix 2* will be required

Any requests for a new device to be considered for inclusion should be sent to ***healthsectorpartnerships@acc.co.nz***

Note: *Any delegated representative from the NZOSS and the NSA or surgeon applying to use a prosthesis, must declare any conflict of interest or potential conflict of interest related to the prosthesis requested for inclusion, so the conflict can be appropriately managed (including but not limited to a relationship with distributors of the device, gifts received from distributors and/or financial interests in the device and/or distributors of the device).*

Acknowledgements

The representatives involved in this protocol development:

- New Zealand Orthopaedic Spine Society (NZOSS) of the New Zealand Orthopaedic Association (NZOA) – Mr Kris Dalzell
- New Zealand Branch of the Neurosurgical Society of Australasia (NSA) – Mr Nicholas Finnis
- ACC – Dr Michael Austen, Fraser Wilkins, Adrian Pretorius, Dr Peter Hunter, Mr Sud Rao, Mr Alex Rutherford, Mr Denis Atkinson and Amanda Bowens

Appendix 1 Operating surgeon

The operating surgeon must meet all the following criteria:

- Be an orthopaedic spinal surgeon; or neurosurgeon with the appropriate spinal training
- Be a member of the NZOSS or the NSA
- Currently carrying out lumbar spine surgery under an ACC contract, including Red List lumbar spine surgery
- Complete an appropriate course on lumbar disc replacement surgery and/or is working with a surgeon qualified in disc replacement surgery

Appendix 2 Criteria for inclusion of disc devices

Criteria for consideration of a prosthesis not on the 'Included prostheses' list

- Technology class –
  - modification of existing technology or
  - fundamentally new technology
- Engineering studies – demonstrating sound wear, strength and biomechanical suitability (including polyethylene and other components)
- Clinical data –
  - Comparative studies – disc replacement compared to fusion. Consideration will be given to study design, weight of evidence, strength of any association and eminence of journal
  - Bias – more weight given to peer reviewed, published, and independent studies as opposed to studies performed by product makers and published on a company website only and not in peer reviewed journals
  - Clinical outcome shows equivalent or favourable results to fusion/comparable approved disc with regard to validated outcome measurements (eg – VAS spinal pain, Oswestry DI, Roland-Morris, NDI, SF-36). More weight will be given to longer duration of follow-up
  - Short-term complication rates (eg infection, non-integration, displacement and loosening) with favourable survivability and reoperation rates over time compared with fusion. More weight will be given to length of follow up
  - Long-term complication rates (eg product failure / toxicity including polyethylene wear and metalosis) with favourable survivability and reoperation rates over time compared with fusion. (More weight will be given to length of follow up)
  - Actuarial impact – impact on index level and adjacent level changes over an appropriate length of time
- External validity
  - List of countries where the device is approved for use. More weight given to devices already in circulation in OECD jurisdictions with comparable health systems and standards to New Zealand
  - Data from manufacturer (or licensee) company regarding how many devices have been placed over what period of time in the above jurisdictions
- Consultation with the Joint Registry

Surgeon's signature