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He Whakaora.
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Cervical 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), have agreed that this protocol will be followed when ACC receives a funding request for a cervical disc replacement (cervical 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 February 2020. This is an update of the 2009 position.

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

Indications

All the following indications are to be satisfied:

- Age 21-60 years
- Magnetic Resonance Imaging (MRI)/Computerised Tomography (CT) evidence of cervical spinal canal or foraminal stenosis causing spinal cord and/or nerve root impingement
- Clinical evidence of cervical myelopathy and/or radiculopathy and/or impingement causing nerve root pain
- One- or two-level disease. Additional levels will require an opinion from an appropriately qualified spinal surgeon
- Failure of adequate (at least six to eight weeks) period of appropriate conservative treatment. Surgery may occur earlier for those with myelopathy and/or progressive neurological deterioration

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))
- Relevant facet joint arthropathy
- Radiological or clinical evidence of instability
- Relevant cervical deformity
- Axial neck pain and/or headaches and/or dizziness as the sole symptom(s) of cervical disease
- Previous radiotherapy to the cervical area

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Second opinion

Any application which does not meet the above indications will require a second opinion from an appropriately qualified spinal surgeon who meets the 'Operating Surgeon' criteria (see Appendix 1). This should be included in the Assessment Report and Treatment Plan (ARTP).

☐ 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, **all cases are to be registered with the National Joint Registry.**

Operating surgeon (qualifications)

ACC will approve surgeons to perform cervical 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 cervical disc replacements

Facility requirements

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

☐ The facility meets these requirements

Prostheses

Included prostheses

☐ Prestige (Medtronic)

☐ Mobi-C (LDR)

☐ prodisc C Nova (Centinel Spine)

☐ M6-C (Spinal Kinetics)

☐ prodisc C Vivo (Centinel Spine)

☐ Baguera (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, Tanya Skaler and Stafford Thompson

Appendix 1 Operating surgeon

The Operating Surgeon must meet all the following criteria:

- Be an orthopaedic spinal surgeon; or neurosurgeon with appropriate spinal training
- Be a member of the NZOSS or the NSA
- Currently carrying out cervical spine surgery under an ACC contract, including Red List cervical spine surgery
- Complete an appropriate course on cervical 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 NZ
  - 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