Lumbar Artificial Disc Replacement

DEFINING APPROPRIATE COVERAGE POSITIONS

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Introduction
North American Spine Society (NASS) coverage policy recommendations are intended to assist payers and members by proactively defining appropriate coverage positions. Historically, NASS has provided comment on payer coverage policy upon request. However, in considering coverage policies received by the organization, NASS believes proactively examining medical evidence and recommending credible and reasonable positions may be to the benefit of both payers and members in helping achieve consensus on coverage before it becomes a matter of controversy. This coverage recommendation reflects the best available data as of 12/5/17; information and data available after 12/5/17 is thus not reflected in this recommendation and may warrant deviations from this recommendation, if appropriate.

Methodology
The coverage policies put forth by NASS use an evidence-based approach to spinal care when possible. In the absence of strict evidence-based criteria, policies reflect the multidisciplinary and non-conflicted experience and expertise of the authors in order to reflect reasonable standard practice indications in the United States.

NASS Coverage Policy Methodology

Scope and Clinical Indications
The impact of chronic low back pain is enormous with far-reaching economic, social and health care policy implications. The optimal treatment for chronic, unremitting, discogenic low back pain is not known. Nonoperative management has proved to have its own challenges, while there are few options for surgical intervention after failed medical management. These are limited to lumbar arthrodesis and lumbar disc replacement/arthroplasty.

Coverage Recommendations
Lumbar Artificial Disc Replacement
is indicated for patients with discogenic low back pain who meet ALL of the following criteria from the Lumbar Fusion Coverage Recommendation:

a. Advanced single level disease noted on an MRI and plain radiographs of the lumbar spine at L4-5 or L5-S1, characterized by moderate to severe degeneration of the disc with Modic changes (defined as peridiscal bone signal above and below the disc space in question) as compared to other normal or mildly degenerative level (characterized by normal plain radiographic appearance and no or mild degeneration on MRI).

b. Presence of symptoms for at least 6 months or greater and that are not responsive to multi-modal nonoperative treatment over that period that should include physical therapy/rehabilitation program but may also include (but not limited to) pain management, injections, cognitive behavior therapy, and active exercise programs.

c. Absence of poorly managed psychiatric disorders, such as major depression.

d. Primary complaint of axial pain, with a possible secondary complaint of lower extremity pain.

Lumbar Disc Arthroplasty is NOT indicated in ANY of the following scenarios:

a. Any case that does not fulfill ALL of the above criteria.

b. Presence of advanced multi-level degeneration (2 or more levels) on a preoperative MRI and plain radiographs.

c. Poorly managed psychiatric disorder.

d. Significant facet arthropathy at the operated level.

e. Age greater than 60 years or less than 18 years.

f. Presence of infection or tumor.

g. As an adjunct to the treatment of primary disc herniation.

h. Above or below or in combination with a spinal fusion or other stabilizing-type procedure.

i. Presence of osteoporosis.
Coverage Recommendations

The Coverage Committee recommends coverage for lumbar artificial disc replacement when the criteria outlined above are met. There have been two and five year follow-up studies published that demonstrate results that are at least equivalent to spinal fusion for discogenic low back pain. The procedure itself is technically challenging and a body of evidence exists that informs us of the technical pitfalls to be avoided. Proper training is required.

Rationale

There are currently two artificial disc replacement devices available in the US market today following FDA approval: PRODISC L® (approved in 2006) and activL® (approved in 2015). The Charité device was introduced in 2004 and then removed from the market by the manufacturer in 2012. Given that the activL® was recently approved in 2015, clinical data remains limited. The FDA-Investigational Device Exemption (IDE) study of the activL® was a prospective, randomized, multicenter, blinded trial (ClinicalTrials.gov NCT00589797) with the control arm treated with PRODISC L. A higher overall treatment rate and radiographic success was reported with activL® compared to the control group. There have now been a number of randomized controlled trials comparing disc replacement with spinal fusion.1-6 In a large, systematic review of the literature, the Cochrane group found the results to be equivalent in terms of pain reduction and improvement in disability. It is reasonable to conclude that if the same inclusion and exclusion criteria used in the FDA trials are used in selecting future patients for disc replacement, then similar results can be expected, provided technical diligence and care is exercised during surgery. Any deviation from these indications, eg, above L4-5 or adjacent to a previous fused level, could result in very different outcomes and is not recommended.

Most published studies providing longer term follow up data focus on the Charité prosthesis and provide no more than 10-11 years of follow-up. In one such study with an eleven year follow up, a reoperation rate of 6.2% was observed.6 This was attributed to adjacent segment degeneration and pedicle fracture (1 case each). Also, a subsidence rate of 9.4% was observed. Longer term data with activL recently became available with up to 6 years of follow up from 32 patients at a single site.2 activL demonstrated superior reduction in ODI and lower reoperation and device related complication rates compared to PRODISC L. A seven-year post approval study with activL is currently ongoing. In one five-year follow-up study, found somewhat better outcomes with TDR as compared to fusion at one year and five years, though at the two-year mark this difference was not present.5

It has been postulated that longer-term results may demonstrate other complications, device failure and deteriorating clinical results. There is a justified concern for polyethylene wear debris and subsequent local tissue reaction or device loosening, as has been well-documented with large joint arthroplasty devices. In a systematic review done for two-year and five-year results separately by Lei Ma et al in 2016, infection rate in fusion group was found to be significantly higher than in TDR. Moreover, while total reoperation rate was found to be similar between the two groups, the rate of reoperation at index level was found to be higher in fusion group at five-year follow-up.6 It has been hoped that motion preservation devices, such as disc replacement, will lessen the risk for adjacent level degeneration. However, this will only be revealed with longer-term studies. There is some weak evidence to suggest that it might be lower.7 In studies with long term follow up, rates of adjacent segment degeneration were as low as 2.5% to 3%. Complications from TDR include device dislocation,8 subsidence,9 and osteolysis related to wear debris10 although these are not unique to the procedure. Most commonly, these complications are related to technical errors during implantation or poor patient selection.

References

2. Yue JJ. Long-term prospective randomized outcomes following lumbar total disc replacement: a single site experience with 6 years follow-up; Paper presented at: ISASS16; April 6, 2016; Las Vegas, NV. 2016.
5. Sköld C, Tropp H, Berg S. Five-year follow-up of total disc replacement compared to fusion: a randomized controlled trial. Eur Spine J.

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Comments regarding the coverage recommendations may be submitted to coverage@spine.org and will be considered in development of future revisions of the work.

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